Controversies in Medical Physics:

a Compendium of

Point/Counterpoint Debates

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and

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PREFACE

The Point/Counterpoint series of debates in *Medical Physics* began in March 1998 and has continued unabated since. Point/Counterpoints are among the most popular articles read in *Medical Physics* as demonstrated by consistently high online readership statistics. Indeed, they are often the most downloaded of all articles in the monthly statistics. To commemorate the first 10 years of Point/Counterpoint debates and, coincidentally, the first 50 years of existence of the American Association of Physicists in Medicine, the journal's Editorial Board decided that to publish a compendium of the debates as a separate, free-access, online book with the title "*Controversies in Medical Physics*".

Although the Point/Counterpoints included in this first volume of debates have been reformatted, they are essentially identical to those that appeared in the journal with one exception—the online version contains links to references within the text and to references cited by the authors. Readers will need to access the original articles in the online journal [http://scitation.aip.org/journals/doc/MPHYA6-home] to take advantage of these citation links. Each Point/Counterpoint has a link on the title page to the original online Abstract where readers can access the full articles if they or their institutions are subscribers to the journal.

Point/Counterpoint debates included in this first volume were moderated by either Bill Hendee (1998–2005) or Colin Orton (2005–2007). The moderators devised most of the propositions, selected appropriate authors and edited their contributions. Persons participating in Point/Counterpoint discussions were selected for their knowledge and communicative skills, and a disclaimer preceded all Point/Counterpoints to the effect that the positions of the authors for or against a proposition "*may or may not reflect their personal opinions or the positions of their employers*."

We hope you enjoy reading the Point/Counterpoint debates included in this first online volume, and look forward to suggestions you may have for future volumes in the series.

Colin G. Orton & William R. Hendee
Editors
February, 2008

CHAPTER 1

General Radiation Therapy

1.1. Monte Carlo techniques should replace analytical methods for estimating dose distributions in radiotherapy treatment planning

Radhe Mohan and John Antolak

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OVERVIEW

Analytical models have traditionally been used to estimate dose distributions for treatment planning in radiation therapy. Recently, some physicists have suggested that Monte Carlo techniques yield more accurate computations of dose distributions, and a few vendors of treatment planning systems have incorporated Monte Carlo methods into their software. Other physicists argue that, for a number of reasons, analytical methods should be preserved. This controversy is the topic of this Point/Counterpoint article. Thanks are extended to Paul Nizin, Ph.D. of Baylor College of Medicine for suggesting the topic.

Arguing for the Proposition is Radhe Mohan, Ph.D. Dr. Mohan received his Ph.D. from Duke University and is currently Professor and Director of Radiation Physics at the Medical College of Virginia (MCV) Hospitals, Virginia Commonwealth University. Dr. Mohan has been actively engaged in research and clinical implementation of advanced dose calculation methods, 3D treatment planning, Monte Carlo techniques and IMRT for 25 years, first at Memorial Sloan-Kettering Cancer Center and now at MCV. He has published and lectured widely on these topics at national and international meetings and symposia.

Arguing against the proposition is John Antolak, Ph.D. Dr. Antolak received his Ph.D. in Medical Physics from the University of Alberta (Canada) in 1992. He then joined the Department of Radiation Physics at The University of Texas M. D. Anderson Cancer, where he is currently an Assistant Professor. He is certified by the American Board of Radiology and licensed to practice Medical Physics in Texas. He is active in the education of graduate students, dosimetrists, and other physicists, and his research interests center around the use of electron beams for conformal radiotherapy. In his spare time, he enjoys playing ice hockey and coaching his son's ice hockey team.

FOR THE PROPOSITION: Radhe Mohan, Ph.D.

Opening Statement

Monte Carlo techniques produce more accurate estimates of dose than other computational methods currently used for planning radiation treatments. Were it not for limitations of computer speed, Monte Carlo methods probably would have been used all along.

With the spectacular increase in computer speed and the development of clever algorithms and variance reduction schemes, Monte Carlo methods are now practical for clinical use. The time required to compute a typical treatment plan has shrunk to a few minutes on computers costing less than $50,000. A few centers have started using Monte Carlo techniques for clinical purposes, and releases of commercial products are imminent.

As with any new product, an "adjustment period" will be needed during which we learn how to apply this powerful tool. Some find the "statistical jitter" in Monte Carlo results troubling. This issue is being addressed by several investigators. The additional cost of hardware and software may be another obstacle, but is likely to be resolved as computers become cheaper and more powerful.

Another issue is whether improvements in accuracy are clinically significant and worth the additional cost. It is difficult to answer the first question unequivocally, because randomized trials in which half the patients are treated with less accurate methods are not feasible. Arguments in favor of using Monte Carlo methods include:
(1) Elimination of the need to continually reinvent approximate dose computation models and to tweak them to meet every new situation, as well as the need for trial and error approaches to obtain acceptable matches with measured data. The medical physics community has been engaged in such exercises for 50 years. It is time to stop.
(2) Broad applicability and accuracy of the same Monte Carlo model for all anatomic geometries and treatment modalities (photons, electrons, brachytherapy). With analytical methods, there is a separate model for each modality and a unique set of approximations and assumptions is required for each type of field shaping device.
(3) Dramatic reduction in the time, effort and data required for commissioning and validating the dose computation part of treatment planning systems.
(4) Improved consistency of inter-institutional results, and greater quality of dose response data because of improved dose accuracy.
(5) Accurate estimation of quantities difficult or impossible to measure, such as dose distributions in regions of disequilibrium.

Until recently, the major reason for considering Monte Carlo methods was the inaccuracy of semi-empirical models for internal inhomogeneities and surface irregularities. Now an equally important justification is the ability of Monte Carlo techniques to provide accurate corrections for transmission through, scattering from, and beam hardening by field shaping devices. Monte Carlo techniques are also able to account correctly for radiation scattered upstream from field-shaping devices. These effects are quite significant for small fields encountered in intensity-modulated radiotherapy.

The transition to Monte Carlo methods will have to be gradual. Even though a few minutes of time to compute a plan may seem insignificant, computer-aided optimization of treatment plans may require many iterations of dose computations. In these situations, hybrid techniques will be needed that use fast but less accurate conventional models for most optimization iterations and Monte Carlo techniques for the remainder.
Since Monte Carlo techniques are now affordable and practical, there is no reason not to use them. It is not necessary to conduct clinical trials to once again prove the clinical significance of

improved dose accuracy. Monte Carlo methods should be deployed in radiation therapy with deliberate speed. For some applications, such as, IMRT optimization, it may be necessary to continue to use high-speed conventional methods in conjunction with Monte Carlo techniques at least for now.

Rebuttal

Dr. Antolak has raised several issues, some of which were addressed in my Opening Statement. With faster computers and clever schemes to reduce variance, the stochastic nature of the Monte Carlo approach is no longer an impediment. Statistical uncertainty of 1%–2% is achievable on grid sizes of 2–3 mm in MC dose distribution calculations, requiring just a few minutes on easily affordable multiprocessor systems. While statistical noise may be unsightly, its effect on the evaluation of dose-volume and dose-response parameters of plans is insignificant. In addition, techniques to smooth out noise are being implemented.

Analytic models introduce systematic errors in dose. They simply cannot achieve the accuracy of MC techniques. While it is true that analytic models consistently produce precise results for the same input data, these results are consistently inaccurate.

Dr. Antolak is concerned that approximations to speed up Monte Carlo computations may affect the accuracy of results. But Monte Carlo developers and users should always ensure that approximations have no significant impact on accuracy. Nothing else should be necessary.

Responses to other such concerns raised by Dr. Antolak are: (1) Considering the uncertainties in dose-response information and other sources of data in the radiotherapy chain, our ability to define "how much noise in the dose distributions is acceptable" is similar to our ability (or lack thereof) to determine the level of dose inaccuracy that may be acceptable. (2) Dose to a point is not a meaningful quantity when Monte Carlo techniques are used. Beam weighting and dose prescription should be specified in terms of dose to fractional volumes (e.g., 98% of the tumor volume). (3) Statistical noise should have practically no effect on inverse treatment planning because the intensity along a ray is affected by the average of dose values over a large number of voxels lying along the ray and not by the dose in any one voxel. (4) Commissioning of Monte Carlo algorithms will be the responsibility of the same physicists and/or commercial vendors who commission conventional methods.

I believe strongly that concerns raised by Dr. Antolak and others are being resolved and that we are now ready to introduce Monte Carlo techniques into clinical use.

AGAINST THE PROPOSITION: John Antolak, Ph.D.

Opening Statement

We have a professional responsibility to ensure that patient treatments are accurately delivered, and the accuracy of treatment planning dose computation is one aspect of this. There are data to support the conclusion "that Monte Carlo techniques yield more accurate computations of dose distributions," provided that the Monte Carlo technique is fully applied. However, in light of other factors detailed below, Monte Carlo methods should not replace analytical methods for estimating dose distributions.

Before arguing against the proposition, it is necessary for me to clarify what I believe the basic difference is between an analytical method and a Monte Carlo method. It boils down to the difference between deterministic and stochastic. The Monte Carlo method is stochastic, i.e., independent calculations of the same problem will give different answers. The analytical method is deterministic, i.e., independent calculations of the same problem will give the same answer, at least to within the limits of numerical round-off and truncation errors. In my opinion and for the purpose of this discussion, any nonstochastic method is considered to be an analytical method.

The accuracy of an algorithm (or method) describes how close it comes to the true answer. Clinical physicists have to worry about the accuracy of both analytical and Monte Carlo methods. The full Monte Carlo method (e.g., EGS4) is considered by many to be the gold standard for accurate dose calculations. The precision of an algorithm is a measure of the repeatability of the answer. Analytical methods have essentially absolute precision. However, the precision of the Monte Carlo method, as measured by the standard error, is proportional to the inverse of the volume of the dose voxels, and to the inverse square root of the computational resources allocated to the problem. For example, reducing the standard error by a factor of two requires four times as much CPU-time. Variance reduction techniques can be used to reduce the computational resources required to obtain a given precision. However, the time (or resources) required for full Monte Carlo simulations of patient dose distributions is currently too great for clinical use. By necessity, current Monte Carlo treatment planning algorithms (those being touted for clinical use) introduce approximations that greatly speed up the calculations, but the accuracy of the results may be affected. At the same time, significant improvements are also being made to the accuracy of analytical algorithms. Also, for the clinical physicist, commissioning analytical algorithms is relatively straightforward, noise is not a problem, and the accuracy can be easily documented.

From the perspective of the clinical physicist, many questions about the use of Monte Carlo algorithms have not yet been answered. How much noise in the dose distributions is acceptable? In the presence of noise, how should beam weighting (e.g., isocentric weighting) be done? What effect does noise have on inverse treatment planning? Who will take responsibility for commissioning the algorithm, and how accurate are the results of the commissioning? How long will the calculation take relative to faster analytical calculations? How will the calculation time affect treatment-planning throughput, particularly when using optimization methods? Is the spatial resolution sufficient for clinical use? Most of the time, Monte Carlo treatment planning calculation times are quoted for relatively coarse (e.g., 5 mm) spatial resolution. Just reducing the resolution from 5 mm to 3 mm requires approximately five times as much CPU-time. These are just some of the issues that need to be resolved and well-documented before Monte Carlo methods can replace analytical methods for treatment planning.

Monte Carlo methods may be used as an independent verification of the dose delivery, or to document (rather than plan) the dose delivery. However, until the questions above are successfully answered, Monte Carlo methods should not replace analytical methods for estimating radiotherapy dose distributions.

Rebuttal

We agree that greater accuracy in dose computation is desirable, Monte Carlo methods can produce more accurate dose estimates, and "Monte Carlo methods should be deployed in radiation therapy with deliberate speed." However, these points are not the proposition we are addressing.

A potential patient recently inquired about the status of Monte Carlo planning at our institution. From what he had read, he believed that Monte Carlo treatment planning is a "silver bullet." Dr. Mohan says it is time to stop reinventing. I believe that implementation of "clever algorithms and variance reduction schemes" is reinventing Monte Carlo treatment planning methods. Further, trial and error will not stop with Monte Carlo. With complete information about source and machine geometry, Monte Carlo calculations can be highly accurate. However, Monte Carlo algorithms usually start with a source model that requires trial and error adjustments to match measured data.

Whereas reinventing analytical methods usually improves accuracy, reinventing Monte Carlo methods may decrease accuracy. In both cases, there is a tradeoff between accuracy and speed, which is often seen if the Monte Carlo approach averages the dose over large voxels. How is the accuracy of a particular implementation judged and to what should it be compared? The "spectacular increase in computer speed and the development of clever algorithms" noted by Dr. Mohan permits significant improvements in analytical models, potentially leading to a model for coupled photon-electron transport under more general conditions.
Future reductions in commissioning and validation efforts will only come from manufacturers' standardization of treatment machines and improved quality in their construction. Modified and new machines will still require extensive commissioning and validation for both Monte Carlo and analytical methods. Considerable research remains to be done to identify the minimum data set sufficient to validate input data that characterizes a treatment machine. Dr. Mohan's last two points are really arguments for greater dose accuracy and apply to treatment planning systems in general, not just Monte Carlo methods.

Dr. Mohan cites the significance of Monte Carlo methods applied to field shaping and intensity modulation devices. These applications can be very complex, but are usually not modeled explicitly. For example, modeling all of the field segments for a complex DMLC fluence pattern is impractical under normal circumstances. Using an approximate approach affects the overall accuracy of the dose calculation, as it would for an analytical method.

Monte Carlo methods are an invaluable tool for improving analytical models to a point where their dose uncertainty is insignificant compared with other uncertainties radiation therapy—such as setup, internal organ motion, target delineation, and biological response. As stated earlier, "Monte Carlo methods may be used as an independent verification of dose delivery, or to document (rather than plan) dose delivery," but should not replace analytical methods for estimating dose distributions in radiotherapy treatment planning.

1.2. D_m rather than D_w should be used in Monte Carlo treatment planning

H. Helen Liu and Paul Keall

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OVERVIEW

D_w, the absorbed dose to water, has traditionally been the normalizing factor for dose computations related to treatment planning in radiation therapy with high-energy x-rays. This normalizing factor relates the treatment plan to the x-ray calibration process described in TG 21 or 51. However, treatment planning employing Monte Carlo techniques allows the expression of radiation transport and energy deposition in patient representative media. The dose reported in this process can be either the dose-to-medium, D_m, or the dose-to-water, D_w, calculated with stopping power ratios. Many physicists believe that D_m is the preferred variable for treatment planning, and that it should replace D_w in this capacity. The controversy of D_m versus D_w is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is H. Helen Liu, Ph.D. Dr. Liu worked on radiation dosimetry and Monte Carlo simulation for her Ph.D. research in the Division of Radiation Oncology at the Mayo Clinic. She completed residency training at the Mayo Clinic upon completion of her Ph.D. in 1997. She is now an Assistant Professor in the Department of Radiation Physics at the University of Texas MD Anderson Cancer Center. Her research interests include Monte Carlo simulation, treatment planning optimization, and biophysical models for measuring radiation response in radiation therapy.

Arguing against the Proposition is Paul Keall, Ph.D. Dr. Keall is currently an Assistant Professor in the Department of Radiation Oncology at the Medical College of Virginia. He has been working on Monte Carlo treatment planning-related research for over a decade. His Ph.D. dissertation involved the development and evaluation of "Superposition Monte Carlo," a dose calculation algorithm combining elements of both the superposition/convolution and Monte Carlo algorithms. Paul has acted as a consultant to the IAEA on Monte Carlo Transport in Radiotherapy. His current Monte Carlo research interests include hip prosthesis calculations, IMRT calculations, EPID dosimetry and large-scale comparisons between Monte Carlo and other algorithms.

FOR THE PROPOSITION: H. Helen Liu, Ph.D.

Opening Statement

The ability to compute the actual dose to medium (D_m) is a unique and advantageous feature of Monte Carlo simulation for radiotherapy treatment planning. The rationale of converting D_m back to the dose to water D_w is driven solely by the desire to comply with tradition. D_w has been used in treatment planning because accurate heterogeneity correction methods were not readily available. As Monte Carlo treatment planning emerges, new standards of practice will be established to reflect the advances that Monte Carlo techniques will bring. The motivation for

using Monte Carlo simulation in treatment planning is essentially to achieve the greatest accuracy in dose calculation. Converting D_m back to D_w requires computing stopping power ratios for local voxels, a process that adds uncertainty in the calculations and makes Monte Carlo simulation more time consuming and complicated. This conversion defeats the purpose of using Monte Carlo simulation.

The clinical impact of switching from D_w to D_m is not expected to be significant, mainly because most tissues of interest in radiotherapy are similar to water. Thus, the difference between D_m and D_w will not change clinical outcomes to a noticeable degree, particularly since the uncertainty of clinical results is several orders of magnitude greater. With respect to radiobiological effects, there is no reason that D_m cannot be used in place of D_w for purposes of linking dose to biological response. In fact, the energy deposited in individual voxels is related more directly to D_m than to D_w.

Insofar as the dosimetry calibration protocol is concerned, the use of D_m in treatment planning will not affect the calibration of D_w recommended by national and international protocols. This is because in Monte Carlo simulation, the relationship is known between dose (either D_w or D_m) and the required number of photon histories to be simulated. From a prescription of D_m in a patient, the corresponding number of photon histories can be converted to monitor units (MUs) through use of the calibrated value of D_w per MU. In other words, the calculation of MU can proceed in the same way for either D_w or D_m in Monte Carlo simulation.

In summary, the advantages of Monte Carlo planning systems are improved accuracy in dose calculations and the possibility of obtaining D_m directly for various tissues. Converting D_m to D_w involves additional complications and adds possible sources of error for Monte Carlo calculations. D_m should be used in Monte Carlo planning, and will not have a significant impact on current clinical practice. Instead, use of D_m allows Monte Carlo planning to establish more accurate dose delivery, and to provide a closer relationship between tissue response and dose.

Rebuttal

Dr. Keall raises some important issues concerning the use of Monte Carlo treatment planning in routine clinical practice. Included in his concerns is a preference for D_w rather than D_m in Monte Carlo treatment planning.

One solution to Dr. Keall point (3) on specification of the medium is to standardize the conversion of CT numbers to radiological properties of the medium in a consistent and uniform manner for different Monte Carlo treatment planning systems. I suspect that this effect may not be clinically significant because D_w and D_m are quite similar for most biological tissues. Nevertheless, the subject warrants further investigation.
With respect to the dosimetry calibration protocol, the relationship between D_w obtained in a reference calibration condition, and D_m for a patient prescription, is known from Monte Carlo simulation. Hence, the monitor unit calculation in Monte Carlo treatment planning is straightforward, and does not affect implementation of standard dosimetry protocols to any degree. For conventional treatment planning, many institutions use dose to muscle rather than dose to water for monitor unit calculation. The ratio between the two is well-known and has been used to scale monitor units in clinical practice.

Obstacles to using D_m rather than D_w for Monte Carlo treatment planning are pragmatic in nature, including how to conform with convention and incorporate past clinical experience. The

relationship between D_w and D_m can be computed, and dose response data for tumor and normal tissues can be easily scaled in order to use D_m for treatment planning purposes. In fact, for cells imbedded in heterogeneous tissues such as lung or bone, dose to the cells is not reflected accurately by either D_w or D_m. This is because the CT imaging resolution is not sufficient to detect subvoxel structures, and D_w or D_m simply represents an averaged dose value in the voxel. In this case, either D_w or D_m can be used to indicate the energy delivered to the cells and the subsequent radiobiological effects.

The use of D_m in Monte Carlo treatment planning is a natural and suitable approach to avoiding the additional complexity and uncertainty of converting D_m to D_w. New standards of practice using D_m should be implemented to provide a smooth transition from conventional to Monte Carlo treatment planning.

AGAINST THE PROPOSITION: Paul Keall, Ph.D.

Opening Statement

I aim to convince you that prescribing, evaluating and reporting dose-to-water (D_w) rather than dose-to-medium (D_m) for Monte Carlo treatment planning is both obvious and necessary for the following reasons: (1) Clinical experience is D_w-based, (2) Dosimetry protocols are D_w-based, (3) The "medium" to report dose in is always a guess, and (4) D_w-based IMRT allows us to achieve the clinical prescription.

1. Clinical experience is D_w-based. Since the introduction of computer-based treatment planning in the 1960s, dose calculation algorithms have assumed that the patient is composed of waterlike composition of varying density. All manual calculations assume waterlike composition. This assumption is reasonable, as water makes up the bulk of our body cells and tissues. All clinical experience, and doses reported in the multitude of clinical trials, both past and ongoing, are with respect to D_w.

2. Dosimetry protocols are D_w-based. As stated in the overview, modern dosimetry protocols (e.g., IAEA, AAPM) are based on D_w. Also, the factors that convert ionization-in-air to D_w for the calibration have been determined or verified by Monte Carlo calculations. It seems reasonable that the reported dose for treatment planning is directly traceable to the calibration, and thus the reported dose should be D_w.

3. *The "medium" to report dose in is always a guess*. In Monte Carlo treatment planning, the CT numbers are converted not only to densities, but also to media. These media are generally obtained from ICRU or ICRP publications. However, who knows whether a patient's organ, e.g., a liver, has exactly the same composition as the `standard" liver? Furthermore, the same CT number can be obtained from a higher density/lower Z medium (e.g., soft tissue) and from a lower density/higher Z medium (e.g., lung). Thus, in the absence of 3D body composition analysis accompanying the CT scan, we can only guess at patient composition. Errors in specifying the medium for the dose calculation will always be present. Thus, reporting D_m when we do not know what the medium is seems somewhat illogical.

4. *D_w-based IMRT allows us to achieve the clinical prescription*. The prescription dose is determined with the aim that the tumor cells receive a lethal dose, whilst the normal cells embedded in the tumor receive a dose they can recover from. Take, for example, a head and neck

cancer in which the tumor infiltrates the mandible. If optimized using D_m, the dose-to-mandible will be equal to the prescription dose, say 72 Gy. However, the dose-to-osteocytes (being waterlike) within the mandibular bony matrix will be close to 80 Gy (assuming a Bragg-Gray cavity). Hence there will be a higher chance of bone weakening, fracture and necrosis than at 72 Gy. If optimized using D_w, we can modulate the intensity and thus dose so that the dose-to-tumor (being waterlike) and dose-to-osteocytes within the mandible receive the prescription dose, 72 Gy. The point here is that D_w, rather than D_m, is the desired quantity from a clinical perspective, and IMRT with D_w Monte Carlo can closely approach the desired prescription.

From the four reasons mentioned above, I conclude that we should use D_w rather than D_m for Monte Carlo treatment planning (as we routinely use in our clinic for our IMRT patients). Furthermore I would advise both commercial and academic Monte Carlo developers to report D_w rather than D_m.

Rebuttal

Dr. Liu presents arguments that converting D_m to D_w introduces (i) additional complexity and (ii) additional uncertainty.

On the issue of increased complexity. Converting D_m to D_w does involve additional computations. There is a small computational overhead associated with scoring D_w rather than D_m. However, we must ask ourselves why we want Monte Carlo in the first place? If complexity was a limitation, we would still be performing 2D treatment planning. If we make the effort to implement Monte Carlo treatment planning, let us do it properly.

On the issue of uncertainty. The additional uncertainty that Dr. Liu is alluding to is the uncertainty of the stopping power ratios of water-to-medium. By virtue of taking a ratio, systematic uncertainties in the stopping powers are reduced. Furthermore, the stopping power values for water are more accurate than those for many other tissues. There are two uncertainties, however, that exceed those of stopping power values. These are (i) the CT voxel composition uncertainty and (ii) institutional variations.

(i) A $1\times1\times3$ mm^3 CT voxel can contain up to 300 thousand cells of differing types and composition. Even the most accurate Monte Carlo is limited by the CT resolution. When we talk about scoring D_m to a voxel, which cell type do we mean? Assuming cells are Bragg-Gray cavities, each cell type within the CT voxel will have a different D_m. However, when we score D_w, Bragg–Gray theory tells us that the dose to each cell within the CT voxel is the same, thus eliminating intra-CT voxel variations.

(ii) Different institutions and Monte Carlo developers/vendors use different material types and density cut offs. For example, the default number of patient representative media in DOSXYZ (a widely used EGS4 Monte Carlo user code) is four. However, advanced users are including either quasicontinuous or continuous media assignments. Thus, D_m will be site dependent. At least, by virtue of Bragg–Gray theory, if D_w is used institutional variations will be reduced.

Dr. Liu also states that *the rationale of converting D_m to D_w is driven simply by the need to comply with convention*. I completely agree. As with dose calibration, for clinical trial results to be meaningful, the dose reported by different institutions should have a consistent convention.

1.3. Over the next decade the success of radiation treatment planning will be judged by the immediate biological response of tumor cells rather than by surrogate measures such as dose maximization and uniformity

C. Clifton Ling and X. Allen Li

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OVERVIEW

Radiation treatment plans have traditionally been optimized by surrogate measures such as dose maximization and uniformity in the target and dose limits to normal tissues. But with emerging molecular technologies, the possibility is evolving to monitor biological responsiveness directly in real-time during treatment with radiation. Whether this approach will replace traditional dose-optimization approaches is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is C. Clifton Ling, Ph.D. Dr. Ling received his Ph.D. in nuclear physics from the University of Washington, Seattle. He has performed studies in radiation and medical physics at Memorial Sloan-Kettering (MSKCC), Massachusetts General, George Washington University, and the University of California San Francisco. He is the Enid Haupt Professor and Chair of Medical Physics, MSKCC. Dr. Ling's research interests range from molecular radiation biology to IMRT, and recently biological imaging for cancer diagnosis, characterization and treatment. Dr. Ling has authored 200 peer-reviewed papers and numerous book chapters.

Arguing against the Proposition is X. Allen Li, Ph.D. Dr. Li is an Associate Professor and the Chief Physicist in the Department of Radiation Oncology, Medical College of Wisconsin. He has been a board certified medical physicist since 1994, and is currently a member of AAPM TG-74 and TG-106. Dr. Li is an Associate Editor for Medical Physics and has published 82 peer-reviewed papers. His research interests include biologically-based treatment planning and image-guided radiation therapy.

FOR THE PROPOSITION: C. Clifton Ling, Ph.D.

Opening Statement

Deficiencies in current radiotherapy planning, directly linked to the history of radiotherapy, are due to the paucity and/or inadequate understanding of biological and clinical data needed for optimum treatment design. Treatment planning was nonexistent or primitive prior to the application of computers in the 1960–70s, and after that, primarily by "convention" such as parallel opposed fields, four-field box or arc-therapy. As to biological and clinical issues, little was known about tumor or organ dose response, dose-volume relationships, and the

heterogeneities of tumor burdens and of radiosensitivity within the tumors. In the absence of meaningful criteria, dose-based surrogates were used by default.

Since the 1980s, 3-dimensional conformal radiotherapy (3D-CRT) technology has made available complete dose-volume information which, when combined with clinical outcome data, has permitted model-based analyses of tumor local control and organ toxicity. These analyses clearly reveal that dose-surrogates by themselves are insufficient to predict the consequences of a particular treatment plan. For example, the tumor control probability of prostate cancers depends on the risk groups in which the patients belong,[1] lung toxicities are more likely in the lower than in the upper lobe,[2] and rectal bleeding may depend on functional reserve.[3] All biophysical models that attempt to describe clinical outcomes contain biological information, be it SF2 (cellular surviving fraction for a dose of 2 Gy) in the Equivalent-Uniform Dose (EUD) model,[4] or the architecture of an organ's functional subunits.[5]

The success of the human genome project and developments in imaging strongly suggest that biological data will be increasingly available for radiotherapy planning in the future. The influence of various gene products on the radiosensitivity and chemosensitivity of tumors and normal tissues is beginning to be elucidated, leading to the suggestion that patient-specific molecular profiling will provide information for the selection of treatment modality and dose-intensity.[6] Understanding of the signal transduction pathway of cellular radiation response has paved the way for combining molecular and radiation therapy with very positive results in clinical trials.[7]

The integration of advanced imaging techniques and knowledge of the molecular basis of cancer will be a powerful influence on cancer management in general and radiotherapy planning in particular. With this approach, one can perform radiobiological phenotyping to characterize the tumor in terms of the factors that influence its radioresponse. A good example is the use of PET for visualizing tumor hypoxia, which is known to be detrimental to the efficacy of radiation treatment in several disease sites.[8] In this case, the biological response of radiation could be re-oxygenation that could be monitored by sequential PET imaging. Another promising assay of biological response, based on an increased understanding of the mechanisms of cell death, involves the use of radio-labeled Annexin V which adheres to the cellular membrane of apoptotic cells.[9] Lastly, the use of various PET tracers (with FDG being the current favorite) for monitoring treatment response holds significant promise.[10] Methods based on magnetic resonance are also being intensively evaluated as tools for planning and assessing radiation treatment.[11]

It is clear that, given the complexity of biological systems, dose-based surrogates are inadequate for describing the radiation responses of tumors and normal tissues. It is also certain that molecular profiling and imaging will provide the approach for improving treatment design and monitoring treatment response. What may be uncertain is the time course for attaining these goals. In that regard, we physicists are very familiar with error and uncertainties estimates—but whether it be a decade or two, the time is now to embrace the brave new world of biology-based treatment planning.

Rebuttal

To cling to dose-based treatment planning, given the recent findings referenced in my opening statement, is to keep "looking for the lost key under the light." We know that using purely physical surrogates for biological endpoints is fundamentally wrong, and that dose was originally

chosen as the basis for treatment planning simply because at the time it was the only thing we could quantify. But should one continue to hold to a system known to be fundamentally flawed because the scientifically correct method is as yet imperfect? Shouldn't one start looking for the key where it was lost by bringing light to that place?

Clearly, radiotherapy physicists must begin learning the pertinent aspects of tumor and radiation biology to better understand the deficiencies of dose-based treatment planning vis-à-vis the potentials (and pitfalls) of biology-based treatment planning. For example, one should know that the assumption that "clonogenic-cell density and radiosensitivity distribution are constant throughout the planning target volume" is wrong, and therefore the conclusion that "a uniform dose distribution maximizes tumor control" of Dr. Li's third reference is incorrect as well.

Radiotherapy planning using biological information may or may not be perfected within the next ten years, but even if not perfected it likely will surpass dose-based methods in predicting clinical outcome. It's only in the last decade or so that analysis of dose-volume histograms has led to a substantial increase in biological understanding of normal tissue complications, and that the potentials of molecular profiling and imaging have emerged relative to the radioresponse of tumors. The pace of these developments can only accelerate in providing the needed information for optimizing radiation planning. It may be a decade or even two before the goals of treatment based on biological end-points is realized, but the time is now for radiotherapy physicists to take their heads out of the warm and fuzzy sand of dose-based treatment planning, and move towards biologically-based treatment planning.

AGAINST THE PROPOSITION: X. Allen Li, Ph.D.

Opening Statement

The generation of treatment plans optimized to maximize tumor-cell killing and minimize normal-tissue damage (biologically-based radiation treatment planning, BBRTP), rather than to deliver a uniform dose to a specific treatment volume (physically-based RTP, PBRTP), has been proposed for many decades. With the recent surge in intensity-modulated radiotherapy and advances in biological/molecular imaging, interest in BBRTP is increasing within the radiotherapy community. I believe that BBRTP will eventually replace PBRTP. However, the central question of this Point/Counterpoint is "Will BBRTP be reliably practiced in the clinic over the next decade?"

Despite many decades of effort and experience, knowledge of tumor and normal-tissue radiation responses, on which BBRTP depends, is meager, unreliable, and not well documented. Unlike PBRTP, biological models are essential to any BBRTP effort. Although there are several phenomenologic and mechanistic models available, their predicting powers are generally poor because of large uncertainties in the biological parameters. Efforts to develop such models have increased in recent years, but progress has been slow, particularly for normal structures. Many sources of uncertainty (e.g., treatment positioning, organ motion, dosimetry, the cell micro-environment, irradiation history, and chemotherapy) contribute to current deficits in information about normal tissue complications.[12] In addition, unified tools to accurately document such information remain to be developed. Although in-vitro data on radiation responses are abundant, they can be applied in the clinic only with a great deal of caution.[13]

BBRTP requires patient-specific information on tumor/normal-tissue biology. Biological/molecular imaging technologies, although they offer great promise in eventually providing such information and even real-time monitoring of biological response, are far from mature. Moreover, tumor and normal-tissue radiosensitivities most likely change during a course of radiotherapy. The models, methods and technology needed to account for these phenomena remain to be developed.

Because of uncertainties in tumor/normal-tissue biology, clinical use of BBRTP is risky for the foreseeable future. For example, the use of incomplete or inaccurate biological information to preferentially target selected regions of a tumor at the expense of other tumor regions may jeopardize the treatment outcome. It may be possible, however, to use a combined PBRTP/BBRTP approach. First, a treatment plan is generated using PBRTP. Then, BBRTP is used to selectively target regions of the tumor that are potentially radioresistant without decreasing the dose to any other region of the tumor. It is known that a uniform dose distribution maximizes tumor control so long as the clonogenic-cell density and radiosensitivity distribution are constant throughout the planning target volume.[14] If the combined plan can be accomplished without appreciably increasing the dose to critical structures, the treatment outcome should be improved. As we gain additional information about the efficacy of BBRTP, more aggressive strategies may evolve. Because clinical trials require many years to complete, the replacement of PBRTP with BBRTP as the standard of practice is certainly unlikely during the next decade. I would like to acknowledge Dr. Robert Stewart for providing comments.

Rebuttal

As expected, Dr. Ling did a superb job explaining why dose-based surrogates are inadequate for treatment planning. I agree with Dr. Ling that there is a compelling need for BBRTP. However, the central issue we are debating is whether or not BBRTP will make a significant impact in the clinic within the next decade. On this issue, our opinions diverge.

A major issue is that the models used to relate dose distributions to treatment outcomes are highly nonlinear, and seemingly small perturbations in physical or biological factors can have a large impact on estimates of biologic response, which is often organ/tumor and patient specific.[13,15,16,17] Dr. Ling suggests that advances related to the human genome project and molecular imaging will provide the patient-specific information needed for BBRTP. There are many hurdles that must be overcome before functional/molecular imaging will have a substantial impact on the routine practice of radiation oncology, including imaging-pathology validation, timing of post-therapy imaging, spatial and temporal evolution of tumors, and lack of clinical outcome studies.[18] For example, it is not clear whether PET or other imaging modalities can accurately depict the microscopic extension of a tumor. The spatial and temporal variation of hypoxia during radiation therapy poses a significant challenge for the use of PET or other imaging modalities. Prospective multi-institutional clinical trials to evaluate the clinical impact of biologically-based planning strategies and novel imaging techniques are almost nonexistent. Until these issues are addressed, BBRTP will need to be applied in an incremental fashion. It may be many years or even decades before BBRTP has demonstrated clinical benefits over PBRTP. Nevertheless, I agree with Dr. Ling that we should embrace the brave new world of BBRTP and actively pursue methods to speed the clinical implementation of these techniques.

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1.4. Image-guided radiotherapy is being overvalued as a clinical tool in radiation oncology

Howard I. Amols and David A. Jaffray
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OVERVIEW

Advances in radiation therapy technology are coming fast and furious, with image-guided radiotherapy (IGRT) being one of the latest developments to be offered by all linear accelerator vendors. The radiotherapy community asked for this and now they have it. Without question, knowing exactly where targets and normal tissues are at the time of each treatment is something that all radiation oncologists would say they want. However, since IGRT systems are expensive and time consuming to use, some would argue that, unless clinically significant improvements in outcome can be demonstrated, the theoretical benefits of IGRT are not worth the added expense. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Howard I. Amols, Ph.D. Dr. Amols received his Ph.D. in Nuclear Physics from Brown University in 1974, followed by an NCI training fellowship in particle therapy at Los Alamos National Laboratory. He has held medical physics positions at the University of New Mexico, Brown, and Columbia Universities. He is currently Chief of Clinical Physics at Memorial Sloan Kettering Cancer Center, where he sheepishly admits to spending a good deal of his time working on IGRT. He has over 100 peer-reviewed papers, many of which are on topics some consider to be even more overvalued than IGRT. He is certified by the ABMP and is a Fellow, a Past President, and currently the Chairman of the Board of the AAPM. His hobbies include horology and arguing just for the sake of argument.

Arguing against the Proposition is David A. Jaffray, Ph.D. Dr. Jaffray graduated in 1988 with a B.Sc. in Physics from the University of Alberta and completed his Ph.D. in Medical Biophysics from the University of Western Ontario in 1994. The following eight years were spent as a Clinical Physicist in the Department of Radiation Oncology at the William Beaumont Hospital, Royal Oak, MI. He is presently Head of Radiation Physics at the Princess Margaret Hospital and Associate Professor in the Department of Radiation Oncology, University of Toronto, where he holds the Fidani Chair in Radiation Oncology and Medical Biophysics. His principal research interests involve the development of novel imaging systems for radiation therapy, including amorphous-silicon-based large-area detectors and cone-beam CT, image-guided radiotherapy, and integration of functional imaging into radiotherapy. Dr. Jaffray is certified in Radiation Oncology Physics by the ABMP, currently serves as a member of the AAPM Science Council, and is a frequent contributor to *Medical Physics*.

FOR THE PROPOSITION: Howard I. Amols, Ph.D.

Opening statement

That image-guided radiotherapy (IGRT) will improve radiotherapy is taken as axiomatic. Improved patient setup accuracy reduces probability of geographic miss and improves treatment

outcome. But where are the data demonstrating that IGRT improves clinical outcome in a ***clinically measurable way?*** If treatment margins (PTV minus CTV) are already larger than setup uncertainties, and if such margins result in acceptable toxicity, what is gained with IGRT? Will IGRT enable reduction of treatment margins? If so, will this ever be testable in a controlled clinical trial? Given the uncertainties in guesstimating CTVs from GTVs, perhaps reducing field margins (naively assuming that IGRT reduces errors) will be detrimental to treatment outcome? Conversely, if one cannot reduce treatment margins what benefits are derived from IGRT?

Ling *et al.*[1] have suggested that an IGRT system should have three-dimensional (3D) imaging of soft tissues and tumors, plus an efficacious process for ***clinically meaningful intervention***. Currently IGRT fails on both counts. Image quality, degraded by the physics of kV cone-beam scattering, is inferior to conventional CT; significant breathing artifacts result from the 30–60 sec scan times. Marginal image quality coupled with imperfect and non-robust image registration software both suggest questionable application of IGRT as currently practiced. Is using IGRT to move a patient around daily by a few millimeters, in ignorance of resulting clinical outcome, better than doing nothing?

Current IGRT systems also do a poor job of monitoring intrafractional errors. Unless these are less than interfractional errors, using IGRT prior to but not during treatment accomplishes little. Again, where are the data?

Even assuming that IGRT can detect setup errors, how should one correct for them? Is rigid-body, bony anatomy registration of IGRT and CT-Sim images sufficient, or must one consider soft tissue deformation? If the latter, then current IGRT systems are deficient. If the former, then aren't existing MV electronic portal imaging systems adequate? When is kV and/or 3D required, and when is two-dimensional (2D) MV sufficient?

Consider also the cost/benefit ratio: 3D-kV imaging systems cost $500,000, which is nearly 1/3 the cost of a linac. If one treats five patients per hour and IGRT adds three minutes this represents a 25% increase. Maintenance, physics, and physician times also increase. Is IGRT worth the price? Lamentably, its benefits will likely never be tested in a clinical trial as it is already widely used without controls or forethought.

I'm not arguing that IGRT is a boondoggle. Indeed, it's counterintuitive to argue against improved accuracy. But like many technological advances IGRT has come too fast, with too little thought, and without serious discussion of which types of patients will benefit. American hospitals have already collectively spent well over $100,000,000 on IGRT without a single peer-reviewed randomized clinical trial demonstrating its benefits. This is another example of new technology searching for a problem before the need has been demonstrated.

Lacking data, we've placed high expectations on an expensive, untested technology. As we should have learned from Record and Verify systems, computerized patient setup doesn't eliminate errors, it merely changes their nature.

I question not IGRT, but rather its current use. To quote Walt Kelly: "*We have met the enemy and they are us.*"

AGAINST THE PROPOSITION: David A. Jaffray, Ph.D.

Opening statement

Radiation therapy is a proven therapeutic agent directed at localized targets with the explicit objectives of achieving control of the neoplasm while minimizing the risk of toxicity in surrounding normal tissues. The relationship between geometric miss and failure in outcome is one of the few relationships in radiotherapy that is not debated. The very fact that we are willing to irradiate *perfectly normal tissues* to ensure tumor coverage highlights the importance of succeeding in the accurate localization of dose and target.

Current practice of radiation therapy devotes substantial clinical and technical effort towards this objective. The introduction of CT simulation, 3D treatment planning, portal imaging, and verification of treatment parameters are existing infrastructure investments. Ongoing operating costs are also substantial. These include daily manipulation of skin marks, checking for SSD discrepancies, applying small shifts based upon portal imaging, and the time consumed in the acquisition of port films and electronic portal images. We should also include time and effort expended in the handling of exceptions by all of the disciplines involved in the management of difficult or complex cases, so as not to have to withhold therapy for some patients due to our inability to solve the technical challenges related to targeting. The recent introduction of IMRT has heightened the concerns around geometric uncertainties as the opportunity to create highly conformal dose distributions places additional pressure on executing the delivery with a known geometric performance.[2]

While these advances have the best of intentions, it is remarkable to note how little quantitative validation is performed for each patient to prove that a course of conformal therapy has been executed as intended over the many fractions of radiation delivery. I would assert that there is a growing inconsistency in the amount of effort placed on the design of therapy compared with the assurance of its execution. In fact, the investments in further refinements in therapy that are occurring upstream should be questioned compared with the clear and unanswered challenge of placing radiation dose with geometric accuracy and precision within the human body. IMRT and biological targeting could be criticized as "tails wagging the dog," however, we don't dictate the order of innovation. IGRT technologies that provide volumetric imaging of both the targeted structures and surrounding normal tissues provide the opportunity to move from an intention to deliver state-of-the-art radiation therapy, to a patient-specific verification that the intention has been satisfied.

There is a need to separate the issues of IGRT technology adoption from the more fundamental underlying question: "What level of quality should be achieved in the delivery of radiation therapy to the individual patient?" Simple population-based performance metrics ring hollow. Clearly, PTV margins designed to cover the CTV in 95% of the patients would not go over well with one patient in twenty. Geometric uncertainty in the localization of therapy is a major controllable factor influencing the performance of radiation treatments, and it has been poorly addressed for too long. Recent studies based upon portal imaging and repeat CTs demonstrate the presence of patient subpopulations that are not well served by current positioning methods.[3,4,5] It is clear that the first step toward confirming the quality for each patient is to be able to measure the geometric performance of the delivery. This requires imaging of internal structures at the time of treatment, i.e., image-guided radiation therapy.

Rebuttal: Howard Amols, Ph.D.

There are three ingredients to good radiotherapy: correct tumor identification, conformal treatment planning, and precise treatment delivery. With the advent of biological imaging (MR, PET, etc.) we're only now learning how to do the first part correctly. We've very nearly perfected the middle step, and as Dr. Jaffray points out, we're still relatively primitive with regard to the third step. But his arguments that IGRT will improve that third step by a clinically significant, or even measurable amount fall short of the mark. While I agree with his argument that IGRT has the potential to improve the situation and should be tested, he makes no compelling argument to justify hundreds of hospitals buying IGRT at this time to the tune of $100,000,000.

For example, he quotes his own studies,[2,5] both of which use conventional CT rather than linac-based cone-beam CT systems, simply to show that adaptive radiotherapy based on multiple CT scans would allow delivery of slightly higher doses to prostate (on average, 7.5% more dose in Ref. 2 and 13% in Ref. 5) without additional rectal toxicity. These are very idealized studies, however, that assume no intrafraction motion and no organ deformation. They also ignore the fact that linac-based IGRT systems have inferior image quality compared with conventional CT, thus rendering them less accurate for identifying soft tissues, positioning patients, or monitoring intrafraction motion. Furthermore, the prostate is a bad example to use to try to demonstrate the utility of IGRT. Zelefsky *et al.*,[6] for example, have already reported an eight-year actuarial PSA relapse-free survival rate for favorable-risk prostate patients treated with IMRT to 81 Gy of >85% with no grade 4 rectal toxicity and only 0.1% grade 3 toxicity, *without the use of IGRT*. Thus, even if IGRT could buy you a 13% dose increment, it would likely be of little clinical value. In fact, the benefits cannot be as large as Dr. Jaffray claims since he has ignored organ deformation and intrafraction motion in his analysis. His other references (Refs. 3,4) are little more than studies demonstrating that conventional 2D EPID improves the setup accuracy of patients—not really news and not really a justification for a $500,000 3D IGRT system.

In diseases where radiotherapy does poorly, IGRT offers even less hope. In brain, for example, IGRT offers little improvement over conventional stereotactic radiosurgery. In lung and upper abdomen, IGRT will be almost useless unless it is respiratory gated, and current systems can't do that. In head and neck, 2D EPIDs seem to work fine.

In short, Dr. Jaffray offers a hypothesis but no real clinical facts, and certainly no data justifying IGRT's price tag or the enormous amount of hype currently associated with it.

Rebuttal: David Jaffray, Ph.D.

The advent of IGRT technologies has provided interesting data to awaken the community to, and refocus our attention on, the targeting problem—something that we have neglected for too long. The recent article by de Crevoisier *et al.*[7] highlights the influence of systematic errors on biochemical measures of outcome in radiation therapy of the prostate. This article describes a retrospective study in which a correlation between rectal-filling-induced displacement of the prostate at the time of planning is correlated with reduced biochemical control. I compliment the authors for exploring this relationship and bringing their observations to the forefront. Daily image-guidance data about the day-to-day positioning of the patient will elucidate the role that important factors such as bowel filling,[7,8] respiratory-induced motion,[9] lung target deformation,[10] and radiation-induced changes in the geometry of normal and target tissues[11,12] have in limiting the precision of radiation delivery.

At this point I have not advocated for margin reduction or dose escalation as a benefit of IGRT. The arguments to date have related to quality assurance of current radiation therapy practice and

how the introduction of IGRT technologies allow us to recognize the elephant in the room ("geometrical miss") for what it is—a blind spot that limits outcomes and prevents understanding of the effects of radiation therapy. The role of image guidance as a quality assurance and education tool cannot be overstated.

So what about the future? Now that we have our dose in a pile, where does IGRT let us go? I believe that the opportunities are enormous.

As there is no known benefit to unnecessary irradiation of normal tissues, IGRT will permit margin reduction, hopefully applied with a strong understanding of the principles of image guidance and residual uncertainties. The frequent argument used against PTV margin reduction is that standard clinical practice is "hiding" disease in the PTV margins. This simply reflects the need for more education on this topic—the reality is that we are "hiding" disease that may not be there. The PTV is a geometric construct to assure dose to the clinical target volume, not a volume known to contain any specific tissue. Clearly, we still have some work to do in educating the community on these concepts.

One side effect of applying radiation therapy without confidence in dose placement is to maintain a strict constraint on the degree of dose uniformity within the target. The emergence of stereotactic radiotherapy protocols that permit hot spots provided "they are in the target" is a harbinger of the importance of IGRT in moving away from the dogmatic and poorly supported practice of delivering uniform dose to targets in radiation therapy.[13] Failure to walk away from this practice within the next decade may truly limit innovation in radiation therapy. The constraint of uniformity forces undue hardship on normal structures and will limit dose escalation for those sites with poor control.

The radiation therapy community needs to remember that we are not standing by ourselves in the field of oncology. The remarkable explosion in therapies grouped under the umbrella of interventional radiology and targeted therapeutics is clearly exploiting advanced technologies such as image guidance to maximize the benefit detected in outcome studies.[14] The accelerated introduction of high-intensity focused ultrasound is made possible with the integration of MR-guided placement and thermometry. It is my belief that radiation therapy wouldn't get out of the FDA gate without image guidance if it were to be proposed anew today. Failure to advance our skill in the application of radiation therapy will leave this proven therapy at the back of the pack and will limit our ability to understand how this agent actually works *in vivo*.

Fundamentally, the adoption of IGRT is about quality in health care and our willingness to assure high-quality delivery for every patient. I would argue that 100% of the patients should achieve the best quality of radiation therapy if it is financially achievable. To bring this about we need to drive industry to provide these tools such that they operate in the current cost envelope. Early adoption is one way of achieving this objective. The answer to the question as to whether IGRT is overvalued is obviously no. The real question is how we are going to innovate our practice to make sure that it isn't overpriced.

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1.5. The value of PET/CT is being over-sold as a clinical tool in radiation oncology

Lei Xing and Barry Wessels

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OVERVIEW

PET and CT are important imaging technologies in the diagnosis and staging of cancer and in monitoring and evaluating the effectiveness of treatment. Combined PET/CT units are being marketed as advantageous because they offer a common platform for the technologies so that patient convenience is improved and mis-registration of information is reduced. Some physicists agree with this marketing message, while others believe that PET/CT is a technology that adds to healthcare costs without contributing substantive value. This controversy is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is Lei Xing, Ph.D. Dr. Xing earned his Ph.D. in physics from the Johns Hopkins University and obtained his medical physics training from the University of Chicago. He is currently an Associate Professor of Radiation Oncology at Stanford University. His major areas of interest are intensity modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT), PET/CT and other emerging molecular imaging modalities, such as MR spectroscopic imaging (MRSI) and fluorescence/bioluminescent imaging, and their integration with radiation therapy treatment planning systems. He has served on the AAPM IMRT Subcommittee, and the Medical Physics Editorial Board. He is certified by the American Board of Radiology.

Arguing against the Proposition is Barry Wessels, Ph.D. Dr. Wessels is currently Professor and Director, Division of Medical Physics and Dosimetry at Case Western Reserve University. He received his Ph.D. in nuclear physics from the University of Notre Dame in 1975. For the next two decades, Dr. Wessels served as a group leader at the MIT reactor laboratory and as a faculty member at The George Washington University. His areas of specialty include the dosimetry and radiobiology of radionuclide therapy, image fusion and clinical trial design. Dr. Wessels is currently a member of the MIRD and REIR committees of the SNM and has served as President of the American Board of Sciences in Nuclear Medicine (ABSNM), Chair of the AAPM Task Group on Radiolabeled Antibody Dosimetry, RTOG committee on physics and the ICRU Nuclear Medicine Advisory Committee. He has published over 200 peer-reviewed journal articles, book chapters, proceeding papers and abstracts.

FOR THE PROPOSITION: Lei Xing, Ph.D.

Opening statement

Hybrid PET/CT scanners[1] are advertised as cutting-edge technology. Many clinics are making purchasing decisions through the influence of advertisements and the pressure of competitors. Since 2000, more than 300 PET/CT units have been purchased, even though the clinical benefits

of the technology have not been unequivocally demonstrated. At this point, the "hopes" for PET/CT greatly outweigh the "facts" about the merit of PET/CT. Subjective impressions have been the dominant factor influencing PET/CT purchase decisions.[2,3]

Hybrid PET/CT systems have several positive features that are absent with stand-alone PET and CT units. PET/CT is a hardware-based image-fusion technology that virtually eliminates the uncertainty and inconvenience of software fusion of separate PET and CT images that are acquired with patients in different positions. However, PET images alone often contain enough information to answer clinically-important metabolic questions[3] without superposition of CT images. For treatment planning in radiation therapy, the use of CT/PET fiducials and software fusion has provided sub-centimeter spatial resolution[4,5] and yielded excellent clinical results.[6]

Currently available fusion software performs well in the head and neck, and less well in the thorax, abdomen and pelvis because of positioning difficulties and involuntary motion. However, reasonable results can usually be acquired in these regions by use of PET transmission scans and close collaboration of PET and CT technologists. Image co-registration is sometimes a problem also with PET/CT in these regions, because the images are acquired sequentially rather than simultaneously.[7] Software fusion requires multiple steps and is tedious, but these problems will ultimately be resolved through research.

The bottom line is that hardware-based fusion is not the ultimate solution for image co-registration, and a hybrid machine is not needed for every combination of imaging technologies that can conceivably yield useful fusion images. For example, a hybrid PET/MRI unit hardly seems necessary, even though some researchers are considering it. It is indisputable that CT measurements for PET attenuation corrections greatly reduces PET scan time—but it also ties up the CT scanner and increases the radiation dose to the patient.

A hybrid PET/CT unit is not a "must-have" clinical tool in radiation oncology, and does not automatically elevate an oncology service to "world-class" status. Conversely, an institution can be "world-class" without a hybrid PET/CT unit.[9] Software fusion, including rigid and deformable image registration, has several virtues and should be targeted for further research. Further, the possible clinical benefits of hybrid PET/CT should be carefully documented by investigators. At the end of the day, the usefulness of any technology is justified only through definitive diagnostic and therapeutic gains.

Rebuttal

Dr. Wessels puts his faith in marketplace trends, and bets that the marketplace cannot be very wrong. That is exactly what concerns me. I caution that, historically, the marketplace can indeed be wrong, and even badly wrong. If one is not convinced, perhaps revisiting the competition between beta and VHS file formats as a video standard in the 1970s will help. That said, I do not totally disagree with Dr. Wessels' argument, but would like to challenge him further by asking: "Can the marketplace be that right?" The marketplace is an interesting arena to watch but should never be a metric for technology assessment. Most likely, the truth of the debate about the value of PET/CT lies somewhere between our respective Point/Counterpoint positions. Clinical and scientific data are needed to objectively determine where PET/CT is located on the coordinate starting from "totally wrong" to "absolutely right," whether the clinical benefit of PET/CT is sufficient to offset its higher capital and running costs, and whether the alternative software fusion is an option.

Dr. Wessels also mentions that the hybrid PET/CT facilitates clinical operation. While the hybrid system is probably not a fundamental breakthrough that changes the paradigm of medical imaging, it does provide a more convenient solution for radiation oncology practitioners compared with the currently available software approach for fusion of PET and CT images. In an era where time, convenience, and efficiency are money, this value should certainly not be underappreciated. On the other hand, we should acknowledge that this benefit does not come for free; there are a number of practical issues associated with it.[3] Aside from the capital and operational costs, increased radiation dose, changes in medical/administrative procedures, appropriate selection of patients, etc., should all be considered. One should also note that difficulties with current fusion software may be short-lived and things may improve in the near future.

The fact sheet for the hybrid PET/CT is multi-dimensional. It is still too early to claim that PET/CT is a technology for everyone, and that the application of PET/CT should not in any circumstance be dictated by reimbursement. It is my view that if multi-modality imaging (not just PET, but also other related modalities) is to have a genuine impact in radiation oncology, a versatile, low cost, and long-term solution other than hardware fusion has to be in place.

AGAINST THE PROPOSITION: Barry Wessels, Ph.D.

Opening statement

Many spirited discussions occur within one or more of the following scenarios: 1) one discussant is talking apples and the other oranges, 2) both positions have overlapping truth sets, and 3) the definitive experiments have not been performed. Such is the case with the present "value" discussion on the net worth of integrated PET/CT for radiation oncology. The fact that a New England Journal of Medicine article in 2003 by Lardinois ,[8] and a Special Supplement in the January 2004 issue of The Journal of Nuclear Medicine, were devoted entirely to integrated PET/CT (Ref. 9) suggests that something major is afoot. Proponents of the proliferation of PET/CT machines would argue that the technology already has had a profound impact on the restaging of disease and for radiation therapy treatment using expanded or contracted target volumes for disease located in the head, neck, thorax and abdomen.[10] The apples and oranges aspect of this argument may be largely due to the simple addition of functional information to the anatomical imaging process alone and may not have anything to do with the method of acquisition. This addition can be accomplished by any one of three image registration methods (visual side-by-side, software, and hardware fusion). The latter of these methods is currently accomplished by the use of relatively costly PET/CT units. Clearly, the definitive experiments have not been completed to resolve the argument over the value of PET/CT. Most studies compare "horse-and-buggy" visual side-by-side fusion with inherently coregistered PET/CT scans, and do not give relatively inexpensive, independent image fusion software packages an even technical match.[11] A common truth set for all applications is 1) the need for a reliable automatic image segmentation algorithm for PET to draw corrected target volumes;[12] 2) the requirement for machine-based fiducial alignment and patient immobilization systems;[13] and 3) respiratory gating for all.[14] One might argue that this truth set is correct, but PET/CT may be the wrong combination of machines. The pundits may have a point here; PET/MR is probably not far around the corner.[15]

But at the end of the day from one who is constantly confronted with patient alignment, fusion, throughput and convenience concerns, the integrated PET/CT scanner has a unique advantage to

potentially solve all of these problems in a single patient visit. The cost in physician, physicist, radiation oncology and nuclear medicine staff time needed for multiple imaging sessions that usually require redundant immobilization equipment in separate departments is just part of the challenge of a nonintegrated PET/CT approach to image fusion. The expanded utility of PET/CT for radiation therapy is driven not just by expert technocrats who have a vested interest in its proliferation. It is also being demanded by referring physicians during combined tumor board case presentations, and ultimately will be expected by patients. Is this not in the same class as the unproven "value added" benefit purported by IMRT treatment for patients in radiation oncology? To this end, can the marketplace be that wrong?

Rebuttal

Virtually all the "facts" stated by both my worthy opponent and me are in substantial agreement regarding this discussion topic. It is heartening that most of the cited literature is shared common ground. However, there is little agreement in the valuation of the cost/benefit ratio for both the investigator and the patient concerning this new technological combination. My colleague states that "software fusion requires multiple steps and is tedious" (agreed!), "but these problems will ultimately be resolved through research." However, improvements to the software fusion process may only add to the tedium with limited returns on effort. This problem can be generalized to all image-guided therapy modalities, namely the functional definition of "real-time." To properly gate for organ motion and provide reproducible patient positioning necessary for accurate therapy, "real time" will be most likely defined in units of milliseconds. Using this metric, both software fusion and PET/CT fail miserably. Typically for software fusion, "real-time" is on the order of several hours to days for the acquisition of separate PET and CT scans taken in the treatment position. For state-of-the-art PET/CT imaging using an attenuation map acquired from CT, "real-time" is still fractions of an hour. The potential for patient movement, misalignment and multiple organ motion remains problematic for both methodologies.

It is reasonable to hypothesize that the "real-time" motion problem will be substantially reduced by the modality that acquires data over a window of time that is an order of magnitude closer to the motion-stopping, millisecond goal. Presently, there is a growing library where software fusion just gets it wrong for patients scanned in different positions using PET or CT originating from separate devices, and where there is no hope for organ-motion gating. Performed by skilled clinical staff, the single appointment PET/CT is the most practical solution to obtain the desired data from a single machine for patients scanned in a predetermined therapy position.

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1.6. Respiratory gating for radiation therapy is not ready for prime time

X. Allen Li and Paul J. Keall

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OVERVIEW

Respiratory motion is a significant cause of geometric uncertainty for the radiation treatment of lesions in the thorax region. This has to be taken into account in the design of planning target volumes (PTVs), and this increases the volume of normal tissue that has to be irradiated. It is well established that PTV size can be reduced if the effect of respiratory motion can be reduced. There are many ways that this might be achieved such as specialized breathing control or breath-hold methods, respiration-synchronized techniques, abdominal compression, and respiratory gating. Since respiratory gating is the least intrusive and most patient friendly of these methods, there have been numerous studies aimed at perfecting this technique and several respiratory gating systems are now available commercially. This technology is, therefore, accessible to all, but there is some concern that making this available in facilities that do not have the expertise to realize its limitations and use it properly could be dangerous. Concern that release of such methods on a wide scale at this time might be premature is the topic of this month's Point/Counterpoint debate.

Arguing for the Proposition is X. Allen Li, Ph.D. Dr. Li is a Professor and the Chief of Medical Physics in the Department of Radiation Oncology, Medical College of Wisconsin. He has been a board certified medical physicist since 1994 and is currently a member of AAPM TG-74, TG-106, and the Bio-effect Working Group. He is a member of the Editorial Board for *Medical Physics* and a reviewer for seven scientific journals and four public and private research funding agencies. He has authored 100 peer-reviewed papers and numerous abstracts. Dr. Li's research interests range from Monte Carlo applications in radiation therapy to biologically based treatment planning, and recently management of respiratory motion in radiotherapy.

Arguing against the Proposition is Paul J. Keall, Ph.D. Dr. Keall is Associate Professor and Director of the Division of Radiation Physics in the Department of Radiation Oncology, Stanford School of Medicine, CA. He obtained his M.S. in Health Physics and Ph.D. in Physics degrees from the University of Adelaide, Australia. He serves the AAPM as a member of the Editorial Board for *Medical Physics* and is a member of the Therapy Research Subcommittee, the Stereotactic Body Radiotherapy TG102, the Monte Carlo in Treatment Planning TG105, and the Summer Undergraduate Fellowship Program Subcommittee. His major research interests are 4-D imaging, planning, and treatment, adaptive radiotherapy, respiratory gating, image-guided radiotherapy, and biological models in radiotherapy.

FOR THE PROPOSITION: X. Allen Li, Ph.D.

Opening statement

Respiratory organ motion, which can be up to 30 mm, reduces the effectiveness of radiation therapy (RT) for thoracic and abdominal tumor targets. This motion degrades anatomic position reproducibility during imaging, demands larger margins during RT planning, and causes errors during RT delivery. In recent years, a variety of methods and techniques have been proposed or developed to explicitly account for respiratory motion in RT. These include respiratory gating, breath holding, and respiration synchronization. The gating method, including internal and external gating systems, is the most widely discussed method so far. It has been well documented that gated RT, if carried out carefully, can significantly reduce margins and, thus, improve sparing of normal tissues.[1] Currently, the only internal gating system used in the clinic is fluoroscopic tumor tracking based on implanted markers.[2] For external gating technology, at least two systems are commercially available for both CT and linear accelerators: the Siemens Anzai pressure belt[3] and the Varian RPM optical system.[4] In my view, gated radiation delivery, although promising, is not yet ready for prime time.

Generally speaking, respiration is an active and vital process not easily lending itself to manipulation. The unpredictable variation in respiratory patterns during and between image acquisition and day-to-day treatment delivery is the most challenging problem for all of the techniques developed for managing respiratory motion. For a gated procedure, this variation can result in inaccurate and/or inefficient dose delivery, and even geographic misses. Although much effort has been expended in searching for effective methods to improve breathing reproducibility, progress has not been remarkable. For example, one method to reduce breathing irregularity is to train patients with audio prompting and/or visual feedback.[5,6] It has been reported, however, that about 50% of patients could not follow both audio and video instructions simultaneously.[7] So far, no reliable training method is available.

For external gating systems, the use of an abdominal motion signal as a surrogate for internal tumor motion is not reliable because of variations in the correlation and phase shifts between the surrogate and internal structure motion.[8,9] In addition, the currently available systems are limited to one-dimensional motion. Although respiratory motion is predominantly in the superior-inferior direction, there are exceptions.[10] These problems can result in significant errors in dose delivery. Furthermore, a robust treatment verification system capable of documenting the dose actually delivered and preventing geographic misses is not available for gated delivery.

For internal gating systems, the high risk of pneumothorax due to the percutaneous insertion of fiducial markers in the lung is a problem, as is also the high imaging dose required for fluoroscopic tracking. These problems make internal gating impractical at the moment.

Respiratory motion is complex and patient specific, and it depends on location. It cannot be predicted by any known medical/physiological models.[10] In addition, clinical parameters to identify suitable patients for gating have not been defined. So far, the data acquired in the clinic for gated radiation therapy have been mostly limited to demonstration of dosimetric benefits. Whether these benefits transfer to outcome gain is unknown.

In conclusion, respiration gating, although very promising, is not mature and can be risky. Its clinical benefits have not been documented. Therefore, for the moment, gated radiation therapy should be performed with caution only for selected groups of patients.

AGAINST THE PROPOSITION: Paul J. Keall, Ph.D.

Opening statement

The recently published AAPM Task Group Report on respiratory motion management recommended that "If target motion is greater than 5 mm, a method of respiratory motion management is available; and if the patient can tolerate the procedure, respiratory motion management technology is appropriate."[1] Respiratory gating is one technique for respiratory motion management that has been seamlessly integrated into the clinical process. Does respiratory gating solve all of the motion issues? Definitely not! But the debate is not "Is respiratory gating with current technology perfect?" The question is "Is respiratory gating better than not accounting for motion at all?" By disputing three fallacies I will argue that respiratory gating is well established and widely available, and that there is strong clinical evidence that it will result in improved patient outcomes.

Fallacy #1: Respiratory gating is not an established technology

The first published article on respiratory gating in radiotherapy was that of O'Hara *et al.*[11] in 1989 in which they described seven patient treatments. Technologies that are now considered mainstream but were actually first clinically used *after* respiratory gating include IMRT, superposition and Monte Carlo-based treatment planning, multi-slice CT scanning, and cone beam CT imaging. Respiratory gating is an established technology and it has been commercially available in the US since 1999.

Fallacy #2: Not many sites have or use respiratory gating

Respiratory gating is the most widely available method of respiratory motion management with several vendors offering respiratory gating products. Over 1000 respiratory gating systems have been sold worldwide. In a recent RTOG IGRT survey, 26 out of 91 sites surveyed were performing respiratory gating (J. Bradley M.D., ASTRO 2006), and the trend is toward increased use. At Stanford, respiratory gating is performed on three linear accelerators with an additional two performing respiratory tracking.

Fallacy #3: There are no clinical data to support the use of gating

The proof is in the pudding as the saying goes—is respiratory gating better for patients? A seminal paper by Fang *et al.*[12] demonstrated that 3D radiotherapy has statistically significant survival advantage over 2D radiotherapy, with 27% (3D) vs. 6% (2D) overall 5-year survival. A compelling piece of data in that study was that patients treated with respiratory gating had a hazard ratio of 0.25 (p=0.05), indicating that patients are four times more likely to survive than those not treated with gating. In multivariate analysis gating was not significant—the study was not powered to address this question—but there is a strong suggestion that respiratory gating does, indeed, improve survival in lung cancer patients. Wagman *et al.*[13] in a liver cancer study found that using respiratory gating reduced fluoroscopically visible motion from 22.7 to 5.1 mm. The use of gating, in combination with a rigorous portal imaging protocol, allowed the CTV-PTV margin to be reduced from 2 to 1 cm. This margin reduction allowed dose increases from 7% to 27%, and also allowed radiotherapy to be given to patients for whom the treatment would otherwise have been too toxic. Several treatment planning studies have reinforced these clinical findings.[14,15,16,17,18,19]

Perhaps the most accurate form of respiratory gating has been implemented by the Hokkaido group,[20,21] where implanted markers are tracked in real-time using fluoroscopy, and the treatment

beam gated on when the markers are within predetermined positions. This active program has treated many liver and lung cancer patients with gated stereotactic radiotherapy.

In summary, if respiratory motion management systems are available, and have shown clinical benefit, we are ethically bound to use them. Today at Stanford we are routinely treating the following abdominal and thoracic sites with respiratory gating and IMRT/conformal radiotherapy: lung, breast, esophagus, pancreas, and lymphoma. Respiratory gating is beyond prime time, it is routine.

Rebuttal: X. Allen Li, Ph.D.

Respiratory gating, which associates with tight margins, is better than not accounting for motion at all only if it is carried out properly. Tight margins, which increase the risk of geometric misses, require accurate treatment delivery. However, such accurate delivery is not trivial during a course of multi-fractionated radiotherapy because of inter- and intrafractional variations. I agree with Dr. Keall that the technology for respiratory gating is reasonably established and the technical implementation of commercial gating systems can be seamless. However, the clinical use of these technologies is not yet mature. The fact that only 26 out of 91 RTOG members are performing respiratory gating reflects the hesitation of using these technologies for patients on a large scale. Gating technology has been commercially available since 1999 and most RTOG members are academic centers that would be expected to have the resources needed to perform respiratory gating, but only a few are actually using it. Issues that contribute to this hesitation include (1) more effective prediction techniques and/or training methods for patient breathing are needed to reduce inter- and intrafractional variations in breathing patterns; (2) more reliable mechanisms are required to correlate external surrogates with internal tumor motions; and (3) proper clinical parameters are needed to identify suitable patients. Until these issues have been fully addressed, respiratory gating should be carried out only in those clinical settings that can provide the considerable resources needed to carefully select suitable patients, cautiously design treatment plans, and extensively validate treatment delivery.

Rebuttal: Paul J. Keall, Ph.D.

I concur with Dr. Li's statements that, if used appropriately in conjunction with methods to manage interfraction variations, respiratory gating allows safe margin reduction. I also agree with the statement that respiratory motion is complex, multidimensional, and patient specific. However, it is precisely for these reasons that we want to manage motion with technologies such as respiratory gating. Ignoring the problem does not make it go away—respiratory gating can reduce the apparent motion by over a factor of 4 (Ref. 13) and can minimize deleterious effects.

Following are my responses to the statements of Dr. Li:

High imaging dose for internal gating: The dose for fluoroscopy-based gating has been estimated to be 1% of the treatment dose.[20]

Unacceptable risk of pneumothorax for marker implantation: Percutaneous[22] and bronchoscopic[23] lung implantation have shown pneumothorax rates of 19% and 2%, respectively. The increased accuracy offered by marker implantation outweighs the associated morbidity.

50% success rate of audio-visual biofeedback: A 24-patient repeat session study found a 100% success rate, reducing the residual motion by an average of 20% at exhale and 25% at inhale.[5]

Lack of verification: The same verification methods used without gating can be used with gating, e.g., portal images. However, as respiratory motion affects many of the landmarks used for planar imaging, such as the diaphragm, chest wall, and carina, verification is even more effective with respiratory gating than without.

To conclude, respiratory gating is at its prime time now. It represents an intermediate step towards the widespread implementation of target tracking technology.

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1.7. Heterogeneity corrections should be used in treatment planning for lung cancer

Nikos Papanikolaou and Eric E. Klein
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OVERVIEW

Corrections in dose distributions for the heterogeneous nature of lung tissue are available with many commercial treatment planning platforms of recent vintage. Use of these corrections is appealing to medical physicists who strive for accuracy in the display of radiation dose in exposed tissues. However, radiation oncology is largely an empirical science. Treatment regimens for patients, including those with lung cancer, are determined largely by experience. This experience has been acquired without the luxury of heterogeneity corrections. Inserting heterogeneity corrections into the planning process can be construed as switching horses in midstream. In addition, some physicists question whether the heterogeneity corrections have been verified sufficiently for all potential applications. These issues are explored in this issue of Point/Counterpoint.

Arguing for the Proposition is Nikos Papanikolaou, Ph.D. Dr. Papanikolaou is currently on the faculty at Emory University School of Medicine. He received master and doctorate degrees in Medical Physics from the University of Wisconsin-Madison. He has lectured nationally and internationally on dose computation algorithms and heterogeneity corrections for photon beams. He is currently the chair of the AAPM Task Group on Inhomogeneity Corrections. Dr. Papanikolaou is certified by the American Board of Radiology and is actively involved with the American Association of Physicists in Medicine, American College of Medical Physics, and European Society of Therapeutic Radiation Oncology.

Arguing against the Proposition is Eric Klein, M.S. Mr. Klein received his master degree in Applied Physics from the University of Massachusetts in 1987. He has been working as a Radiation Oncology Physicist since 1981, the last 11 years at the Mallinckrodt Institute of Radiology, where he is currently an Assistant Professor. Mr. Klein is on the editorial boards of Medical Physics and the International Journal of Radiation Oncology, Biology, and Physics. He was Scientific Co-Director for the 1999 AAPM Annual Meeting, and is a Track Chair for the 2000 World Congress Meeting, and Scientific Director for the 2001 AAPM Annual Meeting. Mr. Klein is a member of AAPM's TG-65 on Tissue Inhomogeneity Corrections for Photon Beams.

FOR THE PROPOSITION: Nikos Papanikolaou Ph.D.

Opening Statement

To do or not to do? That is the question. There are indeed a number of issues to consider when discussing the inclusion of heterogeneity (inhomogeneity) corrections in lung dose computations.

Is the dose calculation algorithm accurate that is used for the computation of heterogeneity corrections? Several algorithms have been proposed to implement some sort of inhomogeneity correction, from the simplified ratio of TARs (RTAR) that yields a correction factor for water-based calculations, to convolution and Monte Carlo methods that include the inhomogeneity in the calculation of patient dose. The latter, and specifically the convolution/superposition algorithm that is becoming the standard for 3D radiation treatment planning systems, can accurately predict the dose even in areas of electronic disequilibrium. Monte Carlo can yield improvements over convolution computations, especially when inhomogeneities of nontissue atomic numbers are involved. Monte Carlo is of lesser importance for lung irradiation. When dose is computed two questions should be answered: (i) does the algorithm account for the three dimensional shape of the patient, including inhomogeneities and, if so, (ii) does it do so for both the primary and the scatter energy transport? The best algorithms meet both of these requirements, and correctly predict the absolute dose to the prescription point and the dose distributions that reflect the spatial distribution of inhomogeneities. The latter is particularly important in the case of lung radiotherapy, since the shape of the isodose curves that encompass the tumor volume will change significantly when lung inhomogeneity computations are used. Similarly, the dose to the isocenter for a given number of monitor units (MU) changes (typically increases) because of increased transmission through the lung.

If we are using an algorithm that correctly transports primary and scatter energy, we have to consider the integration of that information in the prescription dose. However, the medical physicist is not responsible for deciding the prescription dose! Nevertheless, it is our responsibility to educate our physician colleagues and help them interpret treatments when inhomogeneity corrections are included. It has been argued that tissue inhomogeneity corrections should not be used at all since current clinical practice and dose prescriptions are largely based on historical experience with tissue response to doses computed in water. However, clinical data indicate that even for simple anterior–posterior parallel-opposed fields encompassing the mediastinum and lung regions, corrections at the reference target point can range between 0.95 and 1.16, and may be even larger for oblique or lateral fields. Because the entire dose distribution can be distorted by tissue inhomogeneities, not only is the dose to the target volume affected, but also the doses to nearby critical organs which often impose limits to the prescription dose.

On a final note, we know that the level of dose accuracy required for clinical trials depends on the ability to demonstrate a statistically significant improvement in clinical results as the dose is altered. A side but important benefit of including inhomogeneity corrections is the impact on the number of patients required in clinical trials. Inhomogeneity corrections reduce the uncertainty in absolute dose, yielding more controlled studies with less variability in absolute dose delivery. This feature facilitates treatment outcome studies and interinstitutional comparisons.

Clearly, standardization of absolute dose delivery cannot be achieved if one allows uncontrolled variability caused by the anatomy, geometry, and density associated with individual patients. Accurate doses, including inhomogeneity corrections, are an essential component of dose optimization and the objective analysis of clinical results, especially with the advent of 3D precision conformal radiotherapy.

Rebuttal

It is precisely because lung cancer radiotherapy is a complex matter that we have to move away from the current ‘‘canned’’ practice of treatment delivery. How can we improve cure rates for

lung cancer unless we deliver higher doses to the tumor in a precise manner? We can't escalate the dose if we are uncertain about the actual dose to the healthy lung, heart or esophagus, or to the tumor itself. The findings of RTOG 88-08 support this argument: a 33% spread in delivered doses was reported when inhomogeneities were included in calculations. The report concluded that: ''Existing density-correction algorithms are accurate enough to significantly reduce these variations.'' All of the pieces of the puzzle are here: (i) we now have more accurate algorithms for dose calculation (convolution/superposition) than we had before; (ii) workstations provide full 3D computations in only a few minutes; (iii) imaging technology has improved so that we can obtain better, more accurate images faster, even allowing us to gate the images to reduce motion; (iv) accelerator design has improved so that we can deliver (MLC and dynamic MLC) and monitor (portal imaging) treatments more efficiently, including gated treatment options. So why wait? Let's move forward now and do it right!

AGAINST THE PROPOSITION: Eric E. Klein, M.S.

Opening Statement

The use of heterogeneity corrections in treatment planning for lung cancer radiotherapy exemplifies the cliche´ ''the more you look, the more you find.'' The desirability of heterogeneity corrections is still evolving and unresolved. The physics community is gearing the radiotherapy community to a condition where isodoses, treatment time calculations, and most importantly, prescriptions account for the presence of lung. But until algorithms evolve to accommodate this condition, prescriptions should not change. Heterogeneity corrections are not like the recent TG-43/NIST SK change applied to I-125 and Pd-103, where prescriptions changed to deliver the same prescribed dose as the clinician specified before the change. The influence of lung tissue on dose delivery is more complex because of patient variations, variability of algorithm sophistication, and resulting biological considerations. The radiotherapy community is still refining HDR prescriptions, and has just begun to debate intensity modulated radiotherapy prescriptions.

Lung cancer radiotherapy involves complex organs at risk, including healthy lung tissue, liver, heart, esophagus, spinal cord, and brachial plexus. Dose distributions to these organs are obviously affected by low-density lung tissue and also beam energy. To further complicate the issue is the variation of a patient's lung density depending on the patient's status and inspiration/expiration capabilities. Volume and density can differ, day to day, breath to breath, and, more importantly, from scan to treatment. These issues may be resolved with improved imaging information and respiratory control systems. This brings us to calculations.

The AAPM Science Council's Radiation Therapy Committee first assigned a task group to investigate this issue in 1985. To date, no report has been generated, indicating the complexity of the issue. From the simplest correction techniques of linear attenuation (ratio of TARs) and Batho, to today's convolution (FFT and superposition) and Monte Carlo techniques, correction methods have provided the best corrections possible at their period of technological development provided that the corrections are implemented and utilized properly, and their limitations are well understood. Accordingly, national clinical protocols have wisely examined the effect of corrections in a postplanned manner, where corrections are applied using water-based monitor units and uncorrected beam weights. The RTOG 88-08 lung radiotherapy protocol asked facilities to submit water-based plans and post-corrected plans, along with information on the planning algorithm used. Patients were planned, prescribed and treated without corrections. The

post-dosimetric analysis was a comprehensive effort during a 2D planning era, and was therefore limited compared with volumetric dose calculation systems that are now available. This brings us to RTOG 93-11, a 3D dose escalation lung radiotherapy protocol. This protocol also requires prescription and treatment without corrections, and with the unit density and post corrected dose distributions submitted. Early submissions included data using corrections that fall short of what is commercially available today. In other words, clinical experiences and dosimetric analyses never coincide with the most up-to-date technologies. Further accrual of data in response to RTOG 93-11 should bring us closer to knowing the dose delivered after applying corrections, and therefore how prescriptions would be changed to account for the corrections. The timing of modern day algorithms and prescriptions may then finally be coincident.

Rebuttal

Dr. Papanikolaou and I agree that heterogeneity corrections should be used in treatment planning for lung cancer. We differ on the timing of when this should take place. Although I concur that the needed algorithm sophistication is in place, there are still unsettled issues. First, there is no way to mandate or determine that a physicist understands and has properly parameterized, tested, and implemented a sophisticated algorithm. This concern includes the question of how a physicist analyzes dose distributions and calculates monitor units. For example, the algorithm may accurately depict a dose reduction at the periphery of a lung tumor, while the computation of dose based on a reference point located in the middle of the GTV calls for a reduction of monitor units. This contradictory situation could lead to underdosage of the tumor periphery, if one bases monitor unit calculations on an increased transmission through the lung.

I also concur with Dr. Papanikolaou that using proper algorithms and applying resulting prescriptive corrections will reduce the uncertainty in dose reporting for patients enrolled in national protocols. But I do not agree that responsibility for prescriptions is exclusively a physician's obligation. We cannot dictate change unless we can offer advice on how to change. So how do we offer advice? Once the results of heterogeneity corrections on dose distributions have been ascertained from RTOG 93-11, we could consider a plan to change prescriptions. This plan must also include the effects of lung density corrections on critical organ doses.

In closing, the most important task a physicist has in treatment planning is to accurately report the dose to every element of the irradiated volume, targeted or not. But we should not let clinicians make prescriptive changes haphazardly without advising them properly. We can and will soon be able to do this.

1.8. The rate of evolution of radiation therapy planning and delivery systems is exceeding the evolution rate of quality assurance processes

Sheri D. Henderson and Peter J. Biggs
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OVERVIEW

The processes of planning and delivering radiation treatments are experiencing a significant upscaling in sophistication and complexity. Computer-based treatment planning systems utilize medical images, radiation source characterization data, and desired treatment parameters to determine preferred treatment options and predicted dose distributions. Treatment options include low and high dose rate techniques (brachytherapy) and conformal, intensity-modulated and image guided methods (external beam therapy). Medical physicists are responsible for ensuring that the planning and delivery of radiation treatments meet agreed-upon standards for quality assurance. These standards reflect a consensus of medical physicists that is difficult to achieve when techniques are rapidly changing. Whether this dilemma currently exists in radiation therapy planning and delivery is the subject of this Point/Counterpoint issue.

Arguing for the Proposition is Sheri D. Henderson. Dr. Henderson has worked as an independent consultant for the last 10 years in areas of clinical physics, QA of equipment, commissioning and data con figuration of treatment delivery and planning systems; FDA regulatory standards for product introduction, specification, hazard analysis, hardware and software analysis, and testing and documentation of radiation algorithm performance. Prior to becoming a consultant, Sheri had an academic career as a research scientist for the clinical charged particle program at Lawrence Berkeley Laboratory and as an Assistant Professor of Therapeutic Physics at Mallinckrodt Institute of Radiology. Sheri received her Ph.D. in Radiation Biophysics from the University of Kansas.

Arguing against the Proposition is Peter J. Biggs. Dr. Biggs obtained his Ph.D. in high energy physics from the University of London in 1966. He worked at the Daresbury Nuclear Physics Laboratory until 1970 and at MIT from 1970 until 1975, performing research at Fermilab and Brookhaven National Laboratory, resulting in the discovery of the *J* particle. Since 1975, he has been at the Massachusetts General Hospital in the Department of Radiation Oncology where he is an Associate Professor and currently acting head of Radiation Biophysics. He has been active on many AAPM task groups, including, most recently, TG51, the new AAPM dosimetry protocol and TG57, an update of NCRP#49 for radiation therapy; he is currently chairman of PUBCOM.

For the proposition: Sheri D. Henderson

Opening Statement

The processes of radiotherapy planning (RTP) and delivery are experiencing a significant upscaling in enhanced capability and complexity. Past upward movements in these technologies

have not always occurred in concert over time, thereby contributing to the dilemma debated here. Currently, the medical physicist is challenged to ensure that innovations in RTP and delivery systems meet agreed-upon standards for quality assurance (QA). These standards, however, are generally created much later than initial market introduction of the technologies.

At the beginning of this decade, introduction of the dynamic or virtual wedge in radiation delivery preceded RTP implementation and medical physics QA. Although introduced into the market with representative dose data, dynamic and virtual wedges were only sparingly used in the clinics for several years before RTP systems started implementing segmented treatment tables (STTs) for dose calculations, and linear arrays became available for verification. A similar situation existed for introduction of independent collimation and multi-leaf collimators, except these features enjoyed clinical use almost immediately while RTP systems are improving implementation today. Although many scientific papers cover these topics with respect to dose, absent is an agreed-upon QA standard for physicists.

In the middle of this decade, ''3D'' RTP systems with associated graphics and dose calculation algorithms were introduced. This event challenged the medical physicist because QA required a higher understanding of the RTP algorithms. The fact that a symposium is being held in 1999 for basic Monitor Unit calculations for photons reflects the lack of a national AAPM-recommended formalism in the presence of more complex treatments utilizing new technologies. Another indication is a 1999 symposium exploring the use of DOSEGEL for 3D dosimetry. Even more disturbing, however, is the willingness of medical physicists to purchase ''canned'' treatment delivery data loaded into installed RTP systems.

Today, one only has to read inquiries on the medphys server or review current educational symposia offered by the medical physics community and industry to realize that we are endeavoring to master the sophistication (real and imaginary) of RTP systems in conjunction with the technological advances of delivery systems. This state is worrisome as the delivery systems are emerging with technologies of intensity modulation and inverse planning. Certainly, there is doubt among medical physicists that for these new technologies, physics understanding exists, RTP algorithms are sophisticated enough, and QA standards are established to ensure accurate delivery of dose to patients.

Rebuttal

Upon reading Dr. Biggs' position statement, it is apparent that we disagree on our views of history with regard to introduction of new technologies and the subsequent response of the medical physics community to provide adequate QA safeguards. I suspect that our different perspectives may reflect our different experiences. However, I believe that my experience has more viewpoints than Dr. Biggs' because I have existed in the ''ivory tower'' of academia, worked with industry, and labored in the (often isolated) trenches of most practicing medical physicists.

I agree with Dr. Biggs that manufacturers adequately test products prior to introduction. Manufacturers are required by law to practice GMP (good manufacturing practices) and meet product specifications of performance. I also agree that it is the physicist's job to bring the product into clinical operation. However, I disagree with Dr. Biggs' sweeping statement that (all) medical physicists do this with extensive QA procedures that have been disseminated widely in the literature and by professional organizations. My experience in the ''field'' just doesn't support this claim.

Complex technologies are being installed at sites that previously performed only simple hand calculations and Cobalt therapy. They do not have an on-site physicist or QA equipment, and data are often taken by non-qualified individuals. In a recent seminar, a dozen competent physicists could not agree on necessary QA components, the need for each, and the approach to calculation of monitor units generated for a 3D complex treatment plan even after referring to the standard text by Geoff Ibbott and Bill Hendee.

I do not believe that our differing view of ''medical physics history'' or today's debate will be resolved without a measuring bar of standards. The issue of agreed-upon QA standards is not addressed by Dr. Biggs, whereas it is foremost in importance from my view ''from the road.''

Against the proposition: Peter J. Biggs

Opening Statement

The rationale behind this proposition is that we are at the threshold of a computer-based technological revolution that is likely to have a far larger impact on radiation therapy than any experienced hitherto. The fear is that with so many possibilities for new treatment techniques, such as Intensity Modulated Radiation Therapy (IMRT), coupled with increasingly complex 3D planning systems, insufficient effort will be directed toward adequate quality assurance. However, the history of medical physics practice in radiation therapy and the innate conservatism of medical physicists make that scenario highly unlikely. Medical physicists do not embark on new procedures without extensive testing to ensure that calculations, measurements and plans make physical sense. When manufacturers produce either new hardware, such as multileaf collimator (MLCs), or develop new software, such as dynamic wedge or dynamic MLC, these products are tested for efficacy and safety. However, they are not commissioned by the manufacturer—it is the task of individual physicists to bring them into clinical operation. When electron beams first became available, the primary concern of the manufacturers was to ensure that the beams were flat and had a sharp penumbra. It was left to the physics community to perform the necessary dosimetry before patient treatments began. A comparison between commissioning an MLC compared with a dynamic wedge illustrates physicists' conservatism; that for the MLC is relatively short and straightforward, accounting for its rapid and universal acceptance throughout the community, whereas for the dynamic wedge, it is more complicated and thus less well accepted.

New-found knowledge is rapidly disseminated throughout the medical physics community by a network that includes the Medical Physics journal, the AAPM annual and local chapter meetings, summer schools, AAPM task groups, personal contacts and now e-mail listservers.

Is the current technological change far greater than hitherto experienced? Complex technology has been introduced in recent years with adequate quality assurance safeguards. Stereotactic radiosurgery comes readily to mind. This procedure requires positioning accuracy to better than 1 mm for treating lesions a few cm in diameter. This could not have been achieved without additional mechanical devices to assist in the set-up and QA protocols carried out before each procedure. Moreover, 3D treatment planning has been steadily developing over many years; the principles of 3D planning at the Massachusetts General Hospital using beam's eye view and dose volume histograms began with proton therapy in the mid 70's, almost 25 years ago! Interestingly, many of the dose calculation algorithms developed for the first generation computers are still in use today. QA instrumentation has also kept pace with the technology of

dose delivery. For example, detector arrays are now available for dynamic wedge characterization and hardware/software is available for daily, monthly and annual machine checks.

While errors have occurred in adoption of computer-controlled technology, such as Malfunction 54, to the best of this author's knowledge, no other similar faults have occurred since then. This is a bold testimony to the adequate QA procedures that both manufacturers and medical physicists have instituted to avoid repeating such mistakes.

The first sentence of a thesis abstract published in the March edition of *Medical Physics* provides a fitting summary: ''This thesis deals with the implementation of IMRT into the clinic and a method of quality assurance which can be used on each intensity-modulated beam prior to treatment.''

Rebuttal

Dr. Henderson points out the apparent contradiction that while advanced technologies, such as IMRT, are being introduced into the clinic, at the same time a symposium on basic monitor unit (MU) calculations is being held. While IMRT is practiced at several centers, these are major teaching hospitals that have invested significant amounts of time in planning and, more importantly, verifying the dose distributions in the time-honored way of measuring them with film or ion chambers. The need for a symposium on basic MU calculations does not imply that some physicists are calculating correctly and others not, only that there are several methods to achieve the same end. A symposium on DOSEGEL is entirely appropriate at this time since it is a maturing technology and may have a great impact on the field of 3D QA. Dr. Henderson's comments about the delay in the clinical introduction of dynamic wedges echo those I made and are a healthy sign that physicists adopt a careful approach.

A high percentage of academic and community centers now use CT as the primary method of simulation with direct input into a treatment planning computer. I believe this favorable adoption is because the planning can vary from sophisticated 2D to full-blown 3D; the physicists can therefore begin with familiar methodologies and progress to more advanced planning at their own speed. These new technologies also bring new benefits: more accurate customization of blocks through beam's eye view, dose-volume histograms and digitally reconstructed radiographs for comparison with verification simulations and treatment portals.

1.9. Long-term changes in irradiated tissues are due principally to vascular damage in the tissues

John Hopewell and H. Rodney Withers
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OVERVIEW

Changes in irradiated tissues that occur months or years after exposure are one of the potential complications of radiation therapy. The biological processes underlying these changes are disputed among radiation biologists. Some experts believe that the changes are a reflection of radiation-induced damage to the vascular system supplying the tissues, whereas others suggest that the radiation-induced damage is to the tissues themselves. These two perspectives on a fundamental radiobiological problem are discussed in this Point/Counterpoint series.

Arguing for the Proposition is John Hopewell. Professor John Hopewell obtained his Ph.D. from the University of London in 1968 for work related to the effects of ionizing radiation and chemical carcinogens on the central nervous system. He moved to the University of Oxford in 1970 and was appointed Director of Radiobiological Research at the University of Oxford in 1980. The Research Group he heads has focused its attention on the study of the mechanisms of late radiation responses following therapeutic or accidental radiation exposure. Additional research has assisted in the development of the present ICRP Radiological Guidelines for the skin and has helped to improve our understanding of the problems of dose, time, fractionation and volume effects in radiotherapy.

Arguing against the Proposition is H. Rodney Withers. Dr. H. Rodney Withers was born in Queensland, Australia. He received his medical degree from the University of Queensland, and his Ph.D. and D.Sc. degrees from the University of London. His research interests have been in radiation biology and how it relates to radiation therapy for cancer. He has worked at the Gray Laboratory in England, the National Cancer Institute, the M.D. Anderson Cancer Center, the Prince of Wales Hospital in Sydney, and at UCLA where he is Professor and Chair of the Department of Radiation Oncology and holds an American Cancer Society Clinical Research Professorship.

For the proposition: Professor John Hopewell

Opening Statement

Early pathological reports on tissues, showing late radiation-induced changes after therapeutic or accidental exposure, almost unanimously emphasized the prominent appearance of gross vascular changes. These changes were varied in their appearance, affecting arteries/arterioles, capillaries and veins. While an association was frequently suggested it was perhaps Rubin and Casarett (1968), in their classical textbook ‘‘Clinical Radiation Pathology,’’ who first proposed a causal relationship between the slow development of vascular damage and the occurrence of late normal tissue injury. Their proposal initiated a spectrum of studies specifically designed to examine long term time- and dose-related changes in the vasculature of complex tissues and in

simpler models. Such models included the vessels of the mesentery in the mouse, the hamster cheek pouch and even the choroid plexus of the rat brain. The simpler models allowed easier cell and vessel identification. The work was largely driven by the desire to demonstrate target cell populations, a reflection perhaps of an extrapolation from the same approach in acutely responding normal tissues.

These studies demonstrated, in general terms, that both endothelial cells and smooth muscle cells were gradually lost from the wall of blood vessels after irradiation. The magnitude of the loss was dose-related. Endothelial cell loss occurred earlier than that of smooth muscle cells, a feature that could be interpreted by cell proliferation studies to indicate a more rapid turnover of endothelial cells. Evidence for atypical endothelial regeneration has been reported resulting in the appearance of groups of cells (colonies) at irregularly spaced intervals along the wall of a blood vessel. Blood vessels with focal occlusion changes could often be visualized *in vivo*. Suggestions that these groups of cells represented clonogenic cell survival were again driven by classical radiobiological concepts.

Histological studies have indicated that there are occasions where intimal proliferation is so severe that vascular occlusion may result. Associated studies have reported a concurrent reduction in the vascular density of tissues, the severity of which was dose-related. These changes, not surprisingly, were frequently linked to a reduction in regional blood flow. The concept of a reduction in vascular density, and impaired blood flow leading to the development of ischemic necrosis, is best identified by studies on pig skin. Pig dermal tissue is relatively poorly vascularized compared with rodent dermal tissue, and this has been used to explain the difference in dermal radiation response in the two species. Similarly in the central nervous system, the presence of white matter necrosis, in the absence of similar grey matter effects, has been explained by their differing vascular architecture. Whether simple vascular insufficiency and ischemia is the explanation for white matter necrosis in the CNS remains an open question.

More recent studies have focused on functional changes that may develop in endothelial cells either as a direct consequence of irradiation or, more likely, as a result of a reduction in endothelial cell number. The changes are numerous and include, (i) an upregulation of adhesion molecules on the surface of endothelial cells, with the resultant adherence and infiltration of white blood cells into tissues and (ii) modified eicosanoid metabolism, specifically an imbalance in the two key eicosanoids, prostacyclin and thromboxane A_2. White blood cell infiltration has been clearly identified to be a factor in the development of white matter necrosis in the CNS and in the development of glomerular sclerosis.

Pharmacological intervention after irradiation, based admittedly on insufficiently understood vascular mediated effects, has also been effective in reducing the incidence and severity of late effects. Successful outcomes of this type have been reported in the skin, CNS, kidney and lung.

Recent studies in the rat spinal cord have perhaps best exemplified the role of endothelial damage, which sets up a cascade of events leading to the development of overt late tissue damage. Irradiation was with thermal neutrons alone or in combination with a ^{10}B capture agent (borocaptate sodium—BSH). This agent does not cross the intact blood brain barrier. The liberation of short range fission products (<9 μm) from the ^{10}B capture reaction, $^{10}B(n, \alpha)^{7}Li$, allows preferential irradiation of vessels and a relative sparing of the parenchyma. Nevertheless, white matter necrosis was identical irrespective of the mode of irradiation. Studies of glial progenitor survival at iso-effective doses for late damage showed marked differences in both

short and longer term responses, indicating their lack of involvement in the development of necrosis. Furthermore, irradiation involving heterogeneous exposure with sparing of the parenchyma, shortened the latency for white matter necrosis compared with that following uniform tissue irradiation with thermal neutrons. It was implied from these results that irradiation of the parenchyma may actually impair the development of the cascade of events initiated by endothelial vascular injury. On this basis I strongly support the proposition that late effects of radiation are due principally to vascular damage.

Rebuttal

Tissues with a hierarchical structure are frequently thought of as acutely responding tissues, i.e., skin, oral mucosa, etc. The timing of their response will be dependent on the specific total turnover time of that tissue; hence oral mucosal reactions will occur earlier than those in pig or human skin. The way that such tissues react to injury is to increase proliferation in the stem cell compartment. The lens of the eye is also an epithelial tissue, but with a slower turnover, hence cataracts appear at late times via a mechanism that is well understood.

Dr. Wither's main contention is that major variations in the rate of development and radiosensitivity of late effect response tissues and organs are not consistent with a single target structure, blood vessels. By this he implies that blood vessels are rather uniform structures. However, vascular organization varies greatly both between tissues and organs and even within an individual organ. Some vascular networks are adapted for a specific function, i.e., the capillary network of a glomerulus, with a single input and a single output from the capillary network. Other capillary networks have extensive collateral links. Unlike epithelial tissues increased stem cell proliferation is not the usual initial means of response of the vasculature to injury; physiological compensation is possible although variable from tissue to tissue. For example blood flow in normal skeletal muscle can increase tenfold even under moderate exercise.

We have both made reference to the central nervous system (CNS); white matter, or myelinated areas, are verypoorly vascularized compared with grey matter regions. Its vascular physiological reserve is also minimal compared with that found, and indeed needed, for the demands of the grey matter regions of the CNS. Moreover, even in the myelinated regions, which are the most sensitive to the development of necrosis, variations exist. The fimbria of the hippocampus responds more rapidly to radiation exposure than the adjacent corpus callosum. This fact has been related to a difference in vascular supply between these two white matter regions of the brain. The fimbria has what is a terminal vascular supply, while the corpus callosum received a more extensive collateral supply from adjacent grey matter regions making it less vulnerable to the effects of vascular impairment. Differentiated oligodendrocytes, and more specifically their progenitors, have recently been eliminated as a potential target cell population for radiation induced white matter necrosis.

This the diversity of vascular systems could well explain many of the differing patterns of response observed.

Against the proposition: H. Rodney Withers

Opening Statement

Contrary to the general belief that acute effects of irradiation result from killing of parenchymal cells and late effects from vascular injury, I contend that both types of effect result directly from radiation induced parenchymal cell depletion. Vascular damage occurs just as in other late responding tissues. While vascular damage may exacerbate other types of the late injury it is not the primary cause.

The rate of development of overt injury depends upon the rate at which cells of the tissue divide: acute injury occurs in rapidly proliferating tissues, late injuries in tissues which turn over slowly. A late effect is analogous to an acute effect but delayed in its expression by the slow rate at which the target cells turn over. That late radiation injury develops at different rates in different tissues is surely not consistent with a single target structure ~blood vessels!. Also, endothelial injury appears appreciably earlier than parenchymal injury in most late responding tissues. Even if late responses were attributed to non-endothelial elements of the vasculature, a consistently different response rate from tissue to tissue should not occur. The most plausible explanation for the variability in latent intervals lies in the variability of parenchymal proliferation patterns in the various tissues which manifest late responses.

Not only do the rates of development of late effects vary widely among tissues, but so do the doses required for a certain level of injury. Approximate tolerance doses in 2 Gy fractions are kidneys 20 Gy, lungs 15 Gy, heart 40 Gy, brain 50 Gy, bladder 65–70 Gy, and dermis 70 Gy. These differences could be easily explained in terms of varying initial numbers of ‘‘target’’ cells in different tissues and/or variations in their radiosensitivity, whereas it is difficult to implicate blood vessel damage as a universal basis for effects requiring such a wide range of doses.

Another interesting fact is that the $RBE_{n/\gamma}$ varies widely among late responding tissues whereas if all late effects were due to vascular injury it should be constant.

Then there is the nature of the lesions themselves. In spinal cord or brain, the characteristic change is demyelination, implying a loss of glial cells, specifically oligodendrocytes. Why would vascular damage target the myelin producing cells and not the neurons? More likely, the slowly proliferating oligodendrocytes die slowly and the non-proliferating neurons survive, while the blood vessels do their own independent thing. And radiation injury does not develop in sympathetic nerves or ganglia, nor in the posterior pituitary, nor primarily in the gray matter of spinal cord or brain. What makes these non-responsive structures different from the other parts of the nervous system which are susceptible to radiation injury is not that they do not have a vascular supply but that they do not have myelination. Why should myelin-making cells, which turn over slowly, die a vascular death when all other cells are allowed an apoptotic or mitotic death?

One late effect which cannot be the result of vascular damage is cataract formation because the lens has no blood vessels.

Vascular damage happens: blood vessels do not have immunity from radiation. There are a variety of changes in blood vessels to which a role in the etiology of a universe of late effects has been inappropriately assigned. Regardless of what structural or functional injury to blood vessels is chosen as the culprit, vascular degeneration can compromise organ function, but such compromise is more sizzle than steak: the real target cells are specific to the organ, and why should they be considered immune to radiation injury?

Rebuttal

Dr. Hopewell describes many different vascular changes after irradiation but does not explain how they lead to a wide spectrum of late effects. One vascular effect he lists, intimal hyperplasia, could be a direct result of irradiation which causes parenchymal atrophy, or it could be caused by radiation-induced parenchymal atrophy, in which case it would be called degenerative, or atrophic endarteritis: the chicken and egg story.

The response of the central nervous system to alpha particles produced from boron neutron capture (BNC) is not a compelling argument. First, why does similar damage to vessels in the grey matter not produce injury there? Second, alpha particles may pound the vessel walls but they also penetrate the white matter. Third, for spinal cord, the RBE for high LET radiations versus x rays is high (reflecting a low alpha/beta ratio for x rays) and so BNC alpha-particles should produce glial injury at relatively low doses, and quickly.

John Hopewell and I have disagreed on this topic for decades. I still hope that a late effect of this discussion will be his conversion to my point of view.

1.10. The best radiotherapy for the treatment of prostate cancer involves hypofractionation

John F. Fowler and Alan E. Nahum

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OVERVIEW

In a recent publication, Fowler *et al.*[1] proposed that hypofractionation (fewer fractions and higher dose/fraction) should be better than conventional fractionation for the treatment of prostate cancer because of the low α/β for prostate cancer reported in several studies. A low α/β value means that prostate cancer cells have an unusually high capacity for repair of sublethal damage at low doses and low dose/fraction. Hence, Fowler *et al.* argue, low dose/fraction should be avoided and patients should be treated with hypofractionation. However, Nahum *et al.*[2] have suggested that the low α/β values reported for prostate cancer are artifacts caused by ignoring the effect of radioresistant hypoxic cells present in about 20% of prostate cancers. They claim that the true α/β for prostate cancer is about the same as for other types of cancer and therefore hypofractionation should be avoided. We have brought two outstanding scientists to the table to debate this important issue.

Arguing for the Proposition is John F. Fowler, D.Sc., Ph.D. Professor Fowler is Emeritus Professor of Human Oncology and of Medical Physics at the University of Wisconsin, Madison. He retired in 2004 and is now living back in London, England. Dr. Fowler's degrees include a Ph.D. in Radiation Physics in 1956 and a D.Sc. in Radiation Biology in 1974 from the University of London, as well as an Honorary MD in 1981 from the University of Helsinki. Dr. Fowler started his career as a medical physicist, and was Professor of Medical Physics at the Royal Postgraduate Medical School, Hammersmith, London, from 1963–1970. He then turned his talents to experimental radiobiology and was appointed Director of the Gray Laboratory in London, retiring from there in 1988. He then moved to the University of Wisconsin, Madison, where he spent a total of 11 years (1988–1994 and 1999–2004) as a bio-mathematical modeler in radiation oncology. Dr. Fowler's extensive bibliography includes over 500 research papers, numerous book chapters, and a book on heavy particle radiotherapy.

Arguing against the Proposition is Alan E. Nahum, Ph.D. Dr. Nahum's Ph.D. is on Theoretical Radiation Dosimetry from Edinburgh University in 1975. After four years teaching science in schools he joined the Medical Physics Department at Umeå University in Sweden, where his work was primarily on ion-chamber correction factors and dosimetry codes of practice, including a sabbatical at NRCC, Ottawa with Dave Rogers. From 1985 to 2002 he worked at the Royal Marsden Hospital/Institute of Cancer Research, UK, where his research dealt mainly with "biological modelling," especially tumor control probability (TCP) and normal tissue complication probability (NTCP). Short spells at Fox-Chase Cancer Center, Reggio Emilia, and Copenhagen followed. Dr. Nahum currently works at the Clatterbridge Centre for Oncology in the UK and is Visiting Professor at Liverpool University, where his major interest is in using TCP and NTCP models to optimize radiotherapy treatment plans.

FOR THE PROPOSITION: John F. Fowler, D.Sc., Ph.D.

Opening Statement

Four clinical analyses of the α/β ratio of prostate tumors were published between 1999 and 2003 yielding values of 1.5, 1.45, 1.2 and 3.1 Gy.[3,4,5,6,7] The last differed from the first three in that unrealistically early repopulation start-up times (0–28 days) were assumed, otherwise the α/β value would have been similar to the others. Provided the α/β ratio for prostate tumors is not above that for late rectal damage (about 3 Gy), hypofractionation should be safe. Using a calculated reduced total dose (and overall times not too short), there should be no change in late complications or tumor control from conventional schedules. Hypofractionation to reduce fraction number is clearly the "best treatment" for patients' convenience and for less costly healthcare.

Hypofractionation is safe, especially when delivered with intensity modulated radiotherapy (IMRT). In London, 47–55 Gy in 12 fractions and 36 Gy in 6 fractions were used for prostate radiotherapy without major complications.[8] The Manchester group recently reported that 705 patients treated with 16 fractions of 3.1 Gy achieved equivalence to 33 fractions of 2 Gy,[9] which is only true if α/β is about 1.5 Gy. It is clear that 28 fractions of 2.5 Gy are feasible,[10] as are 22 fractions of 2.94 Gy (Ritter, personal communication), 20 fractions of 3 Gy (Toronto and UK, personal communications), 9 fractions of 6 Gy,[11] 5 fractions of 6.7 Gy,[12] 6 fractions of 6.9 Gy,[13] and 4 fractions of 10 Gy.[13]

The intriguing aspect is that there may be a biological bonus for patients. If α/β is significantly lower than 3 Gy then, for equal late rectal reactions, the biological effect on the tumor should be greater for hypofractionated than for conventional treatments. Surprisingly large gains are predicted if α/β =3 and 1.5 Gy for rectum and prostate tumor, respectively.[1] For a schedule of 10 fractions of 4.9 Gy, the rectal normal tissue tolerance dose (in 2-Gy equivalent fractions) is only 78 Gy for a tumor dose equivalent of 91 Gy.[1]

Evidence is mounting that α/β is indeed about 1.5 Gy. Lukka *et al.*[14] randomized 936 patients to 20 fractions of 2.62 Gy vs 33 fractions of 2 Gy in a Canadian trial. The α/β ratio was determined to be 1.12 Gy (95% confidence interval (CI): –3.3 Gy, 5.6 Gy,).[15] This is one of the best datasets and illustrates the problem of identifying α/β values within clinical 95% limits. For example, an Italian nonrandomized trial[16] with 334 patients yielded a point value of α/β = 9.8 Gy (95% CI: 0.7 Gy, 16 Gy,)[15] but, because of the wide confidence interval, this abnormal α/β value can be discounted as evidence that the α/β for prostate cancer is high.

From the work of Demanes *et al.*,[17] we know that α/β is less than 3.0 Gy. They published 5 to 10 year results of 209 patients treated with external beam radiotherapy (20 fractions of 1.8 Gy) + high dose rate (HDR) brachytherapy (4 fractions of 5.8 Gy). For intermediate-risk prostate they found 96% tumor control at 5 years, yielding α/β =1.2 Gy (0.05 Gy, 1.9 Gy, 95% CI). Modeling using α/β =3 Gy would predict 75% tumor control (chi-squared difference from 96% = 10.3, p = 0.001).[18] This demonstrates that α/β is significantly less than 3 Gy, and opens the door to expecting tumor gains with hypofractionation.

I claim the debate. Further clinical trials should be done to improve precision of α/β; but we need fear neither the loss of prostate tumor control from hypofractionation, nor complications, if dose reduction is done appropriately.

AGAINST THE PROPOSITION: Alan E. Nahum, Ph.D.

Opening Statement

Current conventional external-beam radiotherapy for prostate tumors involves between 64 and 90 Gy delivered in 2-Gy fractions. The higher doses are made possible by employment of 3D conformal therapy, most recently IMRT, at many radiotherapy clinics. Local control rates are generally excellent except for advanced disease.[19] Additionally, impressive control rates have been obtained for early-stage disease using low dose rate brachytherapy with I-125 seeds.[20] Thus, in general, radiotherapy for prostate tumors works well when delivered using conformal techniques.

Where, then, does the idea of hypofractionation come from? The answer is that it comes from radiobiological modeling in which the (biochemical) control rates from external-beam therapy have been compared to those from low dose rate brachytherapy.[4] Several such studies[5,7,21] have claimed to demonstrate that the α/β value for prostate cancer is about 1.5 Gy, which is lower than that for the surrounding normal tissues. This led my jousting partner Professor Fowler to advocate fraction sizes much larger than 2 Gy, coupled with a corresponding decrease in the total dose to ensure isoeffective complication rates.[1] Yes, if it really is true that the effective α/β for prostate clonogens is of the order of 1.5 Gy, then this hypo-strategy should yield higher control rates than the current 2 Gy/fraction treatment schedules. But is the α/β for prostate cancer low? Are there any published modeling analyses which do not yield a low α/β? Yes.

Firstly, the use of a tumor control probability (TCP) model incorporating both inter-patient variation in radiosensitivity and hypoxia,[2,22] together with mean radiosensitivity values (α,β) taken from the radiobiological literature, suggested that α/β need not be low. In fact, the mean α/β value derived from in-vitro radiobiological clonogenic assays was 8.3 Gy.[2]

Secondly, can we deduce anything from documented treatment outcomes involving relatively large fractions? One thinks of the Christie Hospital in Manchester which has routinely employed ~3-Gy fractions. In fact, their recently published prostate outcome data[9] are consistent with the predictions of the heterogeneous radiosensitivity-hypoxia TCP model referred to above,[2,23] i.e., this also did not suggest that prostate α/β is low.

Thirdly, if a low α/β favors hypofractionation then conversely it must impede a hyperfractionated schedule. Recently, however, a group in Milan reported on a 1.2 Gy twice-a-day vs 2 Gy once-a-day treatment series.[16] Were control rates worse for the patients treated with 1.2 Gy fractions? Not at all. Outcome was markedly better for the 1.2 Gy than the 2 Gy patients.

The statement being debated is that the best radiotherapy for treating prostate cancer should involve hypofractionation. Taking together the current generally high rates of freedom from biochemical failure achieved with modern conformal therapy using ~2 Gy fractions at (escalated) total doses,[19] the considerable theoretical doubts cast on the radiobiological modeling which yielded $\alpha/\beta \approx 1.5$ Gy, and the apparently good clinical outcomes recently reported from doing exactly the opposite of hypofractionation, i.e., hyperfractionation,[16] I conclude that

hypofractionated radiotherapy for prostate cancer is contraindicated. The old adage "if it ain't broke don't fix it" seems appropriate.

Rebuttal: John F. Fowler, D.Sc.

Dr. Nahum, you're not listening! Hypofractionation for prostate cancer came from biological insight[24] not a comparison of external-beam radiotherapy and low-dose-rate brachytherapy, and this before there were other 5-y results. Since then, comparisons have all been at high dose-rate, either with HDR brachytherapy (Brenner *et al.*,[6] giving α/β =1.2 Gy; Demanes *et al.*,[17] 1.2 Gy; Martinez *et al.*,[25] 1.2 Gy) or with head-to-head linear accelerator trials (Lukka *et al.*,[14] 1.12 Gy; Kupelian *et al.*,[26] 1.1 Gy).

Good clinical results are worth a hundred models. Modeling tumor TCP with hypoxia is notoriously unreliable, with or without reoxygenation or inhomogeneities! The single *clinical* exception mentioned by Dr. Nahum, has been dealt with by Bentzen and Ritter,[15] who demonstrated that the α/β value of 9.8 Gy from the Valdagni *et al.* nonrandomized clinical trial,[16] had 95% confidence limits extending down to 0.7 Gy.[14] Bentzen and Ritter suggested that perhaps the two fractions/day control schedule of Valdagni *et al.* suffered from incomplete repair. That was a penetrating comment because, if α/β were really low (instead of 8.3 Gy), it would cause incomplete repair to contribute disproportionately more to the tumor effect, by reason of the high repair capacity of prostate cancer cells. Then the control arm would have an inflated effect, as reported.

Concerning *in vitro* values that showed a high α/β ratio, they are not relevant. Carlson *et al.*[27] found that *in vitro* α/β values had little relationship to *in situ* values, and concluded that α/β for prostate tumors *is* low.

If *better* tumor results can be obtained with *the same or fewer complications*, *for half the number of fractions or less*[17,25,26] than the conventional 1.8 or 2 Gy schedules, should we deny this unique biological bonus to patients? This question is settled by the good clinical hypofractionated results already quoted.

Rebuttal: Alan E. Nahum, Ph.D.

Professor Fowler is absolutely right when he asserts that hypofractionation is the "best" treatment from the point of view of patients' convenience and healthcare economy (at least in the *macro*economic sense; we are not discussing here the issue of *individual* clinics gaining more income from prolonged, complex treatments such as multifractionated IMRT). But this is about medical *science* not economics. It is not about patients' convenience. What we are debating is whether hypofractionation is likely to lead to better clinical outcomes (i.e., uncomplicated cure rates) than the presently practiced treatments at about 2 Gy/fraction. There are basically two aspects to this issue, the theoretical one and the clinical results one.

Theoretical—any impartial observer would conclude that the theoretical case for a low prostate-clonogen α/β and thus for hypofractionation is deeply flawed, relying on a paucity of clinical data, in particular on one single published brachytherapy study—a case of comparing apples (brachy) with oranges (external-beam).

Clinical—preliminary results from some new hypofractionation studies are emerging which do not immediately kill stone dead the hypo-idea, but it is simply too early to draw definite conclusions. Conversely there is an extensive and well-documented study of patients treated with moderate hypofractionation (at about 3 Gy/fraction) from Manchester, UK (Ref. 9) which did not demonstrate superior results and which is perfectly consistent with an α/β ratio of around 8 Gy.[23] A study of *hyper*fractionation[16] also yielded clinical outcomes inconsistent with a low α/β.

But there are other considerations—if we currently fail to control a significant number of prostate tumors due to hypoxia,[22] then how much worse is this likely to be when much larger fractions are used with the probable consequent impairment of reoxygenation between fractions?

In conclusion, hypofractionated radiotherapy undoubtedly has its place, especially when coupled with excellent conformality, as the extracranial stereotactical treatment of early-stage lung tumors amply demonstrates.[28] Given the current generally excellent results using conformal prostate radiotherapy at about 2 Gy/fraction, however, and the severe doubts cast on the theoretical concept of a low α/β, I conclude that to hypofractionate prostate treatments is to take unnecessary risks with the health of patients suffering from prostate cancer.

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1.11. The routine use of personal patient dosimeters is of little value in detecting therapeutic misadministrations

Arnold Feldman and Fredric Marc Edwards
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OVERVIEW

Analytical models have traditionally been used to estimate dose distributions for treatment planning in radiation therapy. Recently, some physicists have suggested that Monte Carlo techniques yield more accurate computations of dose distributions, and a few vendors of treatment planning systems have incorporated Monte Carlo methods into their software. Other physicists argue that, for a number of reasons, analytical methods should be preserved. This controversy is the topic of this Point/Counterpoint article. Thanks are extended to Paul Nizin, Ph.D. of Baylor College of Medicine for suggesting the topic.

Arguing for the Proposition is Radhe Mohan, Ph.D. Dr. Mohan received his Ph.D. from Duke University and is currently Professor and Director of Radiation Physics at the Medical College of Virginia (MCV) Hospitals, Virginia Commonwealth University. Dr. Mohan has been actively engaged in research and clinical implementation of advanced dose calculation methods, 3D treatment planning, Monte Carlo techniques and IMRT for 25 years, first at Memorial Sloan-Kettering Cancer Center and now at MCV. He has published and lectured widely on these topics at national and international meetings and symposia.

Arguing against the proposition is John Antolak, Ph.D. Dr. Antolak received his Ph.D. in Medical Physics from the University of Alberta (Canada) in 1992. He then joined the Department of Radiation Physics at The University of Texas M. D. Anderson Cancer, where he is currently an Assistant Professor. He is certified by the American Board of Radiology and licensed to practice Medical Physics in Texas. He is active in the education of graduate students, dosimetrists, and other physicists, and his research interests center around the use of electron beams for conformal radiotherapy. In his spare time, he enjoys playing ice hockey and coaching his son's ice hockey team.

FOR THE PROPOSITION: Radhe Mohan, Ph.D.

Opening Statement

Monte Carlo techniques produce more accurate estimates of dose than other computational methods currently used for planning radiation treatments. Were it not for limitations of computer speed, Monte Carlo methods probably would have been used all along.

With the spectacular increase in computer speed and the development of clever algorithms and variance reduction schemes, Monte Carlo methods are now practical for clinical use. The time required to compute a typical treatment plan has shrunk to a few minutes on computers costing

less than $50,000. A few centers have started using Monte Carlo techniques for clinical purposes, and releases of commercial products are imminent.

As with any new product, an "adjustment period" will be needed during which we learn how to apply this powerful tool. Some find the "statistical jitter" in Monte Carlo results troubling. This issue is being addressed by several investigators. The additional cost of hardware and software may be another obstacle, but is likely to be resolved as computers become cheaper and more powerful.

Another issue is whether improvements in accuracy are clinically significant and worth the additional cost. It is difficult to answer the first question unequivocally, because randomized trials in which half the patients are treated with less accurate methods are not feasible. Arguments in favor of using Monte Carlo methods include:

(1) Elimination of the need to continually reinvent approximate dose computation models and to tweak them to meet every new situation, as well as the need for trial and error approaches to obtain acceptable matches with measured data. The medical physics community has been engaged in such exercises for 50 years. It is time to stop.

(2) Broad applicability and accuracy of the same Monte Carlo model for all anatomic geometries and treatment modalities (photons, electrons, brachytherapy). With analytical methods, there is a separate model for each modality and a unique set of approximations and assumptions is required for each type of field shaping device.

(3) Dramatic reduction in the time, effort and data required for commissioning and validating the dose computation part of treatment planning systems.

(4) Improved consistency of inter-institutional results, and greater quality of dose response data because of improved dose accuracy.

(5) Accurate estimation of quantities difficult or impossible to measure, such as dose distributions in regions of disequilibrium.

Until recently, the major reason for considering Monte Carlo methods was the inaccuracy of semi-empirical models for internal inhomogeneities and surface irregularities. Now an equally important justification is the ability of Monte Carlo techniques to provide accurate corrections for transmission through, scattering from, and beam hardening by field shaping devices. Monte Carlo techniques are also able to account correctly for radiation scattered upstream from field-shaping devices. These effects are quite significant for small fields encountered in intensity-modulated radiotherapy.

The transition to Monte Carlo methods will have to be gradual. Even though a few minutes of time to compute a plan may seem insignificant, computer-aided optimization of treatment plans may require many iterations of dose computations. In these situations, hybrid techniques will be needed that use fast but less accurate conventional models for most optimization iterations and Monte Carlo techniques for the remainder.

Since Monte Carlo techniques are now affordable and practical, there is no reason not to use them. It is not necessary to conduct clinical trials to once again prove the clinical significance of improved dose accuracy. Monte Carlo methods should be deployed in radiation therapy with

deliberate speed. For some applications, such as, IMRT optimization, it may be necessary to continue to use high-speed conventional methods in conjunction with Monte Carlo techniques at least for now.

Rebuttal

Dr. Antolak has raised several issues, some of which were addressed in my Opening Statement.

With faster computers and clever schemes to reduce variance, the stochastic nature of the Monte Carlo approach is no longer an impediment. Statistical uncertainty of 1%–2% is achievable on grid sizes of 2–3 mm in MC dose distribution calculations, requiring just a few minutes on easily affordable multiprocessor systems. While statistical noise may be unsightly, its effect on the evaluation of dose-volume and dose-response parameters of plans is insignificant. In addition, techniques to smooth out noise are being implemented.

Analytic models introduce systematic errors in dose. They simply cannot achieve the accuracy of MC techniques. While it is true that analytic models consistently produce precise results for the same input data, these results are consistently inaccurate.

Dr. Antolak is concerned that approximations to speed up Monte Carlo computations may affect the accuracy of results. But Monte Carlo developers and users should always ensure that approximations have no significant impact on accuracy. Nothing else should be necessary.

Responses to other such concerns raised by Dr. Antolak are: (1) Considering the uncertainties in dose-response information and other sources of data in the radiotherapy chain, our ability to define "how much noise in the dose distributions is acceptable" is similar to our ability (or lack thereof) to determine the level of dose inaccuracy that may be acceptable. (2) Dose to a point is not a meaningful quantity when Monte Carlo techniques are used. Beam weighting and dose prescription should be specified in terms of dose to fractional volumes (e.g., 98% of the tumor volume). (3) Statistical noise should have practically no effect on inverse treatment planning because the intensity along a ray is affected by the average of dose values over a large number of voxels lying along the ray and not by the dose in any one voxel. (4) Commissioning of Monte Carlo algorithms will be the responsibility of the same physicists and/or commercial vendors who commission conventional methods.

I believe strongly that concerns raised by Dr. Antolak and others are being resolved and that we are now ready to introduce Monte Carlo techniques into clinical use.

AGAINST THE PROPOSITION: John Antolak, Ph.D.

Opening Statement

We have a professional responsibility to ensure that patient treatments are accurately delivered, and the accuracy of treatment planning dose computation is one aspect of this. There are data to support the conclusion "that Monte Carlo techniques yield more accurate computations of dose distributions," provided that the Monte Carlo technique is fully applied. However, in light of other factors detailed below, Monte Carlo methods should not replace analytical methods for estimating dose distributions.

Before arguing against the proposition, it is necessary for me to clarify what I believe the basic difference is between an analytical method and a Monte Carlo method. It boils down to the difference between deterministic and stochastic. The Monte Carlo method is stochastic, i.e., independent calculations of the same problem will give different answers. The analytical method is deterministic, i.e., independent calculations of the same problem will give the same answer, at least to within the limits of numerical round-off and truncation errors. In my opinion and for the purpose of this discussion, any nonstochastic method is considered to be an analytical method.

The accuracy of an algorithm (or method) describes how close it comes to the true answer. Clinical physicists have to worry about the accuracy of both analytical and Monte Carlo methods. The full Monte Carlo method (e.g., EGS4) is considered by many to be the gold standard for accurate dose calculations. The precision of an algorithm is a measure of the repeatability of the answer. Analytical methods have essentially absolute precision. However, the precision of the Monte Carlo method, as measured by the standard error, is proportional to the inverse of the volume of the dose voxels, and to the inverse square root of the computational resources allocated to the problem. For example, reducing the standard error by a factor of two requires four times as much CPU-time. Variance reduction techniques can be used to reduce the computational resources required to obtain a given precision. However, the time (or resources) required for full Monte Carlo simulations of patient dose distributions is currently too great for clinical use. By necessity, current Monte Carlo treatment planning algorithms (those being touted for clinical use) introduce approximations that greatly speed up the calculations, but the accuracy of the results may be affected. At the same time, significant improvements are also being made to the accuracy of analytical algorithms. Also, for the clinical physicist, commissioning analytical algorithms is relatively straightforward, noise is not a problem, and the accuracy can be easily documented.

From the perspective of the clinical physicist, many questions about the use of Monte Carlo algorithms have not yet been answered. How much noise in the dose distributions is acceptable? In the presence of noise, how should beam weighting (e.g., isocentric weighting) be done? What effect does noise have on inverse treatment planning? Who will take responsibility for commissioning the algorithm, and how accurate are the results of the commissioning? How long will the calculation take relative to faster analytical calculations? How will the calculation time affect treatment-planning throughput, particularly when using optimization methods? Is the spatial resolution sufficient for clinical use? Most of the time, Monte Carlo treatment planning calculation times are quoted for relatively coarse (e.g., 5 mm) spatial resolution. Just reducing the resolution from 5 mm to 3 mm requires approximately five times as much CPU-time. These are just some of the issues that need to be resolved and well-documented before Monte Carlo methods can replace analytical methods for treatment planning.

Monte Carlo methods may be used as an independent verification of the dose delivery, or to document (rather than plan) the dose delivery. However, until the questions above are successfully answered, Monte Carlo methods should not replace analytical methods for estimating radiotherapy dose distributions.

Rebuttal

We agree that greater accuracy in dose computation is desirable, Monte Carlo methods can produce more accurate dose estimates, and "Monte Carlo methods should be deployed in radiation therapy with deliberate speed." However, these points are not the proposition we are addressing.

A potential patient recently inquired about the status of Monte Carlo planning at our institution. From what he had read, he believed that Monte Carlo treatment planning is a "silver bullet." Dr. Mohan says it is time to stop reinventing. I believe that implementation of "clever algorithms and variance reduction schemes" is reinventing Monte Carlo treatment planning methods. Further, trial and error will not stop with Monte Carlo. With complete information about source and machine geometry, Monte Carlo calculations can be highly accurate. However, Monte Carlo algorithms usually start with a source model that requires trial and error adjustments to match measured data.

Whereas reinventing analytical methods usually improves accuracy, reinventing Monte Carlo methods may decrease accuracy. In both cases, there is a tradeoff between accuracy and speed, which is often seen if the Monte Carlo approach averages the dose over large voxels. How is the accuracy of a particular implementation judged and to what should it be compared? The "spectacular increase in computer speed and the development of clever algorithms" noted by Dr. Mohan permits significant improvements in analytical models, potentially leading to a model for coupled photon-electron transport under more general conditions.

Future reductions in commissioning and validation efforts will only come from manufacturers' standardization of treatment machines and improved quality in their construction. Modified and new machines will still require extensive commissioning and validation for both Monte Carlo and analytical methods. Considerable research remains to be done to identify the minimum data set sufficient to validate input data that characterizes a treatment machine. Dr. Mohan's last two points are really arguments for greater dose accuracy and apply to treatment planning systems in general, not just Monte Carlo methods.

Dr. Mohan cites the significance of Monte Carlo methods applied to field shaping and intensity modulation devices. These applications can be very complex, but are usually not modeled explicitly. For example, modeling all of the field segments for a complex DMLC fluence pattern is impractical under normal circumstances. Using an approximate approach affects the overall accuracy of the dose calculation, as it would for an analytical method.

Monte Carlo methods are an invaluable tool for improving analytical models to a point where their dose uncertainty is insignificant compared with other uncertainties radiation therapy—such as setup, internal organ motion, target delineation, and biological response. As stated earlier, "Monte Carlo methods may be used as an independent verification of dose delivery, or to document (rather than plan) dose delivery," but should not replace analytical methods for estimating dose distributions in radiotherapy treatment planning.

1.12. Thermoradiotherapy is underutilized for the treatment of cancer

Eduardo G. Moros and Peter M. Corry
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OVERVIEW

Combining heat (hyperthermia) with radiotherapy (thermoradiotherapy) has a long and somewhat checkered past. There is no question that heat enhances the effect of radiation, but it does so for both cancerous and normal tissues. A number of clinical trials were conducted by the Radiation Therapy Oncology Group in the 1980s and 1990s in the hope of demonstrating that hyperthermia could improve the therapeutic ratio, but the results were not promising enough to encourage widespread interest in thermoradiotherapy by either radiation oncologists or funding agencies. Consequently, at least in the USA, support for hyperthermia research dwindled and reimbursement for hyperthermia treatments was curtailed. Recently, however, promising results have been published on several clinical trials in Europe. This has rekindled interest in thermoradiotherapy and some have suggested that valuable opportunities for the use of hyperthermia are being missed and that hyperthermia is being underutilized. Others disagree. This is the premise debated in this month's Point/Counterpoint debate.

Arguing for the Proposition is Eduardo G. Moros, Ph.D. Dr. Moros received his B.S., M.S. and Ph.D. degrees in Mechanical Engineering from the University of Arizona, Tucson, in 1984, 1987, and 1990, respectively. His graduate research in bioheat transfer and acoustic propagation modeling for hyperthermia therapy applications brought him into the field of Radiation Oncology in 1985. After receiving his Ph.D., Dr. Moros spent a year as an Associate Researcher at the University of Wisconsin at Madison and then joined the Mallinckrodt Institute of Radiology at Washington University School of Medicine, where he eventually became a Full Tenure Professor and Head of the Research Physics Section of the Department of Radiation Oncology. In 2005, Dr. Moros accepted a position at the University of Arkansas for Medical Sciences, Little Rock, AR, as the Director of the Division of Radiation Physics and Informatics of the Department of Radiation Oncology. His major research activities are in noninvasive temperature estimation using ultrasound, radiosensitivity by the cellular stress response, imaging of hyperthermia-induced tumor oxygenation using positron emission tomography and thermal ablation, and the development of clinical devices for thermoradiotherapy, hyperthermia, bioelectromagnetics, and bioheat transfer. He is a Past-President of the Society for Thermal Medicine and a member of the Board of Editors of *Medical Physics* and the *International Journal of Hyperthermia*.

Arguing against the Proposition is Peter M. Corry, Ph.D. Dr. Corry is presently Distinguished Professor and Vice Chairman in the Department of Radiation Oncology at the University of Arkansas for Medical Sciences in Little Rock, AR. From 1986 to 2006 he held the positions of Director of Medical Physics and Director, Radiation Oncology Research Laboratories at the William Beaumont Hospital in Royal Oak, MI. Prior to that (1968–1986) he was Professor of Biophysics in the Department of Physics at the University of Texas M. D. Anderson Cancer Center in Houston Texas. He was certified by the American Board of Radiology in Radiological

Physics in 1965. Dr. Corry was recently elected President-Elect of the Radiation Research Society.

FOR THE PROPOSITION: Eduardo G. Moros, Ph.D.

Opening statement

The following statements are restricted to thermal medicine with mild temperatures (39–43 °C), commonly known as *hyperthermia*. Supported by a wealth of biological data and encouraging initial clinical trials, hyperthermia was embraced by many in the radiation oncology community in 1970s and 1980s as a potent adjunct anticancer modality.[1] New companies produced clinical systems and those for superficial and interstitial therapy quickly received Food and Drug Administration (FDA) clearance. By 1984, the first hyperthermia CPT codes were approved, which indicates a level of general acceptance by practitioners. The enthusiasm was such that the Radiation Therapy Oncology Group (RTOG) organized several clinical trials intended to scientifically establish the effectiveness of thermoradiotherapy. To the surprise of most and the demise of a promising new modality, the results of these clinical trials were negative. The main deficiency was quickly identified as "Quality Assurance" (QA) as evidenced in the titles of several papers reporting on the RTOG trials.[2] I evaluated the QA data for the RTOG-8419 phase III clinical trial that compared interstitial thermoradiotherapy with interstitial radiotherapy of recurrent or persistent tumors.[3] To give readers an appreciation of the problem, my two main observations were: (1) the treatment volume defined by the thermobrachytherapy implants was almost always smaller than the reported tumor volume, and (2) the recorded temperatures in the thermoradiotherapy arm (86 patients) revealed that only one patient had an adequate hyperthermia session. The first finding is indicative of poor volumetric tumor coverage for both modalities while the second argues that adequate hyperthermia was never given. Results from both arms were identical!

The RTOG addressed the QA deficiencies with QA guidelines that were published in a series of papers in the International Journal of Radiation Oncology, Biology, Physics and a new protocol for recurrent breast cancer was initiated. However, by that time enthusiasm had waned and all eyes were being fixed understandably on three-dimensional conformal radiotherapy and other new technologies. In North America, only a small number of clinics continued to practice hyperthermia, and even a smaller number of academic groups continued hyperthermia research. Although the negative news affected Europeans likewise, they managed to perform several phase III clinical trials with emphasis on adhering to internationally accepted QA guidelines. All these European trials have been positive.[4] The importance of QA cannot be overemphasized as it has been the main factor differentiating negative from positive trials.[5,6]

The lesson learned is that hyperthermia is a potent adjunct modality to ionizing radiation, doubling response rates in most cases and extending survival in some cases, *if administered as prescribed*.[7] Furthermore, the main synergistic effects of hyperthermia when combined with radiotherapy and/or chemotherapy—such as inhibition of radiation damage repair, radiosensitization, perfusion changes, reoxygenation, the universal heat shock response, and immunologic effects—require relatively mild and clinically achievable temperatures around 41.5 °C.[8] In conclusion, the growing body of scientific data in support of hyperthermia, the positive phase III clinical trials when adequate QA guidelines are followed, and the remarkable

benefits that it offers to patients, clearly and strongly support the proposition that thermoradiotherapy is currently underutilized in the treatment of cancer.

AGAINST THE PROPOSITION: Peter M. Corry, Ph.D.

Opening statement

Thermoradiotherapy is not presently underused in clinical application for a variety of reasons. In the first instance lower temperature hyperthermia (40–43 °C) has no long-term efficacy when used as single agent therapy. These observations have led to the conclusion that hyperthermia must be applied in combination with other forms of anticancer therapy such as ionizing radiation or chemotherapy. This factor alone decreases the utility of hyperthermia in the armamentarium of cancer treatments.

Over the past decade or so there have been a number of reports in the literature that hyperthermia has some benefit when combined with conventional radiation therapy (thermoradiotherapy)[5,9,10] but these studies have mostly addressed the issue of superficial recurrent, metastatic or advanced tumors. There are no reports of its application to the treatment of potentially curable cancers where a significant impact might be possible. Even in the cases where some benefit was claimed, it was often marginal. For example, in the study by Sneed *et al.*[11] treating recurrent Glioblastoma Multiforme (GBM) with interstitial radiation plus interstitial hyperthermia, it was found that the median survival was only modestly increased from 76 to 85 weeks by the addition of heat to the radiation regimen. Is it worth all the extra effort and expense to add heat to the radiation regimen? Another recent study combining heat with radiation and chemotherapy (thermochemoradiotherapy) for cancer of the uterine cervix was carried out in several institutions in Europe and North America.[12] Unfortunately the reproducibility of the results was less than optimal. In Europe the disease free survival rate was approximately 80% while in North America it bottomed out at approximately 40%. Certainly better reproducibility is required before widespread clinical application is attempted.

Another impediment to widespread clinical application is the paucity of available equipment types and manufacturers for the hyperthermia aspect of thermoradiotherapy. At the present time there are only two manufacturers that sell equipment for FDA approved clinical application in the United States, one using microwaves and the other employing planar ultrasound technology. Neither of these systems is of any utility for other than small superficial tumors (about 3–4 cm) most of which could be easily excised surgically. There are no FDA approved systems available for treating deep seated tumors although some experimental systems are undergoing evaluation. However, none of these systems is able to noninvasively treat tumors in the thorax where the treatment of lung cancer is desperately in need of improvement. There are no systems even on the horizon for this latter application. A final limitation is reimbursement for services rendered which, at the present time, is insufficient to cover the cost of equipment acquisition let alone the myriad of other expenses involved. In general the state of affairs with thermoradiotherapy seems to favor its use in large academic centers where research and development can continue both into the evolution of new systems that can more effectively apply it, as well as investigation into its clinical efficacy.

Rebuttal: Eduardo G. Moros, Ph.D.

Following are my responses to the five major issues raised by Dr. Corry.

Hyperthermia is not an effective single therapy. Early studies showed that hyperthermia alone does not have the lasting effectiveness of mainline therapies (i.e., surgery, chemotherapy and radiotherapy). However, in the fight against cancer combined therapies are the norm. Furthermore, many new molecular therapeutics seek to enhance mainline therapies rather than replace them.[13,14] If a new adjuvant therapy were to produce a doubling of the local control rate and a significant extension of time to recurrence, it would be praised as a breakthrough. Ironically, this is exactly the effect of thermoradiotherapy for several cancers.[1,4,5,7]

No data on curable cancers. As with most new therapies, hyperthermia has been tested clinically with aggressive, recurrent, and persistent cancers that fail to be cured by standard treatments. Thus, Dr. Corry's observation that there is an absence of reports on potentially curable cancers is not surprising. Nevertheless, given that the addition of hyperthermia has been shown to have a significant impact on the treatment of tumors known to be resistant to other therapies, one can reasonably conclude that administering hyperthermia early in the management of cancer patients is warranted. The fact that the addition of only 60 min of hyperthermia, 30 min before and after a brachytherapy implant boost, prolonged the survival of patients with GBM should be a strong incentive for expanding the use of hyperthermia to curable cancers.[11] Is there any other agent that has produced such a positive result with GBMs?

Reproducibility. This is an issue for all therapies and in particular for radiotherapy and hyperthermia. Reproducibility involves complex issues of clinical trial design, patient selection, treatment technique, dosage, sequencing of therapies, quality assurance, etc., that need the expert oversight of cooperative groups like the RTOG. To avoid missing the forest from the trees, however, a look at a summary of clinical trials[4] clearly shows that the net hyperthermic benefit is highly reproducible.

Paucity of equipment and reimbursement. I agree completely with Dr. Corry on this issue. There are three main intertwined factors affecting innovation in hyperthermia. First is the low clinical interest after the negative trials of the 1980s. Second is that reimbursement levels have remained frozen for more than a decade due to the lack of significant clinical volume nationwide. In recent times, payments for hyperthermia have increased, but the new amounts are still too low. Third factor is the 1976 Medical Device Amendments law, which does not allow hyperthermia manufacturers the use of the 510(k) premarket notification for FDA clearance. (Surprisingly, radio frequency ablation devices, which use much higher temperatures to destroy tissues, can use the predicate device route to obtain FDA approval.) Consequently, manufacturers have to invest considerable resources and years of clinical trials to show safety and efficacy using Investigational Device Exemptions. This situation discourages private investment in new hyperthermia technologies that could only improve the hyperthermic effect. One last thing—it is often said that hyperthermia is too time consuming and manpower intensive. I posit that this argument will disappear completely the moment hyperthermia treatments are adequately reimbursed.

Rebuttal: Peter M. Corry, Ph.D.

In his Opening Statement, Dr. Moros presented an admirable account of the difficulties encountered in applying hyperthermia in routine clinical application. He did a comprehensive job of discussing the deficiencies associated with the RTOG clinical trials[2,3] that drastically reduced enthusiasm for, and all but eliminated, clinical hyperthermia applications in North America and, to a lesser extent, in Europe and Asia. He devoted approximately 2/3 of his opening statement to QA issues of early trials. The RTOG attempted to address these shortcomings by convening

study groups that published general QA guidelines for clinical hyperthermia (e.g., see Ref. 15) as well as three specific guidelines for ultrasound, deep seated tumors and interstitial hyperthermia. These guidelines were published in the early 1990s in the International Journal of Radiation Oncology, Biology, Physics. Where Dr. Moros went wrong in his argument was to imply that this effort solved all the QA issues associated with the application of clinical hyperthermia, and that we were now on the road to blissful harmony with our thermal measuring and administration devices.

The published guidelines from the RTOG require extensive thermometry, usually in three dimensions, as just one of the requirements for clinical application. There are also several other requirements for applicator selection, particularly relating to adequate tumor coverage. The rub here is that none of the clinical trials cited by Dr. Moros or me complied strictly with those rather rigid guidelines. Some clinical programs continue to apply "hyperthermia" without measuring intratumoral temperature. Other programs obtain one or two temperature points on day one and assume that, with the given power settings for the equipment, the temperatures will be reproducible throughout the course of treatment. Both of these assumptions have been shown to be clearly wrong.[16] Just a few sensors (1–3) always give a more pleasing picture (falsely) than a larger number, say 10–12. It was also shown that, as one might expect, things change during the course of treatment and that serial temperature measurements are much more enlightening. In short, there is so much variation in the QA aspects of clinical trials published that it is often difficult to evaluate results and sometimes impossible to compare them even among leading institutions in the field.

Why do these problems persist after decades of research and development? There is a simple one-word answer: money. In order to comply with the published thermometry guidelines sophisticated MR thermometry systems are required. This raises the cost of a hyperthermia system by $2–3 million—not to mention facility construction costs, the fact that MR compatible heating systems, which are not widely available, are required, and that a cadre of capable scientists is needed to make sure that everything is running as it should. I discussed in some detail the financial constraints imposed by governments, particularly in North America, in my Opening Statement. They are formidable and challenging. Exacerbating the situation is the drought that we are currently experiencing in the North American research funding arena, which is hobbling more advanced programs in academia. All of this adds up to a rather grim outlook for hyperthermia applications in the near future.

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CHAPTER 2

Highly Conformal Radiotherapy: IMRT, Tomotherapy, Stereotactic Radiosurgery, Proton Therapy

2.1. It is necessary to validate each individual IMRT treatment plan before delivery

Chester Ramsey and Scott Dube

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OVERVIEW

Many physicists take the position that IMRT treatment plans are complex and must be validated before use because small errors can adversely affect patient treatment. These physicists feel that the time devoted to validation is completely justifiable. Other physicists believe that such validation can be eliminated, or at least substantially streamlined, if appropriate dosimetric and quality assurance measures are deployed by the physicist. They argue that validation of individual IMRT treatment plans is a misuse of time and resources. This difference in perspective is addressed in this month's Point/Counterpoint.

Arguing for the Proposition is Chester R. Ramsey, Ph.D. Dr. Ramsey is Director of Medical Physics at the Thompson Cancer Survival Center in Knoxville, Tennessee. He received an M.S. (1996) and Ph.D. (2000) from the University of Tennessee and is board certified in radiation oncology physics (ABMP). He is author or co-author on 12 journal articles and over 75 presentations and has been the instructor of multiple IMRT training courses. Dr. Ramsey is a member of the *Medical Physics* Editorial Board, AAPM Task Group 76, AAPM Economics Committee, and ACR Medical Physics Economics Committee.

Arguing against the Proposition is Scott Dube, M.S. Scott Dube graduated from the University of Colorado Medical Center with an MS in Radiological Sciences in 1979. His first job was working for Rocky Mountain Medical Physics in Denver. Soon he was off to Hawaii to join Mid-Pacific Medical Physics. In 1987 he moved to Oregon and worked for the Northwest Medical Physics Center but returned a year later to be Senior Medical Physicist at The Queen's Medical Center in Honolulu. Although Scott resides in the middle of the Pacific Ocean, he feels very connected to the worldwide radiation therapy community through his participation in various listservers, such as medphys, pinnacle, and impac.

FOR THE PROPOSITION: Chester Ramsey, Ph.D.

Opening Statement

Over the past two years, the number of patients treated with IMRT has been growing at an exponential rate. This growth is due in large part to the approval of IMRT reimbursement by

Medicare, and to the associated "IMRT-hype" from radiotherapy vendors. IMRT has been shown to have the potential to improve outcomes for multiple disease sites and pathologies.[1,2] However, the clinical success or failure of each institution's IMRT program depends on the correct delivery of 3D dose distributions calculated by the planning system (Planned Dose) to the correct location in the patient (Delivered Dose).

There are many potential errors that can arise during IMRT planning and delivery. It is the responsibility of the Medical Physicist to ensure that the Planned Dose "agrees" with the Delivered Dose, and to address any issues arising from geometric or dosimetric errors for each IMRT patient. Unlike conventional and 3D conformal radiotherapy, IMRT plans must be verified for each individual patient because of the many sources of error.

The difference between Planned Dose and Delivered Dose (i.e., Error) in IMRT comes from three sources: (1) Treatment Planning, (2) Treatment Delivery Mechanics, and (3) Time-Dependent Target/Tissue Positioning. Even if all errors are eliminated in the treatment planning process using a complete Monte Carlo based model, it would still be impossible to account for downstream errors without individual verification.

IMRT delivery systems have inherent mechanical errors due to leaf transit time (tomotherapy-based systems) or leaf positional error (MLC based systems).[3,4,5] Likewise, the accuracy of compensator-based IMRT is limited by the accuracy of the milling equipment. In multiple static segmental and dynamic IMRT, dose errors can occur from the rapid "on and off" of the x-ray field.[6] Calibrations can drift on motor encoders, leaf offsets can change during MLC maintenance, and gravitational sagging can effect leaf motion.[7] Even if a linear accelerator existed that operated in a perfectly reproducible manner, there would still be the issue of inter- and intra-fraction motion.[8] Treatment plans are based on a snapshot of static anatomy prior to treatment, and hence they introduce errors between Planned and Delivered Dose. The only method for determining the cumulative effect of all these potential errors is to measure the entire delivery sequence on the linear accelerator.

IMRT measurements can be classified into four levels: Level I measurements are taken using film with or without ion chamber(s) placed in a static phantom; Level II measurements are taken with the phantom moving to simulate intra-fraction motion; Level III measurements are taken during each fraction of treatment, and delivered doses are reconstructed on the planning CT, and Level IV measurements are dose measurements reconstructed on CT images acquired before or during treatment. Ideally, Level IV measurements would be taken on a delivery system such as the HI-ART (TomoTherapy, Inc., Madison, WI). At a minimum, Level I measurements should be taken prior to treatment or within the first three treatment fractions.

Rebuttal

Certain external beam techniques (3D Conformal, Stereotactic Radiosurgery, etc . . .) and brachytherapy procedures (High Dose Rate, Prostate, Cardiovascular, etc . . .) are routinely commissioned prior to the treatment of patients. This is possible because the potential sources of error in these techniques are limited in number and are quantifiable. The IMRT process is an entirely different situation. There are hundreds to thousands of different sources of error throughout the entire IMRT process. That is, there is an almost infinite list of possible combinations of error. Therefore, it is simply impossible to commission the IMRT process in the manner one uses with other treatment techniques.

The question that has confronted every medical physicist who has implemented IMRT is "How much QA is enough?" The ACR and ASTRO have taken the position that verification must be performed for each IMRT patient. This is to be done by irradiating a phantom that contains either calibrated film or an equivalent measurement system to verify that the dose delivered is the dose planned (i.e. Level I measurements). The purpose of this requirement is to ensure that the dose is validated in at least one 2D plane on the actual treatment machine.

It is a mistake to substitute IMRT measurements entirely with a second MU calculation program. Current IMRT MU programs use relatively simple algorithms to calculate the dose to one or more points. The usefulness of these programs is limited to that of a "sanity check." Once Monte Carlo calculational algorithms become available in IMRT planning systems, then it may become appropriate to substitute some Level I and II measurements with calculations.

In conclusion, it is the responsibility of the medical physicist to promote the highest quality medical services for patients. In the case of IMRT patients, it is necessary to perform individual patient-specific testing to verify that the dose delivered is the dose planned.

AGAINST THE PROPOSITION: Scott Dube, M.S.

Opening Statement

The first commercial IMRT system was the NOMOS Peacock which included the Corvus treatment planning computer and MIMiC multileaf collimator. This was an ingenious advancement in radiation therapy whereby treatment plans were developed using inverse planning software, and delivered with beamlets produced by a binary collimator operating independently of the linac. The quality assurance (QA) for this novel technology was far more rigorous compared with conventional radiation therapy. By necessity, it included chamber and film measurements made in a phantom.[9]

Following the Peacock came multileaf collimator (MLC) IMRT. The treatment plan was developed using a similar inverse planning process, but delivered by the MLC integrated with the linac. It was natural that physicists responsible for MLC IMRT relied on the experience of Peacock IMRT users for QA procedures. As a consequence, the tradition of chamber and film measurements continued.

In 2000, the NCI convened a group of experts from AAPM and ASTRO to develop guidelines and recommendations to help the radiation therapy community implement IMRT.[10] In their report, these experts stated the need to commission the planning and delivery system as well as to validate individual treatment plans. The commissioning is crucial because there are many sources of potential error in the process, such as beam modeling of individual IMRT fields with complex fluence maps, summation of individual fields to produce a composite distribution, transfer of beam parameters from treatment planning system to linac, and delivery of the individual IMRT fields by the linac. However, I question the value of validating individual plans. At our facility, we have validated more than one hundred IMRT plans. Through this experience, as well as private communication with many IMRT physicists, I have little evidence that validating treatment plans is worthwhile after the commissioning process has been completed. The additional effort spent for each patient is redundant with the initial testing.

My opinion is supported by the fact we do not validate individual treatment plans for other complex procedures such as SRS or HDR. As with IMRT, proper commissioning will uncover all potential errors, so the physicist can prevent them in the future.

The NCI report also states that monitor units (MUs) must be independently checked before each patient's first treatment. This has been commonly done with chamber measurements in a phantom. Fortunately for MLC IMRT programs, software has been developed that can validate MUs by calculation.[11] This is considerably faster than phantom measurements and yields similar results. Reducing the validation effort frees up time for the physicist to evaluate the entire scope of an IMRT treatment. For example, is the immobilization optimal for the patient? Are the dose objectives consistent with recommendations found in the literature? Are there other beam geometries to consider? Is there a need for TLD to assess skin dose?

In my opinion, the best use of a physicist's time would be to commission the IMRT planning/delivery system, validate the MUs for individual plans, and play an active role in the clinical development of IMRT.

Rebuttal

After considering the remarks of my colleague, I recognize three scenarios in which it would be necessary to validate an individual IMRT plan before delivery.
1. The MU validation yields an unacceptable result. Whether using physical measurement or independent software, there must be a threshold that triggers a further investigation by the physicist.
2. The individual plan differs significantly from the types tested during the initial commissioning. For example, assume the commissioning included a complete evaluation of a representative prostate, nasopharynx, and brain case. If a new site is to be treated (such as breast) or if a new technique is to be used (such as non-coplanar), then validation of that plan would be necessary. Once this new type has been evaluated, it would not be necessary to validate subsequent plans of the same type.
3. Some physicists decide not to perform an initial commissioning but instead validate each individual IMRT plan as their program evolves. That can serve the same purpose of ensuring correct treatments. However, there comes a point of diminishing returns when there is no value in the redundant validation of similar plans. At that point, the validation of individual plans should cease. The time otherwise spent on validating individual plans should be directed toward routine quality assurance of the delivery system. It is critical to assure that the ongoing performance of the MIMiC or MLC is correct.[12] This will benefit all IMRT patients under treatment and not just the new starts.

Keep in mind that the validation of individual IMRT plans is not a panacea. It offers no value in addressing potential problems in the planning process (contouring, defining margins, assigning dose objectives), daily delivery process (mechanical and radiological performance), or anatomical registration (interfraction and intrafraction anatomical changes). The physicist must address these issues by other activities.

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2.2. Every patient receiving 3D or IMRT must have image-based target localization prior to turning on the beam

Michael G. Herman and Douglas P. Rosenzweig
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OVERVIEW

Some physicists contend that complex treatments such as 3D conformal therapy and IMRT require tumor localization by an imaging technique such as electronic portal imaging each time the patient is treated. Other physicists are willing to forego image-based target localization before treatment, in part because such techniques are not reimbursable by 3rd-party carriers, and in part because they believe such complexity is "precision overkill." This issue is debated in this month's Point/Counterpoint.

Arguing for the Proposition is Michael G. Herman, Ph.D. Dr. Herman earned a Ph.D. in experimental nuclear physics in 1986. He joined the Radiation Oncology Division at Johns Hopkins in 1989 where he served on the faculty and in the capacities of Acting Chief and Associate Director of Medical Physics. In 1998, he joined the Division of Radiation Oncology at Mayo Clinic Rochester, where he is currently the Head of Physics, an assistant professor and a member of the graduate faculty. He is board certified by the ABMP with a letter of equivalence from the ABR. Dr. Herman serves actively in the AAPM, the ACMP, CAMPEP, the ABMP and the ABR.

Arguing against the Proposition is Douglas Rosenzweig, Ph.D. Dr. Rosenzweig has been a radiation therapy medical physicist for the last ten years. After receiving his Bachelors in physics from the University of Wisconsin, he received his Masters and Doctorate degrees from the University of Washington, working at its Nuclear Physics Laboratory. His dissertation involved experiments probing pion physics. His medical physics experience began at the University of Rochester, where he helped develop a prototype dynamically controlled collimator for intracranial radiosurgery. He is certified by the ABMP, and has worked as a clinical medical physicist in Milwaukee for the past five years.

FOR THE PROPOSITION: Michael G. Herman, Ph.D.

Opening Statement

The purpose of three dimensional conformal radiation therapy and intensity modulated radiation therapy is to deliver high doses of radiation to the target volume, while minimizing dose to normal surrounding tissues. Increased doses, sculpted specifically to the target, promise improved control with fewer complications.

However, accurate target positioning within the treatment field is not guaranteed by 3D-simulation, 3D treatment planning, three-point skin marks with lasers and weekly portal films.[1] Each step adds uncertainty to the ability to deliver the prescribed dose to the target. Margins used to establish the planning target volume (PTV) must quantitatively take these uncertainties into

account.[2] The larger the uncertainties in patient positioning (setup error) and internal organ motion, the larger the margins required. Magnitudes of target position variation have been summarized,[3] suggesting that margins implemented in the clinic could be inadequate to account for these variations. It would seem that escalating doses or reducing margins should not be routinely practiced until evidence of target localization for each fraction can be produced. The lack of knowledge of where the target is within the field leads either to missing the target, or to increased irradiation of normal tissue. This varies depending on the site being treated, but the dosimetric and patient morbidity consequences are clear and we should do everything possible to deliver the intended dose to the target.

Methods have been developed that allow the treatment team to assess and correct the target position on a daily basis. These methods are efficient and effective in reducing target position uncertainty, such that the PTV could be irradiated completely every day, and margins could even be reduced. Electronic portal imaging devices (EPIDs) and ultrasound based systems are examples of tools being used to reduce target position uncertainty. The clinical implementation of EPIDs is detailed in AAPM TG58 report,[4] and its application for daily PTV targeting has been demonstrated.[5,6] Trans-abdominal ultrasound localization has also been applied for daily target verification.[7] These approaches allow the treatment team to acquire statistically significant data that permit patient-specific treatment improvements.[8] It should be noted that whichever technique is used, it must be properly commissioned and the process for use must be understood.

If we intend to increase dose to the target and reduce dose to surrounding tissues, it is essential that we know where the target is through localization for each radiotherapy fraction. In most cases, this can be done efficiently, but any extra effort required is well worth the knowledge that the intended dose was delivered to the proper tissues within the patient.

Rebuttal

Dr. Rosenzweig correctly points out that we should not blindly recommend the daily use of image-based target localization for every 3D and IMRT procedure. Nor should we blindly adopt new and unproven treatment technology such as IMRT. The treatment team should determine the frequency of imaging and weigh the costs and benefits as part of the implementation process of 3DCRT and IMRT. Only if the treatment team understands the patient-specific process of simulation, planning and treatment delivery can the benefits of these treatments be realized.

ICRU report 62 describes the margins that must be considered to properly define a PTV, and suggests that (internal and setup) margins are, in practice, combined subjectively based on the experience of the treatment team. This suggestion reflects the absence of statistically significant data to describe the margins. Furthermore, the report states that compromises in the prescription dose or PTV due to this subjectivity can reduce the probability of treatment success. ICRU 62 does not provide enough guidance about PTV margins to ensure that we are delivering an adequate treatment. It is the routine use of daily localization techniques that yields the patient-specific and center-specific statistical data needed to define margins and deliver treatments accurately. Perhaps not all conformal treatments require patient specific target localization, but the team can only be certain of which treatments do need target localization if they have adequate data.

Finally, the cost of daily imaging may not be insignificant, and the treatment team must develop an effective protocol for the use of technology to improve the quality of treatment. Clinical

protocols are in place that use daily imaging to localize the target in a time efficient manner without delivering any unplanned radiation dose to the patients.

I agree with Dr. Rosenzweig that we should have a flexible perspective on this topic. But this perspective must be matched with the realization of what we are trying to accomplish with radiotherapy. Using appropriate margins and localizing the target allows us to maximize the benefit to the patient from highly conformal treatment technologies.

AGAINST THE PROPOSITION: Douglas Rosenzweig, Ph.D.

Opening Statement

Clinical practice is rapidly integrating 3D and IMRT (conformal) modalities, and clinicians will soon rely on these techniques to treat even routine sites. Anticipating this expanding load, we must be cautious in assessing the quality assurance requirements entailed, as there will be a broad spectrum of situations with diverse clinical goals. The convenience of imaging devices makes it tempting to rely on their daily use for control of treatment quality; yet such daily use has important implications. Unquestionably, despite the increased convenience, daily imaging introduces substantial operational costs. In addition, dosimetric issues arise regarding the volume irradiated by daily orthogonal films. Alternative quality control strategies exist which may be less burdensome and perhaps safer to nearby structures. Our profession has an obligation to weigh the issue carefully as we enter this new era.

Conformal treatments can produce complex dose distributions. Undeniably, there is potential to compromise therapy when such critically shaped distributions are geographically shifted. With the diversity of treatment sites, though, we must clarify which classes are susceptible to danger, and where we can proceed with more confidence. A blanket requirement of daily imaging for every conformal treatment is premature, and could haunt us. Having recently seen our opinions appropriated in rigid, unintended ways (e.g., the incorporation of TG-40 recommendations as state-mandated QA requirements), we should learn from such examples.

Certainly, there are complex cases where daily imaging serves best to accurately and precisely localize treatment. Because of interfraction organ motion, for example, daily electronic or ultrasound imaging of conformal prostate therapy is likely the best targeting approach. Internal fixation and precise and reproducible immobilization may offer comparable results, yet daily imaging creates comparative efficiency and reduces patient discomfort. On the other hand, we anticipate cases such as conformal palliative brain irradiation where daily imaging would be excessive. Likewise, IMRT of the breast serves to produce homogeneity as opposed to dramatic conformality, and given adequate immobilization methods we should here as well achieve clinical goals without daily imaging. Along the spectrum of conformal cases, we will identify situations where planners can safely define planning volumes based upon reasonable margins as laid out in ICRU Report 62.[9] These margins specifically account for expected random daily geometric uncertainties. Grouping together all applications of conformal technology is unwise when discussing quality assurance protocols.

Having adopted ICRU-62 planning margins, it is inconsistent to suppress random uncertainties further at treatment time. Unfortunately, systematic setup errors remain possible, and daily imaging does identify them. Alternatively, our literature suggests other strategies that can efficiently address these problems early,[10] after which they are controllable through weekly observation.[11] Here, intelligent use of available tools reduces imaging requirements.

Physicists and oncologists must jointly decide the role and frequency of imaging. The costs and efforts involved in daily imaging are substantial, and will be avoidable for some growing portion of conformal treatments. We should be careful to have a flexible perspective on this topic, lest our opinions be set in stone.

Rebuttal

Dr. Herman suggests that conformal treatments have goals of dose escalation and reduced treatment volumes. These are specific goals of the initial application of this new technology, which has focused on difficult cases where precise targeting is critical. However, clinicians and vendors are working towards automation and efficiency that will allow broader application of the technology. As integration progresses, conformal techniques will certainly be applied to more routine cases where positioning accuracy and precision are already acceptable. For some of these cases, less-frequent imaging strategies will be sufficient to achieve clinical goals with confidence. It is our responsibility to understand the individual considerations of each class of treatment. Our standard of practice should be flexible enough to account for the broadening landscape of cases.

Dr. Herman refers to several reports of successful daily imaging programs. It should be pointed out that these cases are limited to imaging of the prostate, where extra effort is appropriate due to dose escalation of a motile target near critical structures. Inferring from such cases that we can or should expend similar efforts for all conformal treatments is not so straightforward. There are many logistical issues that go into streamlining the imaging and decision-making processes required to make daily verification suitably efficient. While these issues have been effectively addressed in the case of prostate treatments, each treatment site has its own set of issues and priorities. Regardless of one's efficiency, there will always be associated incremental costs. We have an obligation to help control these costs at an appropriate level.

Unfortunately for all of us, our society has limited healthcare resources. We must strive to use them appropriately, and must critically analyze additional demands on our clinical operations.

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2.3. Linear accelerators used for IMRT should be designed as small field, high intensity, intermediate energy units

Tiru S. Subramanian and John P. Gibbons, Jr.
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OVERVIEW

Linear accelerators are designed to provide large, uniform x-ray fields for use in conventional therapy. But for IMRT, only a narrow fraction of the beam is used. Redesign of the linear accelerator to IMRT specifications could enhance x-ray production efficiency, decrease cost, and reduce photon and neutron dose outside of the useful beam. But this redesign limits the treatment flexibility of the accelerator. The pros and cons of specially-designed linear accelerators for IMRT are the focus of this Point/Counterpoint.

Arguing for the Proposition is T. S. (Mani) Subramanian, Ph.D. Dr. Subramanian has been a practicing medical physicist in the San Francisco Bay Area for the past 15 years. Some of those years were as an employee of the West Coast Cancer Foundation, and the others as a consulting physicist. Before that he was a consultant physicist in South Florida and a hospital physicist in Illinois. Dr. Subramanian obtained his M.Sc. and M.S. degrees from the University of Madras and University of Detroit respectively, and a Ph.D. in experimental neutron physics at the Crocker Nuclear Laboratory of the University of California, Davis. He has board certification in Radiological Physics from the American Board of Radiology. He has been active with the Florida Radiological Society and the San Francisco Bay Area Chapter of the AAPM.

Arguing against the Proposition is John P. Gibbons, Jr., Ph.D. Dr. Gibbons received his doctoral degree in physics from the University of Tennessee–Knoxville in 1991. He was the first graduate of the medical physics residency program of the University of Minnesota in 1993, and served on the faculty there upon graduation. He is currently the chief physicist for Palmetto-Richland Memorial Hospital in Columbia, South Carolina. He is board certified by the American Board of Medical Physics and the American Board of Radiology. He also serves on several committees of the AAPM and the ACMP, and is Past President and Board Representative of the South East Chapter of the AAPM.

FOR THE PROPOSITION: Tiru S. Subramanian, Ph.D.

Opening Statement

In earlier years, γ radiation from cesium and cobalt units was used successfully (for the times) to treat cancer. The limitations of this approach were high doses to superficial tissues, inadequate depth doses, and lopsided tumor-to-normal tissue dose ratios for deep-seated cancers. As the technology of linear accelerators evolved over time, supported by sophisticated imaging modalities and dose calculation algorithms, techniques were evolved to provide improved, 3-D conformal dose distributions for treatment of tumors.

In cancer management, both the physical (image-based, tumor-conforming dose distributions) and the biological (tumor response and tissue complication relationships for tumors and normal tissues) parameters play significant roles. While the physical parameters are readily understood and improved by technology, the biological components are more difficult to quantify. In addition, technological advances seem to warrant changes in protocols at a pace that is too fast for the biological understanding to catch up with thorough well-designed clinical trials. Also, we have barely crossed the threshold in the effective use of functional imaging modalities to assist in treatment planning and delivery.

The conventional bremsstrahlung linear accelerator has been the mainstay in radiation oncology for decades. IMRT techniques are implemented readily on these linacs with the help of MLCs. The reliability of computer control and verification of linac and couch movements have improved so that patient manipulation through couch movement now compensates for some of the *broadness* of the treatment portal. Thus a smaller beam (and hence the smaller radiation head of the linac) can provide many enhancements in the design of the linac, including a lower isocenter and a greater patient clearance. Also, a smaller beam, or better yet, a scanning beam,[1] means that the thick flattening filter can be diminished or even eliminated, thereby enhancing the dose rate available for IMRT. While the added dose rate may be too much to put to use now, the saying goes that "if you build it, they will come!"

As for the optimum energy for IMRT, there is already a consensus building to focus on 6–8 MV.[2] At this energy, the dosimetry characteristics are relatively well understood in heterogeneous media. Also, 6–8 MV beams are less costly to shield. Currently, higher energies are also used for IMRT for several reasons, including the desire to use all available energies, and the higher dose rate at higher energies.

Rebuttal

Dr. Gibbons states "IMRT is an emerging technology that may become the treatment of choice for perhaps 1/3 of radiotherapy patients." This probably is a factual statement, warranting the question, "Is 1/3 of the patient load enough to plan for the optimized linac?" My contention is that agreeing on a suitable low energy will make it worthwhile.

Dr. Gibbons strives to compare a dedicated IMRT (with usual electron capabilities included) linac to a dedicated electron-only linac. That thought process has since delivered *Mobetron* to the IOERT needs.

Dr. Gibbons acknowledges, "IMRT can certainly be delivered at lower energies using a conventional linac," which supports the importance of energy optimization for IMRT. He also recognizes "the inefficiency inherent in an MLC based collimating system," which supports the need to redesign the linac head. This inefficiency occurs because current linacs are designed to provide a 40×40 sq cm flat beam at isocenter. Never does IMRT require a field this large.

Dr. Gibbons fails to acknowledge the reliability of MLC-based linacs of today. There are many facilities that have a single machine fitted with an MLC to meet the therapy needs of their communities.

Finally, I wish to call on experts to start from a low energy setting and work upward to select the optimum energy for IMRT, instead of the other way around. With this approach, the total body

dose from head leakage, internal scatter and neutrons will be minimized, especially in comparison with enhanced energies above 10 MV.

AGAINST THE PROPOSITION: John P. Gibbons, Jr., Ph.D.

Opening Statement

IMRT is an emerging technology that may become the treatment of choice for perhaps 1/3 of radiotherapy patients. However, it is not yet mature enough to drive manufacturing decisions. The advantages of redesigning linear accelerators (linacs) to better accommodate IMRT are both nebulous and insignificant, while the disadvantages are numerous. Until more data are available, IMRT with conventional linacs is the more viable option.

First, let's look at the supposed advantages. It is argued that these machines would reduce cost. However, it is more likely that the total cost will be *larger*, as departments would require both conventional and IMRT linacs. Although "IMRT-only" linacs might be less expensive, they would still cost more than an IMRT upgrade of a conventional linac. There would be additional costs for vault construction, maintenance, etc., as well as additional personnel to operate the unit. Indeed, if specialized linacs were more cost efficient, "electron-only" linacs (which would be much less expensive than IMRT-only linacs) would already be widespread.

The argument that redesigned linacs could enhance x-ray production efficiency depends on the specific configuration of the linac. For example, the increased output due to a reduction in flattening foil thickness for smaller fields may be offset by the reduced beam intensity ($\sim E^{-2}$) for lower energies. Even if true, this advantage is not unique to a specialized IMRT linac: an additional "IMRT filter" could be added to an existing linac. In many cases, however, it is the collimating system rather than the linac, that limits IMRT dose rates, so improved x-ray production is meaningless. Finally, there is no obvious clinical benefit to enhanced x-ray production.

It is also stated that the photon and neutron dose outside the field would be reduced. The neutron dose advantage is not unique: IMRT can certainly be delivered at lower energies using a conventional linac. The clinical significance of a reduction of peripheral photon dose is not clear. However, it is the inefficiency inherent in an MLC-based collimating system, rather than the linac itself, that is primarily responsible for enhanced dose outside the field. A greater reduction in photon leakage dose could be obtained by using physical attenuators with conventional linacs. The fact that this technique is not widespread is itself evidence of clinical insignificance.

The proposed linacs also have several potential disadvantages. For example, some IMRT treatment sites require large fields, which might not be achievable with an IMRT linac. It would no longer be possible to treat IMRT and a conventional field concurrently without moving the patient between fields. Lower energy treatments would increase dose to regions peripheral to the target. Finally, it would be impossible to treat an IMRT patient on a conventional machine if a specialized linac failed during the treatment course. This latter issue may necessitate the purchase of a backup machine, which would add significantly to the cost.

Rebuttal

Dr. Subramanian summarizes my opening statement well when he says that "IMRT techniques are implemented readily on these linacs . . . ." There is no reason to change a working design, especially if the change results in added cost and reduced flexibility.

My colleague claims that a redesigned IMRT linac offers the advantages of having a lower isocenter and greater patient clearance. It has never been demonstrated, however, that there is a need for either of these enhancements, given that existing systems can treat a wide range of disease sites. Furthermore, it is not clear that either of these mutually-exclusive advantages truly exists, because the reduction in treatment-head size would likely be perpendicular to, rather than parallel with the beam direction.

In the same vein, there is no obvious clinical need for an enhanced dose rate machine. The conjecture that some unknown clinical benefit may yet be found ("you build it, they will come") is simply a radiation field of dreams. It is not clear that any significant enhancement could be obtained, because existing collimation systems are the primary limitation in delivered dose rates. In fact, depending on the linac design, dosimetric errors could increase due to communication delays between collimation and linac control systems.[3]

Finally, Dr. Subramanian states that there is a consensus to utilize 6–8 MV. However, the study he references concludes that lower energies require more MUs, beam segments and number of fields, thereby increasing the overall treatment delivery time. Regardless, there is still no unique advantage as both low and high energies are available on existing systems.

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2.4. Segmental MLC is superior to dynamic MLC for IMRT delivery

Ping Xia and Joseph Y. Ting
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OVERVIEW

Intensity modulated radiation therapy (IMRT) fields can be delivered with multileaf collimators (MLCs) by either segmental or dynamic MLC methods. With segmental multileaf collimation (SMLC) the leaves are stationary while the radiation beam is ON, which means that leaf velocities are unimportant as far as intensity distributions are concerned. This is simpler than dynamic multileaf collimation (DMLC), where the collimator leaves are moving while the beam is ON and, hence, the velocity of the leaves is vitally important. This makes DMLC more complicated to plan and deliver than SMLC. However, DMLC offers more degrees of freedom in the design of intensity distributions. Some suggest that this extra versatility exhibited by DMLC is insufficient to offset the simplicity of SMLC delivery of IMRT fields. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Ping Xia, Ph.D. Dr. Xia is a clinical physicist and an Associate Professor in the Department of Radiation Oncology, University of California, San Francisco (UCSF). Dr. Xia received her Ph.D. in physics in 1993 from the University of Virginia, Charlottesville. She obtained her training in radiation physics from UCSF in 1995–1997 and joined the faculty there in 1997. She serves the AAPM as a member of Science Council, a chapter representative on the Board of Directors, and a member of TG 119. Her main research interests are treatment planning optimization and clinical implementation of emerging technologies.

Arguing against the Proposition is Joseph Y. Ting, Ph.D. Dr. Ting received his Ph.D. degree from Dartmouth College, Hanover, NH, in 1976 and, between 1974 and 1978, he pursued clinical medical physics training at Allegheny Hospital, Pittsburgh, PA and at Thomas Jefferson University Hospital, Philadelphia, PA. During his 30-plus years as a medical physicist, he has held associate professorships at several leading academic medical centers and currently he is the Chief Medical Physicist at MIMA Cancer Center, Melbourne, Florida. Dr. Ting has been involved with IMRT patient treatments and pre-treatment IMRT physics quality assurance (QA) issues since 1998. He is now involved with image-guided IMRT concerns and improvements in treatment setup accuracy and reproducibility.

FOR THE PROPOSITION: Ping Xia, Ph.D.

Opening statement

Using a conventional multileaf collimator, segmental MLC (SMLC) for IMRT delivery is more versatile than dynamic MLC (DMLC). SMLC can deliver IMRT plans as a simple extension to the delivery method used for conventional three-dimensional conformal radiation therapy

(3DCRT). The report of the Intensity Modulated Radiation Therapy Collaborative Working Group[1] predicted in 2001 that "widespread implementation of this form of IMRT is anticipated during the next several years." Although this prediction was based mostly on the fact that "most medical linear accelerator manufacturers are offering SMLC-IMRT capability," the simplicity of SMLC delivery is another reason that this method is well adapted for clinical use.

The pros and cons of SMLC and DMLC delivery methods have been debated since the early clinical IMRT implementation a decade ago.[2] The main advantage of DMLC is that the continuous leaf motion enables the delivered intensity profile to closely match the optimized intensity profiles, particularly for the profiles produced by a beamlet-based optimization. The advantages of the SMLC delivery method stem from its derivation from the conventional 3DCRT delivery technique. It is, therefore, less demanding of the hardware control system of the linear accelerator and permits more straightforward processes of verification and quality assurance. The major disadvantage of the SMLC method is the prolonged treatment time when many segments are used in the treatment plan, especially when each segment is recorded and verified during the treatment. This disadvantage, however, has been eliminated by the recent development of direct aperture-based optimization.[3] It has been proven that the complex intensity profiles created by beamlet-based optimization methods are not a requirement for highly conformal IMRT plans. Several recent studies[3,4] have demonstrated that direct aperture-based optimization can produce plans that are equal to or even better than those from beamlet-based optimization, yet with significant reductions in both the number of segments and the total number of monitor units (MUs). Using breast treatment as an example, with up to six segments per tangential beam one can obtain IMRT plans better than beamlet-based IMRT plans with improved plan quality, yet with 60% fewer MUs. By contrast, dynamic MLC forced us to deliver even a simple field in a complex way. For example, delivering 100 cGy to a 10×10 cm field with dynamic MLC requires 180 to 2100 monitor units with window widths varying from 10 to 0.5 cm, respectively, with ±6% variations in dose uniformity of the profile.[5] For tumors involving respiratory motion, the SMLC delivery method has even greater superiority over dynamic MLC as shown by Yu *et al.*,[6] who demonstrated that, when IMRT beams are delivered with dynamic MLC, the problem of intrafraction motion causes large dose errors in every fraction.

In conclusion, the segmental MLC delivery method for IMRT is superior to the dynamic MLC method, providing us with greater simplicity and flexibility for treating various types of cancers. Furthermore, significant reduction in total monitor units will improve the accuracy of dosimetry, reduce probability of radiation induced secondary cancer, and provide a safer environment.

AGAINST THE PROPOSITION: Joseph Y. Ting, Ph.D.

Opening statement

Long ago, I colored with a few crayons and put a few color patches onto a few numbered areas on paper. It showed a picture. I was happy.

I developed an electronic tissue compensator in 1989.[7,8] It used a few jaw positions (field segments) to generate field-in-field to replace physical wedges. It worked. I was happy.

Modern IMRT plans are composed of hundreds of beamlets and intensity levels. Why, then, should one degrade this fine resolution by using coarse delivery methods?

IMRT delivery methods divide idealistic intensity maps from optimization routines into small physical beamlets. Each beamlet has its unique intensity level. Dynamic or segmental deliveries will result in identical delivered intensity maps if they both use the same number of beamlets, segments, and intensities. If the segmental delivery were to deliver hundreds of intensity levels, it would require many segments. It would take a long time setting each MLC segment, delivering the radiation, and repeating the process. Therefore, most segmental deliveries are limited in the number of segments and intensity levels. Some linear accelerators also impose a limit on the least number of monitor units (e.g., 5) that they can deliver accurately.

With dynamic delivery, the radiation intensity is controlled by adjusting the duration that any given location is exposed to radiation. It adjusts the gaps between pairs of opposing leaves while the pairs move across the radiation field. A moving wide gap exposes the location to radiation longer than a narrow gap.[9] Computer-controlled servo motors operate the MLC leaves as they move across the radiation field. This mode of operation does not thrust the leaf motors at full speed in one direction, stop, then repeat this in the opposite direction. Only when one of the leaves does not reach its target position for the required number of monitor units[10] will the radiation beam be held off until all leaves are at their predetermined positions. However, this situation seldom occurs because the software configures the leaf motion according to hardware and control system limitations.[11,12]

Concerns about dose delivery accuracy with "dynamic MLC" are unfounded. Many investigators have addressed IMRT QA with dynamic delivery. They have answered most of the questions regarding QA techniques, such as varying intensities and sharp gradients across a measurement volume, and electronic equilibrium issues.[10] Furthermore, most of these concerns are equally applicable to segmental delivery because the fundamental composition of the intensity maps is not different. Therefore, QA for dynamic delivery is not more difficult than for segmental delivery.

In summary, if you are happy with a few intensity levels and segments, segmental delivery is for you. It is like a summation of a few irregular fields. For example, there are clinics delivering IMRT using just two segments. On the other hand, if you are an *artiste* worried about intensity and spatial resolutions, and wish to preserve the integrity of an IMRT plan, and you want the best for your patients, dynamic delivery is the most efficient and the best for your practice.

You can paint with four colors and ten patches or you can have a "Rembrandt" with thousands of colors and shades.

Rebuttal: Ping Xia, Ph.D.

I agree with Dr. Ting's analogy that in some aspects medicine is an art. A beautiful painting, however, does not necessarily embrace hundreds or even thousands of different colors and shades. A masterpiece of painting demands careful choices in colors and shades. Beginning artists imitate masterpieces by dividing them into fine grids, confining their painting resolution to the grid, or beamlet. Beamlet-based optimization in IMRT can be analogous to the beginner's painting. It first divides the intensity pattern into grids, and then regroups a number of beamlets into numerous patches (called leaf sequences). Even aided with hundreds of intensity levels, the created intensity patterns are shadowy, making it difficult to envision a beautiful picture. The recently developed aperture-based optimization eliminates the grid and directly optimizes the shapes of radiation apertures and intensities, just as painting masters would do (in my opinion). Aperture-based optimization allows us to create new colors when they are needed. In theory,

dynamic MLC can deliver segments created with aperture-based optimization, but the limited mechanical speed of the MLCs may not be able to deliver these apertures. Certainly, one can use dynamic MLC to deliver IMRT in the same fashion as segmental delivery. I believe that many centers equipped with dynamic MLCs are doing so.

Rebuttal: Joseph Y. Ting, Ph.D.

A duck is a duck. Dr. Xia, we are saying the same thing. Simple fluence maps can be delivered via either segmental or dynamic deliveries with ease. You state that it takes 180 – 2100 MUs to deliver a "flat" 100 cGy IMRT field with DMLC. However, I created a 10×10 field to deliver a "flat" dose distribution at 10 cm depth using an electronic compensator with just 152 MU. Besides, if one wishes to deliver a 10×10 open field, just set the jaws and deliver it. Why bother with dynamic delivery?

Direct aperture optimization can work only if there are simple constraints and planning target volumes. In breast treatments, inverse planning has no role. We use classical tangents with electronic tissue compensators and dynamic delivery. MUs are similar to or less than conventional wedge plans. While tangential breast fields can be delivered easily with relatively few segments, for brain, head and neck, lung, abdomen, or prostate fields, segmental deliveries are a gamble. Some times it works just fine, but it may not, and you will not know that unless you compare both plans and delivery methods. I would stay with the tried and true.

Organ motion during IMRT delivery is not an issue. Multiple fractions and slow delivery will average out these dose differences. Of course, there are methods to deal with organ motion during treatment, such as gating and breath-hold.

An important message is lost. Dynamic delivery ensures the best reproduction of computed fluence maps. Segmental deliveries may be simpler, faster, and easier to understand, but they may not reproduce complex fluence maps properly. One may debate about the need for complex fluence maps; but if you have complex fluence maps, you would need dynamic delivery to reproduce them accurately.

In 1989, prior to MLC and inverse planning, I was delivering "IMRT" fields using collimator jaws with segmental deliveries. Segmental delivery works but you need to know when to use it.

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2.5. IMRT should not be administered at photon energies greater than 10 MV

David S. Followill and Fridtjof Nüsslin

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OVERVIEW

There is a significant increase in leakage radiation for an IMRT treatment compared with conventional radiotherapy due to the increase in the number of monitor units required. The resultant increase in whole body dose to the patient enhances the risk of radiation-induced cancer and genetic effects. These risks are amplified if the IMRT treatments are delivered at photon energies greater than about 10 MV due to neutron production, which increases the dose equivalent to the patient. Some have suggested that this increased risk is not offset by any advantages inherent in the use of higher photon energies and, hence, should be avoided by administering IMRT treatments only at energies less than about 10 MV. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is David S. Followill. Dr. Followill obtained his M.S. degree in Nuclear Engineering from Texas A&M University, College Station, TX and his Ph.D. degree in Biophysics from the University of Texas Health Science Center, Houston, TX. He completed post-doctoral training in the Department of Radiation Physics at the M.D. Anderson Cancer Center in Houston, where he has since spent his entire career. Currently he is an Associate Professor and Associate Director at the Radiological Physics Center, University of Texas MD Anderson Cancer Center. His major research interests have been radiation dosimetry and quality assurance for radiotherapy, and neutron contamination around high-energy linear accelerators.

Arguing against the Proposition is Professor Fridtjof Nüsslin. Dr. Nüsslin received his Diploma in Physics in 1966 and his Dr.rer.nat. in Physics and Physiology both from the University of Heidelberg, Germany. He spent another two years for postdoctoral training in the Max-Planck-Institute for Nuclear Physics in Heidelberg before joining the Department of Radiology at the Medical School in Hanover, Germany for training in radiotherapy and radiology physics. In 1987 he was appointed Chair and Director of the Medical Physics Section of the Department for Radiology at the University of Tübingen, Germany. In 2004 he became Professor Emeritus and joined the Department of Radiation Therapy and Radiological Oncology of the University Hospital of the Technical University, Munich, as Visiting Professor. There he continues to be involved in research and training activities, mainly in radiation therapy, molecular imaging, radiobiology, and radiation protection. Dr. Nüsslin continues to be active in many scientific and professional organizations and, in 2006, he was elected Vice-President of the IOMP.

FOR THE PROPOSITION: David S. Followill, Ph.D.

Opening Statement

Clearly there is a great deal of data to support the statement that radiation can cause cancer. Whenever radiation is delivered for beneficial reasons, the patient will still receive small doses of

scatter and leakage radiation to organs distant from the primary treatment site. For each organ, the dose, no matter how small, comes with an associated risk of development of a secondary cancer. The basis of this statement comes from the linear relationship between risk and radiation dose derived from the A-bomb survivors.[1,2] Some may argue that the risk is small and many of our cancer patients may never live long enough to develop a second malignancy but, in reality, more and more patients are living longer and survival rates for pediatric patients,[3] where the risk values may be 5 to 10 times that of an adult, are increasing.[4]

Prior to the use of IMRT, the radiation oncology community considered the associated risks of secondary cancers to be negligible when compared to the benefits of the radiation treatment. However, with the implementation of IMRT where the number of monitor units has increased 3–9 fold over that for conventional treatments, depending on the dose delivery technique and planning system, the secondary doses and risks may no longer be considered negligible.[5,6] The first IMRT treatments were performed using low (<10 MV) x-ray energies that did not include any neutron contribution. Now, with the use of higher x-ray energies for IMRT treatments, the secondary neutron dose, although small, becomes an important contributor to the total secondary equivalent dose because of the neutron RBE.

The risks and benefits of each patient's radiotherapy treatment should be considered prior to delivering the treatment. Any non-therapeutic dose of radiation that the patient receives represents a potential risk. Data from Kry *et al.* has shown that IMRT treatments with energies of 10 MV or less from a specific make of accelerator, i.e. Siemens or Varian, result in less secondary dose to the patient than treatments with higher energies.[6] This is mainly due to the neutrons produced at the higher energies. The larger secondary doses reported at the higher x-ray energies depended on the actual accelerator's photon energy spectrum, neutron RBE used, number of segments, and total number of monitor units. Depending on the energy, accelerator, and number of monitor units used, the risk of secondary fatal cancers can range from 2.2% to 5.1% for 15 and 18 MV energies, respectively.[7] Taking into consideration the uncertainty in the risk coefficients, the resulting risk from an IMRT treatment with 6 MV has been shown to be statistically lower than for an IMRT treatment with 18 MV.[8] IMRT treatments administered with energies greater than 10 MV produce higher secondary doses and the higher the dose, the greater the risk to our patients.

Therefore, if one wants to use a higher energy (>10 MV) for IMRT, the benefit of the resulting treatment plan should have to clearly outweigh the increased risk of radiation-induced cancer associated with the extra secondary radiation.

AGAINST THE PROPOSITION: Dr. Fridtjof Nüsslin

Opening statement

In order to debate the pros and cons of high energy (i.e., about 15 MV) photon IMRT, one needs to remember some essentials of radiotherapy physics found in old textbooks: higher penetrative quality, more pronounced build-up, lower skin dose, steeper dose gradients at the PTV margin, better dose conformation to the PTV, and more effective dose sparing of normal tissue make high energies the superior beam quality in many clinical situations. Even for head and neck tumors, 15 MV is preferred when the PTV is close to adjacent organs at risk. One disadvantage, however, is the increased neutron leakage at higher energies, but this is small compared to scatter from the useful beam. From a comparison of IMRT plans for head and neck treatments, it turns

out that for 10 and 15 MV the dose distributions are nearly identical. In a few cases, however, about a 20% lower skin dose at higher energies will prevent the loss of patients' hair.
In a recent clinical study of IMRT lung treatment with 6 and 18 MV x-ray beams, Madani *et al.*[9] demonstrated the minor role of energy selection in IMRT. However, what has not been evaluated is the larger volume of normal tissues irradiated at lower doses, i.e., below 5 Gy. There are data emphasizing low-dose radiation induced long-term risks of secondary malignancies[10] and cardio-vascular diseases.[11] These kinds of long-term risks may strengthen the case for high energy IMRT.

Pirzkall *et al.*[12] studied the effect of beam energy and number of fields on IMRT for patients with prostate carcinoma. They found a significant impact of energy selection on the dose distribution in the region beyond a 1 cm margin around the target volume. Even when applying nine fields, higher energies are to be preferred to achieve dose reduction in normal tissues and, hence, to lower the risks for late effects.

In conclusion, as in conventional radiotherapy, there are good reasons to select higher energies in IMRT techniques when treating thoracic and pelvic tumors, mainly in order to prevent late low dose effects in normal tissues. In the head and neck region it may be prudent to apply lower energies, except in a few situations where steep dose gradients at the PTV margin are essential, or where skin dose reduction is expected to be clinically relevant. Finally, I would like to emphasize the need for Monte-Carlo dose calculation models to achieve valid results when doing this type of intercomparison study in IMRT treatment planning.
Although the impact of energy selection is rather small, I would prefer high energy IMRT when dose reduction in normal tissue is an issue.

Rebuttal: David S. Followill, Ph.D.

The treatment decision for every patient is based on an analysis of the benefits versus the risks for the particular treatment. Although a clinician may not rigorously document such an analysis, the process still occurs as the patient's plan and prescription are approved. Clearly the energy to be used to achieve an effective treatment is one of the most important decisions. Will the energy selected achieve proper coverage of the PTV, reduce the dose to the surrounding normal tissues, reduce the integral secondary dose near the target and, finally, leave the patient with an "acceptable" risk of developing a secondary malignancy in distant organs away from the treatment field? The patient's age, overall health, and life expectancy, are also important factors to be considered in this decision-making process.

Perhaps a higher energy may deliver a plan that is dosimetrically better, but is the plan better for the patient, especially a young patient (<45 years) with a long life expectancy? For some patients, the risk of a secondary malignancy is irrelevant but, for young patients, the risk may clearly outweigh any dosimetry benefit derived from using higher energies. The neutrons generated by the higher energies and their associated RBEs clearly do not benefit the younger patients. The differences between high and low energy IMRT are small and typically do not affect the outcome of the therapy. The vast majority of radiation oncology centers continue to deliver IMRT with 6 MV as their standard of care. The use of higher energies for IMRT may just simply introduce another risk while not significantly improving the patient's treatment.
Selection of the beam energy for an IMRT treatment is only one of many factors that must be considered when making treatment decisions and should not be the overriding factor in the decision making process.

Rebuttal: Dr. Fridtjof Nüsslin

Dr. Followill stresses just a single argument, viz. the neutron contamination at higher energies and its impact on secondary malignancies. Therefore, I conclude that we both agree about the many favorable features of IMRT-treatment plans at higher energies (i.e., typically 15 MV, not 25 MV or more).

So what is in the neutron contamination argument? I agree with the statement that above 10 MV the neutron production rate increases with photon energy. However, I disagree with nearly all the speculative conclusions Dr. Followill presented and those in his Refs. 5,7,8. Is it scientifically valid to apply the new radiation-weighting factor from the NCRP Report 116 for risk assessment of developing fatal secondary malignancies despite the warnings not to apply the data of the report to certain populations such as cancer patients? Dr. Followill is aware of the large uncertainties of the risk assessments, but he and his colleagues in his Ref. 7 state "*until there have been decades of evaluation time for patients treated with IMRT, the best estimate of the risk from IMRT treatments is one calculated with these risk coefficients*." One can hardly believe in any significant impact on energy selection in the limited range of 6 and 15 MV when a slightly less than 0.3% difference in the calculated maximal absolute risk of fatal secondary malignancies between 6 and 15 MV, for the same linac, has been calculated.[7] The statement of a risk of fatal secondary malignancies in the range of 2%–5% associated with leakage in an IMRT treatment is not supported by facts and data from radiation biology and radiation epidemiology. Just one out of many arguments omitted: about only 10% of all secondary malignancies following curative radiotherapy are radiation induced, the remaining 80–90% are due to the increased life expectancy.

Nevertheless, we are always challenged to minimize the radiation load to the normal tissue when treating a patient. However, we have to set the priorities appropriately, i.e., increased tumor control and lower complication probabilities, which clearly relate to the dose distribution, rank higher than the speculative and quantitatively overestimated risks for secondary cancers. Certainly manufacturers are challenged to carefully design their equipment before launching new products with significantly higher leakage than well-established alternatives. I am referring to the reported 4–5 times higher leakage of the CyberKnife in comparison to both the Leksell Gamma Knife and linac-based IMRT systems without a proven gain in therapeutic efficiency.[13]

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2.6. New radiation therapy rooms should be designed to accommodate treatments of the future such as IMRT and tomotherapy

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OVERVIEW

Radiation therapy is experiencing major changes with the advent of techniques such as conformal therapy, IMRT, tomotherapy and HDR brachytherapy. These techniques permit refined patterns of dose delivery including dose escalation and field shaping to provide improved therapeutic ratios between tumor and normal tissues. They also impose new design limitations and flexibility requirements on treatment rooms that can increase their cost and complexity. Whether these limitations and greater flexibility, with their attendant costs, should be accommodated through a more modular approach to therapy room design is the subject of this Point/Counterpoint issue.

Arguing for the Proposition is William Van de Riet, Ph.D. Dr. Van de Riet received his Ph.D. from the University of Kansas and is currently practicing Radiological Physics at Bloomington Hospital in Bloomington, Indiana. He is certified by the American Board of Radiology and has served as an examiner for that organization on several occasions. He has also served on several committees of the AAPM and was on the Radiation Advisory Board of the Michigan Department of Health for many years. He has been involved in the design of more than 30 radiation treatment rooms during his career.

Arguing against the Proposition is Richard G. Lane, Ph.D. Dr. Lane received his doctoral degree from the University of California-Los Angeles in 1970. He has held faculty positions at the University of Wisconsin, the University of New Mexico, and the University of Texas Medical Branch at Galveston. He is now a Professor and Group Leader of the External Beam Therapy Services Group in the Department of Radiation Physics at University of Texas M. D. Anderson Cancer Center. He is board certified by the American Board of Radiology in Radiological Physics and by the American Board of Medical Physics in Radiation Oncology Physics. He has served on several AAPM committees, and has been President of three chapters of the AAPM. He also serves on committees of the ACMP, the ACR, and is presently the Chair of the CAMPEP Residency Education Program Review Committee. Dr. Lane has published over 50 papers in peer-reviewed journals.

FOR THE PROPOSITION: William Van de Riet, Ph.D.

Opening Statement

New radiation therapy treatment rooms should be designed to accommodate treatments of the future such as IMRT and tomotherapy. This statement reflects my opinion that the evolution of treatment units makes this easier, the design considerations are not that extensive or costly, and new technology eventually reaches most radiation treatment facilities.

Megavoltage treatment units have changed dramatically since the 1950s and 1960s. The physical techniques to produce high energy photons has changed, treatment units have shifted from fixed to rotational, the maximum photon energy available has increased, and the rotational isocenter distance has changed. Those of us who practiced during these changes can relate the frustrations we experienced when we had to abandon or dramatically remodel treatment rooms that were too small or drastically undershielded. Fortunately, this situation has settled down to a large extent. Today, most treatment rooms are designed for a dual energy electron linear accelerator with 100 cm isocenter distance, maximum energy of 15–23 MV, and multileaf collimation. Most of us do not foresee big changes in these aspects of treatment units in the near future, and a room designed today for conventional treatments should be functional for the next 10–20 years. Because these aspects have stabilized and computer technology has advanced so rapidly, manufacturers and large medical centers have concentrated since the mid 1990s on refining treatment techniques.

The major design considerations for IMRT and tomotherapy are increased leakage radiation and additional cooling. IMRT using a linac with MLC, serial tomotherapy, or helical tomotherapy may increase the leakage workloads by factors of 5, 10 and 20 respectively. As a result, the secondary barrier thicknesses have to be increased by 8–12 inches of concrete (helical tomotherapy units use lower energies of 6–10 MV and have additional head shielding). In addition, for IMRT and serial tomography, the increased neutron fluence can be dealt with by designing a longer maze, turning the entrance door 90 degrees, or using a 25 MV rather than a 15 MV neutron door. These new modalities also increase the cooling requirements of the room by 25 to 30% compared to conventional workloads. Since the labor cost for constructing forms is about the same for a 36 or 48-inch thick wall, the additional cost would only be for material and possibly space. The heating aspect could be taken care of by installing a cooling unit of larger capacity. All of these considerations can be accomplished at substantially reduced cost and with less disruption of service if they are added at the time of initial construction.

New technologies eventually filter down to the community hospital. Hence, new treatment rooms should be designed to accommodate these new modalities.

Rebuttal

Dr. Lane and I agree that large institutions with multiple treatment units will probably dedicate treatment rooms for IMRT. These large institutions will take into account the additional secondary radiation associated with IMRT when they design the dedicated rooms. He argues, however, that no additional design considerations need to be made for conventional treatment rooms housing dual energy photon beam linear accelerators. His reasons are that IMRT techniques will be performed with low energy photon beams, and that the slow throughput will result in the same overall workload as conventional treatments.

Although serial and helical tomography are performed using low energy photons, this is not necessarily the situation for dynamic or static multileaf IMRT. Multileaf collimators are already designed to accommodate high energy photons, and most lesions treated with high energy beams using conventional techniques will likely be treated with high energy beams using IMRT techniques.

I agree that patient throughput for IMRT is slower than for conventional treatments at the present time. But as the output of linear accelerators increases, and computer control of these units becomes faster, the throughput will increase. Just a few years ago, IMRT was performed with

cast blocks, compensating filters and outputs of 300 cGy/minute or less. A few years from now, faster throughput for IMRT will likely yield substantial increases in secondary workloads.

Taking the time to consider "what if" now may pay off in the future. My argument remains that it is much cheaper to provide some "overkill" now than to face large remodeling costs in the future.

AGAINST THE PROPOSITION: Richard G. Lane, Ph.D.

Opening Statement

Preliminary outcomes seem to predict that IMRT is the treatment of choice for about one third of patients treated with external beam radiation therapy. The great concern over accommodating IMRT treatments is that they use radiation inefficiently. The IMRT tumor dose is not much greater than that for conventional treatment, but the number of monitor units (MUs) required to deliver this dose is greater by an order of magnitude for IMRT treatments delivered by sequential or helical tomotherapy. Dynamic or static multileaf IMRT techniques use 2–5 times as many MUs. This requirement greatly increases the leakage radiation and, potentially, the neutron production for each patient treatment. How should one accommodate this aspect of IMRT in the design of new treatment vaults?

Large facilities with multiple treatment units may have dedicated sequential or helical tomotherapy IMRT units in vaults designed specifically for IMRT. However, most facilities will alternate between conventional and IMRT treatments using a dual-use, dual-photon energy, linear accelerator providing low energy photons of about 6 MV and high-energy photons of 15–25 MV. It is my position that there is no need to make special accommodations for IMRT in the room design for a dual-use treatment unit.

The use (U) factor and workload (W) for conventional treatments using the high-energy beam will dominate the shielding calculations for both the primary and secondary barriers. There is little or no difference between IMRT treatment plans that use low-energy photons and those that use high-energy photons. No accommodation needs to be made for increased neutron production because IMRT treatments will be delivered with low energy photons.

It has also been shown that IMRT treatment times are three to four times longer than those for conventional treatments. No accommodation needs to be made for increased leakage in the shielding calculation, however, because the reduction in patient throughput (workload) corresponds almost exactly to the increase in leakage radiation per patient. And the secondary barrier, shielded for conventional, high-energy photon treatments, will easily provide sufficient protection for a small increase in total leakage of low energy photons.

So, there is no need to make expensive room design accommodations for implementing IMRT techniques in radiation therapy.

Rebuttal

The argument presented is that new vaults should be built to accommodate IMRT and tomotherapy because a costly accommodation will be made at some time and that current construction costs are lower than future costs. However, this accommodation will probably never be required.

IMRT is an evolving technology with solutions to several problems already being implemented. For example, serial tomotherapy exhibits some dose uncertainty between treatment slices. Helical tomotherapy addresses this issue. Also, helical tomotherapy incorporates a CT imaging system designed to avoid a geometric miss by providing daily tumor volume localization. In addition, helical tomotherapy incorporates increased head shielding to reduce leakage radiation.

Dynamic multileaf collimation (DMLC) IMRT also addresses the issue of dose uncertainty. However, the multileaf collimator (MLC) was originally designed to be a block replacement device for conventional treatments that average about 4 MLC positions per patient. DMLC IMRT treatments may require over 100 MLC positions per patient. A new generation of MLC is designed to address the issue of MLC reliability under these conditions.

Regulations limit leakage radiation to approximately 0.1% of a conventional treatment tumor dose. This is not only to protect individuals outside the vault but also to limit the total body exposure of the patient. With IMRT leakage workloads that are ten times that of conventional treatments, the exposure of the patient increases to about one percent of the tumor dose. Total body doses approaching 100 cGy may well have an adverse effect on long-term treatment outcomes. Increased leakage radiation associated with IMRT is a major issue that will be addressed by increased head shielding or by changes in IMRT treatment technique. For example, there are IMRT techniques under investigation that are quite efficient in the use of radiation. These include step-and-shoot MLC IMRT and physical attenuator IMRT.

Most radiation oncology facilities will offer IMRT within three to four years. Increased patient awareness of potential improved outcomes combined with increased reimbursement will ensure that all patients have access to this treatment modality. Major problems associated with IMRT will be resolved through evolution of the technique and through modification of the equipment by the vendors.

There is no need to make expensive room design accommodations for implementing IMRT treatment techniques.

2.7. IMRT may be used to excess because of its higher reimbursement from medicare

Bhudatt R. Paliwal and Ivan A. Brezovich
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OVERVIEW

Intensity-Modulated Radiation Therapy (IMRT) is reimbursed by Medicare at a significantly higher rate than conventional radiotherapy. Some physicists are convinced that this differential reimbursement expands IMRT applications well beyond those justified by improved patient care. Others believe that IMRT improves patient care in almost all patients eligible for curative radiation therapy. This controversy is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Bhudatt Paliwal, Ph.D. Dr. Paliwal is Professor of Human Oncology and Medical Physics at the University of Wisconsin in Madison, WI. He is also the Director of Medical Physics in the radiation oncology clinic, and has served in this capacity for twenty-five years. His major areas of interest are image-guided therapeutics, IMRT, brachytherapy and tomotherapy.

Arguing against the Proposition is Ivan Brezovich, Ph.D. Dr. Brezovich is Professor of Radiation Physics at the University of Alabama at Birmingham, AL. He is the Director of the Radiation Physics Division in the Department of Radiation Oncology, and has served in this capacity for almost twenty years. His major areas of interest are IMRT, respiration gated dose delivery, and brachytherapy.

FOR THE PROPOSITION: Bhudatt Paliwal, Ph.D.

Opening Statement

Intensity-modulated radiation therapy (IMRT) is a state-of-the-art cancer treatment method that delivers high doses of radiation directly to cancer cells in a very conformal way, much more precisely than is possible with conventional radiotherapy. This technique can deliver higher radiation doses directly to the target while sparing more of the surrounding healthy tissue. IMRT requires expensive equipment and extra labor on the part of the physician, physicist, dosimetrist and radiotherapist, all of whom are essential members of the IMRT treatment team. IMRT is a relatively complex and ex pensive process compared with conventional radiation therapy. The extra cost is paid by third-party carriers, state and federal healthcare agencies, and patients. IMRT is not a fundamental breakthrough that changes the tumoricidal effect of radiation. It is merely a refinement[1] in the delivery process. It impacts patient care for a subset of the cancer patient population. The efficacy of IMRT should be assessed by the probability of local control. If there were no change in local control, the use of IMRT would be a waste of resources. Even though the enthusiasm for gains in outcome is high, the actual data are sparse to substantiate the claims of IMRT as a more effective treatment course.

There are potential negative aspects of IMRT. Precision radiotherapy by IMRT should be delivered only to targets that can be precisely defined. Many tumors are not imaged well enough to achieve a high degree of precision. An arbitrarily defined target volume has the potential for under-coverage of tumors or over-treatment of normal tissue. IMRT results in a significant increase in total body dose from increased treatment time and leakage radiation.
Because of a higher reimbursement by CMS (Medicare) for IMRT treatments, entrepreneurs, consciously or unconsciously, may be more likely to over-utilize IMRT to enhance the financial gain. Even small clinics with limited resources are pushing IMRT in order to compete in an aggressive market.

Unnecessary usage of IMRT can occur at several clinical sites. IMRT is particularly unjustified if there is no particular need to avoid normal tissues. In the case of the vocal cords, for example, tumors have been treated very successfully with standard therapy. Using IMRT would be overkill. Other sites, such as lung, brain and liver where there is a high risk of treatment failure, may yield minimal benefits for IMRT.

In general, a busy radiotherapy clinic treats about half of its patients with curative intent. It is estimated that about 20 percent of curative patients would derive some benefit from IMRT. Treatment of a significantly higher fraction would be an over utilization of IMRT.

Rebuttal

Dr. Brezovich lists the medical physics developments over the last century to support his position, but does not give any rational basis for making an informed decision for appropriate use of IMRT. This is precisely the problem. We have developed a highly complex, computer controlled technology without providing a decision-making process to determine when and where to use it. Dr. Brezovich also states that "In its current state of development, IMRT is very labor intensive. Excessive use of IMRT occurs only when corners are cut at the expense of quality, in order to generate unearned profits." This is exactly my point. Do I need to argue further?

Precision dose delivery is a lofty objective. Physicists, chemists and pharmacists all strive for a very high level of accuracy in measuring and calculating quantities. They can measure in units of nanometers or millionths of a gram. It would be foolish, however, to measure height and weight of patients to such an accuracy because there is no treatment that demands such accuracy. Similarly, it is absurd to postulate that all radiotherapy treatments require the highest order of accuracy that is technologically achievable and fiscally affordable.

The zeal to achieve high accuracy should not be the primary determining factor in the use of IMRT treatment for a patient. The degree of accuracy achieved should be that necessary to achieve the maximum possible therapeutic gain. But the science of optimizing therapeutic gain lags significantly behind the capability to deliver IMRT. It therefore permits over-utilization and, in some cases, abuse with the intent of achieving greater financial gains. Obviously, physicians, healthcare organizations and vendors recognize the higher reimbursement for IMRT procedures. They are vulnerable to the pressure of marketing forces and reimbursement increases. It is doubtful that the present trend of generous reimbursement will continue if there is excessive use without clear demonstration of improved outcome.

A major drawback of IMRT is its inability to verify treatment fields *in vivo*. Even though the science of calculating and planning treatments has achieved a high degree of accuracy, the

science of precision positioning of organs and tissues in a virtual space defined by the treatment planning system has a long way to go. Patients breath, wiggle, scratch and move while on the treatment couch. The tight margins that are often advocated for IMRT in order to escalate tumor dose lead to greater uncertainty in peripheral doses. This can produce a significant mismatch between the precisely calculated tumor dose and the actual delivered dose. As a consequence, it is unwise to propose IMRT as a generalized prescription for all treatment sites.

It is important to quantify the improvement in outcomes from IMRT. The use of this technology can only be justified through definitive therapeutic gains. Fifty percent of radiotherapy patients are treated with a palliative intent, and it is difficult to see how these patients would benefit from IMRT. In about one-third of the curative population, conventional treatment schemes are very effective in controlling local disease. And if one takes motion uncertainty into account, only about 20% of the total radiotherapy patient pool can be justifiably treated with IMRT. In the current environment, a higher usage is unjustified overuse.

AGAINST THE PROPOSITION: Ivan Brezovich, Ph.D.

Opening Statement

Precise dose delivery has been a major objective of medical physics research ever since ionizing radiation was introduced into the clinic more than a century ago. The recent transition to the TG-51 calibration protocol exemplifies the continuing progress in quantifying radiation. Improvements in spatial dose definition include the replacement of fixed circular cones by continuously adjustable collimators, and custom Cerrobend blocks replacing hand-placed blocks. Photons from high-energy accelerators spare the skin when deep tumors are treated, whereas electrons avoid damage to deep structures when superficial lesions are targeted. The introduction of multileaf collimators in conjunction with high-speed computers made conformal 3D therapy practical. In that context, IMRT is just another step toward better dose localization, likely to be followed by a wider use of protons and other particles such as mesons that allow even more precise targeting.

The ability of IMRT to deliver sophisticated dose patterns with great accuracy has been established in numerous phantom experiments and Monte Carlo simulations.[2,3] Its ability to deliver therapeutic doses to tumors in the head and neck, while sparing the parotid, has also been proven.[4] Similar performance has been observed in the retreatment of vertebral bone metastases[5] and prostate cancer.[6] In tangential breast therapy, IMRT improved dose uniformity.[7,8] There is also evidence that the superior dose patterns translate into improved local control and quality of life.[5,6]

In its current state of development, IMRT is very labor intensive. Complicated cases often require over 10 hours of a medical physicist's time for planning and phantom verification before a patient can be safely treated. Except for extensive trauma surgery, few procedures require as many high-intensity hours of medical specialists. Medicare is well aware of the critical nature of IMRT, and provides reimbursement commensurate with the cost of equipment and specialist time. Excessive use of IMRT occurs only when corners are cut at the expense of quality, in order to generate unearned profits.

Skeptics argue that IMRT diverts scarce money from areas where it could be more beneficial. Therefore, IMRT should be used only rarely, if at all. However, the equitable allocation of

government funds is the responsibility of Congress, and medical physicists must function within the framework laid down by our elected representatives. Medical physicists should strive to use IMRT for every patient who can benefit from it. Furthermore, costs will drop as IMRT matures. Even today, IMRT is often delivered as quickly as standard treatment, because it eliminates the need for time-consuming changing of blocks and wedges.[8] Inverse planning for IMRT is amenable to further automation, and may eventually take less time than conventional planning. Radiation oncologists may become tired of looking at consistently near-perfect treatment plans, and turn over some of the simpler cases to physician extenders, at great savings. The potential of IMRT to provide better patient care at a lower cost greatly outweighs any eventual short-term waste caused by excessive use.

Rebuttal

I share Bhudatt's concern that, at least in some cases, IMRT may hurt patients more than help them. An article in the New England Journal of Medicine[9] shows that—against common expectations—cancer deaths rise with increasing cost of treatment. The article points out, however, that the higher treatment costs at some cancer centers in Florida are correlated with fewer medical physics hours spent per patient. So the elevated cancer death rate could be caused not by the higher cost, but by reduced treatment quality at some of the more expensive facilities. Precise dose delivery afforded by IMRT does not compel radiation oncologists to cut margins beyond safe tumor coverage. It does allow them to exclude tissues known to be disease free, to the immediate benefit of patients. As knowledge concerning tumor extent progresses, margins can be further narrowed. Since normal tissue tolerance is often the dose-limiting factor, dose escalation to small, poorly oxygenated regions of the tumor may increase tumor control rate and survival. Unless we abandon the paradigm that geographically-precise dose delivery is desirable, IMRT spells progress.

Compared with overall healthcare expenditures, IMRT is modestly priced. Distributed over all patients treated during the service life of an accelerator, the equipment cost per patient is well below $1,000. Personnel costs will also drop with increased automation, potentially transforming IMRT into a cost-cutting technology that eliminates the expensive salvage treatments subsequent to failure of initial treatment. Thus, the current high cost to Medicare is simply an initial investment rather than a permanent cost escalation. For patients to derive optimal benefits from IMRT, medical physicists need to become more politically involved, to assure that money spent on behalf of patients is used for their benefit.

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2.8 Future developments in external beam radiotherapy will be unlikely to significantly improve treatment outcomes over those currently achieved with 3D-conformal and IMRT treatments

Robert J. Schulz and Dirk L. J. Verellen

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OVERVIEW

Over the past decade, 3D conformal therapy and, especially, IMRT, have been heralded as major advances in external beam radiotherapy that are likely to significantly improve outcome. Technology has not stopped there, however, and we are faced with many new developments such as image-guided radiotherapy (IGRT), respiratory gating, tomotherapy, proton and heavy ion therapy, etc., all of which might improve outcomes even further. Unfortunately, each of these new technologies increases the cost of radiotherapy, so it is important to address cost/benefit concerns: will the improvements in outcome be significant enough to justify the increased costs? This is the topic of this month's Point/Counterpoint debate.

Arguing for the Proposition is Robert J. Schulz, Ph.D. Dr. Schulz is a charter member and Fellow of the AAPM, Fellow of the ACR, and Diplomate of the ABR. His professional career began at Memorial Sloan-Kettering (1952–1956), developed further at the Albert Einstein College of Medicine (1956–1970), and concluded at Yale University (1970–1992) from which he retired as Emeritus Professor. His major contributions have been in radiation dosimetry having chaired the SCRAD and TG-21 committees, and twice been a recipient of Farrington Daniels Awards. His retirement to northern Vermont, and close friendship and collaboration with A. Robert Kagan, M.D., has broadened his perspective on radiation therapy to include considerations of cost versus benefit, over-diagnosis and over-treatment, the quality of clinical reports, and the impact of new technologies on outcomes.

Arguing against the Proposition is Dirk Verellen, Ph.D. Dr. Verellen is Professor, Vrije Universiteit Brussel (VUB), and director of the Medical Physics Group in the Department of Radiotherapy, Universitair Ziekenhuis, Brussels, Belgium. He received his M.Sc. in solid-state physics from the University of Antwerp, Belgium, and his Ph.D. in medical sciences from the VUB. In addition to his educational duties at the VUB in Medical Physics, he is also guest professor at the Europese Hogeschool, Brussels, in the training program for Radiation Technologists and course director for Image-guided Radiation Therapy at the ESTRO European School of Radiotherapy. He is author of over 40 peer-reviewed scientific papers and editor or contributing author of several books. His main interest is in the clinical implementation of conformal radiotherapy and image-guidance. He serves on the Board of Editors of *Medical Physics*, and chairs the Working Group on New Technologies for the Organization of European Cancer Institutes. He is a member of the Nederlandse Commissie voor Stralingsdosimetrie sub-committee on Guidelines for Stereotactic Treatments, the AAPM Task Group 101 on Stereotactic Body Radiosurgery, and the Belgian Quality Audit Programme for Radiotherapy.

FOR THE PROPOSITION: Robert J. Schulz, Ph.D.

Opening Statement

The seemingly frantic development of technology for radiation therapy that followed close on the heels of 3D-CRT and IMRT continues unabated for reasons that are at best speculative. However, two things are clear: (a) there is no evidence that IGRT, respiratory gating, electronic portal imaging, ultrasonic guided patient positioning, nor even IMRT itself have led to increased survival times; (b) the cost of radiation therapy has risen in parallel. In what can best be described as a blind gallop towards increasingly more precise means of tumor localization, physicists and manufacturers appear ignorant of the vast experience with cobalt-60, linear accelerators, and betatrons that began accumulating in the 1950's. Do they actually believe that failures to achieve local control were due to consistent patterns of geographical miss, or that a gain in the therapeutic ratio is all it will take to improve outcomes?

If future developments in radiation therapy are to significantly improve outcomes, then these developments must impact on those cancers that cause the largest numbers of deaths which, in the USA, are: lung (160 390), digestive system (134 710), breast (40 910), and prostate (27 050).[1]

From 1977–2002, the five-year relative survival for all stages of lung cancer went from 13% to 16%.[1] Surgical resection remains the treatment of choice, while radiation is employed mainly for the medically inoperable but with much poorer results.[2] As for dose escalation, using 3D-CRT Kong *et al.*[3,4] found that in going from 74–84 Gy to 92–103 Gy, overall survival in a small number of patients increased by a statistically insignificant amount, 22% to 28%, but with acceptable levels of toxicity.

Digestive tract cancers are treated mainly by surgical resection with pre- or post-operative irradiation and chemotherapy. Relative five-year survivals range from 65% for colorectal, 14% for esophagus, to 5% for pancreatic cancers.[1] When viewed in terms of the overall treatment strategies for lung and digestive tract cancers, there is nothing to suggest that techniques beyond CT localization and 3D-CRT will improve survival.

The five-year relative survival for breast cancer increased from 75% to 89% over the period 1977–2002[1] due mainly to screening and the detection of carcinoma *in situ*, and small lesions having a low incidence of positive nodes. Radiation following lumpectomy has reduced local recurrence and most of the currently employed irradiation techniques are equally efficacious in reducing cardiac morbidity.

Whether by prostatectomy or 3D-CRT, the current ten-year cause-specific survival for early-stage prostate cancer is 90% or better.[5,6] Late-stage disease does not fare as well but this is hardly due to poor tumor localization. Since this is a disease of older men, 80–85% of men with prostate cancer die of other causes.[7] There is little reason to believe that further refinements in tumor localization, more precisely defined dose distributions, or dose escalation, will affect current levels of outcome.

Despite the myriad technical advances over the past decade, their contributions to survival rates are undetectable, albeit there have been reduced levels of toxicity in some cases. It is far more likely that improvements will come from sensitizing drugs and chemoradiation.

AGAINST THE PROPOSITION: Dirk Verellen, Ph.D.

Opening Statement

The Proposition is without doubt true and, in fact, need not be limited to future developments only. A review of the Swedish registry[8] reveals that cure rates have not improved over the last 30 years stage-by-stage for most solid tumors. Relative survival rates in NSCLC are identical for patients diagnosed between 1964–1966 and 1994–1996, regardless of technological improvements. For breast cancer an improvement has been observed, but this might well be attributed to the Will Rogers phenomenon in that tumors are discovered sooner and tumor volume has decreased stage-by-stage, apparently improving outcome.[9] Apart from the introduction of CT-based dose planning, radiation oncology never experienced revolutionary steps forward in the improvement of treatment outcomes during the past decades. The history of radiotherapy has followed a slow but distinct path of evolutions, each of which represented some improvement. We have to acknowledge that there exist almost no randomized trials with clinically relevant end-points (such as overall survival) proving an evidence-based benefit from these technical innovations, although complications have been reduced. As cancer becomes a chronic disease, quality of life should be reconsidered in the ranking of relevant end-points. Returning to the example of NSCLC, the collaborative group[10] showed that chemotherapy combined with radiotherapy outperformed radiotherapy alone, but introducing a different fractionation schedule (CHART) made an even larger improvement in outcome (without altering the chemotherapy).[11] The latter, however, came at the cost of complications. Imagine the results if these studies would have been performed with the latest IGRT technology: improved outcome with reduced complication rate.

Developments in radiotherapy are technology driven: energies escalated from kV to MV; customized blocks replaced standard shielding which, in turn, were replaced by computer-controlled MLCs; introduction of arc-therapy; 3D-CRT has given way to IMRT; and heavy ions promise some interesting radiobiological advantages. One can say that radiation oncology represents a perfect example of evolution theory in that the most adapted technology survived. The proposition suggests that the current state-of-the-art in 3D-CRT and IMRT has reached its summit. But is this true? As the precise dose distributions produced by 3D-CRT and IMRT are less forgiving in terms of treatment uncertainties these techniques will never reach their true potential without proper image-guidance, and it seems fair to say that the evolution still continues.

Finally, most technological innovations focussed on improving spatial selectivity, and IMRT combined with IGRT might indeed reveal the limits that can be realized with external photon beam delivery. However, some challenges remain: (1) photons might not suffice to combat radio-resistant tumors and heavy ions might present a possible technological improvement; (2) tumor delineation currently represents the weak link in the treatment chain. New imaging modalities will help to avoid inter-observer variation[12] and provide increased functional/biological information about the tumor in order to focus the treatment more efficiently. These developments will help us to "paint dose by numbers" by acknowledging the heterogeneous nature of tumors, which has so far been neglected by delivering homogeneous dose distributions. As always, with each step forward we realize there is an increased number of things we know too little about. We continue to evolve.

Rebuttal: Robert J. Schulz, Ph.D.

In his opening statement, Dr. Verellen points out that treatment outcomes have improved little over the past 30 years. He suggests that "radiotherapy has followed a slow but distinct path of

evolutions, each of which represented some improvement" but then goes on to acknowledge that there is scant evidence linking technical improvements with longer survival time. These observations point to an issue that should be of great concern to physicians and physicists alike: *if* technical developments over the past decade have resulted in improved outcomes, then the extent of these improvements should be documented.

Admittedly, such documentation will be difficult to come by. When increases in survival are likely to be small, which they most certainly are in the case of technical developments, randomized-prospective trials are often impractical because they require large numbers of closely matched patients accrued over many years. On the other hand, retrospective studies, such as four-field box versus IGRT for the treatment of prostate cancer, compare what was done yesterday with something that is being done today. Such studies are on shaky ground because patient management steadily improves, there are periodic changes and inter-hospital variations in how the disease is staged, expanded screening results in the detection of earlier-stage, more curable disease, and newer chemotherapy regimens have come into place.

Lacking such documentation, hypothetical arguments that favor the adoption of complex and costly systems have gained wide acceptance by physicists and physicians alike. This acceptance requires a leap of faith that is anything but *scientific*, while taking our attention away from the critical issue of costs versus benefits. Until the benefits of technical developments are demonstrated, their higher rates of reimbursement cannot be justified on clinical or moral grounds, and such reimbursements rejected by insurers as well as providers.

Rebuttal: Dirk Verellen, Ph.D.

Dr. Schulz misses the point in that adoption of new technology is not a blind gallop but rather an evolution driven by the willingness to improve quality of health care for each patient. Surgeons are not challenged to initiate randomized trials proving possible benefit of superior scalpels, nor did we feel compelled to prove the benefit of portal films (it was accepted as common sense and good QA). Compared to chemotherapy, radiotherapy is modest in cost (5.6% of cancer care costs) and far more cost-effective.[13] The vast experience that Dr. Schulz refers to cannot compare to results obtained with the precise dose delivery achievable today. And yes, I would argue that the large amount of failure in local control could be attributed to geographical miss and poor therapeutic windows due to the need for large treatment margins. It is with the clinical introduction of IGRT that we start to understand the true concept of margins and organ motion. Referring to the example of lung cancer, Dr. Schulz compares apples and oranges with surgical resection of operable, and radiotherapy of inoperable, lung cancer. Recent studies show comparable results between surgery and radiotherapy for similar populations, with less co-morbidity for radiotherapy.[14] For breast cancer, Dr. Schulz argues that improvements will more likely come from chemotherapy, yet provides a nice example where developments in chemo- and radiotherapy need careful synchronization. Herceptine (trastuzumab) is a case in point offering 52% reduced risk of recurrence (five months increased survival), with a factor of four increase in cardiotoxicity.[15,16,17] A safe combination of this drug with radiotherapy requires a highly accurate treatment delivery that spares cardiac tissue as much as possible. Dr. Schulz's final statement that improvement will more likely come from sensitizing drugs and chemotherapy is at best true only if this is combined with an optimal synergy between surgery and state-of-the-art radiotherapy.

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2.9. Compared with inverse-planning, forward planning is preferred for IMRT stereotactic radiosurgery

Fred Hacker and Daniel Low

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OVERVIEW

Stereotactic radiosurgery with IMRT is a complex procedure that demands precision treatment planning. Many physicists believe that this precision is achieved best by inverse planning in which one works backward from a desired dose distribution to determine the placement of intensity-modulated treatment fields. Recent work by one of the authors (F.H.) of this month's Point/Counterpoint contends that inverse planning is unnecessary, and that satisfactory results can be obtained by a conventional forward-planning approach. This contention is debated in this Point/Counterpoint.

Arguing for the Proposition is Fred L. Hacker, Ph.D. Dr. Hacker received his Ph.D. in Plasma Physics from Dartmouth College in 1994. This was followed by a two year Post Doctoral Fellowship at the Harvard Joint Center for Radiation Therapy, where he worked on conformal arc techniques for stereotactic radiosurgery/radiotherapy. Following his fellowship he joined the faculty at the Joint Center. Since 1999 Dr. Hacker has been the chief physicist for the Stereotactic Radiosurgery/Radiotherapy Program at the combined department of radiation oncology for the Dana-Farber Cancer Institute, Brigham and Women's Hospital and The Children's Hospital Boston. He is an instructor in Radiation Oncology at Harvard Medical School and is certified by the ABR.

Arguing against the Proposition is Daniel Low, Ph.D. Dr. Low earned his Ph.D. in intermediate energy nuclear physics at the Indiana University Cyclotron Facility in Bloomington, IN. He began his medical physics career as a postdoctoral fellow in the Department of Radiation Therapy at M. D. Anderson Cancer Center, conducting research in the computer optimization and fabrication of electron-beam bolus. In 1991, Dr. Low joined the Mallinckrodt Institute of Radiology of the Washington University School of Medicine in St. Louis, MO as an instructor, where he is currently a tenured associate professor of Radiation Oncology. His research interests are in the application and dosimetry of intensity modulated radiation therapy and in four-dimensional imaging. He is certified in Radiation Oncology Physics by the American Board of Medical Physics and the American Board of Radiology.

FOR THE PROPOSITION: Fred L. Hacker, Ph.D.

Opening Statement

Radiosurgery is the quintessential form of conformal radiotherapy, where a single large dose of radiation is delivered with submillimeter accuracy to a small intracranial lesion. Traditionally, linac-based radiosurgery has been delivered with circular collimators using noncoplanar arcs. Several authors have compared this technique to fixed conformal fields and to inverse-planned IMRT (IP-IMRT).[1,2,3,4] Generally these studies show that circular collimation with arcs is optimal

for small ellipsoidal lesions. For larger irregularly-shaped lesions, however, substantial improvements are achieved with fixed conformal fields, and a further incremental improvement is achieved through addition of IP-IMRT.

Recently we completed a study evaluating the effectiveness of simplified forward-planned IMRT (FP-IMRT) for intracranial lesions.[5] In this technique initial beam approaches and apertures are set based on conventional beams-eye-view planning. Isodose distributions are assessed, field apertures are modified, and a small number of subfields are added to a subset of field approaches. This process is repeated iteratively until the desired isodose distribution is achieved. We compared this technique to plans generated with IP-IMRT using dynamic MMLC delivery. Plans were compared for nine lesions treated with fractionated stereotactic radiotherapy (SRT). Lesions treated with SRT tend to be larger and more irregular than those treated with radiosurgery, and should present a greater advantage for IP-IMRT. Plans were evaluated for normal tissue involvement, target coverage, dose homogeneity and organ-at-risk sparing. For all categories the IP-IMRT and FP-IMRT plans showed comparable performance. There was no difference in normal tissue involvement at the prescription level. The IP-IMRT plans had a slight (14%) advantage in average normal tissue involvement at 80% of the prescription level, but at 50% and 20% of prescription the IP and FP-IMRT plans were within 6%. The FP-IMRT plans had a marginal advantage in tumor coverage and dose homogeneity. There was no difference in maximum dose to adjacent organs at risk between the FP and IP-IMRT plans.

While there is little dosimetric difference between IP and FP-IMRT, there are substantial practical advantages to FP-IMRT, most notably a reduction in required quality assurance. Since the FP-IMRT plans use a few relatively large subfields, standard hand-calculation models can be used to verify dose. The complex fluence maps derived from IP-IMRT must be verified with patient-specific phantom measurements, typically requiring a minimum of 2–3 hours of additional physics QA. This time can be of critical importance in radiosurgery where a rigid head frame is used. The FP-IMRT plans should also be less prone to delivery errors caused by small errors in MMLC characterization and calibration. It has been indicated[6] that IP-IMRT plans with small average leaf separations are particularly susceptible to these errors. Of lesser significance is a reduction in required monitor units, with corresponding reduction in leakage radiation, and a reduction in wear on the MMLC. Given these practical advantages to FP-IMRT, and the lack of any compelling dosimetric advantage for either, FP-IMRT is clearly the preferable choice for radiosurgery.

Rebuttal

Dr. Low is correct in his assessment of the limitations of traditional radiosurgery techniques using the Gamma Knife or a linac with circular collimation when treating large irregular lesions. As he points out, several authors have shown the advantages of using conformal arc or conformal static field techniques for these lesions. Some have also shown further improvement in moving from conformal open field techniques to inverse planned IMRT. This, however, does not answer the question posed in this Point/Counterpoint. The question here is does inverse planning for intensity modulation provide an advantage over state of the art forward planning incorporating intensity modulation (FP-IMRT) for radiosurgery.

Intuitively it would seem inverse planning would provide an advantage. In practice, however, we have not found that to be the case for moderately sized intracranial lesions. One reason for this is that in radiosurgery many noncoplanar fields are typically used, with their approaches spread through a large solid angle. In this case the dose distribution characteristics are dominated by

beam selection, and intensity modulation primarily fine tunes the high dose isodose distribution. With a large number of field approaches to choose from, and the rapid dose calculation provided by most radiosurgery dose algorithms, it is relatively easy to design a selection of subfields that tune the distribution as desired. When inverse planning is used for these cases we have found that the individual field fluence maps generated are more complicated, while the composite isodose distribution is not significantly improved.

Although the potential dosimetric advantage of IP-IMRT can be debated, there are clear delivery advantages for FP-IMRT. Perhaps the most significant is that the few relatively large subfields used in FP-IMRT will be less sensitive to errors in MLC delivery, compared with the complex fluence maps determined through IP-IMRT. Radiosurgery is a one-time event, so reliability of delivery is critical. That is one reason why the use of circular collimators has persisted, despite the many studies showing the advantage of field shaping. If one is going to change to a more complicated treatment technique that is potentially less reliable to deliver, there must be a corresponding dosimetric benefit. At this point IP-IMRT does not provide that benefit. As new objective functions and leaf sequencing methods are developed, this may change and the debate can be reopened. But for now FP-IMRT is preferable to IP-IMRT for radiosurgery.

AGAINST THE PROPOSITION: Daniel Low, Ph.D.

Opening Statement

Stereotactic radiosurgery traditionally uses converging arc beams with cylindrical collimators[7] to treat relatively small target volumes. These arc-based treatments were developed prior to the introduction of inverse treatment planning, and have the advantage that the entrance and exit doses are distributed over a relatively large volume. However, they suffer from heterogeneous target doses, and customization of critical structure avoidance is difficult. There is now a growing consensus that fixed-field treatments can be used as substitutes for arc delivery,[8,9] and that intensity modulated radiation therapy (IMRT) provides advantages over open field techniques.[10,11,12] For example, Kulik *et al.*[12] recently compared fixed-field IMRT using five fields against a Cobalt-based irradiator (Gamma Knife) and conventional stereotactic irradiation. They found that for larger or more complex shapes, intensity modulation improves conformity and provides lower doses to critical structures compared with conventional approaches. For relatively large target volumes, the use of intensity modulation may also provide improved treatment efficiency because conformation of larger targets using conventional stereotactic treatment planning typically requires sequential deliveries to multiple isocenters.

The answer to the question posed in this Point/Counterpoint may therefore be a function of target-volume size. For large targets, the question becomes: Is inverse treatment planning necessary for conformal dose delivery? Of course, development of optimal fluence distributions requires an objective function and input parameters that allow full use of the steep and relatively shallow dose gradients along the lateral and depth directions, respectively, for external photon beams. While the optimal combination of these characteristics has not yet been identified, evidence shows that dose conformality is possible to an extent not previously attainable,[13] indicating that even with suboptimal algorithms, significantly improved dose distributions are possible. One reason that IMRT provides highly conformal dose distributions is that it sends a fraction of the fluence through the critical structures. Reviews of multileaf collimator field sequences of clinical IMRT treatment plans reveal that for most beams, the treatment planning system irradiates the critical structures with nonzero fluence. It is unrealistic to expect that a

treatment planner could determine the best distribution of fluence to deliver through projecting critical structures.

For small target volumes, fluence modulation becomes less important than selection of beam orientations. Kulik *et al.*[12] also showed that beam orientation optimization improves doses to normal structures relative to larger numbers of preselected orientations. The process of optimizing beam directions is more complex compared with fluence modulation, because the influence of reorienting beams on the dose distribution is highly nonlinear. The number of possible beam orientations rapidly becomes untenable, especially when noncoplanar beams are allowed, as is typical of stereotactic radiosurgery. For example, if the number of beam directions is constrained to 201 (the number of individual Cobalt sources on the Gamma Knife), then the number of directional combinations for 1, 2, and 3 beams becomes 201, 40 200, and 8×10^6. This example demonstrates the rapid increase in the available treatment planning space with even a relatively small number of beams. While many of the theoretically available combinations would be excluded because of trivial clinical issues (e.g., entering through the lens), the number of combinations still precludes the manual optimization of beam directions.

The use of manual optimization is appealing because of its apparent simplicity and because of the historic dependence of radiation therapy treatment planning on previously acquired clinical experience. Limitations inherent in the use of manual techniques to explore all possible delivery combinations suggest that manual techniques will eventually be replaced by automated techniques. As the sophistication of both the treatment planner and commercial planning systems expands, the benefits of inverse planning will be exploited for the patient's benefit, while quality assurance processes will ensure patient safety.

Rebuttal

Dr. Hacker makes some excellent points in his argument for the use of forward planning for stereotactic radiosurgery for relatively large target volumes. Only routine quality assurance is necessary if the FP-IMRT is delivered using relatively large radiation portals for which independent monitor unit calculations are accurate. When coupled with dose distributions that are almost as good as IP-IMRT, the practical advantages of FP-IMRT do indeed win out.

However, any current advantages of FP-IMRT may be short lived. As commercial objective functions improve and delivery constraints are explicitly considered in the inverse planning process, both the dose distribution quality and the delivery accuracy of IP-IMRT dose distributions will improve. Quality assurance of IP-IMRT dose delivery, now requiring significant manpower, will become more convenient, and will ultimately use automated calculation-based verification methods. The potential for IP-IMRT to automate the treatment planning process will eventually make it the more efficient process.

More important is the ability of IP-IMRT to explicitly consider and avoid critical structures that surround the target. In the case of stereotactic radiosurgery, these may be subregions that are manually defined or located using functional imaging tests. As the technology of functional brain mapping improves, we may be able to use this information to preferentially deliver normal brain doses in an attempt to retain specific brain functions. IP-IMRT will be instrumental in the treatment planning of these patients.

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2.10. Very high energy electromagnetically-scanned electron beams are an attractive alternative to photon IMRT

Lech Papiez and Thomas Bortfeld
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OVERVIEW

Very high energy electron beams on the order of 150–250 MeV have potential advantages for tumor irradiation compared with scanned x-ray beams or photon-mediated Intensity Modulated Radiation Therapy (IMRT). Some physicists believe that VHEE therapy should be developed because it (1) presents an interesting technical challenge; and (2) promises to offer improvements in treating certain tumors. Others feel that the improvements, if any, would be marginal at best, and that the cost of developing VHEE technology for radiation therapy is not defensible. This controversy is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is Lech Papiez, Ph.D. Dr. Papiez obtained his Ph.D. in physics from Silesian University, Katowice, Poland. He was a fellow in theoretical physics at the Dublin Institute for Advanced Study, Ireland, from 1980 to 1983. In 1984 he moved to Canada where he worked as a researcher in applied mathematics. In 1989 he enrolled in the medical physics residency program at the London Regional Cancer Center, Ontario, Canada. In 1992 he moved to the Department of Radiation Oncology, Indiana University, where he is now Associate Professor and Director of Radiation Physics. Dr. Papiez's research interests focus on transport theory and optimal control modeling in radiotherapy applications. Dr. Papiez's section was written with the assistance of Robert Timmerman, M.D., Colleen DesRosiers, M.S., and Vadim Moskvin, Ph.D., from the Department of Radiation Oncology, Indiana University School of Medicine, Indianapolis, IN.

Arguing against the Proposition is Thomas Bortfeld, Ph.D. Dr. Bortfeld trained in medical physics at the German Cancer Research Center (DKFZ) and in 1990 received his Ph.D. in physics from the University of Heidelberg for the development of an early inverse IMRT planning system. He proved the feasibility of MLC-based IMRT at the MD Anderson Cancer Center in Houston and continued his career at DKFZ, where he and his research team worked on the clinical implementation and further refinement of IMRT. Since 2001 he has been director of physics research in radiation oncology at the Massachusetts General Hospital in Boston, where he is also an associate professor at Harvard Medical School. Dr. Bortfeld wishes to thank his colleagues in the department of radiation oncology at MGH for helpful comments.

FOR THE PROPOSITION: Lech Papiez, Ph.D.

Opening Statement

Image Guided 4D IMRT (IG-4D-IMRT) is the next, potentially key, advance in radiation therapy.[1,2] Optimal accounting for all aspects of IG-4D-IMRT will require extremely flexible delivery of radiation dose. In particular, IG-4D-IMRT will require creation of time-dependent intensity fields (motion picture fields). While existing MLC-based photon IMRT can deliver still

pictures of modulated intensity accumulated over the total time of delivery, it is far from an optimal tool for IG-4D-IMRT delivery.

Electromagnetic scanning of a keV-level pencil beam of electrons is a proven technique for motion-picture delivery of electroluminescence intensity in television. A similar technology can be applied for delivery of IMRT with MeV-level beams of charged particles. The existing application of scanned proton pencil beam therapy[3] demonstrates that this approach can be applied in clinical treatments. The ideal choice of charged particle for scanning radiation delivery should be light, cost effective to accelerate and reliable with respect to clinical throughput and maintenance. Electrons meet all of these criteria, provided that they are energetic enough to deliver dose to any region of the human body.

Studies of very high energy (200–300 MeV) electron beams (VHEEB) performed to date justify their utilization in radiation oncology.[4,5,6,7] VHEEB are superior to photon beams due to their specific physical properties of dose deposition, as attested to by the following factors: (1) the ratio of integral dose to the target, compared with the integral dose to healthy tissue/sensitive organs, is higher for VHEEB than for photon beams,[4,5,6,7] and (2) the absence of electronic disequilibrium at interfaces for VHEEB therapy avoids under- and over-dosage at boundaries of organs, and leads to a more uniform dose distribution throughout the target.[4,5]

VHEEB can be scanned at a speed and intensity that allows simultaneous tracking and IMRT treatment of moving or deformable targets, a feature absolutely necessary for 4D-IMRT. This feature is facilitated by high dose rates of VHEEB (of the order of Gy/s), making possible nearly instantaneous (1–2 sec) delivery of the full dose per fraction per field. It also helps assure independence of dose contributions to each point from individual pencil beams.[4,5] In contrast to photon MLC IMRT, VHEEB pencil beam independence ensures that dose calculations for VHEEB IMRT can be accurately determined through linear (additive) operations. Furthermore, optimal intensity maps for VHEEB treatments are directly deliverable without being compromised by contamination and scattering characteristics encountered with photon MLC treatments.

While an individual VHEEB yields a higher surface dose compared with photon irradiation, this aspect can be overcome by using multiple directions of delivery and sufficiently high energies.[4,5] Higher energy electron beams also address the problem of a large penumbra at depth encountered in lower energy electron therapy.[4,5] Studies show that the clinical relevance of neutron contamination associated with VHEEB is negligible.[4,8] Altogether, VHEEB therapy is a very promising approach in the future of therapeutic radiology.

Rebuttal

Indeed, scanning VHEEB units are currently not in production. However, the idea is not out of reach. VHEEB would be less expensive than proton therapy. Technology already exists for building compact, table size (1.9 m×0.75 m) 100 MeV electron microtrons.[9] Progress in superconducting magnets offers the possibility of further decreasing the cost of producing and controlling VHEEB. Superconducting magnets, including high magnetic field control/scanning devices, are being used in research, industry and medicine (MRI), proving that much of the needed know-how has been developed.

Existing comparisons of VHEEB and photon IMRT in homogenous media[6,7] indicate that improvement in dose sparing of sensitive organs for VHEEB is larger than for MLC-based

IMRT, each in comparison with conformal 3D therapy. Physical properties of VHEEB make the method less sensitive to heterogeneities, facilitating construction of dose distributions in non-homogeneous tissues that modulation of photon beams cannot achieve.[4,5]

Most importantly, fast-scanning VHEEB allows realistic, efficient solutions to problems of 4D image guided radiotherapy. Linac-based MLC beam-intensity shaping is an awkward method for fast delivery of optimized treatment for moving tissues. Improvements in dose shaping offered by MLC-based IMRT always come at the cost of decreased efficiency, particularly when tissue-movement compensation is needed (gating). Only fast electromagnetic scanning of charged particles offers simultaneous improvements in dose shaping and effective delivery of 4D radiotherapy.

VHEE may be an acronym not only for "very highly expensive electrons." Before the modern era, the same abbreviation could have been used to label the automobile, i.e., an unrealistic concept of "very highly expensive emulation" (of horse and carriage). Opinions were voiced then that such a "VHEE" was not needed because its construction was expensive, its use uncertain and horses were cheap, abundant and perfect for transportation. And yet . . .

AGAINST THE PROPOSITION: Thomas Bortfeld, Ph.D.

Opening Statement

Very high-energy electron (VHEE) radiotherapy is not a viable alternative to photon intensity-modulated radiotherapy (IMRT). The reason is simple: VHEE does not exist, whereas photon IMRT is a widely available treatment option. The more relevant Point/Counterpoint question is: does VHEE therapy provide a potential advantage and, if so, is it worthwhile to pursue it? Of course, with high-energy electrons one obtains a sharper beam, because the increased relativistic mass, E/c^2, leads to less side scatter. The price to be paid for this attribute (besides the expensive high-energy machine) is a relatively flat depth-dose distribution. Unlike existing clinical electron beams of 10–20 MeV, VHEE electrons do not stop in the patient and do not provide any sparing of healthy tissues behind the tumor. To the first order, VHEE with 200 MeV electrons is dosimetrically equivalent to photon therapy at about 15 MV.

There are some differences between VHEE and IMRT. In soft tissues the lateral dose fall-off is comparable for VHEE and photons,[4] but VHEE is less sensitive to tissue heterogeneity.[5] It would be of interest to perform treatment planning comparisons for cases with substantial tissue heterogeneity in which the sharpness of photon beams is not quite satisfactory, viz., for lung treatments.[10] A few comparative treatment planning studies have been published for VHEE and IMRT,[6] but they used uniform water-equivalent phantoms. VHEE pencil beams exhibit a concave depth-dose shape, which is somewhat more favorable in terms of integral dose to normal tissues compared with the slightly convex depth-dose shape of photon beams. On the other hand, photons provide better skin sparing than do VHEE electrons. There are several additional issues related to VHEE that have not been addressed sufficiently in the literature, including questions regarding beam emittance and neutron contamination.

One thing that is clear about VHEE is that a clinical treatment machine for 250 MeV electrons would be relatively bulky and expensive. Modern 6–10 MeV electron linacs for photon production are compact devices (their length can be reduced to less than 0.5 m) that can be easily mounted onto a gantry, even without bending magnets, or onto a robotic arm, which allows for

very flexible irradiation geometries. At energies as high as 250 MeV one should consider using positively charged particles such as protons or heavier ions because of their good lateral resolution and excellent depth dose characteristics.

It seems to me that VHEE stands primarily for Very Highly Expensive Electrons. The potential dosimetric advantages of VHEE are quite small. It has always been difficult to prove a clinical benefit for a new treatment technique, even when the dosimetric advantages are distinctive.[11] In the case of VHEE, it is unlikely that we would see a clinical benefit even if it were a hypothetical reality. The high expense to develop and build VHEE radiotherapy facilities are therefore simply not justifiable.

Rebuttal

Image-guided spatio-temporal IMRT is indeed a very promising development in radiation oncology. Fortunately, it can be realized with technology that is available today or will become available very soon; it does not rely on the hypothetical development of VHEE therapy. Tumor tracking is not absolutely necessary to substantially reduce the impact of motion in radiation therapy; breath holding and respiratory gating are clinically established methods.[12] If the potential efficiency or precision of tumor tracking is desirable, it can be done well with photons and MLCs. The leaf speed of 2 cm/s with commercial MLCs is sufficient to follow respiratory motion.[1] There are some additional issues in the case of IMRT, but they can be solved by straight-forward extensions of current technologies.[13]

I share Dr. Papiez's enthusiasm regarding scanning beam technology. However, the development of an electromagnetic scanning system for radiation therapy is not as easy as Dr. Papiez suggests. In the almost 50 year history of radiotherapy with protons and heavier particles, scanning systems have been used for patient treatments only in very recent years and only at physics-based institutions.[3,14] From a technical and control point of view, scanning VHEE beams would not be any easier than scanning heavier charged particles. In realistic cases where the tracking data are imperfect, scanning with a narrow beam leads to an interplay between the scanning beam and the remaining motion of the tumor relative to the scanning grid,[15,16] which is worse than with MLC delivery. This effect can be reduced, but not completely avoided, by multiple re-scanning.

The potential of scanned VHEE therapy to deliver dose nearly instantaneously (dose rates of Gy/s) to a treatment volume might be characterized with one word: scary. Possible point dose rates of several 100 Gy/s would pose an enormous challenge for the dosimetry and the control system. Further complicating issues specific to scan-beam delivery of VHEE beams include the significant bremsstrahlung contribution with maximum photon energies of about 200 MeV, which almost certainly would create significant shielding problems.

In summary, I do not see a role for scanned VHEE beams. We should rather focus our efforts on the extension of existing radiotherapy modalities with image-guided spatio-temporal concepts. Electromagnetic scanning systems for IG-4D-IMRT should utilize the physical (and biological) advantages of heavier charged particles and therefore be IG-4D-IMPT systems.

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2.11. Intensity-modulated conformal radiation therapy and 3-dimensional treatment planning will significantly reduce the need for therapeutic approaches with particles such as protons

T. Rockwell Mackie and Alfred R. Smith
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OVERVIEW

The advantage of radiation therapy with particles such as protons has been recognized for many years, and a few institutions have made substantial investments in accelerators for proton therapy. These advantages yield an improvement in the tumor to normal tissue dose relationship for protons compared with conventional therapeutic approaches employing high-energy x rays. However, improvements in the conventional approaches are significantly reducing the gap between dose distributions provided by proton therapy and those achievable with x-ray therapy. These improvements include intensity-modulated and conformal radiation therapy, sophisticated treatment planning systems, and eventually, image-guided intensity-modulated conformal radiation therapy. Whether these improvements reduce the need for further pursuit of particle (proton) therapy is the subject of this Point/Counterpoint issue.

Arguing for the proposition is T. Rockwell Mackie. Dr. Mackie is a Professor in the University of Wisconsin Departments of Medical Physics and Human Oncology with membership in the University of Wisconsin Comprehensive Cancer Center and the Program in Biomedical Engineering. He is best known for his work on radiotherapy treatment planning including the convolution/superposition and the Monte Carlo methods of dose computation. Recently he has concentrated his efforts on helical tomotherapy, which is the integration of radiotherapy optimization, intensity-modulated radiotherapy, and tomographic treatment verification. His career has involved co-founding two companies (Geometrics Corporation and TomoTherapy Corporation), serving on national committees, and being active in the AAPM.

Arguing against the proposition is Alfred R. Smith. Dr. Smith is a Professor at Harvard Medical School, and a Biophysicist at Massachusetts General Hospital. He supervises clinical physics for proton therapy research conducted at the Harvard Cyclotron Laboratory and is Associate Director for the construction of the Northeast Proton Therapy Center at MGH. He has worked in neutron (M. D. Anderson Cancer Center), negative pi-meson (Los Alamos Scientific Laboratory), and multi-leaf conformal (Hospital of the University of Pennsylvania) therapy. At the NCI he initiated studies for the evaluation of treatment planning for heavy particles, x rays, electrons, brachytherapy, and radio-labeled antibodies. He is Past President of the AAPM and a Fellow of AAPM and ACMP.

For the proposition: Thomas Rockwell Mackie

Opening Statement

Proton beam therapy, as practiced today, is much better than conventional photon beam radiotherapy but often inferior to photon intensity-modulated radiation therapy (IMRT). Because

the cost of proton facilities is much greater than for photon IMRT, the cost effectiveness of photon IMRT is currently much superior.

Utilization of the Bragg peak of proton beams is most effective when there are highly sensitive tissues immediately distal to the target volume. Unfortunately, this aspect cannot always be used because of uncertainty in the proton range due to uncertainty in tissue density obtained from CT scans. Tissue density uncertainty has far less effect on photon beam 3D radiotherapy treatment planning.

Proponents of proton radiotherapy often do not point out that the lateral falloff in dose, the dose penumbra, at deeper depths from high-energy proton beams can be less steep than low-energy photon beams produced by linacs. This means that the beam area has to be made larger than a photon beam to ensure that a deep-seated target volume is not in the penumbra. The sharp penumbra of photons is what is being exploited in photon IMRT to conformally avoid neighboring sensitive tissue structures. Multiple proton scattering causes high-gradient hot and cold spots to develop if the beam travels through highcontrast heterogeneities or steep surface irregularities which are typical of head and neck radiotherapy.

Multiple proton scattering also makes junctioning fields tricky. While possible in principle, it is highly unlikely that we will be making use of proton beam radiography for setup or dosimetric quality assurance in the near future. By contrast, photon IMRT can account for surface irregularities and tissue inhomogeneities, can reduce the need for elaborate field junctioning, and will be capable of geometric and dosimetric verification using an exit detector.

The cost-effectiveness of proton radiotherapy for the vast majority of patients must be questioned. Results of planning comparisons of conventional proton and IMRT photon radiotherapy indicate that photon IMRT is often the better plan when the dose distribution requires a complex conformal shape. Any radiotherapy department can now practice photon IMRT for a tiny fraction (2 to 5%) of the capital cost of a proton facility. And often, the photon IMRT patients will get a far better treatment! There are a few cases, such as eye tumors, whereby low-energy proton beams, will be superior. Unfortunately, there would not be enough cases, except possibly in the largest managed care networks, to keep a proton facility busy treating those patients that can really benefit from the expense.

Proton IMRT combined with x-ray verification capability may outperform photon IMRT but at an even greater expense. Before new proton facilities are built it would make sense to wait until proton radiotherapy is both capable of verifiable IMRT and its acceleration and beam transport technology is significantly reduced in price.

In summary, photon IMRT reduces the need for proton beam radiotherapy and other more exotic particle types. This is because photon IMRT is now more cost effective than proton radiotherapy in the vast majority of cases.

Rebuttal

My esteemed colleague has confirmed my central point. The major difference between conventional proton beam radiotherapy and photon IMRT (IMXT) is cost. Professor Smith related a planning comparison for a nasopharynx case, where for equal NTCP, IMXT had a TCP of 86% and conventional proton radiotherapy had a TCP of 88%. Given uncertainty in biological

models, these results are indistinguishable except that the proton treatment would have cost, by Professor Smith's estimates, 50% to 100% more.

The rest of my rebuttal will examine the issue of intensity-modulated proton radiotherapy (IMPT). IMPT is technically possible (I am a co-inventor, with Joseph Deasy and Paul Deluca, on an IMPT patent), however, IMPT will be even more expensive because both beam intensity and beam energy must be controlled simultaneously. Before IMPT is feasible, more accurate dose computation is required. Before IMPT is practical, the cost and size of proton accelerator systems must be reduced.

Perhaps the proponents of conventional proton radiotherapy and IMXT should join forces? The Bragg peak of a conventional proton beam could be exploited to deliver the bulk of the treatment dose but be augmented with the addition of IMXT. Junction difficulties could be reduced wherever possible by making the proton dose gradient in the match region low (and linear if possible). In this way, IMXT could deliver most of its dose to smaller volumes, near critical structures and at the boundaries of fields, where their placement could be radiographically verified. This combination could approach the theoretical advantages of IMPT at a fraction of the investment in time and money.

Until dosimetry issues are resolved and proton accelerators are reduced in price, IMPT is a questionable investment. What makes the most technical and financial sense is to concentrate research and development in IMXT and to adapt IMXT for use in conventional proton facilities as well.

Against the proposition: Alfred R. Smith

Opening Statement

The proposition ''intensity-modulated x-ray (IMXT) dose distributions (*rival those for protons, and therefore*) significantly reduce the need for protons,'' is not supported by basic physics, treatment planning intercomparisons or clinical results. The proposition is unsupported for standard proton treatments and even less supported for intensity (fluence)-modulated proton treatments (IMPT).

Clinical proton beams are characterized by depth-dose distributions having a relatively uniform low-dose entrance region, followed by a region of uniform high dose (the spread-out-Bragg peak) at the tumor/target, then a steep falloff to zero dose. In contrast, single x-ray beams exhibit an exponentially decreasing depth dose after a maximum near the surface, a nonuniform dose across the target, and appreciable dose beyond the target. Therefore, compared to protons, single x-ray beams deliver higher doses to normal tissues/organs proximal to the tumor, nonuniform dose across the tumor, and significant dose to tissues beyond the tumor where the proton dose is zero. The physical advantage of protons for single beams extends to multibeam treatments, including intensity modulation. Compared to x rays in comparable beam configurations, protons will always have superior dose distributions. Moreover, proton beams can be aimed directly at critical structures lying beyond the target in situations where x-ray beams might be disallowed in IMXT. As a consequence, for equal normal tissue complication probability (NTCP), protons deliver higher tumor dose, thus increased tumor control probability (TCP). Conversely, for equal TCP, protons deliver less dose to normal tissues/organs and hence produce lower NTCPs than do x rays.

Treatment planning intercomparisons have been conducted between IMPT and IMXT for nasopharynx and paranasal sinus carcinomas, Ewing's sarcoma, and non-small-cell lung cancer.[1] For nasopharynx, when total NTCPs are normalized to 5%, the total TCP was 97% for IMPT compared to 86% for IMXT assuming $D50$(tumor) = 67.5 Gy. Our standard, non-IMPT, proton plan gave a TCP of 88%. The results for the other clinical sites were similar. Generally, IMPT plans reduce integral dose by about a factor of two compared to IMXT. It is axiomatic that normal tissues/organs should not be unnecessarily irradiated.

Using standard, non-IMPT, proton boost treatments, clinical studies have demonstrated: superior TCP =(80% at 3 years), without visual damage, for paranasal tumors; TCP = 97 and 92% at 5 and 10 years, respectively, for skull-base chondrosarcomas; and superior results in a subgroup of poorly differentiated prostate tumors. For uveal melanomas, using protons alone, the 5-year actuarial TCP is 96% within the globe (99% in the high dose volume), with 90% of patients retaining their eye.

If protons and x-rays cost the same, there would be no justification for using x rays for external-beam cancer treatments. The additional cost factor for proton therapy over that for high-technology x-ray therapy is now 1.5–2.0. This will decrease with time. Patients/providers are paying these additional costs to receive the superior clinical benefits offered by protons. Many more proton therapy facilities are needed.

Rebuttal

Dr. Mackie states that proton therapy, as practiced today, is often inferior to photon intensity-modulated therapy (IMXT). We have seen no data supporting this claim. IMXT gives a bath of irradiation to normal tissues/organs that is not present in standard proton plans, therefore, for the same NTCP, TCP will be higher for standard protons (target coverage is comparable). More importantly, IMPT plans will *always* be superior to IMXT plans. This is dictated by the laws of physics and is unchangeable. In the new proton facility at MGH, IMPT will be delivered with scanned pencil beams.

Dr. Mackie's descriptions of proton beam delivery are misleading. When beams are pointed directly at critical tissues/organs immediately distal to the target, protons will irradiate only a small fraction of the down-stream nontarget volume because they stop, whereas photons will irradiate all structures in their path distal to the target (and also deliver more dose upstream of the target). Up to medium depths, lateral penumbra is comparable for photons and protons and, except for small, spherical volumes, the photon penumbra cannot overcome the advantage of the stopping and sharp distal fall-off of protons. Proton treatment fields are fully compensated for surface irregularities, tissue inhomogeneities, and shape of distal target volume. We use an x-ray tube in the treatment nozzle to set-up and verify treatments. Field junctions and patched fields are routinely used.

Proton treatment capacity is the problem, not patient accrual. We have a 3–4 month waiting list for treatments; in our new facility we will treat two shifts/day. Dr. Mackie misstated the relative expense of photons and protons by a factor of 10 if one compares 30-year costs of facilities having 3–4 treatment rooms. Patients and referring physicians will make treatment decisions based on superior clinical results rather than relatively small differences in expense.

[1]For nasopharynx, IMPT performed by T. Lomax, PSI, Switzerland and IMXT performed by T. Bortfeld, DKFZ, Germany. For other sites IMPT and IMXT performed by T. Lomax.

2.12. Proton therapy is the best radiation treatment modality for prostate cancer

Michael F. Moyers and Jean Pouliot
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OVERVIEW

Proton therapy for the treatment of cancer has been around for about 50 years, albeit mainly for ocular tumors. Recently, however, there have been several reports of excellent clinical results obtained with higher energy beams for the treatment of deeper lesions and these, combined with the commitment of several manufacturers to provide high-energy proton machines, have led to a surge of interest in proton radiotherapy. It is likely that the number of proton therapy facilities worldwide will double in the next few years, so it is important to determine which disease sites might benefit the most by treatment with this new technology. The results published for the treatment of prostate cancer with protons have been excellent. This has led some to postulate that proton therapy is better than any other form of radiotherapy for the treatment of prostate cancer. Others argue, however, that current therapies are quite adequate and, because of the high cost, proton therapy for prostate cancer is both extravagant and unnecessary. This is the topic of this month's Point/Counterpoint debate.

Arguing for the Proposition is Michael F. Moyers. Dr. Moyers received an M.S. in Radiation Biophysics from the University of Kansas, Lawrence, KS, and a Ph.D. in Medical Physics from the University of Texas Health Science Center, Houston, TX. Between 1990 and 2005 he was employed at the Loma Linda University Medical Center where he was a Senior Medical Physicist and Professor of Radiation Medicine, and was awarded several patents regarding proton therapy equipment. In 2005 he joined Proton Therapy, Inc. as its Technical Director to build, educate, and manage multiple particle beam facilities around the world. He was certified in Radiation Oncology Physics by the ABMP in 2001 and is currently a member of the AAPM Workgroup on Particle Beams.

Arguing against the Proposition is Jean Pouliot. Dr. Pouliot received an M.Sc. in Experimental Physics and a Ph.D. in Nuclear Physics from Université Laval, Québec, Canada. From 1993 to 1999 he was a Medical Physicist in the Department of Radiation Oncology at Hotel-Dieu de Québec and Associate Professor at Université Laval, Québec. He is currently Professor, Department of Radiation Oncology, at the University of California, San Francisco. Dr. Pouliot's main research interests are the development and clinical integration of dose-guided radiation therapy with megavoltage cone-beam computed tomography (CT) for patient verification, organ motion and tumor evaluation studies during cancer irradiation, and inverse planning for dose distribution optimization and relative biological effectiveness of image-guided high dose-rate and permanent prostate implant brachytherapy.

FOR THE PROPOSITION: Michael F. Moyers, Ph.D.

Opening Statement

The goals of cancer therapy are to maximize the tumor control probability (TCP) and minimize the normal tissue complication probability (NTCP). The TCP can be increased by escalating the tumor dose. The NTCP can be reduced by de-escalating the normal tissue dose and using noninvasive procedures and, because treatments are provided on an outpatient basis, potential complications due to hospitalization are eliminated.

In the past, intensity modulated radiation therapy (IMRT) with x rays has been used in an attempt to escalate the tumor dose and reduce the normal tissue dose compared with traditional three dimensional (3D) megavoltage x-ray beam therapy. Unfortunately, megavoltage beams deposit dose maximally near the patient's surface and then continue to deposit dose as they traverse through to the opposite side. There is little that can be done to affect the total energy deposited within the patient, i.e., the integral dose. The most that can be achieved using IMRT is to move dose from one sensitive part of the body to a less sensitive part. In contrast, proton beams deposit dose maximally at the depth of the tumor and deliver no dose distal to the target. If each x-ray beam in an optimized IMRT plan is replaced by a proton beam which has been range modulated to give the same depth-dose distribution over the target volume as the x-ray beam, then it is obvious that much less dose will be delivered outside of the target volume.[1] Although this type of plan does not take full advantage of a proton beam's characteristics, the exercise does demonstrate that proton therapy (PT) can always deliver a better dose distribution than IMRT. For typical PT treatments, the integral dose given to nontarget tissues is only a factor of 0.5–0.6 of that delivered by IMRT.

Brachytherapy (BT) is another modality that has been used in an effort to escalate the tumor dose and reduce the normal tissue dose. BT is an invasive procedure that has associated risks of compromising blood vessels, nerves, and other critical tissues. BT also has the risks associated with anesthesia, infection, and edema. None of these risks is encountered during PT. In addition, not all patients are candidates for the BT procedure because of preexisting medical conditions and/or gland size. Another disadvantage of BT is that there is a large range of doses and dose rates delivered to the tumor cells because of the large inverse square gradients around each source. This makes the biology of BT difficult to understand and optimize.[2,3] In contrast, delivering a uniform dose throughout the target with PT is accomplished simply by modulating the depth of the Bragg peak. Yet another disadvantage of BT is the difficulty in treating the seminal vesicles and/or lymph nodes if involved. Most often, PT can encompass all three targets within one field.

As of 2006, over 8000 patients have been successfully treated worldwide for prostate cancer using PT. The demand for PT is increasing rapidly in part because highly motivated and informed patients find this modality attractive due to its equivalent cure rate and small risk of morbidity compared with other treatment modalities. The use of intensity modulated proton therapy, which is just now becoming available, will further reduce the dose to normal tissues and may allow further escalations of tumor dose.

AGAINST THE PROPOSITION: Jean Pouliot, Ph.D.

Opening Statement

Proton therapy is a good example of the level of technology the fight against cancer may require. Add that prostate cancer is the most prevalent type of cancer among men, and one may be tempted to infer that PT is best for prostate cancer. There are, however, two main reasons that

preclude reaching this conclusion. First, prostate cancer patients can count on an armada of well-proven and long-term validated treatment approaches. And second, there are several significant unanswered questions related to the technical implementation of PT for prostate cancer.

Very good long-term local control of early-stage disease is obtained with permanent prostate implant (PPI) brachytherapy. For external beam radiation therapy (EBRT), recent randomized studies have shown that men with localized prostate cancer have a lower risk of failure if they receive high- rather than conventional-dose conformal radiation.[4,5] When the same high dose is used, published proton results are nearly identical to EBRT.[6] Thus, the key point is that men with prostate cancer, in particular those with advanced local disease, benefit from dose escalation. A UCSF[7] study shows that the response of the tumor to PPI is more rapid than for EBRT, not a surprise since the BT dose is substantially higher than the EBRT dose. High dose rate (HDR) BT, as a boost to EBRT, can also provide significant dose escalation with very good sparing of organs at risk (OARs).[8] Furthermore, the finding that treatment failures of EBRT patients were located in the proximity of known macroscopic disease,[9] suggests that dose escalation to these regions would be beneficial. This has been performed with EBRT, PPI and HDR,[10] where increasing the dose to the (MR spectroscopy defined) dominant intraprostatic lesion (DIL) was achieved without increasing dose to OARs.

Can PT safely boost a DIL within the prostate? Does PT produce the most conformal dose distribution? The physics can indicate the theoretical potential of each technique: Bragg peak vs inverse square law (and short distances) vs IMRT. But in the end, it depends on the specific clinical implementation. For instance, the prostate moves from day to day, sometimes from minute to minute. Anatomical changes such as rectal filling may have a large impact on local control when using EBRT.[11] Therefore, where the dose is delivered is of equal importance to dose escalation itself. Prostate motion and setup uncertainties are not an issue for BT, and for EBRT are accounted for by precise daily alignment of the prostate using markers or other forms of image guided radiation therapy (IGRT). Does PT resolve the organ motion problem? There are technical problems of using high-*Z* markers in proton beams, especially with a small number of beam angles. Daily rectal balloons can be tolerated by patients during PT, but they may push the rectum into high dose regions, and residual prostate motions are observed. What are the consequences of a sudden Bragg peak displacement due to bowel or rectum fillings being replaced with gas? Because of the sharp dose falloff, it is even more important to integrate the lessons learned with IGRT in PT before its benefit for prostate may be realized. There are other questions: economics, neutron dose, biology, etc.

PT may be equivalent in some prostate cases to other radiation therapy modalities, but the answer today to the Point/Counterpoint Proposition is clearly NO. Perhaps PT might offer a unique approach for a subset of prostate patients, or even be the best approach in the future. It is only by performing more research and pursuing more developments that future prostate patients will have their hope of being cured increased while enjoying a high quality of life.

Rebuttal: Michael F. Moyers, Ph.D.

Dr. Pouliot's first argument against PT is that there are many well-proven and long-term validated treatment approaches for prostate cancer. While this is true, there is still room for improvement in TCP and NTPC. IMRT and BT have already been highly optimized and further technical improvements in these delivery approaches are not obvious. Indeed, Dr. Pouliot's reference showing the benefits of dose escalation was performed with proton beams.[5] The low rate of complications in this study indicates that even further dose escalation is possible with PT.

The basic technique for PT is two uniform lateral beams.[12] If advanced imaging techniques could demonstrate a localized region of the prostate with a high concentration of tumor cells, then a boost dose could easily be provided by strategically placing proton Bragg peaks at the site of those tumor cells using narrow beams from only one or a few directions that bypass critical normal tissues.

Dr. Pouliot's second argument concerns a number of perceived technical issues, most of which have been answered over the last 20 years. All prostate patients that have received PT were localized daily with orthogonal kilovoltage x rays. In fact, IGRT has always been an integral component of PT. Most patients had the prostate immobilized between a urine-filled bladder and a constant-volume water-filled balloon inserted into the rectum. This technique, which was well tolerated, displaced gas cavities from the path of the protons, and pushed most of the rectum and bladder out of the irradiated volume.[13,14] A study that compared a set of four implanted marker seeds with skeletal landmarks demonstrated that both intra-fraction and inter-fraction motion were minimal using this immobilization technique.[15]

With regard to neutron dose, a recent study has shown that, in the plane of the isocenter, the neutron dose equivalent from an entire course of treatment is roughly equivalent to that received from a single CT exam.[16]

In conclusion, there appear to be no impediments to dose escalation using PT while maintaining a low risk of complications.

Rebuttal: Jean Pouliot, Ph.D.

I agree with Dr. Moyers that some of the inherent theoretical physics characteristics of proton beams are of prime significance for prostate cancer treatment. However, in an era of evidence-based medicine, the best modality provides the best disease control with the least complication rate at the lowest cost, along with the best global quality of life.

Studies show that what is most invasive for one patient may be least for another. For the same treatment outcome, completing a treatment in one or two days, even with needle insertion, may sound appealing compared with several weeks of daily commuting in order to receive a fractionated course of treatment. Years of improvements on the practical issues have led to sophisticated treatments using either IMRT or BT, which can address the practical issues for each specific cohort of patients. PT is in its infancy compared to IMRT or BT, and if you can afford the price tag, it can offer an equivalent treatment outcome. IMRT and BT are also evolving. In many ways, we are faced with a moving target. A fair evaluation should compare the best of all three modalities.

If there is one thing that I remember of my transition from nuclear to medical physics, it is that a solid fundamental concept is only the beginning of a long uphill road leading to an improvement in care. Radiation Oncology is a multidisciplinary field with, at its core, a unique human being in need of treatment. One should devote all efforts to perfect the treatment today to make it better than the one of a few years ago, while still realizing that new knowledge may eventually make today's treatment obsolete, and the sooner the better.

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2.13. Proton therapy is too expensive for the minimal potential improvements in outcome claimed

Robert J. Schulz and Alfred R. Smith
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OVERVIEW

The use of high-energy proton beams for radiotherapy is increasing rapidly, with dozens of new proton therapy centers planned to open in the next few years. The main advantage of protons over photons is physical (due to the Bragg peak) since there is little, if any, biological benefit. However, numerous studies have demonstrated that highly conformal dose distributions can be obtained with photons using, for example, intensity modulated radiotherapy (IMRT), at significantly lower cost. One might question, therefore, whether-or-not further improvements in dose distributions with protons over those already obtainable with IMRT will result in outcomes that will be improved significantly enough to justify the increased cost. This is the question debated in this month's Point/Counterpoint.

Arguing for the Proposition is Robert J. Schulz, Ph.D. Dr. Schulz is a charter member and Fellow of the AAPM, Fellow of the ACR, and Diplomate of the ABR. His professional career began at Memorial Sloan-Kettering (1952–1956), developed further at the Albert Einstein College of Medicine (1956–1970), and concluded at Yale University (1970–1992) from which he retired as Emeritus Professor. His major contributions have been in radiation dosimetry having chaired the SCRAD and TG-21 committees, and twice been a recipient of Farrington Daniels Awards. His retirement to northern Vermont, and close friendship and collaboration with A. Robert Kagan, M.D., has broadened his perspective on radiation therapy to include considerations of cost versus benefit, over-diagnosis and over-treatment, the quality of clinical reports, and the impact of new technologies on outcomes.

Arguing against the Proposition is Alfred R. Smith, Ph.D. Dr. Smith received his Ph.D. in Physics in 1970 from Texas Tech University. He accepted a postdoctoral fellowship at the M. D. Anderson Cancer Center in Houston and joined the faculty in 1971. In 1975 he moved to the University of New Mexico Cancer Center and became Director, Negative Pi Meson (Pion) Clinical Physics at the Los Alamos National Laboratory. From 1982–1985 he was a cancer expert at the National Cancer Institute. In 1985 he became Professor, University of Pennsylvania Medical School, and Director of Clinical Physics, Department of Radiation Oncology at the Hospital of the University of Pennsylvania. In 1992 he moved to Boston where he held appointments of Professor at the Harvard Medical School, Biophysicist at the Massachusetts General Hospital, and Associate Director of the Northeast Proton Therapy Center. He currently holds appointments of Professor at the University of Texas M. D. Anderson Cancer Center and Director, Proton Therapy Development. He has served the AAPM as President and Chairman of the Board of Directors.

FOR THE PROPOSITION: Robert J. Schulz, Ph.D.

Opening statement

I submit that the efficacy of any treatment modality depends upon the following: (a) it improves the rate of cause-specific survival or achieves a similar rate of survival as other treatment modalities but with fewer complications; (b) it is widely available to patients who will benefit from it; (c) its benefits outweigh its costs. I further submit that proton therapy (PT), having failed in each of these categories, should be denied reimbursements beyond those provided for conventional and equally efficacious treatments.

Although proton dose distributions are unique, except in a few instances the results of PT are indistinguishable from those achieved by conventional modalities. One exception might be the treatment of certain large ocular tumors.[1] Whereas small to mid-sized choroidal melanomas are efficaciously treated by radioactive plaques,[2] for larger tumors (2,400 new cases, 230 deaths in the USA per year) PT is accepted to be superior. However, ocular tumors require proton-beam energies no higher than 70 MeV, less than a third of the energy of a general-purpose PT machine.

It has been widely speculated[3,4,5] that PT should be used for the treatment of solid pediatric tumors (8,400 new cases, uncertain deaths) because of its potential to reduce the impairment of future development of organs surrounding the tumor. However, there is a paucity of long-term follow-up data that support these speculations. Also, with advancements in chemoradiation that require smaller tumor doses, reductions in long-term impairment are equally as likely to be achieved by 3D-CRT.

As for cancers of the respiratory and digestive systems, and the prostate (680,000 new cases, 330,000 deaths), about the best that can be said for PT is that it is well tolerated.[6,7,8] Clearly, any detectable improvements in the cause-specific survival of these high-profile cancers that could be attributed to PT would have received banner headlines in the press and medical journals.

There are about 210,000 patients (30% of the 50% of cancer patients who receive radiation therapy) who, if treated by PT, might do as well as those conventionally treated. Assuming that three patients are treated per hour in an 8 h day, and each is treated for six weeks, a four-gantry PT facility could treat 832 patients per year. Therefore, to make PT available to these 210,000 patients would require 232 PT facilities. At a cost of $125 million per facility,[9] the capital cost for these facilities could be $29 billion. As for per treatment costs, these have been estimated[10] to be 2.4 times higher than IMRT but a factor of three is more realistic when PT is compared with the actual practice of radiation therapy. Simply put, in the current economic climate the cost-benefit ratio of PT is unacceptable.

Worldwide, over 47,000 patients have received PT. It would seem that if it had something to offer patients that x rays don't, something that could justify its high capital and operating costs, then that *something* should have long since been recognized.

AGAINST THE PROPOSITION: Alfred R. Smith, Ph.D.

Opening statement

We have insufficient data on costs and benefits for proton therapy to make a definitive statement about the Proposition. However, I offer some comments about which, I think, reasonable people can agree.

Clinical/biological issues: (1) Dose escalation will increase local control for those tumors that exhibit dose response;[11] (2) Increased local control improves long-term disease-free survival for some tumors;[11] (3) Significant toxic effects in critical normal tissues can limit the potential of dose escalation, particularly when concurrent chemotherapy is given;[12] (4) Highly localized dose distributions have a greater probability of providing increased local control and decreased late effects than those with a lesser degree of localization;[13] (5) There is no rationale for exposing critical, uninvolved, normal tissues to radiation when it can be avoided.

Physical properties of treatment beams: (1) Throughout the history of radiation therapy, improvements in clinical outcomes have been correlated with improvements in dose localization. Imaging has improved localization of tumors and normal tissues, but this knowledge is of limited value if one cannot selectively localize the treatment; (2) The "ideal" dose distribution is one that provides high dose to the treatment target and zero dose to uninvolved normal tissues. Protons approach the ideal dose distribution to a greater extent than do photons and have about a factor of 2 less integral dose.[14]

Costs of proton therapy: (1) Capital investment and operating costs for intensity modulated proton therapy (IMPT) are *estimated* to be about two times higher than for intensity modulated x rays;[10] (2) Prototype proton therapy systems are expensive but standardization will reduce costs of individual units (economy of scale) and spare parts inventories. Costs per patient will be reduced through greater efficiency and fewer treatment fractions. These factors can further reduce the cost of proton therapy by 30%–40%;[10] (3) The high cost of caring for patients who are not cured, or who suffer injuries from treatment, is usually not considered in cost calculations. When such costs are included, proton therapy may be less expensive than photons, particularly for pediatric patients;[15] (4) Smaller and more cost effective proton therapy facilities are being designed.

Proton therapy has significant potential to improve clinical outcomes; this potential has been borne out in a number of studies.[16] It is more expensive than x rays but costs will be reduced over time. The question is not whether protons will achieve better clinical outcomes, it is "how much better" and "is the differential gain worth the additional cost?" We have not optimized proton therapy; IMPT will first be used in the USA in 2007. Multi-institutional clinical trials are being planned. When we have quantified the clinical benefits of optimized proton treatments, and established their true costs, we can then solve the cost/benefit equation.

Rebuttal: Robert J. Schulz, Ph.D.

Dr. Smith outlines the precepts for what I'm inclined to call Faith-Based Radiotherapy: if it seems reasonable, then lack of supporting data should not stand in the way of its implementation. There is no clearer case of Faith-Based Radiotherapy than PT. Consider that PT began in the 1950s, that there have been as many as 31 clinical programs of which 24 are still active, and that over 47,000 patients have been so treated (Janet Sisterson, Personal Communication). Yet despite unimpressive results, its proponents argue that there are insufficient data to arrive at a cost-benefit ratio, and that unspecified clinical trials are required.

Randomized clinical trials require that the experimental (PT) and control (perhaps 3D-CRT) groups end up being closely matched. Patient accrual can be slow, and when as with PT the differences in survival are likely to be small, a rigorous trial would require thousands of patients

and take up to ten years if 5-year survival was the end point. With PT being promoted as the modality *du jour*, a definitive assessment cannot await the results of a clinical trial.

Protons do to living tissues what x rays have been doing for the past century. Indeed, protons have unique dose distributions but beyond this their advantage ends, and cost and complexity weigh heavily against their adoption (just think, port films cannot be made with protons). As for dose escalation, Dr. Smith's first reference (Kong *et al.*[11]) reveals that in going from doses of 74–84 Gy to 92–103 Gy, the 5-year survival for NSCLC went from 22% (32 patients) to 28% (18 patients). Clearly, this small number of patients distributed over stages I–IIIB cannot be considered a clinical trial, and provides little support for Dr. Smith's first proposition.

There were 564,000 cancer deaths in the USA in 2006, and nine out of ten were due to metastatic disease. Are we to believe that PT will have a detectable impact on this statistic?

Rebuttal: Alfred R. Smith, Ph.D.

Dr. Schulz provides (his own) criteria for judging treatment modalities then declares that proton therapy fails on each point. He sets himself up as judge and jury then arrives at a false verdict. He asserts:
(a) Proton therapy does not provide the same rate of survival (as x rays) but with fewer complications. *This statement is unfounded.*
(b) Proton therapy is not widely available to all who would benefit from it. *This is because it is a new modality, but it is experiencing an impressive growth rate.*
(c) The benefits of proton therapy do not outweigh its costs. *Unfounded–we have not determined the overall benefits of proton therapy nor do we know the true costs.*

Since the majority of the 47,000 cases that have been treated with protons have been for choroidal melanomas, Dr. Schulz discredits a potentially important treatment modality for other cancers before it has been sufficiently tested against standard radiation therapy. Unless the laws of physics are changed, protons will be superior (in terms of local control, acute and late effects) to x rays for a broad range of cancer sites, particularly for pediatric cancers. Clinical trials are being conducted.

He provides unbalanced facility costs and erroneous operating premises. The MGH facility cost about $42 million. There are smaller proton facilities in final design that will cost less. Facilities can be used 2 shifts/day, 6 days/week and large ones will treat over 2000 patients/yr. He misrepresents the conclusions of Goitein and Jermann[10] who state: "*The cost of intensity modulated proton therapy, compared to IMRT, might be reduced to a factor of 1.7 over the next decade*." His "factor of 3" is an invention.

We can understand Dr. Schulz's position on the future of radiation therapy from his quote, "**. . .** clinical trials over the past decade suggest that a plateau has been reached and that the impact of new modalities such as proton beams and IMRT on overall cancer mortality will be difficult to detect."[17] He clearly believes that there is nothing we can do to improve clinical outcomes with radiation therapy—this is in direct contradiction to highly regarded clinicians who actually treat patients.[18,19]

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2.14. Within the next decade conventional cyclotrons for proton radiotherapy will become obsolete and replaced by far less expensive machines using compact laser systems for the acceleration of the protons

Chang-Ming Charlie Ma and Richard L. Maughan
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OVERVIEW

Because they exhibit a Bragg peak, proton beams have been considered potentially superior to photons and electrons for radiotherapy for over 50 years.[1] Yet few proton therapy facilities exist, primarily because the costs involved are great. Recently, several publications have endorsed the use of compact laser systems to accelerate protons in place of the very expensive cyclotrons and synchrotrons that are currently in use. Much research and development is still needed, but some say that such compact systems may replace conventional accelerators for proton therapy within the next decade. This conjecture is the topic of this month's Point/Counterpoint debate.

Arguing for the Proposition is Chang-Ming Charlie Ma, Ph.D. Dr. Ma received his Ph.D. in medical physics from the University of London (UK) and is now Professor and Director of Radiation Physics at Fox Chase Cancer Center (FCCC). Dr. Ma is active in research, education and clinical implementation of Monte Carlo simulation techniques for radiotherapy dosimetry, quality assurance and advanced treatment planning for intensity-modulated radiotherapy and electron therapy. Since 1999 Dr. Ma has been investigating proton and light ion acceleration using laser-induced plasmas. He is currently the project leader for laser-proton acceleration in radiation therapy at FCCC.

Arguing against the Proposition is Richard L. Maughan, Ph.D. Dr. Maughan received his Ph.D. in physics from the University of Birmingham in England. He started his career at the Gray Laboratory, London in 1974, and moved to Wayne State University (WSU) in 1983 where he was responsible for the medical physics aspects of a neutron therapy program. He also was an active participant in the WSU Medical Physics Graduate Program. He is now Professor, Vice Chair and Director of Medical Physics in the Department of Radiation Oncology at the University of Pennsylvania. His research interests are particle therapy (neutrons, protons, heavy ions), with a particular emphasis on proton therapy.

FOR THE PROPOSITION: Chang-Ming Charlie Ma, Ph.D.

Opening Statement

For treatment of cancer with radiation, the use of proton or light-ion beams provides the possibility of better target dose conformity and normal tissue sparing, compared with commonly used photon and electron beams.[1] Proton, helium and heavier ion beams were used for biomedical studies in the early 1950s. The first human patient was treated for a pituitary tumor in 1954, about forty thousand patients have been treated since with proton beams worldwide. Light

ion and other particle beams have also shown encouraging results, particularly for well-localized radioresistant lesions.

Given this advantage, why is proton or ion beam therapy only offered at a few facilities worldwide? The answer is high expense. Conventional proton or ion facilities are either cyclotron- or synchrotron-based. An accelerator that is big enough to accelerate protons to the required therapeutic energies can cost in excess of $50 million. Also, heavy charged particles are difficult to handle and require a massive gantry for beam delivery. The amount of concrete and steel used to shield a proton treatment room is an order of magnitude or so greater than for a conventional linac room. Although use of an expensive accelerator can be made more efficient by sharing the therapy beams among multiple treatment rooms, this approach requires additional space for a switchyard housing vacuum beamlines, dipole bending magnets, steering magnets, focusing quadrapole magnets, power supplies, and cooling equipment. The cost of the gantries and the building increases the total capital cost to about $100 million for a proton facility, and 2–3 times that for an ion facility.

Laser acceleration was first suggested for electrons.[2] Rapid progress in laser-electron acceleration followed the development of chirped pulse amplification and high fluence solid-state laser materials such as Ti:sapphire. Recently, charged particle acceleration using laser-induced plasmas has illuminated the search for a compact, cost-effective proton or ion source. Proton acceleration is achieved by focusing a high-power laser pulse onto a thin target. The short (femtosecond) pulse width of the laser produces a high peak intensity that causes massive ionization in the target and expels a great number of relativistic electrons. This sudden loss of electrons leaves the target with a highly positive charge, yielding an effective electric field of $\sim 10^{12}$ V cm^{-1}. This transient field then accelerates protons and other light-positive ions, if present, to high energies. Laser-proton acceleration has been investigated by major laboratories worldwide, and energetic protons up to 58 MeV have been generated using high-intensity, short-pulse lasers.[3] Theoretical studies show that at a laser intensity of 10^{21}–10^{22} W cm^{-2}, protons may be accelerated up to 300 MeV with a spectrum and angular distribution.[4] An experimental facility dedicated to laser-proton acceleration for cancer treatment has recently been established[5] with support from the U.S. Department of Health and Human Services. Because of the small acceleration distance, a laser-proton/ion accelerator will be much more compact than conventional cyclotrons or synchrotrons. Once developed, the laser-proton ion accelerator may be the best candidate for particle therapy.

AGAINST THE PROPOSITION: Richard L. Maughan, Ph.D.

Opening Statement

At the present time laser accelerators for use as electron, proton or heavy ion accelerators are in an early stage of research and development.

For proton acceleration, with potential use as a source for proton therapy, the best published data are those presented by Malka *et al.*[6] Using a 10 Hz laser system with a peak irradiance of 6×10^{19} W cm^{-2}, they have accelerated protons in a broad spectrum from 0–10 MeV. They estimate that a peak irradiance of 2×10^{21} W cm^{-2} is required to accelerate protons to the energies required for proton therapy, (i.e., a laser at least 30 times more intense that used in their experiment). The highest reported proton energies[3] are 58 MeV. The ability of laser accelerators to produce sufficient dose rate has not yet been demonstrated. Lasers producing beams of this peak intensity have yielded only a single laser pulse approximately every 20 minutes There are

no reports of laser proton beams being transported from the proton producing target along a beam line to a remote experimental location. That is, laser produced proton beams have not yet been used in any practical application.

Laser produced proton beams have a broad energy spectrum which is problematical.[4] A magnetic spectrometer has been proposed to produce a pseudo monoenergetic beam.[7] Even after removal of unwanted protons (~99.5%) in this manner, the energy spread on a laser-produced proton beam is still inferior to a conventionally-accelerated proton beam, leading to a significant degradation in the sharpness of the beam's distal edge. The 99.5% of the beam that is stopped in the spectrometer will present considerable shielding challenges, due to neutron production and materials activation. A detailed analysis of this problem has not been published, but the shielding requirements may be a significant impediment to mounting the laser on a gantry.

Laser pulses are only a few ps long, so there is no opportunity for beam scanning during the pulse and, at best, a laser may produce only up to 600 pulses/minute. Even if the intensity and energy of each pulse could be accurately controlled (problems which have not yet been addressed), 600 pulses/minute are insufficient for delivery of a spot-scanned treatment in a reasonable time (1–2 minutes). Only scattered beam delivery would be possible, and not only would this approach yield an inferior distal edge, but also it would not be capable of conforming to the proximal tumor edge. A scattered system requires a long beam path (~2 m for divergence and to improve the Bragg peak-to-plateau ratio; this requirement, combined with the magnetic spectrometer and the necessary shielding, will produce a gantry of similar proportions to a conventional gantry. Thus, there will be little or no cost savings on the gantries, which constitute a major part of the cost of a multi-room proton therapy facility. Hence, the cost and space requirement advantages of a laser accelerator are questionable.

For all these reasons it is unlikely that laser beam technology will replace conventional acceleration techniques in proton therapy facilities within the next decade.

Rebuttal: Chang-Ming Charlie Ma, Ph.D.

Radiation therapy has experienced revolutionary changes over the last 100 years, ranging from kilovoltage x-ray therapy to isotope teletherapy, megavoltage x-ray and electron therapy. From time to time, technological breakthroughs have brought marked improvement in treatment efficacy. Laser-proton acceleration is still in its infancy. Like many other new findings, its success depends on the advancement of science and technology. Significant progress has been made in laser physics in the last decade including new laser materials, novel amplification methods and compact, high-power laser systems. A number of petawatt lasers are being built worldwide with higher rep rates and intensities (10^{21} W cm^{-2} or higher). Based on particle in cell simulations, the dose rate of protons using such lasers may reach 10+ or even 100+Gy/min.[7] Because of the broad energy spectrum of laser-accelerated protons, it is easier to obtain a desired spread-out Bragg peak by selecting protons across a narrow range of energies. The shielding for a laser-proton treatment gantry may not be much more than that for a conventional proton gantry, because most unselected protons have energies well below 50 MeV. The broad angular distribution of laser-accelerated protons will actually provide superior dose profiles without the need for large SSDs. Beam scanning is an effective way for proton beam intensity modulation but it is not the only way. For example, conformal proton dose distributions can also be achieved using multileaf collimators and port-specific compensators via aperture-based plan optimization.[8] This method requires a lower dose rate than the beam-scanning method. A laser can also serve multiple treatment rooms with little additional cost, since the transport of laser light is much

easier to achieve than is the transport of protons. It is expected that many scientific and engineering issues must be resolved before laser-accelerated protons can be used for cancer therapy, but they also represent exciting challenges for future research.

Rebuttal: Richard L. Maughan, Ph.D.

With present technology the capital costs of proton therapy are certainly high, but it is not clear that laser accelerators can significantly reduce overall facility costs.

Regardless of the proton acceleration method used, most components of the facility remain unchanged. The cost of a proton gantry with bending magnets, a beam nozzle and patient support system is high. Scattered proton beams require a gantry of large dimensions, because double-scattering systems require a path length of 2.5 to 3 meters to spread the beam to clinically useful dimensions. These space requirements are the same for all accelerators. The laser system requires an energy selector magnet with neutron shielding and, therefore, gantries may be similar in mass and cost to existing gantries. A laser accelerator needs to produce a proton beam of the same energy and intensity as existing beams, so with similar gantries, treatment room size and shielding requirements will be identical. Hence, at best, the only cost savings are on the beam switchyard and the accelerator, which are a small proportion of the total facility cost. Although a research laser may be of modest price ($1M), a fully-developed, FDA-approved, commercial laser accelerator, with all the necessary safety features, will probably cost 3 to 5 times more. Thus, a laser-based facility could cost $85M or more, in comparison with an existing facility costing $100M.

Recent laser experiments on plasma channeling demonstrate the possibility of producing quasi-monoenergetic particle beams,[9] thus offering a potential solution to the energy selection and neutron shielding problem. This may allow for development of a lightweight, less expensive gantry-mounted laser accelerator for installation in a single shielded room. This would be a significant advance for proton therapy, but one that is unlikely to occur within the next decade.

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2.15. High energy electron beams shaped with applied magnetic fields could provide a competitive and cost-effective alternative to proton and heavy-ion radiotherapy

Frederick D. Becchetti and Janet M. Sisterson

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OVERVIEW

Work at several institutions has demonstrated that intense magnetic fields can be used to confine and shape high-energy electron beam-dose profiles. It is conceivable that this approach might compete effectively with hadron therapy. However, the technique gives rise to several technical challenges, some of which may be insurmountable. Whether the technique has enough potential to be pursued as a possible approach for radiation therapy is the subject of this month's point/counterpoint debate.

Arguing for the Proposition is Frederick D. Becchetti, Ph.D. Dr. Becchetti has worked primarily in accelerator-based nuclear physics including the application of large super-conducting magnets to nuclear reaction studies and recently, application of the latter to radiation oncology. He has served on the Board of Editors of *Review of Scientific Instruments* (1999–2001) and was associate program chair for the recent Symposium on Radiation Measurements and Applications held in Ann Arbor, Michigan, May 21–23, 2002. Dr. Becchetti has chaired or co-chaired a number of Ph.D. thesis committees dealing with medical imaging, radiation oncology or related areas in nuclear medicine.

Arguing against the Proposition is Janet M. Sisterson, Ph.D. Dr. Sisterson trained as a Medical Physicist in London following receipt of a Ph.D. in high-energy physics from the University of London. She spent 25 years at the Harvard Cyclotron Laboratory where she helped develop many of the techniques used worldwide in proton radiation therapy. In 1998 she moved to the Northeast Proton Therapy Center, Department of Radiation Oncology at the Massachusetts General Hospital. She holds a joint appointment as Assistant Professor in the Department of Radiation Oncology at Harvard Medical School. She is the principal investigator on a NASA grant to measure proton and neutron cross sections needed for cosmic-ray studies.

FOR THE PROPOSITION: Frederick D. Becchetti, Ph.D.

Opening Statement

Calculations[1] and measurements using phantoms[2,3] have shown that the radiation dose profile from high-energy electron beams typically used in radiotherapy can be confined using high (*viz.*, a few tesla) magnetic fields. The large penumbra associated with scattering of electron beams in tissue-like material is thereby greatly reduced. In addition, for magnetic fields parallel to the initial beam direction, additional, 3D focusing of the electron beam may be obtained. The net effect is a greatly enhanced dose near the end of the electrons' range. The dose profile resembles a degraded Bragg curve.[2,3] This feature could be exploited in conformal radiotherapy to furnish an alternative to proton or heavy-ion radiotherapy, at least for certain types of tumors, and to

provide an economical, on-site electron-beam therapy facility for many hospitals. High-energy electron accelerators (e.g., linacs and microtrons) and electron-beam gantries are affordable by many hospitals. This is in contrast to current proton and heavy-ion radiotherapy units, which are large, costly facilities located far from most hospitals and hence not practical for widespread use, especially when fractionated doses are needed. Many of the technical problems have been solved, particularly the use and efficient operation of large-bore superconducting magnets and such magnets are in routine use in MRI units at most large hospitals. Such magnets can be designed, if needed, to allow rotation with a treatment gantry.[4] Recently mechanical coolers have been utilized which can further simplify a gantry-mounted system, and nonmagnetic treatment gantries and tables are feasible. Further research and development appears warranted and if successful could lead to animal and, eventually, human clinical trials in the near future.

Rebuttal

It is not necessarily claimed that electrons confined by a magnetic field are preferable to high-energy protons (or heavy ions) for many types of radiotherapy. Instead, as noted, the high cost of high-energy ion accelerators, gantries, radiation shielding and buildings has greatly limited the number of patients that can be treated with protons. For some patients, magnetically-confined electron-beam therapy may in the future provide a viable alternative to protons at lower cost. The experiments cited in Refs. 2 and 3 utilized a hospital-based "table top" 50 MV electron racetrack microtron. 100 MV electron microtrons used for physics research are similarly in operation. Providing an accurate 3D focus for stereotactic treatment with electrons is perhaps the major challenge. As noted in the opening statement, large-bore superconducting magnets (e.g., 1 m diam. bore×1 m long $B \gtrsim 5T$) are feasible, and can be gantry mounted. Such magnets are presently used in research and industrial applications as well as in medical applications (high-field MRI). Thus much of the needed engineering has already been done. The key issue is to demonstrate that magnetically-confined electron-beam radiotherapy may have advantages over other modalities, even x-ray IMRT in certain circumstances.[1,2,3,5] However, this issue can be addressed definitively only by further research including realistic treatment simulations and animal clinical trials.

AGAINST THE PROPOSITION: Janet M. Sisterson, Ph.D.

Opening Statement

Computer simulations and some experiments show that intense magnetic fields can be used to delineate the geometry and control the dose distribution of high-energy electron beams. For this reason, electron beams have been proposed as a cost-effective alternative to heavy ion beams, with a similar therapeutic benefit. Simulations and experiments have been conducted in an attempt to overcome the inherent limitations of electrons, all due to the small electron mass, and to mimic, by external means, the inherent properties of ion beams. The goal of these experiments has been to identify applications where electron beams can be equally or preferentially used to treat specific tumor sites.

The inherent physical properties of ion beams are used to advantage in radiation therapy. These properties include: (1) little penumbral scattering as the beam penetrates tissue; (2) a finite range in tissue, accurately controlled by the beam energy; (3) a very sharp fall-off in the distal edge of the dose distribution; and (4) a maximum rate of energy loss near the end of range: "the Bragg peak effect." These properties are used to achieve dose distributions that are uniform over large

target volumes, with a sharp penumbra in all directions perpendicular to the beam and along the axis. The resulting dose distributions conform closely to the target volumes, leading to maximum sparing of adjacent normal tissues and sensitive structures.

Electrons, as continuously ionizing particles, share some of the properties of heavy ions. In electron beams, however, the benefit of these properties is lost because of the extreme scattering of individual electrons. Intense magnetic fields can limit the scattering effects to a significant degree. Still, they do not allow electrons to achieve the properties of an ion beam Bragg peak or the dose distributions attainable by summation of such peaks. For example, the proposed magnetic fields focus primarily in one dimension. This implies that any magnetic focusing technique will require much more sophisticated, three-dimensional control of the magnetic focus inside the patient. In addition, electron energies up to 100 MeV may be needed to cover the full range of therapeutic applications. The construction of a device that delivers high-energy electron beams with a precisely controlled three-dimensional magnetic focusing lens may prove to be an insurmountable, and certainly not cost-effective, engineering task.

In contrast, intensity and energy modulated ion therapy is already a reality, and permits precise control of dose deposition in volumes as large as 20 000 cm^3 with a resolution of 0.125 cm^3. The technology for delivering these fields is proven and uses off-the-shelf magnetic devices and control techniques. Field delivery is accurately controlled in both time and space, a critical benefit when considering patient-specific concerns such as organ motion.

In summary, one-dimensional magnetic control of electron fields may improve the therapeutic gain compared with "conventional" electron fields. Such control is no match for intensity modulated x-ray therapy, conventional ion therapy, or intensity modulated ion therapy. There is simply not a clear rationale to justify pursuit of such a nontrivial and expensive engineering task as magnetic field-controlled electron beam therapy.

Rebuttal

Our colleague claims that electron beams, modified with (strong) magnetic fields, can be delivered and controlled in a clinical setting to produce therapeutic dose distributions that might be an alternative to proton or heavy ion radiotherapy. Such an alternative is deemed desirable due to the high cost of a proton or ion facility, and the implied geographic separation of such a facility from a hospital. We believe there are several misconceptions in this position. First, the Harvard Cyclotron Laboratory/Massachusetts General Hospital collaboration (HCL), with over 9,000 patients treated, shows that fractionated proton radiotherapy can be successfully accomplished using a facility located about three miles from the hospital campus. Second, it is true that proton and ion therapy were pioneered at existing accelerator facilities, often under many constraints. However, there are currently many hospital on-site proton centers treating patients, under construction, or planned. Such facilities are expensive but can still be cost-effective. For example, the cost of such a facility is amortized over the 30-year lifetime of a cyclotron. (Of note, the HCL operated for 50 years!) Over that lifetime, a conventional clinic, albeit a large one, would purchase about 12 linear accelerators comparable to the multiple treatment rooms in a proton therapy facility. This analysis certainly reduces the gap in spending between a conventional clinic and a clinic that also provides proton therapy. Finally, we again stress that the predicted electron dose distributions are not comparable to conventional, energy-modulated, proton Bragg peaks, and certainly not to intensity and energy modulated proton beams or photon IMRT.

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2.16. Modern linac stereotactic radiosurgery systems have rendered the Gamma Knife obsolete

Frank J. Bova and Steven J. Goetsch
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OVERVIEW

Precise localization of high doses of radiation in small volumes of tissue has been one of the strong marketing advantages of Gamma-Knife technology. New linear accelerators, with 0.5 mm isocentric accuracy and software support for conformal targeting of dose, approach the precision of Gamma Knife systems. Some physicists think that this precision, combined with the greater versatility of linacs, make the Gamma Knife an obsolete technology. Others believe that the exactness of dose delivery with the Gamma Knife ensures that the technology will continue to be useful. These opposing points of view are explored in this Point/Counterpoint.

Arguing for the Proposition is Frank J. Bova, Ph.D. Dr. Bova attended Renesslear Polytechnic Institute and in 1972 graduated with a Bachelor in Biomedical Engineering and in 1973 with a Masters in Biomedical Engineering. He went on to receive a Ph.D. in Nuclear Engineering Sciences from the University of Florida in 1977. In 1978 Dr. Bova joined the Department of Radiation Oncology at the University of Florida. In 1991 he was appointed as the Einstein Fund Professor of Computer-Assisted Stereotactic Neurosurgery within the Department of Neurosurgery. In January of 1999 he joined the faculty of Neurosurgery at the University of Florida and was appointed Professor of Neurosurgery.

Arguing against the Proposition is Steve Goetsch, Ph.D. Dr. Goetsch is a self-employed consultant in radiological physics. He received a Master's degree in Health Physics from Northwestern University in 1974 and worked as Radiation Safety Officer for Amersham/Searle. He later returned to graduate school, receiving a Doctorate in Medical Physics from the University of Wisconsin in 1983. After 7 years at the ADCL, he accepted a position at the UCLA Medical Center in Radiation Oncology, working there from 1990 to 1994. Since 1994 he has been Director of Medical Physics at the San Diego Gamma Knife Center. He continues to consult and do research in stereotactic radiosurgery.

FOR THE PROPOSITION: Frank Bova, Ph.D.

Opening Statement

Any radiosurgery procedure involves three steps: Imaging, planning, and treatment. A radiosurgery imaging system must include stereotactic imaging and localization systems that provide sub-millimeter accuracy in specifying the position of target and nontarget tissues. The treatment planning system must allow the user to develop a highly conformal plan that has rapid dose falloff for all nontarget tissues, not just the tissues in a specific plane. This is an area where the plan designed using a linac system can differ from a plan designed using the Leksell Gamma Knife system. When designing a Leksell Gamma Knife plan, the user encounters a practical

limitation in his or her ability to restrict the angles at which the beams can be directed to the target tissues. Blocking too many beams leads to an unacceptably low dose rate. For linacs, the user is free to limit the number of beams without affecting the dose rate. If, however, the dose from noncoplanar beams is spread over less than 400 to 500 arcing degrees, the dose concentration and falloff are adversely affected. We believe that, regardless of the system, plans that use too few isotropic beams to deliver the dose to each isocenter violate one of the basic principles of radiosurgery, namely that all target tissues should experience the full isotropic set of radiation beams. If the radiosurgical planning system supports isotropic arc placement to target tissues, then the only questions left for the planning process are a) how large should each isocenter be, b) how close should the isocenters be spaced, and c) what are the relative intensities of the various isocenters? These questions are identical whether planning a linac-based radiosurgery treatment or a Leksell Gamma Knife treatment. Because the questions are identical irrespective of the radiosurgery system used, an expert user or an automated treatment planning system can generate identical treatment plans for either system.

The final question is one of plan delivery. Can the treatment system deliver the planned distribution accurately and in a time-frame rapid enough to prevent repair of sublethal damage during the dose delivery process? This is simply a matter of user interface design. Linac delivery systems have been designed that either duplicate or surpass the accuracy of Leksell Gamma Knife beam delivery.[1] These systems have been designed so that the dose to each isocenter can be delivered in a time frame that is comparable, if not equivalent, to that of a freshly loaded Leksell Gamma Knife.

In summary, if tissue differentiation and spatial location are not issues, if dose distributions and dose gradients can be made equivalent, and if treatment delivery can be as accurate and rapid, then where lies the debate between a linac and the Leksell Gamma Knife? Can it be the that linac radiosurgery systems have a greater potential for incorporation of new dose delivery techniques?

Rebuttal

I fully agree with Dr. Goetsch in crediting Lars Leksell and Borge Larsson with the innovative approach linking stereotactic targeting with multiple nonconvergent beam planning. These tools have allowed radiosurgeons to deliver large single-fraction doses with submillimeter accuracy. I also agree with Dr. Goetsch's claims for the required accuracy and convenience. As for his claims for uptime, all I can say is that at the University of Florida we have treated over 1700 radiosurgery patients and only had to use a backup linac for two patients, giving us an uptime of 99.88% over a thirteen-year period.

While Dr. Goetsch and I agree on most points, there is a single point where we disagree. That point is not that all linac systems will be as accurate and user friendly as a Leksell Gamma Knife system, but instead that a linac system can be made to match the accuracy and convenience of a Leksell Gamma Knife. For this to occur, some modifications or additions to the basic medical linac are required. If asked, "Can I purchase a stereotactic head frame and, using my standard external beam planning system and room lasers, deliver high quality radiosurgery?," my reply would be "no." But if a facility is willing to obtain planning code tailored specifically to radiosurgery planning, and to adapt their linac to provide the accuracy, stability, and ease of use required for the small field, high precision, single fraction therapy, then my reply would be "yes."

In his statement Dr. Goetsch appears to make the assumption that a radiosurgery patient must be planned and treated on the same day. Currently we obtain nonstereotactic MR scans of our

patients a day or two prior to the planned radiosurgery. We develop a plan for that patient based on the nonstereotactic MR scan. On the day of the radiosurgery, we apply the stereotactic head ring and obtain a CT scan. Fusing the previously nonstereotactic MR scan to the stereotactic CT scan provides the transform required for plan transfer. On the radiosurgery day, it only requires 10–15 minutes for image fusion, plan transfer and plan verification. We know the time required for treatment, and can adjust the treatment schedule accordingly.

As for current and future innovations I find the advent of mMLC for high resolution intensity-modulated planning, extracranial stereotactic approaches, fractionated stereotactic radiotherapy systems and high dose-rate linacs to more than compensate for the Leksell Gamma Knife's inclusion of limited automatic isocenter positioning.

AGAINST THE PROPOSITION: Steven Goetsch, Ph.D.

Opening Statement

The first Gamma Knife was created in 1968 by Lars Leksell and Borge Larsson. The device expanded on a number of previous concepts, including x-ray and proton radiosurgery, stereotaxis, and Co-60 teletherapy. It offered unparalleled spatial accuracy and remarkable conformity of dose delivery (90%–50% isodose falloff in as little as 1.0 mm). All that was lacking in 1968 was modern transaxial imaging, such as computed tomography and magnetic resonance imaging, and high speed computers. The advent of angiography in the mid-1970s made visualization and treatment of arteriovenous malformations possible, and thousands were treated in a few years. Invention of the CT scanner by Hounsfield in 1972 eventually eliminated the necessity of administering painful, difficult pneumoencephalograms to all Leksell Gamma Knife patients. This allowed the device to treat brain tumors as well as functional diseases such as parkinsonism and trigeminal neuralgia for which it was originally designed. Introduction of the Leksell GammaPlan treatment planning program with a modern UNIX workstation in 1992 made it possible to quickly devise complex, multi-isocenter treatment plans with multiplanar dose planning. Development of stereotactic MRI allowed unparalleled visualization of target and normal tissues.

Today the virtues of the Leksell Gamma Knife include remarkable geometric convergence (less than 0.3 mm for all 201 beams), rapid dose falloff, extremely high reliability and dedication to cranial applications. Neurosurgeons have frantically busy schedules, including a major role in trauma cases, and have learned to count on the availability of the Leksell Gamma Knife at predictable times, typically early in the morning, so that clinical and surgical schedules can be reliably scheduled. Nondedicated linear accelerator based radiosurgery frequently involves starting procedures at the end of a long clinical day, with treatments often stretching into the night hours.

The San Diego Gamma Knife Center treated 1090 patients in its first 62 months of operation with only two days of planned downtime. No Leksell Gamma Knife cases were postponed or cancelled because of machine unavailability. A reload of the Model U unit was conducted in January, 2001. This required only 21 days of clinical downtime (the newer Models B and C would require about 10–15 days). This yields an overall system availability of 98.3% over 63 months, including reloading. Very few linear accelerators with complex stereotactic radiosurgery accessories can match this record of availability.

The Leksell Gamma Knife has not remained frozen in time. The new Model C with an Automatic Positioning System offers both computer control of the irradiation process and Record and Verify capability. The treatment plan is networked to a console which controls the *X*, *Y*, and *Z* stereotactic coordinates and can move the patient through a limited range of motion between shots. The treatment time, *X*, *Y*, and *Z* positions, helmet size, gamma angle and shot number are all automatically checked. This promises to decrease the reported misadministration rate even more. I believe this new innovation will continue to assure the place of the Leksell Gamma Knife as the gold standard of radiosurgery.

Rebuttal

The Leksell Gamma Knife offers an extraordinary number of "beam ports" providing a tremendously conformal absorbed dose distribution. This has been true since the first prototype 33 years ago. What has changed since then is that the "all or nothing" irradiation schemes first used with single-shot plans have been replaced by modern multi-shot plans utilizing differing helmet sizes, shot weights and patient head angles. Up to 100 of the 201 gamma ray portals can also be selectively plugged. The planning challenge is to effectively harness all of these myriad possibilities. The Spring, 2001 issue of *Business Week* magazine recognized the University of Maryland for use of "data mining" to create Leksell Gamma Knife treatment plans in its annual "Masters of Innovation" awards. Thus, everything old is new again.

The original Gamma Knife was devised to treat functional disorders such as trigeminal neuralgia and Parkinson's disease. The modern Leksell Gamma Knife is still unsurpassed in treating single-shot 4 mm diameter volumes very rapidly and efficiently, with remarkably little scattered dose to adjacent critical structures. This is still very difficult to do with linac-based radiosurgery.

Brilliant innovators such as Professor Bova and his neurosurgical colleague Bill Friedman have achieved outstanding results in accelerator-based radiosurgery. Precise figures for the total number of linac radiosurgery treatments performed annually are not available, but the number is clearly growing as the technique gains acceptance. Still, the 65 American Leksell Gamma Knife Centers treated over 10 000 patients in calendar year 1999, clearly a large fraction of all radiosurgery performed in this country. With 143 Leksell Gamma Knife units installed worldwide and over 150 000 patients treated, this device is certainly not obsolete today, and will not become obsolete for many years to come.

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2.17. In stereotactic radiosurgery, implanted fiducials are superior to an external coordinate system

Eric G. Hendee and Wolfgang A. Tomé
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OVERVIEW

Successful stereotactic radiosurgery requires the delivery of radiation dose exactly to the volume of tissue to be treated. One approach to accomplishing exact delivery is to immobilize the patient within an external coordinate system. Another approach is to use implanted fiducial markers for patient alignment. Both approaches have their advocates, and their comparative merits are discussed in this Point/Counterpoint.

Arguing for the proposition is Eric G. Hendee, MS. Mr. Hendee completed his graduate and clinical training at the University of Wisconsin Madison, where he served as a clinical physicist and Assistant Professor through the University of Wisconsin LaCrosse. He is currently practicing at Waukesha Memorial Hospital in Wisconsin and is certified by the American Board of Radiology in Therapeutic Radiological Physics. He has extensive experience in commissioning, treatment planning, and training for stereotactic radiosurgery. He also developed the UW ADCL program for gamma knife quality assurance, and has worked in the medical device industry to develop quality assurance tools for radiation oncology.

Arguing against the proposition is Wolfgang Tomé, Ph.D. Dr. Tomé obtained his Ph.D. in theoretical physics from the University of Florida and completed a two year residency in Radiation Oncology Physics at the Shands Cancer Center at the University of Florida. He is currently working as an Assistant Professor of Human Oncology at the University of Wisconsin and is board certified by the American Board of Radiology in Therapeutic Radiological Physics. His fields of primary expertise include Stereotactic Radiosurgery, Frameless Optically Guided Fractionated Stereotactic Radiotherapy and Intensity Modulated Radiotherapy, as well as Ultrasound Guided Stereotactic Extracranial Radiotherapy.

FOR THE PROPOSITION: Eric G. Hendee, M.S.

Opening Statement

The use of fixed points of reference, or fiducials, has its origin in ancient celestial navigation as a straightforward and effective method of localization. In stereotactic radiosurgery, the use of implanted fiducials is efficient, convenient, and cost effective, with proven accuracy comparable to frame-based systems. In addition, implanted fiducials provide patient verification from portal images obtained at the time of treatment.

There are four general methods to define a stereotactic coordinate system: (1) a frame rigidly attached to the skull, (2) a temporary frame that conforms to the patient (so called relocatable frames), (3) fixation of fiducials to the patient that are referenced to the treatment target, and (4) the use of anatomical surfaces, lines or points that are defined with respect to the target. The first

two methods are referred to as "frame-based," the last two are termed "frame-less." Frame-based systems may use the frame for both patient immobilization and localization, whereas frame-less systems allow the design of rigid patient immobilization independent of localization.

The concept of stereotaxis was developed around frame-based systems for neurosurgery early in the last century, and has evolved to the widespread use of frame-less methods. The use of implanted fiducials for high precision radiotherapy and radiosurgery is a more recent development, first appearing in the literature 10–12 years ago.

Positional accuracy of implanted fiducials has been extensively investigated, including comparison with the accuracy of frame-based systems. Ultimately, the characteristics of the imaging procedure determine set-up accuracy for either system, but it is fair to state that in careful hands there is little, if any, difference in the accuracy obtainable with frameless or frame-based systems. The fundamental advantage of implanted fiducials over external reference frames is that the stereotactic coordinate system is permanent. Therefore, the target can be localized with respect to the treatment beam based on the imaged location of the fiducials. The image provides information on the patient and isocenter setup, whereas an external reference system provides information only on the external coordinate system, requiring one to assume that the target is always in the same relative position. From a quality-control standpoint, it is helpful to remove intermediate steps in localizing the stereotactic frame space with respect to the linac isocenter.

The use of frame-based systems involves frame placement, imaging, treatment planning, QC, and treatment, often making the day long for the patient and staff. By comparison, implanted fiducials are quicker and reduce the chance of error caused by an exhausted staff treating late in the evening. Implanted fiducials also reduce the chance of compromising the quality of the treatment plan due to time constraints.

While this debate focuses on radiosurgery, it is undeniable that implanted fiducials facilitate stereotactic radiotherapy (i.e., fractionated) and treatment of recurrent disease. This is because they are permanent and therefore always available for precise localization. Finally, implanted fiducials can be used to localize and treat extracranial lesions, particularly when implanted in a mobile target such as the prostate. With the advent of improved portal imaging systems that can distinguish fiducials in real time, it is likely that extracranial applications will increase.

Rebuttal

Dr. Tomé's position is that an invasive fixation system is more accurate in immobilizing the patient, and I agree with him in that regard. However, in addition to immobilization, stereotactic radiosurgery and radiotherapy have many components which contribute to the end result, including localization, fractionation, implementation, and verification.

Several studies have demonstrated comparable localization accuracy between frame-based and frameless systems. Also, localization of the frame is not the same as localization of the patient. In other words, frame-based systems provide no verification that the frame has not moved after the imaging study or that there is any flexure associated with positioning. On the other hand, implanted fiducials cannot move relative to the patient. The margin of 1 mm in Dr. Tomé's opening statement is questionable, and is applicable for frame-based treatments as well since there is no verification of target position at time of treatment. Also, margins are subject to limitations introduced by the finite number of cones, which often occur in steps of 5 mm.

Two important aspects of patient treatment are convenience and dignity. Placement of an invasive head ring is uncomfortable for the patient, and does not allow fractionation. The head ring also requires imaging and treatment on the same day, a restriction that does not exist for implanted fiducials.

For CT imaging, there should always be a rigorous QC program in place, as required for frame-based systems and external-beam patients.

With regard to verification, triangulation with fiducials allows the isocenter to be correctly positioned, even if the patient is not in exactly the same position as the imaging study. Values for yaw, pitch and roll are reported and the clinical team establishes acceptable limits, but this does not preclude positioning the target at the isocenter. Still, an effective immobilization system must be in place to keep the patient from moving during treatment.

In conclusion, after considering the entire stereotactic program, one can identify a number of advantages of implanted fiducials over frame-based systems. We are obliged to remain current with the technologies that we adapt for our patients. As neurosurgery is progressing with frameless systems, we should follow these advances closely for possible adaptation to radiotherapy.

AGAINST THE PROPOSITION: Wolfgang A. Tomé, Ph.D.

Opening Statement

For stereotactic radiosurgery (SRS) and especially for functional stereotactic radiosurgery (functional-SRS), the relationship of the collimated x-ray beam to a specific target within the treatment room is critical. The success of radiosurgery lies in the fact that the patient's position is fixed in space with an invasive fixation system (stereotactic head ring) throughout the imaging and treatment process, i.e., the patient is treated in the same position as imaged. With such fixation, only uncertainties caused by limitations in imaging, and mechanical uncertainties in the radiosurgery system, need to be accounted for during treatment planning and delivery. Hence, a high degree of conformality can be achieved while simultaneously sparing normal tissues.
A noninvasive immobilization system coupled with the use of implanted fiducial markers introduces additional uncertainties in treatment planning and delivery due to patient repositioning and imaging of implanted fiducials. These additional uncertainties have to be accommodated in the planning and delivery process, and lead to increased margins of uncertainty around the treatment volume. This uncertainty results in inferior conformality when compared with invasive fixation systems. To put it more plainly, the margins around the target tissue have to be increased, so more normal tissue is included in the treatment volume. This is not a trivial point as the following example shows.

For a spherical 30 mm lesion, an additional inaccuracy of 1 mm due to imaging and localization of the implanted fiducial system implies that an extra margin of at least 1 mm must be considered to exist around the lesion. This margin, in turn yields an increase in irradiated normal tissue of up to 21%. While this increase may be acceptable for patients with malignant lesions or brain metastases because of the inherent biological uncertainties at the edges of these lesions, it is clearly inappropriate for benign lesions in which the interface between lesion and normal tissue is very well defined.

The most commonly-used external stereotactic localization system, the Brown–Roberts–Wells (BRW) System, is an independent localization method. It consists of nine carbon-fiber rods arranged into three N-shaped structures placed at 120-degree angles around the patient's head. Three N-shaped fiducials provide an overdetermined system of linear equations that allow for the unique definition of an independent, absolute coordinate system. Therefore, one does not have to verify the table indexing of the CT scanner, since the slice position of each scan can be uniquely determined. This may or may not be the case for an implanted fiducial system, which therefore requires a rigorous QC program for the CT scanner.

It follows from the above discussion that implanted fiducial systems are not superior to an external coordinate system for SRS. Rather, they are at best equivalent, and may well be inferior.

Rebuttal

As pointed out by my colleague Eric Hendee, the use of implanted fiducials establishes the imaging procedure as the principal influence on setup accuracy at the time of treatment. This uncertainty is not present in frame-based radiosurgery. Therefore, implanted fiducial systems cannot be superior to frame-based fiducial systems in terms of accuracy. In stereotactic radiosurgery, we aim to conform the prescription dose shell as close as possible to the target—i.e., to provide optimal conformal radiotherapy. In this situation, cost effectiveness of a procedure cannot be used as an argument for superiority if the outcome is inferior in terms of accuracy. Since frame-based radiosurgery offers a higher degree of accuracy, it is clearly the method of choice for optimal stereotactic radiosurgery.

Implanted fiducials can be employed in fractionated stereotactic radiotherapy and extracranial stereotactic radiotherapy. Their use in these applications, however, is still affected by the uncertainty of localizing the fiducials by using orthogonal radiographic images. Translations of a target can be corrected rather easily using orthogonal radiographic images and implanted fiducials. However, it is very difficult to identify rotational misalignment of a target using this imaging technique. Therefore, it stands to reason that minimally-invasive Optically Guided Patient Localization Systems, which correct for both translational and rotational misalignment of the target, as well as ultrasound-guided systems, are preferable since they permit interfraction patient localization that is equivalent to frame-based radiosurgery[1] and CT-guided extracranial radiotherapy.[2]

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2.18. Three-dimensional rotational angiography (3DRA) adds substantial information to radiosurgery treatment planning of AVM'S compared to angio-CT and angio-MR

Carlo Cavedon and Frank Bova
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OVERVIEW

Three-dimensional rotational angiography (3DRA) is available in most institutions where arteriovenous malformations (AVMs) are treated radiosurgically. Some physicists believe that 3DRA should be employed to guide AVM treatment with radiosurgery. Other physicists feel that computed tomographic angiography (CTA) is the preferred technique for use with radiosurgical treatment of AVMs. This difference in opinion is debated in this month's Point/Counterpoint.

Arguing for the Proposition is Carlo Cavedon, Ph.D. Dr. Cavedon graduated with a Ph.D. in physics in 1992 from Padova University, Italy. His research field was experimental nuclear physics. He then specialized in medical physics at the University of Milano. He has been serving as a medical physicist in Vicenza Hospital since 1997, where he conducted research on dosimetry and monte carlo simulations. His current research interests are robotic radiosurgery, functional imaging, and image processing aimed at treatment planning. He is a member of the AAPM and the Italian Association of Medical Physics. He has had several teaching appointments in Italian medical physics courses.

Arguing against the Proposition is Frank J. Bova, Ph.D. Dr. Bova received B.S. and M.S. degrees in Biomedical Engineering from Renesslear Polytechnic Institute, and a Ph.D. in Nuclear Engineering Sciences with specialization in Medical Physics from the University of Florida. Dr. Bova joined the Department of Radiation Oncology at the University of Florida in 1978. In 1991 he was appointed Einstein Fund Professor of Computer-Assisted Stereotactic Neurosurgery in the Department of Neurosurgery where he currently holds the rank of Professor. Dr. Bova also holds appointments in the Department of Nuclear and Radiological Sciences, Department of Biomedical Engineering and the Department of Neuroscience. He is a Fellow of the American Association of Physicists in Medicine, the American College of Radiology and the American Institute of Medical and Biological Engineering. Dr. Bova holds seven patents in stereotactic guidance.

FOR THE PROPOSITION: Carlo Cavedon, Ph.D.

Opening Statement

Angiographic images are used extensively in planning radiosurgery for arteriovenous malformations (AVMs). Visual superposition of angiographic images onto CT slices is not possible because CT is a tomographic visualization process, whereas angiography is a projection imaging process. This difference leads to a lack of visual correlation between the two techniques. Still, there is a need for image correlation between the two methods. This need can be met by fully exploiting the capabilities of three-dimensional rotational angiography (3DRA), a

technology that has only recently become available. Though used mainly for 3D visualization, 3DRA allows tomographic reconstruction so that datasets can be spatially registered to CT images, as well as to other tomographic modalities such as MRI. Spatial accuracy of the registration can be a concern, but studies have confirmed its suitability for clinical applications.[1,2]

Advantages of 3DRA in planning interventional radiology have been described.[3,4,5] Many of these advantages also apply to radiosurgery planning, even if they are related solely to 3D visualization rather than tomographic use of 3DRA data. Other modalities such as CT angiography (CTA) and MR angiography (MRA) offer tomographic information valuable for AVM radiosurgery planning.[6,7] These techniques are well known and more available than 3DRA, but they lack important characteristics such as sufficient speed (allowing use of a smaller amount of contrast medium) and selectivity (offering the possibility of injecting contrast medium separately into different feeders (e.g., carotid and vertebral arteries) to reveal information about the AVM structure).[8]

CT and 3DRA are both x-ray transmission modalities, which provide an advantage over MRA for which a multimodality registration would be required. This advantage is of key importance when using frameless radiosurgery techniques, where 3DRA is of maximum benefit because image registration allows correlation of angiography to CT without the need for a stereotactic frame.

At present, 3DRA equipment is not available in every radiosurgery center. 3DRA is a significant imaging improvement, however, and will undoubtedly become widely available in the near future. For the time being, 3DRA examinations with frameless operation can be performed in an imaging center, and the data used (even at a different time) in a separate radiosurgery center. A survey among major 3DRA manufacturers reveals that the distribution of 3DRA equipment is probably wider than imagined. In Europe, for example, there are approximately the same number of 3DRA machines as there are radiosurgery centers, although the two are not necessarily in the same locations. It is likely that available 3DRA equipment within the community simply needs to be located. Physicists must then select the appropriate registration technique and perform commissioning tests. This is not an easy job, but it is certainly worth doing.

Rebuttal

I share Dr. Bova's healthy skepticism of unsound methods, and agree with his criticisms of fixed projection angiography. But 3D rotational angiography is a true 3-dimensional technique and its novelty, compared to orthogonal projections, lies in its ability to surmount the limitations of fixed-position angiography. A key advantage of 3DRA is that the number of projections is not two (or three), but on the order of one hundred. This allows thin slice reconstruction to be performed, with the typical case of 256^3 voxels and an 18 cm field of view for a slice thickness of 0.7 mm. The main difference of 3DRA compared with CT is the use of a cone beam instead of a fan beam. This should certainly not be regarded as a disadvantage, since cone beam tomographic reconstruction is used in high-level algorithms. Indeed, these algorithms are now beginning to be used in new-generation CT equipment.[9,10]

If a flaw can be identified in 3DRA, it may be with regard to its timing characteristics, which are as yet not comparable to fixed projections. This prevents the use of 3DRA for distinguishing between feeders and draining vessels. Nevertheless, as outlined in my opening statement, 3DRA has significant other advantages which are useful in angiographic examinations.

Dr. Bova starts his proposition by praising methods based on numbers. I certainly agree with him, as demonstrated by the case under discussion. Registering 3DRA to CT by means of a state-of-the-art algorithm, e.g., mutual information maximization, provides a quantitative, operator-independent method to exploit this new technique in AVM radiosurgery.

Finally, physicists should be keen to explore new capabilities rather than limit themselves to the application of consolidated ones. 3DRA represents an innovation whose potential, though still to be explored in all of its aspects, can elicit significant information of vital use in radiosurgery of vascular malformations.

AGAINST THE PROPOSITION: Frank Bova, Ph.D.

Opening Statement

As medical physicists, we must be certain that we clearly see the underlying principles of our science. As Lord Kelvin once said, "If you can not express your knowledge in numbers, it is of a meager and unsatisfactory kind." For many decades, medical physicists have relied upon orthogonal radiographs to define the geometry of radioactive implants. During the 1960s and 1970s, the reconstruction debate concerned stereo-shift radiography versus orthogonal radiography. Our long success with orthogonal reconstructions of implants may have blinded us to the underlying requirements of orthogonal spatial definition. We may have forgotten that the first requirement of orthogonal reconstruction is identification of identical points in each view. As implants became more complex, and more and smaller sources were added, this requirement posed more of a problem. Undaunted by this warning, the high spatial accuracy promised by orthogonal reconstruction continued to seduce medical physicists into trying to fit this square peg into new round holes. Before CT, when stereotactic systems were first introduced into neurosurgical procedures, stereotactic targets often were inferred from points identified on orthogonal ventriculograms. While these techniques provided some measure of success, the advent of true 3D datasets provided by CT scanning, and subsequently MR imaging, have rendered them obsolete. As treatment planning increased in complexity, precise complex 3D target descriptions were required. These descriptions are best supplied by a CT or MR scanner.

The potential errors of orthogonal imaging of a solid structure can be easily demonstrated. Imagine an ellipse with its center at the origin and its long axis oriented at 45 degrees to the XY axis. The orthogonal projection of this ellipse to either axis can be encompassed by a circle with a diameter of the length of the ellipse divided by the square root of two. Unless unique points on the target's extreme edges can be identified in each view, it is impossible to deduce the original length of the long axis of the ellipse. Instead of an ellipse, suppose you placed the letter "C" at the same point in space. Orthogonal projections would not yield the shape of this target, and an accurate description of the target would be impossible.

The strength of orthogonal projections is their ability to accurately reconstruct points in space. When we reconstruct an implant, we are reconstructing identifiable points. When we are defining stereotactic targets, however, we are defining 3-dimensional volumes in which individual points are seldom identifiable. While it has often been suggested that a third view can provide the information required to define a specific object through orthogonal imaging, it can easily be demonstrated that the new solution can be fooled by a simple rotation of the target to render the reconstructed target invalid. The only method of providing a true description of a 3-dimensional object is to image the object with a true 3-dimensional imaging technique. Thin slice CT and MR

imaging provide such descriptions of clinical targets, and therefore are the image modalities that should be used when developing conformal treatment plans.

Rebuttal

One of the basic rules of image guided therapy is never say "no" to a high fidelity image detailing the target tissues. There is no doubt that in selected situations, the addition of 3DRA sheds light on target definition. At the end of the day, however, the clinical team must choose which stereotactic coordinates to target and which stereotactic coordinates to spare. The true 3D data set provided by multislice CTA provides the gold standard for such targeting.

The Achilles heal of 3DRA is the time required to complete the rotation needed for image acquisition. One should not confuse the time required for a planar angiographic image acquisition at many images per second, with the time required to complete the rotational needed for 3DRA.

CT scanners can acquire 16 slices per second. These images can cover the entire transaxial extent of the target tissue and 8 to 16 mm of axial extent, while maintaining submillimeter pixel resolution. If 3D prospective imaging is needed, post processing can provide high fidelity renderings of the target vessels.

While planar angiography remains the gold standard for diagnosis of vascular abnormalities, the playing field for radiosurgery targeting is firmly grounded in true 3D data sets. Although one can detect a target in 2D, you need an accurate 3D fix to target from multiple trajectories.

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2.19. New methods for precision radiation therapy exceed biological and clinical knowledge and institutional resources needed for implementation

Sarah S. Donaldson and Arthur L. Boyer
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OVERVIEW

New methods for precision radiation therapy (e.g., conformal, intensity-modulated and tomographic radiotherapy) have the potential to distribute radiation to tumors and normal tissue to any desired degree of exactness. Whether such methods are justified in light of the biological and clinical uncertainty about tumor anatomy and physiology is debatable. Also debatable is whether precision methods require more time and personnel than can be allocated in a busy clinic. These debatable issues are the subject of this Point/Counterpoint.

Arguing for the Proposition is Sarah S. Donaldson, M.D. Dr. Donaldson obtained her M.D. from Harvard Medical School. She completed Radiation Therapy Residency Training at Stanford, where she is now Professor of Radiation Oncology. She serves as Associate Chair of the Radiation Oncology Department and Associate Director of the Clinical Cancer Center. Dr. Donaldson's professional interests are in Pediatric Radiation Oncology, and late effects from cancer treatment. As a clinician, researcher and educator, she carries responsibility for setting standards for the safe and effective delivery of radiation. She is a past President of ASTRO and the ABR, and is an elected member of the Institute of Medicine.

Arguing against the Proposition is Arthur L. Boyer, Ph.D. Dr. Boyer is a tenured Professor (Radiation Physics) at Stanford University School of Medicine. He serves as Director of the Radiation Physics Division of the Department of Radiation Oncology. He received a B.A. in Physics from the University of Dallas in 1966, and a Ph.D. in Physics from Rice University in 1971. He has held appointments at the Massachusetts General Hospital and the Harvard Medical School in Boston, the Cancer Therapy and Research Center in San Antonio, and the M. D. Anderson Cancer Center in Houston.

FOR THE PROPOSITION: Sarah Donaldson, M.D.

Opening Statement

Among the new advances for precision treatment, intensity-modulated radiation therapy (IMRT) currently occupies the greatest clinical attention; therefore, I have chosen it for the focus of my commentary. Aggressive IMRT reporting and marketing promise to improve upon three-dimensional conformal therapy (3-D CRT) and to yield substantial improvements over existing technologies.[1] Before accepting such assertions, clinicians need to confirm that the promise of projected dose escalations and organ-sparing techniques will result in improved local/ regional control and reduced long-term morbidity. Concern with this technology include uncertainties related to:

(1) technical issues of patient immobilization and uncontrolled organ motion;
(2) imaging inaccuracies in determining accurate tumor volume;
(3) lengthy planning and delivery times;
(4) dose inhomogeneities and Dose-Volume Histogram (DVH) interpretation;
(5) quality assurance procedures, verification and documentation of beam delivery;
(6) biologic unknowns including carcinogenesis; and
(7) economic considerations.

Despite the theoretical arguments for incremental benefits of IMRT over standard or 3-D CRT, there are little clinical data to support general noninvestigative use. Efficacy and complication data come from very few centers, in which only select adult tumor types have been studied. Long-term follow-up is not yet available.

Clinicians experienced with IMRT appreciate the inaccuracies associated with masks, moulds, shells, cradles, vacuum bags, and rectal balloons for patient immobilization. Organ motion remains beyond physician/physicist control. Dose inhomogeneity is substantial. Thorough understanding of partial organ tolerance and acceptable DVH values is lacking. Acceptable quality assurance procedures for IMRT are in their infancy. The need for retreatment following marginal recurrence has not been addressed. Unique and individualized treatment plans create long delivery times that are often difficult for the patient, and are disruptive in a busy clinical department. Both dynamic leaf movement and the step-and-shoot methods take longer than conventional 3-D CRT. Furthermore, while for some anatomic sites a limited number of standard IMRT fields may be routine, large tumor and nodal volumes, and doses to diverse areas of the body in pediatric cancer, cannot follow standard templates. They require even more lengthy planning and delivery.

Fusion of CT/MRI images is imprecise; the most knowledgeable experts are uncertain about exact tumor boundaries, thus undermining the scope of precision therapy. The impact of multifield, low-dose radiation exposure, and higher total body doses from leakage radiation associated with longer ‘‘beam-on’’ times and leaf transmission, carry risks of radiation-induced carcinogenesis that cannot be accurately assessed.[2]

Start-up and maintenance of IMRT equipment are extraordinarily expensive. Additionally, there is a costly learning curve for professional and technical staff, contributing to an increase in time per patient for the complexities of IMRT. Despite these higher costs, reimbursement for 3-D CRT and IMRT is equivalent from most providers. Specific IMRT CPT codes are not yet developed, and are unlikely to ever fully reimburse actual expenses.

Thus, we must conclude from clinical, biologic and economic standpoints, that IMRT is only appropriate at a very few highly sophisticated research centers with enormous institutional, professional and technical commitment. IMRT must remain an investigative tool until clinical trials comparing IMRT with rival treatment approaches show safety and efficacy using clinically important end points of tumor control, side effects, quality of life, and health costs. We should not implement this technology outside a research setting without the answers to these unknowns.

Rebuttal

The new technology of precision radiation therapy ushers in issues beyond those covered in the definitions of ‘‘biological knowledge’’ and ‘‘clinical knowledge’’ addressed by Dr. Boyer. Among the most critical issues are the time, effort, and institutional resources needed to support

the new technology, and the need to balance these resources against existing institutional requirements. It must be recognized that the added efforts to utilize the technology efficiently for precision radiation therapy need to be integrated into a departmental strategic plan without adversely impacting the current full-time requirements inherent in the practice of clinical medicine. This is a challenging task that requires increased personnel and added expense.

Furthermore we must recognize and respond to the many uncertainties that technologic advances create, because these uncertainties may impact clinical outcome, including localregional control. Dr. Boyer and I agree that radiation oncologists today must ''explore the potentials and limitations of new technologies.'' This statement reiterates my position for investigation and research prior to widespread implementation of precision radiation therapy.

We must conclude from current clinical, biological, and economic standpoints that new methods for precision radiation therapy belong in a research setting where tumor control, complications, quality of life, and health costs can be investigated in order to justify a broader implementation of the new technology.

AGAINST THE PROPOSITION: Arthur L. Boyer, Ph.D.

Opening Statement

New methods for precision radiation therapy are emerging in radiation oncology. Image-guided prostate seed implants, high dose-rate brachytherapy, and stereotactic, 3-D conformal, and intensity-modulated radiotherapy are among these new methods. The proposition concerning these new methods is in fact three separate but interrelated propositions that deal with biological knowledge, clinical knowledge and institutional resources. I will address the three manifestations of the proposition in turn.

''Biological knowledge'' is the ability to model and predict the response of the whole patient to a given course of treatment. I concede that such knowledge is not available for the new methods. To make accurate predictions one needs to know the genetic profile of the patient and understand the signal transduction pathways that determine the rate of apoptosis following a course of treatment. But, models with this level of predictive power are not available for conventional methods either. A broader interpretation of ''biological knowledge'' is the ability to predict trends at approximate dose levels based primarily on clinical experience coupled with an experimental understanding of underlying but unquantified processes. With few exceptions, conventional therapeutic methods were developed gradually over the years, simultaneously with the accumulation of this ''biological knowledge.'' I see no different way forward with the new methods. The lack of biological knowledge did not block techniques used now, and should not block the implementation of improvements on the methods.

''Clinical knowledge'' refers to the skills needed to anticipate the clinical outcome of a given treatment procedure accurately enough to make decisions that will prevent unacceptable harm. Physicians using traditional methods of radiation oncology make these decisions routinely with less information about the target volume and the three-dimensional distribution of dose over organs at risk than that provided by the new methods. The problem facing radiation oncologists using the new methods is that they have additional 3-D dose information, and additional control over the extent and limits of the dose distribution, but do not know how best to use them. Experienced radiation oncologists have the necessary background to explore the potentials and

limitations of the new technologies. It will take some time before academic centers have acquired the needed experience and can teach new residents how to use new methods. However, the foundation for acquiring this knowledge is already in place.

With regard to institutional resources, there are more than 2000 radiation oncology centers in the US. The style of practice and resources in these centers is spread over a spectrum. The spectrum encompasses academic centers where expectations and resources foster research and development as well as private practice centers where the focus is on efficiency and finances. The implementation of new methods depends largely on the location of the facility in this spectrum. Implementation means the installation, testing, and commissioning of the new technology which requires an infrastructure of advanced linacs, computer networks, and skilled radiation oncologists, physicists, dosimetrists, and therapists. Where these resources and motivation exist, implementation of the new methods has already occurred and will continue to occur. Acquisition of new oncology technologies is expensive.

Vendors are still recovering their development costs. In time one expects performance to improve and costs to lower, leading to a spread of the new methods over more of the facility spectrum. However, the implementation of the new methods should continued to be pursued energetically in appropriate environments.

Rebuttal

Dr. Donaldson has chosen to focus on IMRT, and concedes that this new radiotherapy methodology should be implemented in research settings. She addresses a number of important aspects of implementing IMRT. Not all of her statements are strictly accurate. For example, she leaves the impression that an IMRT treatment may be many times longer than a comparable conventional treatment. With adequately engineered delivery systems that are currently available, extraordinarily long IMRT delivery times are avoided. I agree completely that data describing the response of normal structures to low doses is important to understanding the limits of IMRT.

However, the key debatable issue is the preferred scope and speed of implementation of IMRT, or in fact of any new treatment modality. On the one hand the radiation oncology community might begin treating patients with IMRT too hastily, and in the process precipitate experiences that condemn the process. On the other hand, we might approach the problem so conservatively that we unduly postpone the realization of the advantages of the new technologies. Good judgment and common sense must be used to strike a balance.

The question becomes whether it is developed as an investigative tool with the intent of adding to the knowledge base of radiation oncology, or whether it is regarded as a routine clinical procedure whose outcome is as certain as the outcome of more familiar procedures. I concede that new methods should be regarded as the former. It is the responsibility of the facility to approach a given implementation with the care and caution that is due a new treatment method. Appropriate quality assurance and record keeping are essential.

Clearly there are many unanswered questions about IMRT, stereotactic radiotherapy, high-dose rate brachytherapy, and endovascular brachytherapy that will require considerable research before the outcomes of treatment are predictable. The fact remains that these procedures must be implemented in enough facilities to provide the pragmatic experience needed to answer the clinical questions.

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2.20. Kilovoltage imaging is more suitable than megavoltage imaging for guiding radiation therapy

Lei Xing and Jenghwa Chang
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OVERVIEW

Image-guided radiation therapy involves the use of imaging to delineate the structures of interest, to plan appropriate treatment fields, and to ensure that treatments are administered as planned. It is becoming increasingly common to utilize in-room imaging and localization systems for these purposes and, most often, these involve use of either MV x rays directly from the linear accelerators used to treat the patients, or kV x rays from auxiliary x-ray machines. It could be argued that the kV option is superior because kV imaging is bound to provide better quality images. On the other hand, some might argue that MV systems are preferable because, among other things, they use identical geometry to that used for treatment and hence provide more accurate geometrical information. There are many arguments for and against each of these modalities and this is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Lei Xing, Ph.D. Dr. Xing earned his Ph.D. in physics from the Johns Hopkins University and obtained his medical physics training from the University of Chicago. He is currently an Associate Professor and Chief of Research in the Department of Radiation Oncology at Stanford University. His major areas of interest are image-guided and adaptive radiation therapy, treatment planning, and dose optimization, and the application of PET/CT and other emerging biological imaging modalities in radiation oncology. He currently serves on the AAPM workgroups on IMRT and Molecular Imaging in Radiation Oncology, and the ASTRO Collaborative Committee on IGRT, and has served on the Board of Editors of *Medical Physics*. He is certified by the American Board of Radiology in Therapeutic Radiological Physics.

Arguing against the Proposition is Jenghwa Chang, Ph.D. Dr. Chang obtained an MS degree in Computer & Information Science, and MS and Ph.D. degrees in Electrical Engineering, all from the Polytechnic University of New York, Brooklyn, NY. He is board certified by the ABR in Therapeutic Radiological Physics and the ABMP in Radiation Oncology Physics and is currently an Associate Member of the Medical Physics Department, Memorial Sloan-Kettering Cancer Center, New York, NY. His major research interests are intensity modulated radiotherapy, respiratory gating, and various forms of imaging for radiotherapy including cone-beam CT, portal imaging, functional MRI, and magnetic resonance spectroscopy.

FOR THE PROPOSITION: Lei Xing, Ph.D.

Opening Statement

When talking about onboard imaging for therapeutic guidance, one has a number of options: the best imaging plus the best therapy, so-so imaging plus the best therapy, not-so-good imaging plus

the best therapy,…, so-so imaging plus so-so therapy. The issue here is not which modality is better for IGRT, rather where we should settle in this long list of choices. The first thoughts one may have are what defines the best imaging technology and what is the best therapy machine? Instead of going through a lengthy description, I simply suggest visits to the exhibit halls at the RSNA and AAPM annual meetings. Current state-of-the-art imaging devices are displayed each year at the RSNA meeting, but finding an MV CT scanner there is improbable, much like trying to find a Co-60 machine on the AAPM exhibition floor. If still unconvinced, perhaps comparing MV and kV films on a light box in your clinic would help, whence it should become transparent that, compared to its counterpart, kV x rays are better in providing image guidance. All in all, it is written on the wall as well as in physics books that the tissue needs to absorb a sufficient number of photons to be seen, and a structure needs to absorb a significantly different number of photons from its neighbors to be visualized. Compton scattering simply cannot beat the photoelectric effect in this regard.

Poor soft tissue contrast alone is sufficient for the MV imaging system to shy away. But there is more. MV imaging delivers more radiation dose to the patient. IGRT is rapidly moving toward adaptive replanning[1,2,3] and/or real-time (or at least reasonably frequent) feedback of anatomical information during the beam delivery process,[4,5] I simply cannot see how MV alone can meet the increased demand for frequent imaging. Image truncation in current MV volumetric imaging may present another problem since volumetric data are required for dose reconstruction[6,7] and adaptive replanning.

Not every system in the real world is made of a combination of the greatest things for various reasons. Each choice often comes with a different price tag and other pros and cons, and the optimal choice is a result of balancing different competing factors. In the issue debated here, the equation in front of us is actually not that complicated. On one hand, one has a kV imaging system mounted on the LINAC gantry, which is reasonably affordable and provides superior soft tissue contrast and full 3D anatomic information. On the other hand, there is an MV-based approach, which uses the treatment beam for volumetric imaging and has a long list of serious compromises. While the configuration of the MV system is simpler, the sacrifice we have to make in image quality and patient radiation dose is simply too large to justify the routine use of this modality in the clinic.

Let me conclude by saying that an ideal IGRT solution should be composed of the best imaging plus the best therapy machine, and an onboard kV imaging system fits this philosophy well. No seeing, no hitting. Futuristically, I also see more hope for kV image-guidance since much more research is being devoted to kV x-ray imaging, which may further enhance the performance of kV devices. Some day, we may see onboard phase-contrast CT, or inverse-geometry CT, or even multiplexing nanotube-based CT in radiation oncology clinics. In the spirit of "the best plus the best," I am also glad to see that the hybrid of MRI and linear accelerator is on the horizon.

AGAINST THE PROPOSITION: Jenghwa Chang, Ph.D.

Opening Statement

Multiple factors, including clinical usefulness, technical complexity, and cost, must be considered to determine the best combination of technologies for IGRT. It is a general conception (or misconception) that megavoltage MV imaging can never compete with kV imaging because image quality and dose are orders-of-magnitude worse. Recent advances in MV cone-beam

computed tomography (CBCT), however, suggest that MV imaging may in fact be more suitable than kV imaging for many IGRT applications.

Recent improvement in MV imagers has enabled them to produce clinically useful images with acceptable imaging dose.[8,9,10] Although the quality of MV images is generally inferior to kV images, the difference narrows as the patient thickness increases,[10] and almost vanishes for CBCT due to the much higher scatter for kV CBCT compared to MV CBCT.[11] The imaging dose of MV CT/CBCT is slightly higher but the difference is now less than a factor of 2 and MV imaging dose can be readily included in the treatment planning process to minimize its adverse effects.[12]

MV imaging has been successfully used for two-dimensional IGRT applications including tracking of implanted markers or bony anatomy for target localization and setup correction[13] with an accuracy comparable to kV imaging.[14] Observing intrafractional motion in the beam direction on an MV imager makes more clinical sense than on a kV imager perpendicular to the beam. MV CT/CBCT systems have also been successfully applied to three-dimensional setup and verification with excellent accuracy.[8,9,10] MV CT/CBCT imaging is superior in its linear relationship between relative electron density and CT number for dose calculation.[9] Because artifacts due to metal objects and beam hardening are less critical for MV sources, MV CBCT scans have been acquired to complement diagnostic CT scans when these artifacts are severe.[9]

Technical complexity is a major concern for clinical implementation of IGRT because more complex systems demand more quality assurance (QA) and are more susceptible to errors. MV imaging using the MV source and imager on a linear accelerator is technically simple and robust, and has a lower cost for hardware than kV imaging that requires an extra detector and x-ray source. The QA for MV CBCT systems is basically the same as that for an MV imager, while the more complex QA for kV CBCT systems[15] demands additional manpower and therefore costs more.

Yoo *et al.*[15] pointed out that the most critical QA of an IGRT system involves maintaining geometric accuracy for patient repositioning. In this regard, kV IGRT systems are overly complex because three isocenters (MV source, kV source, and laser) need to be identified and constantly checked.[15] MV IGRT systems with coincident treatment and imaging isocenters, on the other hand, are true "what you see is what you treat" systems that can do without the complex, error-prone calculation of systematic shifts between isocenters.

In conclusion, clinical usefulness of MV imaging is comparable or in some cases even superior to kV imaging for IGRT. There are no reasons to buy a more expensive and error-prone system if a significantly cheaper and notably less technically challenging alternative is available.

Rebuttal: Lei Xing, Ph.D.

In order to debate whether kV or MV imaging is more suitable for IGRT, the clinical goals must be clear. If IGRT is all about locating static metallic fiducials and bony structures, nothing discussed here matters, since even MV projection images will do the job. In reality, the drive to "see" the soft tissue and tumor target, mostly in real time, promotes the development of on-treatment imaging technology. MV image quality is limited by the physics, whereas the problems with kV imaging pointed out by Dr. Chang can be addressed. For example, metal artifacts with kV CT imaging can be removed with appropriate reconstruction algorithms. With the ongoing research in the field, one has every reason to believe that the quality of kV imaging, which is

already superior to the competing MV technology, will be further improved. Indeed, with the use of primary modulation with spatial variant attenuation materials for scatter removal, a significant improvement in kV CBCT image quality has been demonstrated.[16]

To be fair, in-line MV imaging is useful in the localization of implanted metallic fiducials. However, it generally requires a larger marker size and, in a realistic clinical situation, the auto-detection of the fiducials is more difficult, especially when a high temporal resolution is required. MV imaging alone is hardly a solution for real-time fiducial tracking and a simultaneous kV beam seems to be desirable.[17]

Yes, in principle the large MV imaging dose can be accounted for during treatment planning. But, "accounting for" does not mean that no extra dose, which can otherwise be avoided by shaping the treatment beams, will be delivered to the adjacent sensitive structures. For a breast cancer patient, for example, the imaging dose is delivered not only to the ipsilateral breast, but also the contralateral breast, the heart, and the lungs. For patients with a long life expectancy after radiation therapy, radiation dose resulting from real-time and/or routine adaptive imaging is of particular concern. MV imaging falls short in this aspect and seriously compromises the value of image guidance.

QA of the kV imaging device entails additional effort, but the task is quite manageable and can be automated by well-designed phantom and analysis software tools.[18] Given the potential impact resulting from image-guided 4D and adaptive therapy, the minimal extra QA effort is clearly worthwhile. After all, 2D/3D kV imaging is providing us with better, and often additional, information for therapeutic guidance.

Rebuttal: Jenghwa Chang, Ph.D.

What is the best IGRT system? Should it be the best imaging plus the best therapy device as Dr. Xing proposed, or, as I pointed out, the system that best meets overall clinical needs? For conventional radiotherapy, the imaging devices for simulation and the therapy devices for treatment can be separately optimized because the simulation and treatment delivery processes are independent. For IGRT, however, optimizing each device on its own may not lead to the best solution because the imaging device is used to guide the therapy device.

Dose, time, and personnel constraints will limit routine use of lengthy, repeated on-board CT scans for adaptive replanning or real-time feedback of anatomic information. Instead, tracking implanted markers is often sufficient for monitoring intrafractional tumor motion. Although both kV and MV imaging can be used,[13] tracking marker motion relative to the beam direction with an MV imager is more intuitive and makes more clinical sense. In cases where the benefits of replanning outweigh dose and practical time concerns, MV CBCT provides more accurate CT number information and is less sensitive to metal artifacts.[9]

Dr. Xing is correct in stating that kV imaging is superior to MV imaging in terms of image quality and dose. However, the difference is probably clinically insignificant. Major research efforts have made the soft tissue contrast and imaging dose of MV imaging comparable to those for kV imaging.[8,9,10] In fact, neither kV nor MV on-board imaging devices for IGRT can compete with diagnostic imaging devices in image quality, but both can be registered with simulation images for setup and verification. Imaging dose can also be easily included in treatment planning for both modalities,[12] though adding the kV dose requires new beam data that are not collected as part of a normal commissioning process.

In conclusion, we should focus on the overall clinical needs when evaluating IGRT devices. MV IGRT systems are truly "no seeing, no hitting" and more cost-effective, and therefore more suitable than their kV counterparts for guiding radiotherapy.

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CHAPTER 3

Brachytherapy

3.1. HDR Brachytherapy makes Cs-137 intracavitary therapy for cervix cancer a breach of good practice

Michael T. Gillin and Jatinder R. Palta
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OVERVIEW

In many institutions high dose-rate (HDR) brachytherapy has become the method of choice in treating cancers of the cervix and uterus. Advantages include improved dose distributions, reduced treatment times, and decreased hazards to personnel compared with the older treatment method employing sealed 137Cs sources. Still, the latter method is used in many institutions, in part because they have not yet acquired the technology and expertise for HDR brachytherapy. This edition of the Point/Counterpoint series explores the issue of whether these institutions are meeting the current standards of good clinical practice.

Arguing for the Proposition is Michael Gillin. Michael T. Gillin, Ph.D., has worked in the Department of Radiation Oncology at the Medical College of Wisconsin since 1975 and is a professor of radiation oncology. His graduate degrees are from the University of California, Davis. He completed a two year fellowship in Radiological Physics at Walter Reed Army Medical Center. His research interests include brachytherapy and clinical trials. He is chairman of the RTOG Medical Physics Committee and has helped organize the first RTOG prostate implant protocol. He is the head of a five person medical physics group and his daily activities are centered on insuring that patients are treated in a safe and appropriate manner in clinics in which he and his clinical and physics colleagues practice. Professor Gillin loves stimulating discussions with his colleagues, his teenage children, and, most of all, his wife.

Arguing against the Proposition is Jatinder Palta. Jatinder R. Palta, Ph.D., is Professor and Chief of Physics within the Department of Radiation Oncology at the University of Florida. He received his Ph.D. in medical physics in 1981 from the University of Missouri and completed his postdoctoral training at the M. D. Anderson Hospital in 1982. Dr. Palta's professional career has developed around the traditional triad of scientific investigation, clinical contributions, and teaching. His research interests include radiation dosimetry, three-dimensional treatment planning, and conformal therapy. The goal of his research endeavors is to bring new, emerging technologies safely into the clinic. He is currently the chairman of the Radiation Therapy Committee of the American Association of Physicists in Medicine.

For the proposition: Michael T. Gillin

Opening Statement

Continuous evolution of radiation oncology techniques and treatments is the norm. The point in time when a new approach replaces traditional practice is difficult to define. For some time it has not been good practice to use radium sources for intracavitary applications and it is now not good practice to perform low dose rate (LDR) applications with Cs-137 sources.

The standard of care for patients with cervical carcinoma, as defined through Patterns of Care studies, includes both external beam and intracavitary applications.[1] The historical dose specification, based upon milligram-hours, is still used, although the actual dose prescription to specific points is the norm. The sum of the external beam dose and the intracavitary dose is routinely calculated to obtain a total dose, despite the fact that these are biologically very different doses.

The physical properties of a Cs-137 source, namely a source diameter of 3.1 mm and a physical length of 20 mm, limit the applicators available to the oncologist. Cs-137 applications generally require the use of general anesthesia and 48–72 h of treatment, requiring the patient to be confined to bed. The combination of general anesthesia and bed rest represents a risk to the patient with a 6% life threatening complication rate and an overall mortality rate of 1.5%.[2] The appropriate number of LDR applications has never been established. The importance of good geometry for an implant cannot be overstated.

High dose rate (HDR) intracavitary treatments are generally performed on an outpatient basis using multiple fractions. The oncologist can specify multiple dose prescription points. The dwell times and dwell positions can be optimized to meet this prescription. The dose prescription can be modified for each fraction to customize the treatment. HDR applicators are smaller in diameter, reflecting the smaller diameter HDR sources, and are designed to be coupled together to provide a better geometry. The suggested number of fractions and the dose per fraction have been published by the University of Wisconsin and others. [3]

HDR intracavitary treatments have been successfully incorporated into routine treatment management for patients with carcinoma of the cervix. They avoid the problems associated with LDR treatments while offering the advantage of customizing the brachytherapy dose distribution to the clinical situation. The smaller applicators increase the probability of a good geometry and permit CT based dosimetric analyses. Multiple fractions offer the advantage of brachytherapy treatments that can be modified as the tumor shrinks and the patient's anatomy changes. The risks associated with a one or two fraction LDR procedure with prolonged bed rest should no longer be tolerated.

Rebuttal

Dr. Palta expressed both general and specific concerns. His general concern about the lack of randomized trials comparing HDR and LDR can be expanded to most developments in radiation oncology. For example, there are no prospective, randomized trials comparing high energy x rays with Co-60, or CT-based treatment planning with non-CT-based planning. This concern is almost never addressed as treatment techniques evolve.

Dr. Palta's specific concern relates to ''possible late radiobiological effects of using several large doses of radiation.'' Teshima *et al.*[4] reported complications in patients treated from 1975–1983 to be higher for the HDR group, although within acceptable levels, as compared with the LDR group. Patel *et al.*[5] reported the results of their prospective, randomized HDR versus LDR clinical trial, which was conducted from 1986–1989. Their only statistically significant difference was a 19.9% incidence of overall rectal complications for the LDR arm as compared with 6.4% for the HDR arm. These data support the American practice of more fractions (5–12) and a lower dose per fraction.[6]

Dr. Palta is correct in his observation that ''HDR provides greater flexibility in optimizing the dose distribution for each patient'' for each application. We both agree that the importance of the intracavitary application in managing patients with cervical carcinoma should never be underestimated. In my opinion, the ability to customize the dose distribution for each application is the strongest argument for HDR treatments. A fundamental belief in radiation oncology is that better dosimetry results in better local control and lower complications.

The worldwide experience is substantial for HDR applications to treat patients with cervical cancer. The North American experience continues to grow. It is my opinion that HDR brachytherapy is clinically proven and, in the hands of those who have mastered its technical challenges, offers significant dosimetric and patient care advantages that can no longer be ignored.

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Against the proposition: Jatinder R. Palta

Opening Statement

Low dose rate brachytherapy has a long history of clinical use originating with preloaded radium, to afterloading radium and cesium in the 1950s, and more recently to remote afterloading of sources. Although the use of high dose rate (HDR) brachytherapy for cervical cancer is increasing, low dose rate (LDR) brachytherapy is the most commonly used and most extensively defined technique in the United States. It has been demonstrated unequivocally that including LDR intracavitary brachytherapy in the treatment of cervical cancer improves the

survival rate for patients with advanced stage disease. Therefore, the importance of LDR intracavitary therapy in the treatment of cervical cancer should never be underestimated.

The perceived advantages of HDR (improved dose distributions, reduced hospitalization of patients, and decreased radiation hazards to personnel) are marred by a poor understanding of the possible late radiobiological effects of using several large doses of radiation.

The classical radiobiological dilemma of large doses per fraction causing relatively severe late damage to normal tissue has put the onus on proponents of HDR brachytherapy to demonstrate that long-term complications with this modality are either less than or comparable to those for LDR brachytherapy. Recent literature on this subject has focussed on finding the optimal number of HDR brachytherapy fractions to limit the risk of late complications while achieving local control rates equivalent to those for LDR techniques. HDR brachytherapy for cervical cancer is still in its infancy. With a few exceptions, randomized trials have not compared HDR and LDR brachytherapy. Most of the current controlled experience with HDR brachytherapy is limited to a few institutions that have initiated in-house clinical protocols to compare HDR results with historical LDR brachytherapy data for cervical cancer.

It is not prudent to extrapolate the experience of a few clinics to establish universal standards of clinical practice. Randomized investigations are necessary to demonstrate that HDR fractionation and dose schemes provide favorable rates of local control and decreased long-term complications. HDR brachytherapy also requires a more rigorous set of dose distribution criteria compared with LDR brachytherapy because HDR provides greater flexibility in optimizing the dose distribution for each patient. At this time it is premature to consider LDR brachytherapy with cesium sources, a proven treatment technique for cervical cancer for decades, a breach of good practice, especially when the alternative HDR brachytherapy is still unproven in the clinical arena.

Rebuttal

A new modality of treatment becomes a standard of good practice when its clinical efficacy, cost benefit, safety, and preference by patients are well established. HDR brachytherapy for intracavitary applications has yet to pass this test. Dr. Gillin cites a number of potential advantages of HDR over LDR brachytherapy for cervical cancer, including the opportunity to customize dose distribution, the outpatient nature of the procedure, decreased anesthesia requirement, and greater patient convenience; but he fails to provide a convincing argument for the advantage of HDR over LDR brachytherapy in terms of the most important criteria: tumor control and risk of late normal-tissue complications. There is a paucity of randomized trials comparing LDR and HDR brachytherapy. Most investigators who report results of HDR therapy contend that they are comparable to those achieved with LDR therapy.

Dr. Gillin further argues that the physical properties of Cs-137 sources limit the applicators available to radiation oncologists and the ability to customize dose distributions. This has not been a problem over the past 30 years. Excellent results in terms of local control and survival have established the benefits of conventional applicator systems for LDR treatment of cervical cancer. The risk of perioperative mortality is negligible, less than 0.2% at most institutions. The physical advantages of HDR over LDR can never compensate for the loss of the dose-rate effect. It has been suggested that HDR treatment is more convenient to the patient. A recent study1 has shown that patients prefer LDR brachytherapy because most women dislike pelvic exams, especially when they involve manipulation of a tumorous uterus. Moreover, another

study2 has concluded that LDR brachytherapy is a more cost-efficient treatment in the United States compared with other options, based on the RVUs for each option.

HDR intracavitary treatments have been incorporated into routine treatment management of patients with cervical cancer only in Europe, Asia, and some third-world countries. The impetus for HDR brachytherapy in those places is principally expeditious treatment. It is premature to make a drastic change in the treatment approach in the United States, in light of the large degree of uncertainty about the dose and fractionation of HDR brachytherapy required to provide control tumor without major late complications.

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3.2. Reimbursement for high dose rate brachytherapy should be based on the number of dwell positions of the source during treatment

Geoffrey S. Ibbott and James M. Hevezi
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OVERVIEW

The charge for a radioactive seed implant for cancer treatment is based in part on the number of seeds used in the implant. This procedure is justifiable because there is an acquisition cost per seed, and the complexity of implanting the seeds and estimating the resulting dose distribution increases with the number of seeds. In many institutions, this charge model has been followed in high dose rate (HDR) brachytherapy where reimbursement is based on the number of ''dwell'' positions of a single source employed for treatment. For example, a source moved in 0.5 cm increments yields a higher charge than one moved in 1 cm increments, even though the finer increments may not yield a significant improvement in dose distribution. This Point/Counterpoint article explores the legitimacy of this practice.

Arguing for the Proposition is Geoff Ibbott. Dr. Ibbott began his career in medical physics at the University of Colorado Medical Center in Denver in 1968. He received an M.S. degree in medical physics from the same institution in 1981 and received a Ph.D. in Radiation Biology from Colorado State University in 1993. He has been Director of Medical Physics at the University of Kentucky since 1994 and is the President of the American Association of Physicists in Medicine. Dr. Ibbott has served on several committees of the AAPM Professional Council and was chair of the Council from 1993 to 1997, during which time he developed an interest in reimbursement issues.

Arguing against the proposition is James M. Hevezi. Dr. Hevezi spent the early part of his career in Diagnostic Radiological Physics at M. D. Anderson Hospital (1970– 1979), and switched to Radiation Therapy Physics at the University of Arizona in the early 1980s. There he worked in clinical hyperthermia methods to treat cancer. In 1983 he moved to the Phoenix metro area as vice president of Radiological Physics Services. There he helped develop the first Nucletron HDR source procedure to treat bronchogenic cancer and other applications. He is currently Director of Medial Physics at the Cancer Therapy & Research Center in San Antonio and holds a faculty position at the University of Texas Health Science Center at San Antonio. Dr. Hevezi serves as Chair of the Economics Committee of the ACR Commission on Medical Physics and has been active in determining policy for medical physicists in this area.

For the proposition: Geoffrey S. Ibbott

Opening Statement

Reimbursement for radiation oncology is classified under codes published in the CPT manual.[1] Providers and payers of medical services including HCFA, the agency that administers the Medicare program, use this guide almost universally. Other than the CPT manual itself, there is

a paucity of published assistance regarding use of CPT codes for HDR brachytherapy. The ACR published a User's Guide a number of years ago,[2] but it now is out of date, and the HDR CPT codes were not published until after the ACR guide appeared.

Four CPT codes are used for HDR, where the number of ''source positions or catheters'' determines the complexity. The descriptions indicate that reimbursement is tied to the number of dwell positions. Reimbursement for brachytherapy treatment planning is requested using CPT codes 77326 to 77328 where, for HDR, the manual indicates that the complexity of the plan is tied to the number of ''sources.'' This terminology should be interpreted as referring to HDR dwell positions, as HDR units have only one source.

Dose planning includes the review of localization films and performance of calculations to determine the number of dwell positions, their locations, and the dwell time at each position. In many departments, the use of 1 cm spacing between dwell positions is customary. A large target volume might require many dwell positions, perhaps distributed among several catheters. The more complex the arrangement, the more effort is required to determine the ideal source configuration and to verify the accuracy of the calculations.

The dwell position information is transferred to the console of the HDR unit and the accuracy of the transfer is verified. Prior to treatment delivery, the position of the applicator or catheters may be verified by fluoroscopy. A more complex arrangement requires more effort to confirm to the physician's satisfaction that the position of the applicator or catheters is correct. When delivery begins, the staff must monitor the patient and the position of the source. Treatments involving more dwell positions generally are more complex and take more time. Consequently, the cost to the facility increases with number of dwell positions. The time and effort required by the technical staff and the physicist are increased, and to a small extent, supplies such as catheters also increase. The effort exerted by the physician also increases as the complexity of the procedure increases.

As was suggested in the Overview, the linking of reimbursement to the number of dwell positions may bring about the temptation to artificially increase the dwell positions over the number required for an acceptable dose distribution. Such practice is inappropriate and is to be discouraged, just as the unnecessary use of complex external beam therapy should be avoided when a simpler field arrangement yields a satisfactory dose distribution.

Rebuttal

Dr. Hevezi's recommendation is to base reimbursement on the number of catheters used for an HDR treatment. The tissue volume treated with HDR units are three dimensional, and in many cases, the number of catheters used determines two of the dimensions. But the number of dwell positions determines the third dimension. Generally, the total number of dwell positions increases with the size of the target volume. Basing reimbursement on the number of catheters would roughly maintain the proportionality between complexity and number of dwell positions, but would reduce reimbursement overall.

Dr. Hevezi refers to a new Radiation Oncology Draft Manual for Policy Development. This document, as the title indicates, is still in draft form and is not yet policy so is not presently available to guide reimbursement. However, as he points out, one provision would allow uncoupling of the level of complexity of the technical component from that of the professional component. This would be an appropriate change, but unfortunately it would be of little benefit

to hospitals and other entities that bill the technical component separately. Today at least, the technical relative values (RVUs) are the same for all four reimbursement codes for HDR. Technical reimbursement from Medicare is independent of the level of complexity!

Professional reimbursement does vary with complexity, but the RVUs are quite small, and there would be little to gain by escalating the complexity level.

Rather than changing the reimbursement policies arbitrarily, a complete analysis should be done of the cost of the procedure. This can be done, as has been done for the procedures and charge codes, by surveying a representative sample of treatment centers. The cost of the equipment, supplies, and attendant personnel (some mandated by NRC Regulations) must be considered. The relationship between reimbursement and complexity level (based either on number of catheters or number of dwell positions) then can be determined in a realistic and unambiguous fashion.

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Against the proposition: James M. Hevezi

Opening Statement

Low dose rate (LDR) interstitial or intracavitary brachytherapy is a common procedure. Recently, the CPT manual[1] has indicated that the complexity of the procedure should be tied to the number of sources involved in the procedure. As High Dose Rate (HDR) procedures have become prevalent, similar criteria for complexity have been entered into the CPT manual. Instead of the number of sources, however, the complexity of the procedure is tied to the number of dwell positions of a single source. Although this discussion specifically addresses HDR procedures, policy decisions for HDR reimbursement should not be separated from those for LDR procedures.

There are two levels of reimbursement guided by whether the procedures are hospital-based, in-patient procedures or, either hospital-based, out-patient or freestanding centerbased out-patient procedures. This discussion is confined to the latter two, i.e, fee-for-service CPT-directed reimbursement (versus DRG based reimbursement). Most LDR brachytherapy procedures involve introduction of many sources to achieve an appropriate dose rate and distribution to the target. Usually, the number of sources exceeds the limit required for definition as a complex planning and delivery scheme. Exceptions are simple, gynecological procedures using Cesium sources, but these are generally DRG driven in-patient procedures. Most out-patient brachytherapy procedures should be scaled to the number of needles or catheters used. In this manner, implants that require only a few catheters or needles, whether HDR or LDR, will be allotted to the simple or intermediate realm, and those that require many needles or catheters will be relegated to the more complex reimbursement levels.

In the new Radiation Oncology Draft Manual for Policy Development,[2] several of the professional societies support consigning the level of procedure complexity to the number of needle/catheter tracks rather than to the number of individual sources used in the implant. With the new paradigm, procedures such as ultrasonically guided prostate seed implants will not change their level of complexity because they use enough needle tracks for the procedure to be classified as complex.

The situation is more acutely impacted for HDR procedures where single or double catheter tracks would be relegated to reimbursement as a simple procedure. HDR procedures involving the use of multiple catheters, such as template techniques or the HDR version of prostate implants, would still be complex. A point to emphasize is the ‘‘uncoupling’’ of procedure segments. Prior to the recommendations of the new Radiation Oncology Draft Manual for Policy Development, if one segment of a procedure was complex the entire procedure was classified as complex. Now, each segment is to be evaluated as its own complexity level for reimbursement considerations. Also, the professional segment could be evaluated as simple or intermediate, while the technical effort could be complex. Or the reverse could be the case. The question then becomes, does it take more effort to produce a plan/treatment for a complex HDR procedure compared to an intermediate or simple procedure? There will be financial separation between these entities in a catheter/ needle based approach versus a dwell position/source based approach. It is clear that a single catheter in an HDR bronchial application, for example, requires less effort than a 20 catheter gynecological or prostate template procedure. The catheter/needle approach works for both HDR and LDR procedures.

Rebuttal

Dr. Ibbott does not address the key issue here. Does the use of dwell positions to drive procedure complexity actually result in a separation of appropriate reimbursement levels for HDR procedures? And, if it does not, can we identify another reimbursement paradigm that will effect this separation and, at the same time, fairly recompense each segment of the procedure? Clearly the use of the needle/ribbon paradigm of driving procedure complexity for reimbursement purposes will result in a better separation of these entities—both for HDR and LDR brachytherapy procedures. In addition, using the needle/ribbon paradigm for reimbursement levels will discourage the practice of utilizing 0.5 cm or 0.25 cm dwell position separations in order to drive the procedure into a complex level for reimbursement purposes.

This practice was alluded to by Dr. Ibbott at the end of his opening statement and, although he appropriately cautioned individual users against artificially increasing the number of dwell positions when unnecessary, his caution will not result in reducing these practices. Linking procedure complexity to the number of needle/ribbon positions will allow those individuals who wish to use smaller dwell position separations to do so without fear of reprisal while satisfying their clinical decision making process. Many HDR planning systems allow the user to merely fill all of the dwell positions available for catheter tracks with a single selection keystroke. This is an efficient way to automatically load HDR catheter tracks, but generally results in the smaller separation and many dwell positions.

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3.3. Calculation of brachytherapy doses does not need TG-43 factorization

Haijun Song and Gary Luxton
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OVERVIEW

In brachytherapy, data needed to derive the radial dose function (RDF) and anisotropy function (AF) (as defined in AAPM TG-43) are equivalent to data in the relative along-away table (RAAT). In fact, the RAAT data can be derived from the RDF and AF, if a geometry factor is assumed. The TG-43 approach involves factorization and reproduction of the RAAT. An alternate approach is to use the RAAT directly along with the dose rate constant (DRC) in TG-43. Both approaches yield the same dose calculation. Since RAAT can be easily obtained (e.g., with radiochromic film), the direct RAAT approach is simpler and the TG-43 factorization is unnecessarily complicated. We propose using RAAT directly instead of the TG-43 factorization.

Arguing for the Proposition is Haijun Song, Ph.D. Dr. Song developed a miniature neutron probe [Med. Phys. **29**, 15–25 (2002)] for his Ph.D. thesis at MIT. He held postdoctoral positions at the Laboratory for Accelerator Beam Applications at MIT and the Center for Radiological Research at Columbia University, before he trained in medical physics at the Thomas Jefferson University Hospital. He was part of a team that performed more than one hundred prostate brachytherapy implants in one year. He held a faculty position at the Jefferson Medical College of Thomas Jefferson University, before recently joining the faculty of the School of Medicine of Yale University.

Arguing against the Proposition is Gary Luxton, Ph.D. Dr. Luxton received his Ph.D. in physics from Caltech in 1970, then did research in experimental particle physics at SLAC, Argonne and Fermilab. Beginning in 1975, he worked at Stanford on a design for negative pi-meson radiation therapy. He is certified by the ABR. As director of physics at USC/Norris Comprehensive Cancer Center, he led development of programs in ophthalmic plaque brachytherapy and radiosurgery. He returned to Stanford in 1998 as Associate Professor, where he is presently Chief of Clinical Physics. Current interests include radiobiological modeling of IMRT, and quality assurance for IMRT and robotic radiation delivery.

FOR THE PROPOSITION: Haijun Song, Ph.D.

Opening Statement

The Dose Rate Table (DRT) for a brachytherapy source can be used as a look-up table to calculate dose distributions in the clinic. The DRT is the same as the traditional along-away-table, one example of which is for the Cf-252 needle shown in Table 1 of Ref. 1.

The AAPM TG-43 protocol takes a "dissemble-and-assemble" factorization approach: The Dose Rate Constant (DRC) and other factors, including the Radial Dose Function (RDF), the Anisotropy Function (AF) and the Geometry Factor (GF), are derived from the measured DRT. In clinical practice, these factors are multiplied to reproduce the measured DRT. While the DRC improves the accuracy of dose determinations over the pre-TG-43 exposure rate constant, the advantage of adopting the other factors is debatable.

Since the GF tends to dominate the dosimetric properties in the immediate vicinity of a brachytherapy source, the RDF, with the GF accounted for, offers a better tool than the DRT for assessing radiation quality. However, such an assessment is needed only during the early phase of selecting a particular isotope for clinical use. One example might be assessment of the numerous brands of I-125 seeds, for which the TG-43 factors are usually published without comparison with other brands or other isotope species.

Under the point isotropic source approximation, the AF is reduced from a two-dimensional matrix to a one-dimensional anisotropy factor, or even further reduced to a single anisotropy constant. The TG-43 dose calculation formula takes the simple form of $1/r^2$. However this approximation is accurate only for energetic radiation at large distances. This situation does not call for a protocol with the sophistication of the TG-43. For low energy brachytherapy sources, the anisotropy constant will be phased out.[2] Also note that the angular dependence can be averaged out for the DRT in the same way that the AF is reduced to the anisotropy factor.

A full-blown two-dimensional AF has the same grid points as the measured DRT. The same look-up and interpolation will be performed on the AF and the DRT. Extra calculations are needed for the GF and the RDF. Thus dose calculations using the DRT are more efficient.

The GF is based on assumed geometry, which is sometimes an approximation of the "true" geometry for convenience. A "wrong" geometry does not affect the dose accuracy so long as identical GFs are used by the factor-generating people and the dose-calculating people. This shows the arbitrariness and dosimetric irrelevance of the GF. In reality the GF is not always published along with the other factors, and error can be introduced when the seed geometry is approximated differently.

Because of the GF arbitrariness and the inter-dependence of the RDF, AF and GF, uncertainties of the RDF and AF cannot be determined based on the uncertainty of the DRT. With uncertainties unknown, the value of the RDF and the AF as a "gauge" for radiation quality and characteristics of seed construction is compromised.

In summary, dose calculations for brachytherapy sources can be done more efficiently by using the DRT directly, or equivalently a normalized (to the reference point) DRT with the DRC. Where it is valid, the point isotropic source approximation offers a convenient dose calculation formula. However the TG-43 would be an over-kill if its sole benefit were to provide the point isotropic source approximation.

Rebuttal

The TG-43 factorization is not necessary in the sense that 2-D dosimetry, which is required for cylindrical sources as in Ref. 1, can be performed without it. With regard to relying on intuition for interpretation of dosimetry data, thereby contributing to QA, manual calculations, etc., this benefit does not seem to be readily accessible. First, the radial dose and anisotropy functions

for ^{125}I and ^{103}Pd seeds are steep curves and, the anisotropy for high-energy ^{192}Ir seeds can deviate 20% from unity. Intuitive right or wrong judgments cannot be made for these curves. Variations in the radial dose and anisotropy functions make manual calculations cumbersome, if possible at all. Second, aside from the potential problems stated in the Position Statement, the geometry factor can be a challenge for manual calculations, even with the help of computers. For example, try an evenly distributed cylinder that is 3 mm long. Then try stacking 14 of these cylinders in a string with 1 mm separations. Then try even more complicated activity distributions.

The geometry factor does not account for differences such as construction materials, x-ray production and attenuation. If we go down the road of factorization, we will have to introduce a "construction factor" to remove brand dependence from the radial dose and anisotropy functions for different brands of seeds made of the same isotope. And that would introduce another unnecessary burden for dose calculations.

Compliance with the TG-43 factorization by major brachytherapy planning systems and the physics community should not be taken as evidence for or against the necessity of the TG-43 factorization.

AGAINST THE PROPOSITION: Gary Luxton, Ph.D.

Opening Statement

Brachytherapy dose calculations are steeped in tradition, and when TG-43[3] was convened, the majority of clinical ^{125}I and ^{192}Ir seed implants were being calculated with point source dose models. One issue addressed by the Task Group was to recommend how clinical brachytherapy dose calculations should take into account the 2-D properties of cylindrically-symmetric seeds just then being measured or calculated using Monte Carlo, and how to implement the recommendation. This was not an entirely trivial task. It was widely recognized that accuracy could be significantly improved, particularly for small-volume treatments such as radioactive plaque therapy for ocular melanoma or interstitial brain implants. Commercial brachytherapy planning systems, however, offered little support for 2-D seed dose models. The problem was one of providing a smooth transition path from 1-D to 2-D seed source models that would actually be used clinically and supported by commercial brachytherapy planning software.

A solution was adopted in the form of the factorization algorithm, representing the 2-D dose distribution from a seed as a product of three factors. One factor extracted the geometric modeling of the distribution of source material including the inverse-square law, another accounted for attenuation and scatter build-up behavior as a function of transverse distance from the source, while the third, the anisotropy function, depended on both angle and distance. By extracting the line source or other geometry factor, the remaining factors readily lent themselves to physical interpretation, which was worthwhile from the point of view of error detection and quality assurance in both commissioning and daily practice.

Dose rate behavior in close proximity of a source can be understood by the geometry factor. The slowly-varying behavior of the anisotropy function can be approximated by a few values, enabling the formalism to provide convenient manual calculation checking capability. Physical interpretation of a source model lends itself to intuitive and rapid source data checking, with only limited data needed to achieve reasonably accurate dose calculation. The factorization

model also offers seamless attachment to traditional point source model calculations through the anisotropy constant.

Certainly, the model could be replaced by a rectangular grid of relative dose rates. Bare numbers are not particularly intuitive, however. Verification of data would be less transparent and the medical physicist's ability to design an implant would not be facilitated.

The TG-43 factorization model appears to be supported by all major brachytherapy planning systems, and much seed data has now appeared in this form, such as in Refs. 4 and 5. The model has robustly been applied to the emergent technology of gamma source intravascular brachytherapy.[6] To illustrate its usefulness, we note that for five different source models, in close proximity (2 mm) to an HDR ^{192}Ir source, dose rate per unit source strength is approximated to within 2–3% over a large fraction of total solid angle by the geometry factor multiplied by the point source dose rate constant.[7]

Rebuttal

Dr. Song suggests that TG-43 factorization for brachytherapy source dosimetry is deficient because it requires extra interpolation calculations, is unnecessarily sophisticated and subject to operator error, and is needed only during early clinical isotope evaluation. We consider these objections in turn.

Using several factors in place of a single 2-D function does require more interpolations in computer calculations. However, this is a minor cost for the added clarity of a geometric model. Computer interpolations are fast, and most of the cpu time is spent on calculating seed and calculation-point orientation vectors, which are needed in the DRT method as well. The offsetting advantage in TG-43 is its greater ease in performing accurate manual calculations.

The argument is made that TG-43 is unnecessarily sophisticated for large r, for which the geometric factor reduces to $1/r^2$. There remains a need here, however, for the RDF, g(r), which is more easily visualized and understood than is a Cartesian matrix. Dr. Song's reference to a plan to phase out the anisotropy constant for the 1-D model actually refers to retaining accuracy by using the distance-dependent anisotropy factor.

TG-43 algorithm calculations are stated to be subject to possible errors because a different geometric factor may be used to construct dose tables than is used for dose calculations. The line-source model is a good approximation for practical sources; only in very demanding applications might a different model be used for which a significant difference could arise. Given such a circumstance, it is unlikely for an error of the type described to be made. In producing and using a source model, error is not less likely in transcribing and interpolating DRT matrices.

Complete TG-43 sophistication may indeed be necessary only during clinical isotope evaluation, but this does not detract from its making available an advanced, easily-calculated source model. No model is perfect, but TG-43 factorization has proven to be resilient, and has served the brachytherapy community well.

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CHAPTER 4

General Imaging: Image Quality, Magnetic Resonance, Ultrasound

4.1. The development of technologies for molecular imaging should be driven principally by biological questions to be addressed rather than by scaling down macro-level imaging technologies

Gary D. Fullerton and John D. Hazle

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OVERVIEW

A recent review of Molecular Imaging[1] suggests that fundamental biology, rather than design engineering, should guide the development of imaging technologies at the molecular level. However, the history of biomedical imaging reveals a pattern of exploiting technology developments in other fields and adapting them into biomedical research and clinical care. These two different approaches to technology development are the subject of this month's Point/Counterpoint.

Arguing for the Proposition is Gary Fullerton, Ph.D. Dr. Fullerton, Ph.D., a graduate of the University of Wisconsin medical physics program, serves as the Malcolm Jones Distinguished Professor of Radiology at the University of Texas Health Science Center at San Antonio. As founding director of the Radiological Sciences graduate program, he directs 60 faculty members in supervising the studies of 52 students. Dr. Fullerton was secretary of AAPM in 1981–1983, and president in 1991. He has served as president of the Society of Magnetic Resonance Imaging and founding Editor-in-Chief of the Journal of Magnetic Resonance Imaging 1990–2000. He was co-president of the World Congress on Medical Physics and Bioengineering in 1988 and served as Secretary General of the IOMP and IUPESM 1997–2003. Dr. Fullerton's present research focus is on translation of biomolecular imaging into clinical practice.

Arguing against the Proposition is John Hazle, Ph.D. Dr. Hazle received the Ph.D. from The University of Texas Graduate School of Biomedical Sciences. He joined the M. D. Anderson faculty in 1989 as Assistant Professor in the Department of Radiation Physics. He is now Professor and the first Chair of the Department of Imaging Physics. John is certified in diagnostic radiological, therapeutic and magnetic resonance physics. His research interests are minimally-invasive image-guided therapies and small animal imaging. He is Director of the NCI-funded

Small Animal Cancer Imaging Research Facility and a driving force in the creation of a new Center for Advanced Biomedical Imaging Research at M. D. Anderson.

FOR THE PROPOSITION: Gary Fullerton, Ph.D.

Opening Statement

The statement, "The development of technologies for Molecular Imaging should be driven principally by biological questions to be addressed rather than by simply modifying existing imaging technologies," proposes a fundamental shift in the paradigm responsible for the development of medical imaging since the discovery of x rays. Over the 20th century, medical imaging development was driven by technological innovation and engineering improvements in physical equipment. A new imaging modality driven by development of the biological knowledge base represents a fundamental change. Understanding such an important change is of utmost importance to medical physicists working in imaging research. The measure of success, and the economic growth of medical imaging, reside firmly in the ability to implement new procedures with higher diagnostic specificity and sensitivity. Such imaging methods, though expensive in themselves, can in many cases provide cost-competitive resolution of patient healthcare problems.

We will consider three arguments; (1) the opinion of leaders in molecular imaging, (2) the scientific focus of self-proclaimed molecular imaging investigators and (3) the major NIH investment in genomic and proteomics research. These arguments lead me to conclude that the statement by Dr. Piwnica-Worms is correct. Medical physicists must either learn to include the biology of molecular imaging in their research programs or prepare to become irrelevant to the future of radiology.

A search of the molecular imaging literature leads to a small circle of key individuals and institutions. They are the leaders of the Society of Molecular Imaging which has the stated purpose, "An international scientific educational organization whose purpose is to advance our understanding of biology and medicine through noninvasive *in vivo* investigation of cellular molecular events involved in normal and pathologic processes."[2,3] It is clear from this statement and from the web pages of the leaders of molecular imaging that they as a group believe that biology rather than an underlying technology is driving their field.

A review of the most recent program of the Society of Molecular Imaging[4] shows a primary focus on biological questions, design of optical or radioactive molecular imaging probes and/or potential clinical applications. Less than 10% of the program (only one of twelve major symposia) is devoted to technological development, while the remaining 90% is devoted to biology and chemistry. The ACR Primer on Molecular Imaging,[5] a commercial special issue on Molecular Imaging,[6] and the more popular radiology news journals[7] all share this focus on biology. The bulk of specialists in molecular imaging are conducting studies of biology using imaging as the tool of choice.

The final consideration is the substantial refocus of federal funding on genomics, proteomics and the relation of these concepts to medicine and health care. Examples of the growing significance of these areas to world science are the special issue focus of journals such as Science[8] and Nature[9] on the fundamental importance of these discoveries.

All three arguments support the contention that biological knowledge, rather than technological evolution of existing devices, dominates the development of molecular imaging. This is a recognizable shift from the development of imaging in the 20th century. It holds great promise for increasing the importance of medical imaging in healthcare decision making around the world.

Rebuttal

I agree with many of the points made by my colleague, but he has missed the main point of the discussion, which is "should technology development be driven by biological questions or the evolution of existing imaging technologies?" There are two examples that clarify the magnitude of this omission. First consider the only session on technology at the 2004 Society of Molecular Imaging Congress which had the following objective: "To address molecular and small animal imaging challenges, revolutionary developments have occurred in hardware and software. This session is designed to highlight the newest cutting edge developments in instrumentation and new strategies that will enable us to "see" more with greater sensitivity and specificity."

Existing imaging technologies are being reconfigured and adapted to the size and biology of mouse and rat models. Rodent biology is driving technology development.

A second example is the introduction of human CT/PET units for clinical molecular imaging. These instruments are optimized to integrate anatomical information from CT with molecular functional information from PET. The medical need for co-registration of anatomical and functional information has driven the development of the technology. I readily accept that molecular imaging cannot prosper without continued improvement of imaging technology. The direction of these developments, however, will be dictated by biological questions that can only be answered through molecular imaging.

AGAINST THE PROPOSITION: John Hazle, Ph.D.

Opening Statement

At the end of the first Michigan State workshop on Molecular Imaging in 2001, Dr. Elias Zerhouni moderated a discussion to define molecular imaging in the context of creating a new scientific society (Society for Molecular Imaging). The discussion was lively, and eventually a vision for the new society was adopted consistent with the definition of molecular imaging accepted by The American College of Radiology's Commission on Molecular Imaging. The ACR definition is: "Molecular imaging may be defined as the spatially localized and/or temporally resolved sensing of molecular and cellular processes *in vivo*."

I will argue that for most *in vivo* applications the best approach to developing molecular imaging hardware is to optimize existing technologies. It is relatively clear that new molecular probes have a significant probability of yielding leap-step advances. The lofty goal of molecular imaging cannot be achieved without significant advances in instrumentation as well.

The two imaging modalities that will likely have the most impact in patients over the next decade are positron emission tomography (PET) and magnetic resonance (MR). For PET, sensitivity has been an issue since the technology's inception. Detector composition, electronic component capability and instrument geometries have all been improved in order to enhance sensitivity.

Advances in crystal design and composition still hold promise for improving overall sensitivity. New experimental systems and flat-panel detectors may provide significant improvements in sensitivity. Further, advances in electronics are permitting new counting strategies, and advances in computing power are allowing for new reconstruction algorithms with enhanced sensitivity.[10] Biology will drive the development of new probes that will create opportunities for rapid advancement. Refining existing technologies to detect positron-induced annihilation radiation is the approach most likely to yield significant results for instrumentation.

The case is much the same for MR. Advances in magnet design are allowing higher field strengths for both animal and human imaging. There are now several whole-body instruments operating at 7 T, and there is an 8 T system at Ohio State and a 9.4 T system at the University of Illinois at Chicago. These magnets provide improved sensitivity, with detectability of low-contrast detail improving by a factor of 10–15 in going from 1.5 T to 9.4 T. Coupled with advances in coil and electronics performance, a 20–30 fold increase in sensitivity may be achievable. The real opportunity for leap-step improvement in detectability is the development of field-strength-specific contrast agents.[11] Although the potential sensitivity of new probes may be 10–100 fold, the mechanism of detection is likely to be a permutation of an existing approach (pulse sequence of acquisition strategy). That is, continued development of more mature instrumentation is likely to yield the most significant advances in the modality.

Optical imaging is an exception in this debate. Here probes and detector systems are tightly coupled. The potential is present to find a new probe system based on biology that requires a new detector technology. This potential could drive instrumentation development. Nevertheless, there is still a lot of potential in continuing to optimize existing technologies for improved sensitivity and depth resolution.

In conclusion, I believe the development of the instrumentation used for molecular imaging is best driven by continued optimization of existing instrumentation for known tracers and contrast mechanisms.

Rebuttal

I whole-heartedly agree that medical physicists must learn more biology, including physiology and metabolism, to pursue research in molecular imaging. However, we need to remember that our core value comes from the deep technical knowledge we have of the instrumentation (i.e., tools) used to detect these processes, and the optimization of the performance of these devices. To fully exploit this knowledge we must understand the biological questions to a degree greater than most of us were prepared for in our educational careers. Second, the focus on genomics and proteomics is not surprising because these are new fields with broad potential applications. The molecular imaging community needs to develop ways to exploit advances in these areas with new probes and tracers. Unless these systems require fundamentally new imaging techniques, we will need to incrementally build better instrumentation technologies for molecular imaging.

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4.2. Functional MRI is fundamentally limited by an inadequate understanding of the origin of fMRI signals in tissue

John C. Gore and Robert W. Prost

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OVERVIEW

Functional magnetic resonance imaging (fMRI) is an exciting and dynamic area of imaging research. Many proponents of this technology believe that its clinical applications will yield major breakthroughs in the early diagnosis of brain abnormalities, mental conditions and behavioral deficiencies. Others think that these major breakthroughs will be severely limited by the phenomenological nature of fMRI research, and progress will be curtailed until the physiological origin of fMRI signals is understood. This difference of opinion is explored in this month's Point/Counterpoint.

Arguing for the Proposition is John C. Gore, Ph.D. Dr. Gore is Chancellor's University Professor of Radiology and Biomedical Engineering, as well as Physics and Molecular Physiology and Biophysics, at Vanderbilt University. He trained in Physics in London, and has worked in medical imaging research for over 30 years, and in the field of MRI since 1979. His research interests include the use of NMR to study tissue biophysics and factors that modulate MRI signals from tissues, such as the BOLD effect. He has contributed over 300 papers and chapters to the imaging literature, including many studies using fMRI to investigate human cognition. After 20 years at Yale University, he moved in 2002 to direct a new Institute of Imaging Science at Vanderbilt University.

Arguing against the Proposition is Robert W. Prost, Ph.D. Dr. Prost is an Assistant Professor of Radiology at the Medical College of Wisconsin, where he serves as Chief of MR Technical Advances. In that capacity he is responsible for technical aspects of translational MR research, including pulse sequences, post-processing and RF coil development. Before joining the Medical College in 1992, he was Lead MR System Designer for General Electric Medical Systems. Dr. Prost's primary research concerns are in functional MR imaging and low-field MR spectroscopy.

FOR THE PROPOSITION: John C. Gore, Ph.D.

Opening Statement

FMRI indirectly detects blood flow and oxygenation changes that accompany neural activity. For some applications such as neurosurgical planning, the primary aim of fMRI is to accurately depict the spatial locations of regions selectively recruited after a stimulus. In these cases, a precise interpretation of the blood oxygenated level dependent (BOLD) signal is not essential. In other contexts, however, such an empirical approach is fraught with potential dangers of misinterpretation. It is also likely to overlook valuable additional information that may be obtainable. In studies of human cognition, for example, maps may be recorded depicting

distributed networks of regions that respond to a specific task. Inferences may then be drawn about the significance of the relative weights of different nodes within the network, and about differences in the amplitude and area of activation among groups or conditions. Implicit is the premise that the BOLD signal reflects, at least semi-quantitatively, the degree of neural activity. However, we currently have little basis on which to interpret the amplitude of BOLD signals.

Numerous studies show that the BOLD signal changes with behavior, learning, intervention and physiology, but does not respond linearly to stimulus intensity.[1] The relationship between electrical discharges and BOLD signal is confounded by unknowns in essential couplings at different stages (e.g., between electrical and synaptic activity of neurotransmission, between metabolic demand and blood flow and oxygen use, and between hemodynamic changes, vascular architecture and the NMR signal). The BOLD signal is affected by several factors and physiological variables that are not yet understood. It is well known, for example, that baseline vasodilation (e.g., breathing air enriched with carbon dioxide, or even heavy breathing) reduces the BOLD effect dramatically, and that the signal amplitude is dependent on the degree of cerebrovascular reserve and age. Less well documented are the effects of, for example, mild hypoglycemia (which reduces the BOLD signal to 60%[2]), variations in blood pressure or autoregulation, and the presence of common vasoactive pharmacological agents such as nicotine and caffeine, or hormonal levels such as estrogen. These factors modulate the BOLD signal and contribute to the variance in results reported within and between subjects. In addition, the relationship between blood volume, blood flow and oxygen extraction is not a constant. For example, even brief periods of hypercapnia have been shown to affect the coupling of the BOLD signal and flow.[3]

In infants, the BOLD effect is often reversed compared to adults,[4] suggesting that the balance of physiological variables is different and changes with development. At a more fundamental level, we do not even know how to interpret BOLD signals in terms of net activation—whether, for example, inhibitory inputs to a region contribute to the metabolic demand (and hence the BOLD signal) in the same way as excitatory elements. These issues are tractable research questions that deserve further attention. Understanding the physiological factors that affect the BOLD signal will provide a better basis for interpreting the magnitudes of activation, the differences between conditions, and avoiding possible confounding conditions that may obfuscate the effects of true differences in behavior.

Rebuttal

An empirical approach to applying new discoveries in medicine may indeed reap benefits. There are, in fact, many examples of developments that are useful but not totally understood. Nevertheless, reaching the full potential of new discoveries is often limited by an incomplete understanding of the underlying science. Cavalier adoption of new methods without such understanding can be dangerous. For example, the primary impact of aspirin on health care (in preventing heart attacks, not in analgesia) was overlooked for almost 100 years because we did not know how the compound worked. The history of medicine is littered with examples in which so little was understood at the time of use of new drugs and treatments that major harm was inflicted on innocent people. Thalidomide is one notorious example of this problem. Another example is the link between aspirin use and Reye's syndrome, which was not made until quite recently.

The clinical use of MRI Diffusion-Weighted Imaging is limited in practice by our ignorance, because we do not know how to interpret the serial changes in MRI signals in terms of cellular

edema, reversible ischemia, necrosis, infarction, or other biologically-meaningful descriptions. A new diagnostic technique has to meet qualitatively different standards than an experimental treatment that looks promising, especially when there are existing alternatives that are less glamorous but known to work. It seems highly unlikely that studies of weak correlations in BOLD signals would be adopted by neurologists as persuasive and specific for a major brain disorder, especially in a way that would affect the patient's treatment or diagnosis, until it has been established that such variations reflect neural activity, and that their evolution directly implicates a disease-relevant biochemical or structural process in the brain. That is, these correlations will probably remain curious observations until we understand more about fundamental mechanisms.

We know enough already to be cautious about the sensitivity and accuracy of BOLD imaging and the inherent subjectivity of functional data in some studies. FMRI already provides ample opportunities for making significant errors in judging the scale and locations of activated cortex. To reach beyond simple mapping of sensory areas to a more widespread impact in detecting, diagnosing and treating brain disorders will require "the creation of a reliable tool and appropriate training of users," as my colleague emphasizes. In this context, however, reliability will demand understanding the biological and physical factors that affect the results, and training will require understanding the relationship between indirect BOLD measurements, neural activity and human cognition.

AGAINST THE PROPOSITION: Robert W. Prost, Ph.D.

Opening Statement

Many phenomena within functional magnetic resonance imaging by the BOLD contrast mechanism are not yet understood. These phenomena include the steps coupling increased neuronal activity to the dilation of the end arterioles that control flow in the capillaries.[5]

Despite an incomplete understanding of the mechanisms involved, the clinical use of fMRI is expanding rapidly. A growing number of clinical problems are amenable to investigation, and more importantly, diagnosis by fMRI. One example is the presurgical localization of functions within the eloquent cortex relative to a lesion. The prediction and prevention of postsurgical neurological deficit has proven to be of great benefit for both patients and surgeons.

The history of medicine is replete with examples of breakthrough treatments in which the mechanisms of action are poorly understood, if at all. The most obvious is aspirin. Salicylate, an extract of willow bark, was described by Hippocrates in 400BC. A synthetic salicylate, acetylsalylic acid, was first commercially produced by Bayer Pharmaceuticals in 1899. It is still widely used. The inhibition of cyclo-oxygenase was not discovered until 1990 to be the cause of the analgesic/anti-inflammatory effect of aspirin. Discovery of the mechanism of action in acetylaslylic acid did not change the utilization rate of aspirin. The use of aspirin as an antiplatelet, anticlotting drug was also discovered during the course of treating hemophilic children with aspirin.[6]

Diffusion-weighted MRI (DWI) is evolving in a similar manner. Changes in images of the mean diffusivity of water in the brain have been used to diagnose and determine the spatial extent of infarct.[7] New studies have cast doubt on the mechanisms originally proposed for the observed

changes. However, the absence of consensus on mechanisms has not detracted nor derailed the clinical use of DWI.

Extensions of fMRI to other clinical problems will occur largely independently of an increased understanding of underlying mechanisms. An example is the concept of resting oscillations in the BOLD effect, which have been detected by fMRI.[8] Li *et al.* have described the loss of coherence in these resting state oscillations associated with early stages of Alzheimer's dementia.[9] Mechanisms underlying the loss of coherence are not yet understood. Development of a tool for early AD diagnosis will likely not depend on the answer.

None of this is to say that fMRI will not suffer misuse. The path to a stable clinical test is typically littered with the burned-out remains of early adopters, abusers and discarders. Greater utilization and stability/reliability are dependent on the availability of integrated packages with stable quality assurance methods and appropriate phantoms. They will also depend on training radiologists to read and interpret fMRI studies. The rate-limiting step in the clinical utilization of fMRI is not an understanding of mechanisms, but the creation of a reliable tool and appropriate training of users.

Rebuttal

While the amplitude of the BOLD signal may not be a linear function of the intensity of the stimulus, this fact does not preclude the use of fMRI in the clinical setting. Intensity of the stimulus has been shown to correlate with the number of activated voxels. In bilingual subjects, the number of activated voxels is always greater in the non-native language.[10] Our recent work has shown the number of activated voxels in the auditory cortex increases with the intensity of pure tones.[11] This would be expected, based on the mechanism of signal transduction in the hair cells of the inner ear. The firing rate of hair cells increases linearly with increasing tone intensity between 20 and 40 dB. Above 40 dB, the firing rate of an individual hair cell is saturated. Increasing tone intensity above 40 dB is encoded by increased recruitment of, rather than increased response of, individual neurons.

A further barrier to understanding BOLD signal amplitude is the manner in which neuronal activity is coupled to the elements of metabolic support for the neuron. Studies of glucose and oxygen utilization show that vasodilatation of the capillary venules always exceeds the increased metabolic demand of the stimulated neurons.[5] The amplitude of the BOLD response may signify nothing more than the effect of postneuronal activation factors on the over-reactive vascular response.

An improved understanding of the BOLD response will be an important factor in broadening the role of fMRI in the clinical domain. However, like so much of medicine, applications of fMRI will not await a complete understanding of underlying mechanisms. In the interim, fMRI has already become a valuable clinical tool. The time to start using it is now.

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4.3. Simultaneous PET/MR will replace PET/CT as the molecular multimodality imaging platform of choice

Habib Zaidi and Osama Mawlawi

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OVERVIEW

With the combination of PET and CT images in dual-modality PET/CT units, it is now possible to accurately align the functional information obtained with PET to the anatomical structures revealed by CT. This is a significant improvement over previous methods of combining these two modalities by "fusing" images obtained in sequential studies, with all the problems associated with precise patient positioning. The oncological community has so embraced this new technology that PET/CT units are now becoming commonplace. Indeed, PET units are now rarely purchased without being combined with CT. However, many would argue that the anatomical data derived from CT is not as complete as that which could be obtained with MRI, and the metabolic information that can be obtained with PET is somewhat limited compared with that which might be obtained with magnetic resonance, especially with functional MRI (fMRI) and MR spectroscopy (MRS). This has led to the recent development of combined PET/MR units, which are being promoted as even better than PET/CT. The premise that PET/MR will replace PET/CT as the molecular multimodality imaging platform of choice is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Habib Zaidi, Ph.D. Dr. Zaidi received a Ph.D and Habilitation (Privat-docent), both in Medical Physics, from the University of Geneva. He is senior physicist and head of the PET Instrumentation & Neuroimaging Laboratory at Geneva University Hospital, where he is actively involved in the development of imaging solutions for cutting-edge interdisciplinary biomedical research and clinical diagnosis. He is a member of the editorial board and/or serves as scientific reviewer for several scientific journals. He is a senior member of the IEEE and Vice Chair of the Professional Relations Committee of the IOMP. He is involved in the evaluation of research proposals for European and international granting organizations and participates in the organization of international symposia and conferences. He is a recipient of many awards and distinctions and has been an invited speaker of many keynote lectures at an international level.

Arguing against the Proposition is Osama Mawlawi, Ph.D. Dr. Mawlawi received his Ph.D in Biomedical Engineering from Columbia University in NY. He did his graduate training in PET imaging at Memorial Sloan Kettering Cancer Center in New York City before accepting a joint faculty position in the Departments of Radiology and Psychiatry at Columbia University Medical Center, where he focused on neuroreceptor imaging using PET. He is currently an Associate Professor of Imaging Physics at M.D. Anderson Cancer Center in Houston, Texas, and is the lead PET/CT physicist at the center. Dr. Mawlawi is a reviewer for numerous international journals, has been an invited speaker at many national and international conferences, and is the recipient of several grants from public and private sources.

FOR THE PROPOSITION: Habib Zaidi, Ph.D.

Opening Statement

The recent introduction of PET/MR technology is considered by many experts to be a major breakthrough that will potentially lead to a paradigm shift in healthcare and revolutionize clinical practice. Several research groups in academic and corporate settings are focusing on the development of various configurations of MR-compatible PET inserts to allow simultaneous scanning using the most highly sophisticated molecular imaging technologies available today.[1,2,3,4,5,6] Compared to PET/CT, where sequential scanning was (erroneously) considered to be the ultimate solution for image coregistration to correlate structural and functional information thus allowing anatomic localization of abnormal tracer uptake or facilitating the process of differentiating normal from abnormal uptake, simultaneous PET/MR has many additional features. First, for small animal studies, *simultaneous* scanning reduces time under anesthesia and enables scanning under identical physiological conditions. Second, high-field MRI generates high resolution anatomical and structural images offering better soft-tissue contrast resolution and a large variety of tissue contrasts compared to CT, and allows for functional MRI, thus enabling temporal correlation of blood flow with metabolism or receptor expression in brain studies and, more importantly, is capable of assessing flow, diffusion, perfusion, and cardiac motion in one single examination. Third, MRI can be combined with MRS to measure spatially matched regional biochemical content and to assess metabolic status or the presence of neoplasia and other diseases in specific tissue regions. Finally, MRI does not use any ionizing radiation and therefore can be used without restrictions in serial studies, for pediatric cases, and in many other situations where radiation exposure is a concern.

A major advantage cited for PET/CT is that it enables a reduction in the overall scanning time by using CT images for attenuation correction. However, it does this at the expense of a substantial increase in absorbed dose, a significant issue when scanning normal subjects and small animals, as it might change the animal model being studied.[7] In comparison to CT, MRI typically is more expensive, involves longer scan times, and produces anatomical images from which it is more difficult to derive maps for attenuation correction of the PET emission data. However, some solutions do exist as demonstrated by a proof of concept for using segmented MRI-guided attenuation compensation in brain PET,[8] and plenty of opportunities remain for creative advances in MRI-guided attenuation correction in whole-body PET imaging.

Whereas many technical problems have been recently solved, it is recognized that implementation and operation of a combined PET/MR system is still facing many important challenges that must be overcome through research. Many design configurations based on the use of detector readout technologies insensitive to magnetic fields have been proposed, including avalanche photodiodes and, more recently, silicon photomultipliers, particularly for preclinical systems. Moreover, one of the major vendors recently married a PET insert to a 3T MR head scanner,[4] making its application to humans in research settings (and possibly extension to clinical whole-body PET/MR) a near certainty as prototypes are being deployed in some European institutions.

Weighing the advantages and drawbacks of each technology renders the conclusion "*simultaneous PET/MR will replace PET/CT as the molecular multimodality imaging platform of choice*" not only plausible but also obvious. This technology will likely succeed in unifying the four promising molecular imaging techniques PET, structural MRI, fMRI, and MRS, which is in sharp contrast to the limited information provided by dual-modality PET/CT imaging.

AGAINST THE PROPOSITION: Osama Mawlawi, Ph.D.

Opening Statement

It is always difficult to predict the extent of success a new technology will achieve particularly when it is still in its infancy as is the case with PET/MR. In general however, for a nascent technology to successfully replace an established standard, its capabilities should not only emulate the standard but also constitute a demonstrable advantage that undeniably leads to its widespread use, while its disadvantages should not offset its potential benefits. In this regard I will argue, for now, that PET/MR will not replace PET/CT as the modality of choice for molecular imaging at least from a *clinical* evaluation standpoint. For research applications on the other hand, much can be said in favor of PET/MR.

PET/MR has the capability of emulating the achievements already established by PET/CT. Scan duration with PET/MR is anticipated to be similar to PET/CT or slightly longer depending on the pulse sequence used.[9] This can, however, only be achieved if the design of PET/MR allows for concurrent rather than sequential data acquisition, as is the case with PET/CT. Furthermore, the instantaneous fusion of anatomical and functional data, which facilitated the acceptance of PET/CT, can be accomplished with PET/MR[9,10,11] and the use of MR for attenuation correction, although challenging, is also presumably feasible as has been shown at least for brain imaging.[8] However, as mentioned earlier, for PET/MR to replace PET/CT it should, in addition to emulating the advantages of PET/CT, provide a clinically practical and tangible advantage in image acquisition, interpretation, and diagnosis.

PET/CT is currently mainly used for whole-body oncological evaluations, an application comprising the majority of reimbursable indications for PET/CT.[12] In this regard, for PET/MR to replace PET/CT it should be able to provide a better alternative particularly in whole body imaging. However, since the pairing of MR with PET is not envisioned to further improve the PET imaging portion over what has already been accomplished with CT but rather to augment it with functional (fMRI) or spectroscopic (MRS) data, both of which are not routinely used for diagnostic evaluation, the question then becomes: Is it better from a diagnostic perspective to pair a PET scanner with CT or MR? The answer to this question largely depends on the application, ease of use, and cost. Since its introduction in the early 1980s, MR has steadily gained acceptance, but it has not replaced CT in many areas, mainly because of the reasons above. The same applies to PET/MR replacing PET/CT in routine clinical imaging. Until the diagnostic advantages of whole body PET/MR are well established, reimbursable, and supersede any additional diagnostic advantages that PET/CT might introduce, I believe that PET/MR will be restricted to research and will have difficulty replacing the widely accepted use of PET/CT.

One area where PET/MR has a clear advantage over PET/CT is lower patient radiation exposure. This advantage should by itself be sufficient to predict that PET/MR will replace PET/CT. Unfortunately, however, we have repeatedly seen that efforts for dose reduction are circumvented by other dominating factors such as cost, speed, and ease of use[13,14] suggesting that this reasoning might not be strong enough to induce the suggested change in PET imaging.

In summary, PET/MR scanners have a lot of potential advantages. However, for these advantages to assist PET/MR in replacing PET/CT in routine clinical evaluation, they first have to be cost effective and easy to realize and, most importantly, become a necessary component of the routine whole body diagnostic evaluation of cancer patients using PET imaging.

Rebuttal: Habib Zaidi, Ph.D.

I concur with my colleague that current PET/CT technology is more comfortable for end-users and that the use of PET/MR in clinical and research settings requires extensive technical and organizational efforts that may restrict its use in the short term to academic centers having the required scientific resources. I also agree that any new technology should be assessed carefully with respect to benefits conveyed to patients before widespread acceptance and adoption. We clearly need large-scale studies to demonstrate the clinical benefits of PET/MR and, more importantly, to define where PET/CT is sufficient and where PET/MR is needed. However, I disagree with the main arguments raised to claim that PET/CT is, and will remain, the clinical standard in the foreseeable future. First, combined PET/MR is also aiming at improving the diagnostic relevance of the PET imaging portion but in a more profound way, which is not limited to providing anatomical information for mapping of metabolic abnormalities and shortening transmission scanning time, as PET/CT does. In addition to offering a diversity of tissue contrasts, MR will provide a wealth of additional information through fMRI and MRS to enhance the diagnostic performance and quantitative capabilities of PET. More importantly, using simultaneous (rather than sequential) scanning will resolve many of the impediments to precise coregistration of anatomo-molecular information and accurate attenuation correction. Second, reimbursement issues are mainly driven by prospective clinical studies that demonstrate improvements in health outcomes conveyed by an imaging modality for a given indication. Therefore, given the higher soft tissue contrast resolution of MRI and its highest sensitivity and specificity for many indications (e.g., detection of liver metastases),[9] coverage for PET scans will undoubtedly be expanded.

This having been said, I would like to challenge my colleague further by asking: "Is PET/CT unanimously recognized as the standard imaging technology for clinical oncology?" One should bear in mind that this is still a controversial issue, since many investigators claim that it has a limited role in many indications including lymphomas, lung nodules, and brain tumors.[15] Time will dictate whether PET/MR will influence the standard for future PET instrumentation, which is poised to advance molecular imaging and influence clinical and research practice.

Rebuttal: Osama Mawlawi, Ph.D.

I agree with Dr. Zaidi that PET/MR has many potential advantages, provided that current technological barriers facing its development are resolved. As I mentioned in my opening statement, PET/MR theoretically provides the same advantages that PET/CT provided to dedicated whole body PET imaging such as anatomical landmarks, shorter scan durations, and attenuation correction. In addition, PET/MR potentially can augment PET imaging with a wealth of other information such as functional and spectroscopic data that may be helpful in improving patient management as well as understanding tumor biology. Furthermore, with PET/MR this information is obtained at a reduced patient radiation exposure compared to PET/CT. So in essence, pairing PET with MR can only provide an added advantage over PET/CT. However, going as far as suggesting that PET/MR will replace PET/CT might be premature at this stage, particularly since none of the suggested added advantages of PET/MR have been shown to be clinically justified, practical and, most importantly, cost effective in routine whole body oncological imaging.

There is no doubt that in order to assess the need for PET/MR in a clinical setting, such a hybrid modality should be made available at least in large research centers. Results from studies conducted on these systems will then provide the necessary data to justify their routine clinical

use and eventually convince the medical community about the merits and cost effectiveness of PET/MR. Until that happens, I believe that PET/CT will continue to be the modality of choice in whole body oncological imaging.

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4.4. Methods for image segmentation should be standardized and calibrated

Edward Chaney and Geoffrey Ibbott
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OVERVIEW

Methods of image segmentation and fusion are being widely deployed to characterize three-dimensional (3D) treatment volumes in intensity modulated radiation therapy (IMRT) and other sophisticated therapeutic approaches. Some physicists believe that these methods must be standardized, and that calibration methods must be developed, in order to ensure that the 3D treatment volumes depicted by the methods are true representations of the volumes of interest in the patient. Other physicists believe that image segmentation and fusion are evolving technologies that should be allowed to progress without the constraints of standardization and calibration. This controversy is the subject of this month's Point/Counterpoint. (Note: the authors emphasize that the positions on the proposition are taken in the spirit of debate, and do not necessarily reflect their personal or their employers' viewpoints.)

Arguing for the Proposition is Edward Chaney, Ph.D. Dr. Chaney is a Professor in the Department of Radiation Oncology at the University of North Carolina (UNC) School of Medicine, where he was Director of the Physics Division from 1979 until 2003. In 2003 he retired as Director to devote more time to research and teaching. He is a senior investigator in the Medical Image Display and Analysis Group at UNC and focuses on computer-based methods for image analysis with image-guided radiation treatment planning and delivery as primary driving problems. He is a cofounder of Morphormics, Inc., a startup company specializing in computer systems for image analysis.

Arguing against the Proposition is Geoffrey Ibbott, Ph.D. Dr. Ibbott is Professor and Chief of the Section of Outreach Physics at the UT M.D. Anderson Cancer Center in Houston. The section includes several programs known to many medical physicists, including the Accredited Dosimetry Calibration Laboratory, Radiation Dosimetry Services, and the Radiological Physics Center (RPC). As Director of the RPC, Dr. Ibbott has a particular interest in the quality assurance of cooperative group clinical trials. When not busy with his professional activities, Dr. Ibbott can be found ballroom dancing with his wife, Diane, or sailing in Galveston Bay.

FOR THE PROPOSITION: Edward Chaney, Ph.D.

Opening Statement

The accuracy and reproducibility of radiation therapy can be improved by standardizing and calibrating image segmentation methods. Segmentation is a commonly performed procedure that affects critical treatment planning and delivery decisions. Image-guided 3D and emerging four-dimensional (4D) planning and delivery methods require one or more user-created models of the patient to localize and display objects of interest, position beams, and shape beam apertures,

compute DVHs and volume-weighted metrics, characterize temporal changes in patient anatomy, and transfer information from one or more reference images to inter- and intra-treatment images for accurate and reproducible targeting. The structures comprising the patient model are defined by segmenting volume images. Due to the large number of departments practicing image-guided planning and delivery, it is likely that segmentation is performed more often as a clinical procedure in radiation oncology than for all the other medical specialties combined.

Calibrating a dose to a point in water has served well the two–dimensional (2D) and nonconformal 3D eras but is insufficient for the modern era, which is distinguished by tight margins and steep dose gradients intended to shrink-wrap the high-dose region around the target while conformally avoiding nearby normal tissues. The modern approach, particularly in conjunction with inverse planning methods, is exquisitely sensitive to geometric variations in the patient model. The quality of manual segmentation is degraded by user-specific systematic and random intra- and inter-user variabilities that in turn are manifested as suboptimal plans and imprecise targeting. Emerging automatic methods[1,2,3,4,5,6,7,8] promise to significantly reduce random variabilities, leaving predominantly systematic errors that in principle are correctable by training, algorithm "tuning," or supervised editing. While it would be impractical if not impossible to calibrate human segmentation, it is possible to standardize and calibrate automatic methods. Standardization would eliminate nonuniform in-house practices that confound comparison of clinical studies from different sites and impede accurate export and import of protocols. Calibration would assure compliance with an accepted standard.

Current automatic methods produce approximate segmentations intended for supervised editing. As automatic methods improve and gain the confidence of users, and as the number of imaging procedures increases, it is likely that practice will shift toward minimal supervision and eventually to almost complete reliance on automation. Minimal supervision elevates the desired standard of performance and adds urgency to finding standardization and calibration solutions. Now is the time to begin working on the issues related to finding those solutions. One challenge to be faced is characterizing the performance of algorithms in clinically relevant terms. Performance characterization is of interest in computer vision and important questions are being addressed.[9,10,11] Practical issues include agreeing on standard practices and developing calibration methods that can be widely implemented. The AAPM can take a leadership role by including focused sessions during annual meetings and forming task groups to study the major issues and make recommendations. Inaction assures that the promises of standardization and calibration will be lost.

Standardization refers to developing protocols to encourage uniform segmentation practices. A protocol for the rectum might specify, for example, the length of rectum to be segmented, and whether the rectal wall and/or the anterior portion near the prostate should be segmented. Calibration refers to quantitating segmentation accuracy and reproducibility.

Rebuttal

Dr. Ibbott presents a clear picture of the professional and scientific challenges that must be addressed to find widely acceptable solutions for calibration and standardization of image segmentation for radiation therapy. Standardization of target volumes is particularly problematic and his point is well made that better understanding and consensus are needed. This argument applies to organs at risk (OAR) as well, but the imaging issues are not as complex. Also in the scientific arena, further research is needed to develop, validate, and calibrate segmentation methods. Traveling the road to understanding and consensus is a community venture that

requires compiling and vetting information, education, airing ideas, and open debate. Professional and scientific organizations such as the AAPM can play an important role in this process.

AGAINST THE PROPOSITION: Geoffrey Ibbott, Ph.D.

Opening Statement

In nearly every aspect, standardization in radiation oncology is a desirable objective. It is widely agreed, for example, that treatment machine calibration must be traceable to national standards, to assure that dose delivery is consistent among departments.[12] Data communication, particularly that involving radiological images and radiation therapy treatment plans, must be conducted according to protocols such as DICOM to ensure that the data are received intact. Seemingly obvious things such as the units and coordinate systems used for describing radiation beam size and orientation must be standardized to facilitate the accurate communication of these parameters.[13] Several unfortunate accidents in radiation therapy have occurred because of misunderstandings of the coordinate system used to describe the placement of the radiation field, or confusion over the units of a calibration coefficient.[14]

With regard to the definition of target volumes and OAR in radiation therapy, it would seem that standardization would have many benefits. Defining target volumes according to a standard could streamline operations in a radiation therapy department, and might result in time and cost savings. Perhaps even more significantly, standardizing target volume definition processes could improve the quality of clinical trials by ensuring that patients receive equivalent care at multiple institutions. One day, we will probably reach this point.

Today, however, may be too soon to develop standards for defining target volumes and OAR. Numerous studies have shown that physicians rarely agree on the shape and size of a target volume.[15] Physicians involved in clinical trials suggest that inconsistent identification of target volumes is probably a greater cause of variations in patient treatment than is the implementation of new treatment technologies.[16] There is no "gold standard" for any target volume or other structure. In fact, in a recently closed multi-institutional study of IMRT for treatment of the oropharynx, the principal investigator revised the contours drawn by physicians registering patients in the trial, to assure that dose-volume histograms were calculated according to his criteria.[17] Another RTOG/NSABP trial that opened recently requires that participants demonstrate their willingness and ability to define the target volume according to the principal investigators' criteria.[18] It is unlikely that these PIs would have accepted a standards agency's definition of the targets and other structures.

The expansion into radiation therapy planning of imaging technologies such as MR and PET is changing the way target volumes are defined. On the horizon are molecular imaging techniques that promise to allow routine identification of tumor-bearing tissue in organs such as the prostate, further improving the radiation oncologist's ability to define the target. In addition, the current interest in 4D imaging and treatment to accommodate respiratory motion raises new uncertainties in the identification of target volumes. Standardizing now could limit the development of these techniques and discourage new research.

Until the identification of tumor volumes is better understood and consensus is achieved in the radiation therapy community, the standardization of target volume segmentation should remain a research project.

Rebuttal

In his opening statement, my opponent claims that standardization and calibration of segmentation methods can improve the accuracy and reproducibility of radiation therapy. It is hard for me to disagree with this claim. As one whose career has been intimately associated with the development of standards,[13] and the supervision of calibration laboratories,[12] I support both activities. But I question whether automatic segmentation can improve the quality of radiation therapy. Is it true, as it is with dosimetry, that complying with a consistent standard is more important than that the standard be correct?

With regard to defining target volumes, being consistently in error is not acceptable. Removing random variabilities could be detrimental to patient care, if the wrong standard is chosen.

Dr. Chaney says that calibration of segmentation techniques would assure compliance with an accepted standard. If only there were such a standard! The literature is filled with examples of the disagreements encountered when one asks several physicians to define target volumes[15,19,20] There are also examples of the disagreements demonstrated when different imaging modalities, such as CT and MRI, are used for the segmentation procedure.[21] The introduction of PET has improved the ability to identify the location and extent of lung tumors, leading radiologists to change the volumes delineated on CT images.[22]

My opponent points to a recent publication discussing the development and design of a segmentation algorithm.[3] In a related paper, the algorithm is used to perform segmentation of kidneys from CT images.[23] While the performance of the algorithm is impressive, the authors note that significant disagreements occurred between two experienced physicians who contoured the same kidney. The disagreement between the automatic segmentations and those drawn by humans was similar. It is not clear how well this algorithm might function with structures that are less clearly defined than the kidney, which is the case for many tumors.

Dr. Chaney concludes that the challenges facing the implementation of segmentation algorithms include finding ways to characterize their performance, developing calibration methods, and agreeing on standard practices. Developing the consensus needed to address these issues could be supported by the AAPM. I wholeheartedly agree, and look forward to progress in this area. In the meantime, as was stated before, I believe automatic segmentation should remain in the research arena.

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4.5. Standards for image quality and radiation exposure impede the pursuit of optimized quality/dose ratios in radiology

David Goodenough and Caridad Borrás

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OVERVIEW

Universal standards for radiation exposure and image quality have long been objectives of numerous *ad hoc* task groups, various government agencies and national and international organizations, and committees of the AAPM and many other scientific and professional organizations. Efforts directed to attaining these objectives or measuring compliance with them have occupied the time and effort of almost every medical physicist involved in medical imaging. However, these efforts may be antithetic to the optimization of quality/ dose ratios in medical imaging, because they establish intermediate goals for physicists that divert their search for the best combinations of image quality and patient dose. One of the first rules of Total Quality Improvement (TQI), according to its developer W. Edwards Deming, is to do away with all standards so as not to impede the commitment to continuous improvement of quality. The apparent conflict between development of exposure and quality standards, and principles such as TQI and Total Quality Management, is explored in this issue of Point/Counterpoint.

Arguing for the Proposition is David Goodenough, Ph.D. Dr. Goodenough is Professor of Radiology and Co-Director of The Institute for Medical Imaging and Image Analysis at The George Washington University. He received his B.S. in Physics in 1967, and his Ph.D. in Medical Physics in 1972 from the University of Chicago where he served as a member of the Radiology Faculty and Center for Radiologic Image Research. In 1974 he served as Visiting Associate with the Bureau of Radiological Health (FDA) before serving as Assistant Professor of Radiology at Johns Hopkins University. In 1975 he moved to GWU. Dr. Goodenough is interested in CT, MRI, and SPECT as well as PACS and teleradiology systems, ROC curves and efficacy studies.

Arguing against the Proposition is Caridad Borrás, D.Sc. Cari Borrás came from Spain to the United States in 1966 as a Fulbright-Hays scholar. In 1974 she received a Doctoral of Sciences Degree from the University of Barcelona, Spain, following completion of a thesis carried out at Thomas Jefferson University, Philadelphia. She then worked at the West Coast Cancer Foundation in San Francisco. Since 1988 she has been the Regional Adviser in Radiological Health at the Pan American/World Health Organization in Washington, DC, where she advises the Ministries of Health of the Americas concerning the development and adoption of Radiological Standards. She is an ABR examiner and a Fellow of the ACR.

FOR THE PROPOSITION: David Goodenough, Ph.D.

Opening Statement

Standards for Image Quality and Radiation Exposure may sometimes be necessary, but they should be a course of last resort. The need for standards may often mean that the prevailing educational and common sense approaches have failed. In particular, such standards may set a

‘‘lower bar’’ of performance rather than lead to an ever-increasing search for improvement and optimization.

Standards also tend to breed bureaucracies of enforcement sometimes filled by power seeking individuals with little or no knowledge of the scientific facts. I am sure most of us could identify scores of agencies and groups considering such issues. Such bureaucracies add cost and consternation to many well-meaning endeavors.

Standards are particularly doubtful in a complex multivariable paradigm, such as the relationship between Dose and Image Quality. One variable may legitimately trade-off with another, e.g., increased resolution may lead to increased noise; or increased dose may be necessary for lower noise? Then too, Dose regulating bodies seem fond of imposing an upper limit on dose. Why not a lower limit? It could be argued that the worst radiation burden is Dose that cannot supply the required diagnostic information, as for example, an underexposed film. Moreover, consider the legitimate choices of image receptor sensitivity, resolution, film speed, grid ratio (or no grid). Speed differences range over orders of magnitude. Can anyone who is not thoroughly familiar with the scientific data monitor and regulate this choice? In fact, regulators would need thorough medical knowledge of the kinds of signals to be detected. It is probable that most individuals would far prefer to bear the risk of added radiation burden if it meant the difference between finding or missing a small life-threatening lesion.

Another important issue in regulation of image quality and radiation exposure is the differentiation between screening versus indicated studies. Clearly, a known cancer induction risk needs to be balanced against diagnostic efficacy of a screening device (such as mammography). In that sense, dose guidelines may be appropriate; however, even here a ‘‘one Dose limit fits all’’ approach does not always make sense. Exceptions may need to be made based on individual patient factors if it means the difference between detection or miss.

One problem is that standard groups seem to be moving into the arena of indicated procedures, e.g., CT scanners. It is my belief that the great majority of CT procedures can and should be performed for indicated reasons. In this case, it seems the benefit/risk ratio is already greatly in favor of the CT procedure. CT should not generally be used for screening purposes. Over the years, I have seen various CT vendors promote or criticize competitors’ Dose levels often out of envy of their image quality. Likewise, Dose optimization is often a cover for limited power capacity of x-ray tubes, or limited dynamic range of detectors. There may be many agendas in play at the same time.

More than standards, we need increased physician education of actual dose levels and the legitimate dose tradeoffs for Image Quality.

Rebuttal

I admire my counterpart for carefully defining her use of the term ‘‘standard.’’ In the sense of her definition of the term, I am not opposed to the concept of standards when defined as ‘‘precise criteria’’ or as ‘‘definitions.’’ Such attributes are the bulwarks of much of scientific methodology. I am certainly not opposed to ‘‘guidelines.’’ I do, however, continue to oppose that part of the definition that includes ‘‘rules’’ that, I believe, need a ‘‘regulatory body’’ to enforce.

My counterpart notes convincingly, with her example of the 200 vs 400 film speed issue, some of the many complications that may arise in standardization efforts. These are the kinds of issues that concern me.

I also agree with my counterpart, that standards for radiation dose and image quality should not divert the Medical Physicist's search for the best combination of both. However, the reality is that in today's managed care environment, the Medical Physicist may be an endangered species. Administrators may not be receptive to efforts to improve a situation that may involve additional costs, particularly when the current system ''meets the regulatory guidelines (rules).'' Other than a polarity change, the ''concern about cost'' gene may be similar in regulators and administrators.

I do not believe we should follow the European Community's compulsion to regulate and standardize everything, including aspects of dose and image quality. In my opinion, American Radiology and Medical Physics need broad opportunities for creative excellence, not rigidly formulated rules or standards that may actually impede exploration of improved techniques.

AGAINST THE PROPOSITION: Caridad Borrás, D.Sc.

Opening Statement

I strongly disagree with the application of W. Edwards Deming's concept of standards—mostly developed as production standards—to image quality/dose ratios.

According to the New Webster dictionary, a standard is ''anything taken by general consent as a basis of comparison, or established as a criterion.'' According to the International Organization for Standardization (ISO),[1] technical ''standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics to ensure that materials, products, processes and services are fit for their purpose.'' Based on these concepts, standards for image quality and dose should be understood as criteria that document the state of the art in image quality and dose at the time of their publication/adoption. They need to be revised as radiological technology and radiologists' training evolve. (ISO revises its standards every five years.)

The problem is that while there are published reference or guidance levels for diagnostic exposures,[2–4] there are few ''quantitative'' standards on image quality, and when they exist, they are not correlated with dose. For example, FDA's Quality Mammography Standards require phantom images with a ''minimum score'' (a quantity, albeit determined subjectively) and doses per craniocaudal exam not to exceed 3 mGy, an upper boundary. Correlation between dose and image quality was attempted in European guidelines on quality criteria, which were defined in terms of anatomical details seen in a radiograph.[4] However, in its final publication and with the objective of improving the recommended radiographic techniques, film speeds were changed from 200—the speed used in most of the facilities where reference doses were measured—to 400, which made the correlation invalid!

Measurements of image quality and dose and their comparison with the standards should not divert the Medical Physicist's search for the best combination of image quality and patient dose, but foster it. Furthermore, not implementing image quality/dose standards may result in regulatory authorities making compliance with diagnostic reference levels mandatory, regardless of image quality. Regulators' zeal for dose reduction, and their potential to equate low doses in

diagnostic examinations with good quality, may be detrimental for patients undergoing a radiological examination in a facility where the radiologist—because of his/her training—requires low noise images for an accurate radiographic interpretation.

Rebuttal

There are many issues in Professor Goodenough's opening statement with which I fully agree. It seems that we both abhor regulators, who ''seem fond of imposing an upper limit on dose.'' He questions, ''Why not a lower limit?'' Indeed, why not? It all depends on how standards are defined. The ''International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS)'' [3] states that ''guidelines levels'' are to ''be used as guidance by medical practitioners'' and are to ''be derived from data from wide scale quality surveys.'' It stresses that ''corrective actions'' are to ''be taken as necessary if doses or activities fall substantially below the guidance levels and the exposures do not provide useful diagnostic information and do not yield the expected medical benefit to patients.'' Also, ''reviews'' are to ''be considered if doses or activities exceed the guidance levels as an input to ensuring optimized protection of patients and maintaining appropriate levels of good practice.'' However, ''these levels should not be regarded as a guide for ensuring optimum performance in all cases, as they are appropriate only for typical adult patients and therefore, in applying the values in practice, account should be taken of body size and age.'' Characterized in these terms, who can argue that these standards will not benefit patients? No wonder they were endorsed by the member states of six international organizations!

I agree that the relationship between dose and image quality is a complex issue and that ''more than standards we need increased physician education of actual dose levels and the legitimate dose trade off for image quality.'' However, how is this education to be achieved if the radiologists do not have the means of comparing and judging what they do? How many radiologists are aware of the doses involved in certain procedures? How can they optimize patient protection without dose/image quality relationships? Why can they not participate in their formulation? Who says that standards are synonymous with regulations?

I disagree that ''standards may set a 'lower bar' of performance.'' Why should they? Do we stop when we reach a goal or do we use it as a stepping stone to further improvement? Alas, the answer does not lie in physics, but in human nature with its inherent quest for perfection.

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4.6. Diagnostic ultrasound should be performed without upper intensity limits

William D. O'Brien, Jr. and Douglas Miller
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OVERVIEW

As with most diagnostic technologies, ultrasound imaging reflects a trade-off between image resolution and energy absorption in tissue. With diagnostic ultrasound, current upper limits on beam intensity have not been correlated with demonstrated harmful effects. Microcavitation has been observed at intensities near these limits, but its biological significance is unknown. This Point/Counterpoint explores whether upper intensity limits should be removed to permit improvements in the quality of ultrasound images.

Arguing for the Proposition is William D. O'Brien, Jr., Ph.D. Dr. O'Brien is Professor of Electrical and Computer Engineering and of Bioengineering, College of Engineering; Professor of Bioengineering, College of Medicine; and Director of the Bioacoustics Research Laboratory at the University of Illinois. Previously, he worked at the Bureau of Radiological Health (currently the Center for Devices and Radiological Health) of the U.S. Food and Drug Administration. He is a fellow of four professional societies; has served as president of the IEEE Ultrasonics, Ferroelectrics, and Frequency Control Society and the American Institute of Ultrasound in Medicine; and is Editor-in-Chief of the IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control. His research interests involve the many areas of ultrasound–tissue interaction, including spectroscopy, risk assessment, biological effects, tissue characterization, dosimetry, and imaging for which he has published 215 papers.

Arguing against the Proposition is Douglas Miller, Ph.D. Dr. Miller is a Senior Research Scientist at the University of Michigan Department of Radiology. He received a Ph.D. in Physics from the University of Vermont in 1976, and worked at Battelle Pacific Northwest National Laboratory on bioelectromagnetics and ultrasonic biophysics research before moving to Michigan. Dr. Miller has served on ultrasound safety review groups of the American Institute of Ultrasound in Medicine, World Federation of Ultrasound in Medicine and the National Council on Radiation Protection and Measurements. Present NIH projects include research on the bioeffects associated with contrast aided diagnostic ultrasound and on ultrasound enhanced cancer gene therapy.

FOR THE PROPOSITION: William D. O'Brien, Jr., Ph.D.

Opening Statement

Regulatory control of diagnostic ultrasound equipment in the U.S. can be traced to passage of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act. When the FDA initiated the regulation of diagnostic ultrasound equipment in its 1985 "510(k) premarket notification," *application-specific* intensity limits were set that manufacturers could not exceed.

The 510(k)'s purpose was for the FDA to assess if a new device was "substantially equivalent," in safety and effectiveness, to diagnostic ultrasound equipment on the market prior to 1976. However, the intensity limits were *not* based on safety or effectiveness but rather on the maximum intensity limits of diagnostic ultrasound equipment at the time when the Amendments were enacted, in 1976; hence the term *pre-amendments levels*. To emphasize the FDA's date-based regulatory approach, as opposed to safety and efficacy based, the American Institute of Ultrasound in Medicine notified the FDA in mid-1986 that there existed prior to May 28, 1976 at least two diagnostic ultrasound devices with intensity levels greater than the 1985 *application-specific* intensity limits. In early 1987, the FDA updated their limits to the higher intensity levels.

Following widespread approval of the voluntary Output Display Standard (ODS) in early 1990, the FDA essentially adopted the ODS for its regulatory guidelines. The ODS did not include upper limits. Nevertheless, the FDA added *application-nonspecific* guideline upper limits that were still based on the 1976 *pre-amendments levels*.

Problems with the date-based upper-limit regulatory approach include (1) a complicated set of rules and procedures by which manufacturers verify to the FDA that their equipment is in compliance, and the costs associated with these requirements; (2) a perception that these upper limits are safe; (3) a demonstrated lack of attention to ODS education materials about the safety-based biophysical indicators; (4) the exposure of patients at these upper limits for which there may be safety concerns; (5) a limiting of future clinical benefits by preventing the development of more advanced diagnostic ultrasound systems at higher levels; and, finally, (6) a recognition that limiting diagnostic ultrasound capabilities may, in fact, be responsible for greater patient risk due to either an inadequate diagnosis, or to the use of an additional diagnostic procedure for which there is a defined risk.

The elimination of the upper-limit regulatory approach would have the following benefits: (1) a less complicated set of rules and procedures by manufacturers, and at less cost; (2) the elimination of the perception that there are safe limits; (3) more attention to the ODS education materials; (4) more attention to the ODS-based biophysical indicators; (5) making available research opportunities to develop advanced diagnostic procedures; and (6) providing the diagnostic capability to obtain an adequate diagnosis if higher levels are required.

To apply rigid controls to ultrasound intensity without a proper scientific justification benefits no one, particularly the patient. The physician is a professional trained to provide health care by making informed benefit–risk judgements. The FDA's regulatory approach had denied the physician the *need* to become informed about such benefit–risk issues, and for that we are all worse off.

Rebuttal

The current government-mandated upper-intensity-limit regulatory approach has placed the risk side of the risk–benefit decision on the FDA, not with physicians trained to make such decisions. This is not how good medicine should be practiced. In an ideal world, the government would protect us. The government consists of individuals like you and me, and none of us have the knowledge or wisdom to know how to provide long-distance protection. Protection goes well beyond making sure that diagnostic devices do not produce any bioeffects. Protection must include on-the-scene decision making. In other words, a fundamental clinical issue is an accurate and safe diagnosis of the patient. That is why physicians receive extensive training in the risk–benefit decision making process.

My opponent argues that risk can be eliminated by limiting outputs to values below the threshold. Obviously, this refers to ultrasound-induced risk. What about the risk associated with an insufficient diagnostic quality image? What about the follow-on diagnostic procedure that might have a significant hazard? We cannot view risk narrowly. It must be viewed in the broadest sense, that of providing the best diagnosis of the patient.

My opponent also argues that limits provide a conceptual separation between diagnostic and therapeutic uses of ultrasound, and that built-in safety limits free the operator from basic issues such as safety, equipment operation, and complex dose calculations. Arbitrary boundaries between types of equipment are artificial, but operator training is not. Users must have appropriate training. The safety issue must be argued on what is best for the patient's health.

My opponent finally argues that without limits, manufacturers would be prone to engage in competition for higher power for anticipated marginal increases in image quality. Even if these were true, and this is unsupported, the marginal increase in image quality might make the diagnostic difference for some patients. Is this not worth it? Should we not try it?

AGAINST THE PROPOSITION: Douglas Miller, Ph.D.

Opening Statement

The use of upper limits appears to be an ideal way to promote the safety of diagnostic ultrasound examinations. Bioeffects of ultrasound occur by way of indirect mechanisms, such as heating or acoustical cavitation, and appear to have identifiable thresholds. The risk of such an effect can be eliminated by limiting outputs to values below the threshold. Of course, the exact forms and values of upper limits on instrument output should be continually questioned and improved. The present guideline limits[1] are arbitrarily linked to the state of the art in 1976, rather than to scientific principles.

However, through deliberation and consensus within the ultrasound community, the restrictive limits originally applied to many examinations have been raised to the benefit of effective diagnosis. In addition, on-screen readouts of thermal and mechanical exposure indices provided on many recent systems are valuable for the identification and management of worse-case conditions, for which some potential for bioeffects exists with current machines both from heating (most likely of bone) and from mechanical effects (most likely on lung or intestine).

The use of well-chosen upper limit guidelines for diagnostic ultrasound also has several other benefits. Limits provide a conceptual separation of diagnostic and therapeutic uses of ultrasound, thus delineating regimes for patient safety on the one hand, and for effective treatment (e.g., physical therapy, surgery, or lithotripsy) on the other hand. Simple built-in safety limits free the operator from complex dose calculations, detailed risk/benefit determinations or extensive safety training for use of an instrument. Furthermore, authoritative upper limits engender a degree of public confidence in the safety of examinations not possible without them.

Eliminating upper limit guidelines is a bad idea for several reasons. If this were done, instrument manufacturers would be prone to engage in competition for higher power for anticipated marginal increases in image quality (e.g., a doubling of intensity only provides an additional 6% imaging depth, even for linear propagation[2]). Alternately, higher output power might be

substituted for expensive receiver amplifiers, thus increasing risk with no real patient benefit. Most importantly, it seems likely that patient harm would eventually be encountered.

In summary, guideline upper limits for diagnostic ultrasound have many advantages, and even the present imperfect limits have served manufacturers, physicians and patients well. Eliminating limits, which would likely be of only marginal value for improving image quality, would also eliminate the confidence of the medical community and the general public in the safety of diagnostic ultrasound examinations. Diagnostic ultrasound should not be performed without upper intensity limits.

Rebuttal

Dr. O'Brien has clearly stated the problems perceived to be associated with the existence of guideline upper limits for diagnostic ultrasound. However, removing the present limits would not solve the problems he has listed because (1) manufacturers would still have to follow complicated procedures in order to provide the output display indices for FDA clearance; (2) the present limits are justified, to some extent, by extensive research and through considerations of bioeffects mechanisms; (3) the elimination of limits would do little to advance knowledge or education about safety issues; (4) safety concerns related to present outputs would certainly not be ameliorated by the removal of upper limits; (5) in fact, higher levels are not prohibited, and a truly compelling new device requiring levels in excess of the guidelines can gain FDA approval by demonstrating safety and efficacy; (6) greater advances in diagnostic ultrasound would be obtained by improving training in imaging procedures, safety issues, and diagnostic interpretation than by slight improvements in images at higher intensities.

The removal of guideline limits would permit manufacturers to design diagnostic ultrasound instruments to engineering limits regardless of safety issues, even though the engineering objective may not serve more general medical needs and desires. Physicians and sonographers should focus on the art of sonography and diagnosis rather than on complex safety issues related to the selection of an intensity for each examination. Many patients do not receive any discernible benefit from a diagnostic test, and consequently expect to be protected from unnecessary levels of risk. The present upper limit guidelines, though less than perfect, satisfy these general needs and work well in the real world of incomplete safety information and inadequate education. Manufacturers, sonographers, and patients all benefit from the framework provided by the existing approval process. Guideline upper limits for diagnostic ultrasound should be continually improved, but should not be removed.

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CHAPTER 5

X-Ray Imaging

5.1. In the next decade automated computer analysis will be an accepted sole method to separate "normal" from "abnormal" radiological images

Kenneth R. Hoffman and Joel E. Gray

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OVERVIEW

Computer-assisted analysis of radiographs has proven effective in enhancing the detection of lesions, especially in mammographic and chest images. Most articles describing this technology have emphasized that automated computer analysis is adjunctive to, and not a substitute for, review of films by a radiologist. Yet ROC curves for lesion detection with automated analysis alone are comparable to those of radiologists alone. In comparing these techniques as a method to separate ‘‘normal’’ from ‘‘abnormal’’ images, one should recognize that computer analysis does not have to be perfect; it needs to be only as good as the typical radiologist. This issue of Point/Counterpoint examines the future feasibility of using computer analysis alone as a way to separate ‘‘normal’’ from ‘‘abnormal’’ images.

Arguing for the Proposition is Kenneth R. Hoffman. Dr. Hoffmann received his Ph.D. in solid state physics from Brandeis University in 1984. He joined the Kurt Rossmann Labs at the University of Chicago in 1984. He is currently an Associate Professor of Radiology at the University of Chicago. He has been active in research in vascular imaging, 3D reconstruction from biplane and single-plane images, computer-aided diagnosis (CAD) of lung diseases from single projection images, and analysis of CT data sets with the goal of facilitating application of CAD techniques to 3D data sets.

Arguing against the Proposition is Joel E. Gray. Dr. Gray received his Ph.D. in Radiological Sciences from the University of Toronto in 1977. He joined the Department of Radiology, Mayo Clinic where he was a Consultant and Professor in the Mayo Graduate School of Medicine until 1997. He introduced the concept of quality control to medical imaging in 1976 and published *Quality Control in Diagnostic Imaging*, and coauthored the ACR Mammography QC Manual. He has published over 130 papers in peer-reviewed journals on most aspects of diagnostic medical physics. Dr. Gray is an independent consultant to healthcare organizations, industry, and government in Medical Technology Management and Assessment, Medical Physics, and Imaging Sciences.

For the proposition: Kenneth R. Hoffman

Opening Statement

Computer analysis is already being used to separate normal from abnormal images. The many receiver operating characteristic (ROC) trials of various computer-aided diagnosis schemes rely on computer analyses to specifically perform this task. Over the years, a number of these analysis techniques have improved in accuracy, and, more importantly, in sensitivity *and* specificity, that is, the area under the ROC curve (the classification performance) for these analyses has increased. Some of these techniques are currently outperforming residents and attendings, though not the experts, not yet. A number of investigators (and study section members) see opportunities for improving these techniques further by using neural network training and case-based reasoning because of their similarity to human ways of learning.

So far, most computer analyses perform a specific task, usually a binary task of evaluating images for a specific disease. To date, no computer algorithm can take an image and evaluate whether *and* which disease is present. For this evaluation, more than the image information alone must be presented to the computer, as it is to the radiologist. Indeed, many computer analyses have become more sophisticated with clinical information incorporated with image information to improve further classification performance. Some preliminary results for differentiating specific types of lung disease have appeared. We can expect analysis techniques to continue improving. Cognizant of the history of computer analysis of radiographs, can we rationally say that for some (and perhaps increasing numbers of) diseases, normals and abnormals will never be separated by the computer alone? Will radiologists always defeat a ‘‘Big Blue’’ of radiology? It seems that the question is not whether, but when, will computers be allowed to read radiographic images in place of radiologists?

The answers to these questions depend on the criteria that are used to determine whether (when) computers can be left alone to diagnose groups of patients or a particular patient. When would you *want* a computer evaluating your radiograph as opposed to a nonradiologist, an attending who reads those types of studies occasionally, or an expert? What are you willing to pay? For yourself or as part of society?

At least in part, the issue here is ‘‘alone.’’ Does the computer have to replace the radiologist in all aspects of diagnosis, i.e., be left alone, without the occasional intervention by expert radiologists? Resident physicians do not function in this manner. Attendings refer to colleagues with greater expertise in various areas. Radiologists receive certification (of expertise) for various specialties. Should we not think about applying the same standard to the computer? Are there (initially) simpler tasks which could be performed by the computer?

Could the computer be asked, for example, to ‘‘rule out pneumonia’’? When should computers be allowed to make the decision to call in an expert, as an attending would do?

We need to answer these questions, and we will. It is a question of when.

Rebuttal

With the last sentence in his initial argument, Dr. Gray implies that it is no longer a question of whether computer technology will be used to differentiate normals from abnormals, rather it is a question of *when* to ‘‘bless’’ it.

Computer aided diagnosis (CAD), as a second opinion, has already been shown to improve diagnostic accuracy. False positive rates continue to drop as techniques improve (for example, in mammography), and studies indicate that false positives from CAD have not resulted in increased call backs. When techniques outperform individual radiologists in detection and classification ~as some currently do!, are we to deny patients the right to a more accurate diagnosis? Are we willing to pay the additional emotional and financial costs when we do *not* use the results of the (more accurate) computer analysis? Who will be willing to tell the patient that the film *has* to be read by a radiologist, especially when that radiologist may be less accurate than the computer?

Results indicate that with CAD diagnostic accuracy can be increased while reducing the time for diagnosis, primarily by facilitating sorting out the ‘‘normals.’’ When ‘‘for sure normals’’ are determined with greater accuracy than a given radiologist can achieve, will that radiologist not *want* to use the computer and have more time to inspect the ‘‘abnormal’’ cases? Will we demand that a radiologist read *every* film, even though the computer reads at least some subset of films more accurately and quickly? The experience with Pap smear testing may provide some insight and a precedent.

Use of the computer for diagnosis will demand increased involvement by the medical physics community. This technology needs to be developed further, evaluated properly, and monitored carefully. Medical physicists in particular have an obligation to patients to perform these duties specifically because of their understanding of the variety of issues and their expertise in addressing them.

Against the proposition: Joel E. Gray

Opening Statement

Computer assisted diagnosis (CAD) has been in the wings for many years. Hopefully it will stay in the wings! Although several groups are working to ‘‘perfect’’ CAD, it is doubtful that it will ever be widely adopted by radiologists. Would medical physicists accept software that would make their jobs unnecessary? A dosimetrist with software could easily replace a medical physicist in radiation oncology—but who would benefit from this? The administration may save a few dollars on the medical physicist’s salary. However, elimination of the professional input from highly skilled medical staff (be they radiologists or medical physicists) is not in the best interest of the patient and quality healthcare.

Proponents claim that CAD will improve diagnostic accuracy, i.e., lesions will not be overlooked by the radiologist. However, CAD systems are not perfect and introduce false positives. These false positives increase the time the radiologist must spend on a particular case. They also increase the number of biopsies or other diagnostic procedures, thereby increasing the cost of medical care. Health economists tell us that there are already too many biopsies in mammography, and that we should be doing everything possible to reduce the biopsy rate.

What is the advantage to a diagnostic radiologist to have cases separated into ‘‘normal’’ or ‘‘abnormal’’? Will the typical radiologist trust the computer and sign-off on ‘‘normal’’ films

without reading them? Who gets sued for malpractice if the patient with a ‘‘normal’’ examination (which was not read by a radiologist) is found to have malignant disease six months later, and the lesion was present in retrospect in the ‘‘normal’’ film? If the radiologist trusted the computer and signed off on the film, then the radiologist will be spending a lot of time with attorneys.

And what about ‘‘abnormal’’ films? The radiologist will, by necessity, spend a lot more time looking at these ‘‘abnormal’’ films, especially when the computer indicates disease in a region that appears normal to the radiologist. ROC curves clearly demonstrate that we can reach perfection (100% true positive rate) if we are willing to tolerate an increase in the number of false positive readings. However, each and every false positive comes at an additional cost, both emotional and financial. The emotional cost is borne by the patient who is told there is a suspicious area in her breast and a biopsy is recommended. From the time these fateful words are spoken until the biopsy results prove that there is no disease, the patient will be in such emotional turmoil that words cannot possibly describe her feelings. The financial cost will be borne by the insurance company or healthcare system, which ultimately means the patient. All of us will pay increased premiums to cover the cost of more biopsies or additional examinations to assure the radiologist that disease is not present.

So what are the reasons for wanting to adopt this technology? Just because it is computer based does this mean it is better for patient care? Is technology driving our healthcare decisions, or do we control the technology that will be used? The proponents of full breast digital mammography are required by the FDA to demonstrate that the diagnostic capability of this ‘‘new modality’’ is at least as good as screen- film mammography. As a result, several controlled clinical trials are being carried out by manufacturers to compare screen-film and digital mammography. Why has CAD not undergone similar scrutiny? Where are the clinical trials of several thousand patients that indicate the efficacy of CAD, the added cost in terms of the radiologist’s time, and the increased number of biopsies or other additional diagnostic examinations?

We should not accept technology for the sake of technology. CAD may offer benefits in the future, but it is unclear at this time exactly what those benefits are. It is time for extensive clinical trials before the FDA blesses this technology for use in the diagnostic armamentarium.

Rebuttal

While Dr. Hoffman and I agree that computer assisted diagnosis (CAD) is not ready for prime time (not ready for clinical application), our views diverge on most of the other issues associated with this topic. Software available today can sort unknown films into ‘‘normal’’ and ‘‘abnormal’’ for limited disease states. However, the radiologist is normally faced with the potential for any of a number of diseases and in some cases, multiple diseases, something which cannot be addressed by today’s software. Most importantly, how can software handle the myriad of potential diseases or conditions often discovered and referred to as ‘‘incidental findings?’’

Can software locate a fractured bone when it is looking for pulmonary nodules; a soft tissue tumor when it is looking for a fractured femur; or tuberculosis when ruling out pneumonia? These are the tasks which separate the non-radiologist physician from the radiologist when reading films, or separate the radiologist from the radiology-expert.

Dr. Hoffman asks if you are willing to pay for a non-radiologist or an attending to read your films, or if you want the expert to read them. This is not really the appropriate question! The real

question is ‘‘Are you willing to pay the price of a poor or missed diagnosis when the expert did not read your films?’’ This price could be additional tests, unnecessary surgery, or the possibility of a serious condition not being diagnosed in a timely manner leading to complications or worse. When CAD reaches the performance level of the expert this will not be an issue. In fact, when CAD reaches the expert level then all films should be ‘‘read’’ by the computer. Unfortunately, this is not the time—and that time will not come for at least another ten years!

5.2. In x-ray computed tomography, technique factors should be selected appropriate to patient size

Walter Huda and Stewart C. Bushong
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OVERVIEW

A *USA Today* article in mid-January claimed that 1500 deaths will occur annually as a consequence of CT exams to the heads and abdomens of children. The article states that most of the deaths could be avoided by "calibrating" the scanners (i.e., using technique factors) appropriate for children rather than adults. A few physicists had advocated the adjustment of CT technique factors to patient size well before appearance of the *USA Today* article. Others feel that the article is editorial hyperbole, and that there is no compelling reason to alter technique factors. This controversy is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Walter Huda, Ph.D. Dr. Huda obtained his Ph.D. in medical physics at the Royal Postgraduate Medical School (Hammersmith Hospital) at the University of London. Dr. Huda worked for five years at Amersham International, a company specializing in radioactive products. In 1982 he moved to North America, and worked in medical physics at the Manitoba Cancer Treatment and Research Foundation (Winnipeg) and the University of Florida (Gainesville). Dr. Huda is currently Professor of Radiology at SUNY Upstate Medical University (Syracuse), and Director of Radiological Physics. His research interests are in medical imaging and radiation dosimetry, and he has published over 150 papers.

Arguing against the Proposition is Stewart Bushong Sc.D. Dr. Bushong obtained his doctorate at the University of Pittsburgh and then joined the faculty of Baylor College of Medicine where he has enjoyed an exceptionally productive 35 years. During that time he has published over 125 scientific papers and 30 books. Radiologic Science for Technologists, now in its 7th edition, is the standard text for such training programs. He has always been active in the affairs of the AAPM and ACMP.

FOR THE PROPOSITION: Walter Huda, Ph.D.

Opening Statement

X-ray CT scanners are digital imaging systems that offer users a wide range of latitude in terms of technique factors (i.e., mAs and kVp). Choice of technique factors affects the image contrast to noise ratio (CNR) and patient dose, both of which are dependent on the size of the patient.

Increasing the patient weight from 10 to 120 kg for abdominal CT scanning reduces the transmission of x-ray intensity by about a factor of 100.[1] Maintaining the *same* radiographic technique factors results in the CNR being determined by the size of the patient![2] This state of affairs is illogical, since CNR should be determined by the imaging task at hand. Maintaining the same technique factors for infants substantially increases image CNR.[1] There are no data

whatsoever that this procedure improves diagnostic performance. On the contrary, increasing evidence indicates that CT technique factors could be reduced, with no loss of image quality.[3]

In large US hospitals, CT scanning accounts for more than 10% of diagnostic radiology examinations and two thirds of the radiation dose.[4] The lifetime cancer mortality risk for a one-year-old patient attributable to the radiation exposure from an abdominal CT is estimated to be 0.18%.[5] Individual and collective CT doses are substantial, and need to be taken seriously. Although the issue of radiation risk associated with low doses is controversial, it is difficult to argue against the *as low as reasonably achievable* dictum recommended by the International Commission on Radiological Protection. Given that a CT examination is justified by the benefits to the patient, there is no need to use more radiation than is required to obtain a diagnostic image.

There is little doubt that diagnostic CT scans of infants and children could be acquired using much lower technique factors,[1] with substantial savings in patient dose. Additional benefits include longer x-ray tube lifetimes and longer scan lengths in helical scanning. Taking into account the size of the patient is simple to achieve,[6] eliminates unnecessary radiation to patients, and carries no significant penalty. Modifying CT techniques to account for patient size is clearly the "no brainer" of a recent editorial in the *AJR*.[7]

Rebuttal

There appear to be many areas of agreement between Dr. Bushong and myself. Radiographic technique factors should be adjusted to take into account patient size and to eliminate unnecessary radiation exposure. There are large uncertainties in current radiation risk estimates, and it is theoretically possible for "benefits" to exist at low radiation levels (hormesis). There are substantial benefits to be gained from radiographic imaging procedures such as CT, but these should always be weighed against estimated radiation risks.

At organ doses of tens of mGy associated with CT examinations, there are no definitive scientific data related to (any) radiation risks. There is also insufficient knowledge of radiation-induced carcinogenesis to make theoretical predictions. Accordingly, the scientific community cannot quantify radiation risks from CT examinations. Furthermore, determining what level of risk is "acceptable" is *not* a scientific issue.[8,9] Society as a whole, through the normal political process, must decide how to deal with current uncertainties in the scientific understanding of radiation risks. My (political) preference is to agree with the ICRP philosophy which requires that exposures be justified by the benefit received by the patient, and elimination of all unnecessary radiation.

Historically, medical physicists working in diagnostic imaging have paid considerable attention to equipment specification, commissioning of imaging systems, and ongoing QC programs. Imaging equipment is becoming increasingly complex, and patient-imaging protocols would benefit from *explicit* input from medical physicists. As imaging and radiation experts, medical physicists should help ensure that patients are examined in a manner that ensures optimal image quality. This requires the signal-to-noise ratio to be sufficient for the diagnostic task at hand, and that patients receive no more exposure than is required for diagnosis.

AGAINST THE PROPOSITION: Stewart Bushong, Ph.D.

Opening Statement

At 7:30 a.m. on Monday January 22, 2001 I answered the phone and it was Robert Malone, M.D. By 9:00 a.m. that morning I had received three more phone calls. Inquiries by radiologists and patients haven't stopped yet. Headlines on the front page of that day's *USA Today* shrieked "CT scans in children linked to cancer later." "What does this mean?" "What do I tell my patients?" "Who is David Brenner?" The answers are quite simple but the damage done to CT imaging, and maybe to x-ray imaging in general, will be hard to correct.

I agree with Lee Rogers[7] that this is "a no brainer." Regardless of the x-ray examination, technique factors should be adjusted to body size or body part. This is basic training for radiologic technologists. The paper by Donnelly *et al.*[6] is good medicine for facilities that do not now practice technique optimization. The paper by Paterson *et al.*[10] should not have been published. Check the Results section . . . "(chest and abdomen) medical CT examinations (n = 58)....and children (n = 32)" . . . "in one (11%) of these examinations . . . "

Based on a study population of 90, conclusions are suggested for the US population which allowed *USA Today* to report "about 1.6 million children in the USA get CT scans . . . and about 1500 of those will die later in life . . . " This is *not* the experience at the CT imaging facilities of the Texas Medical Center.

Brenner's paper[5] and the two companion papers[6,10] in the February issue of the *American Journal of Radiology* conveyed the correct message. If CT technique is not adjusted to patient size, some patients, especially children, will be exposed to unnecessary radiation dose. Fair enough! A good message for those few facilities that do not presently reduce technique for pediatric patients.

However, Brenner performs calculations suggesting that the alleged unnecessarily high dose in pediatric examinations causes 1500 excess cancers in children. This is the message that was picked up by *USA Today*.

If a single pediatric CT examination is refused by a parent worried about the consequence of a CT radiation exposure, far greater harm could be the result.

I wish to thank David Brenner for the reminder about dose efficiency. However, why couldn't he, or someone, title the paper "Estimated Benefits . . . " rather than "Estimated Risks . . . "? The flawed exercise regarding risk may be academically satisfying but is having the negative effect of replacing patient *care* with patient *scare*. The application of BEIR W_T coefficients without acknowledging the current raging debate over the linear nonthreshold dose response relationship,[11,12,13] and the postulated existence of radiation hormesis,[14] results in a great disservice to our patients and our colleagues. It is a one-sided statistical exercise that should have been balanced with an outcome analysis of the benefit of pediatric CT examinations.

But then there would have been no headlines.

I could critically respond to Brenner's simplistic approach to radiation risk. His assessment is one of an attributable risk. It is not a real risk. Much damage has been done by such exercise of academic privilege. If Brenner had only stayed the course of his main conclusion—adjust dose by CT technique to body size or part, as we do consistently for radiography.

Rebuttal

It is hard to argue with the stated proposition or with Dr. Huda's opening statement. Technique optimization is a principle component of all radiography training programs. Radiologic technologists certified in CT by the ARRT are expected to know technique optimization in CT. Indeed, most CT operating consoles have pediatric techniques as part of the selection protocols.

I fear that the fuss generated by the *AJR* articles will lead to another layer of government radiation regulations. I hope the ACR recognizes this possibility as it develops its CT accreditation program.

Look what happened with mammography. First voluntary ACR accreditation, then mandated federal regulations—MQSA. Clearly MQSA has been a success, but at what a cost—registration, medical physics acceptance testing and continual performance evaluation, followed by the inspection process.

So we are detecting more breast cancer earlier and making a dent on breast cancer mortality. The question is, how much of this benefit can be attributed to MQSA? I suspect very little because radiology is self driven to excellence in every area.

I have never seen an outcomes analysis of mammography relative to MQSA and I bet I never see an outcomes analysis for pediatric CT regardless of radiation dose.

On the other hand, as I have preached to medical physicists may times . . . radiation regulations are good for us. They should be developed with four C's in mind: The more *complex*, the better; the more *confusing*, the better; the more *convoluted*, the better; and, the more *costly*, the better. MQSA could be renamed MPSA—Medical Physicist Security Act!

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5.3. Next-generation x-ray CT units will provide <500 msec images with 3D resolution comparable to today's projection radiography

Mahadevappa Mahesh and Dianna Cody
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OVERVIEW

Some physicist savants believe that spiral scanning is just the beginning of a new generation of CT units, and x-ray tubes with greater output and x-ray detectors with faster response will provide images in the not-too-distant future that meet the specifications stated in the proposition. Other thoughtful physicists consider this belief to be wishful thinking, not only because of technology limitations, but also because it reflects a technology imperative that is unrealistic in today's cost-conscious healthcare environment. This difference in opinion is the Point/Counterpoint topic for this month's issue.

Arguing for the Proposition is Mahadevappa Mahesh, Ph.D. Dr. Mahesh is the Chief Physicist at Johns Hopkins Hospital and is on the faculty at Johns Hopkins University School of Medicine, Baltimore. Dr Mahesh obtained his Ph.D. in Medical Physics from the Medical College of Wisconsin. He is past president of the Mid-Atlantic Chapter of AAPM, and serves on several AAPM committees. Dr Mahesh is currently the Curator for the Partners in Physics program. He is certified in Diagnostic Radiologic Physics from the American Board of Radiology, and is a member of the Radiation Control Advisory Board for the State of Maryland. He was the director for the continuing education course on CT and for the symposium on CT dose reduction at the 2002 AAPM annual meeting.

Arguing against the Proposition is Dianna D. Cody, Ph.D. Dr. Cody trained as a bioengineer at the University of Michigan and attained board certification in Medical Physics (Diagnostic) while on staff at Henry Ford Hospital in Detroit, Michigan. She spent 13 years at Henry Ford, and in 2000 she joined The University of Texas M.D. Anderson Cancer Center in Houston, Texas as an Associate Professor. She is Co-Director of the Image Processing Laboratory, and provides CT physics support for 11 clinical scanners, 2 research scanners, and 4 scanners housed in therapy. She is also involved in small animal CT imaging research, CT medical physics graduate education, and CT related workshops for practicing medical physicists.

FOR THE PROPOSITION: Mahadevappa Mahesh, Ph.D.

Opening Statement

CT technology has evolved considerably over the past 30 years. Evolution of the technology can be viewed as a progression towards optimizing the information content of CT images and extending the method to three dimensions, i.e., to achieve isotropic resolution—the holy grail of medical imaging.[1] I believe that the technology is poised for further breakthroughs with scanners capable of rotation speeds less than 500 msec, while providing very high resolution images as

stated in the proposition. In defense of the proposition, scanners reaching the marketplace can already operate at 400 msec scan speeds with very high spatial resolution.[2]

Before spiral CT, critics thought that CT technology had reached a plateau and further developments would not be cost effective. Moreover, true 3D reconstructions were thought to be impractical in body regions subject to physiologic motion. However, technological advances such as slip-ring gantries, high power x-ray tubes and interpolation algorithms produced a true technological revolution.[1] With early single row spiral CT scanners, 3D volume acquisitions within a single breath-hold became possible. Still, resolutions approaching isotropic could be attained only over very small volumes with very high tube loads.[3] During the latter part of the past decade, considerable progress has been achieved with introduction of multiple row detector array CT (MDCT) (2-sections and 4-sections per rotation). Now, with introduction of 16+ section scanners, it is possible to scan at sub-millimeter spatial resolution with high temporal resolution.[4]

The next generation of CT scanners will provide scan speeds of less than 500 msec per scan rotation, aiming towards 100 msec scan speeds. The latter scan speed is ideal for cardiac imaging without physiologic motion to yield very high spatial and temporal resolutions. Fabrication of thin detectors (0.5–0.75 mm) with very fast response times (e.g., ceramic scintillators) will enable acquisition of images of thin sections with high spatial resolution in all directions. In addition, development of cone beam reconstruction algorithms, now capable of achieving 8 to 16 thin sections per rotation, will generate even more sections (32–40) per rotation.[5,6] With modern reconstruction algorithms it is possible to achieve very high temporal resolution on the order of 100–200 msec, enabling new protocols like CT angiography.[7] Also, the number of detector rows in the *z*-direction will increase from 16 to 40 to 64 and beyond. Already there is progress towards fabricating even greater rows of detector elements (256 rows) to permit a larger volume acquisition in a very short time. The arrival of flat panel detectors, development of sophisticated cone beam reconstruction algorithms,[7] and utilization of high speed computers to handle voluminous scan data, are not very far in the future. These advances will be accompanied by light-weight x-ray tubes with minimal moving parts, detectors with faster response, and even faster computers. Rising health care costs might impede further spending on new technologies. As seen in the past, however, the initial cost of new technologies does not tend to hinder the ultimate progress of medical technology.

As stated in the proposition, new generation CT scanners will make high resolution, 3D CT images a reality in the near future. These scanners will pave the way to newer clinical applications, further widening the application of CT in medicine worldwide.

Rebuttal

Dr. Cody and I agree on the stated proposition; our differences are in the "time and challenges" in achieving it. I agree that the next generation CT (it all depends on how "next generation" is defined) may not be able to provide 3D images of quality comparable to projection radiography. However, I respectfully disagree on some of the reasons she lists in her opening statement.

The goal of CT has always been to provide images of spatial resolution similar to projection radiography, but in three dimensions. It is true that the cost of CT is greater than projection radiography, but so too is the information it provides. The increased information from multidetector CT has led to additional clinical applications, including several in cardiology. With increasing utilization, the cost of the scanner and its maintenance shrink in comparison with the revenue the scanner generates.

The increasing workload to process 3D data sets is certainly due to the data explosion of multidetector CT. Novel methods to manage large data sets and workstations are being developed. When cross-sectional CT was introduced, a relatively short time was needed for clinicians to adjust to reading CT images. Similarly, clinicians will learn relatively quickly how to handle 3D images. Yes, the initial costs of presenting and managing large data sets are higher, but the effectiveness of 3D images on diagnosis will overcome this cost over time. At our institution, the chief of surgery insists on seeing 3D images on his patients before performing surgery. I believe it is only a matter of time before every clinician demands the same.

I agree that the radiation dose in CT is very important. Even though the clinical content of most CT exams outweighs the radiation risks, one should carefully compare the risks and benefits before implementing newer applications. We in the medical physics community have an obligation to help our clinical colleagues perform better risk—benefit analyses for all new CT protocols. Increasing scrutiny on this issue has led manufacturers to reduce patient dose. In the near future, true automatic exposure-control CT systems may become available. It is always essential to consider the appropriateness of every CT examination.

Shorter scan time and higher spatial resolution are critical to image quality, especially for rapidly moving organs such as the heart. The current emphasis in CT technology is targeted primarily at imaging cardiac anatomy and function. In closing, I wish to emphasize that even though the challenges are many, they will be met and we will soon see very fast CT scanners capable of producing 3D images with resolution comparable to projection radiography.

AGAINST THE PROPOSITION: Dianna Cody, Ph.D.

Opening Statement

Arguing against this proposition is a bit like stating that the sun won't rise tomorrow. Ultimately, 3D imaging will provide results comparable to today's projection radiography. However, the challenges to this destiny are many and severe, and 3D imaging will not emerge with next-generation CT units. Instead, this evolution will require several iterations in its progression.

The major challenges to the progression of events are:

Cost: Increasing CT equipment utilization will shorten its lifespan and increase its maintenance cost. CT scans cost at least one order of magnitude more than projection radiographs. The current relative value unit (RVU) assessments for a single view P/A chest and a no-contrast routine chest CT exam are different by only about a factor of 6, due in part to the level of complexity of the examination.[8] Hardware and software needed to form 3D views would be required, along with the infrastructure to produce 3D images on a routine basis.[9] These requirements would further increase the relative cost of producing a 3D study.

Radiation Dose: The radiation dose delivered by CT is currently under scrutiny.[10] The difference in skin dose between a routine P/A chest radiograph and a routine non-contrast chest CT is about two orders of magnitude.[11,12] Even if we could produce 3D CT data sets that are comparable in resolution to radiographs today at this dose level, the question remains: Should we?

Workload: The time required to process a 3D data set is not trivial. Unless the data set preparation can be done accurately and automatically, radiologists will probably insist on making

manual adjustments to the resulting display. They will also expect the original CT images to be readily available for reference. The concept of interpreting only the 3D display in place of original CT images may be attractive, but it is unrealistic.

Scan time and resolution: Current CT scanners provide CT images in under 500 msec. This time limit constrains the 3D view to a short span (around 2 cm). A combination of faster gantry speed and wider x-ray tube collimation may further increase CT scan speed. Current multi-row system specifications claim 400–500 μm isotropic high-contrast resolution. This does not compare well to projection radiography available with resolution of 30–200 μm, depending on the application. Cross-sectional views do not include overlying anatomy and may not require as much resolution to detect abnormalities. Acquiring more CT data faster, however, may require tradeoffs that diminish low-contrast resolution.

There are other issues that should be considered. What about the cost of following up additional false-positive findings that would emerge from the CT images? And will the 3D data set, or just the 2D views of the 3D object, be saved to the picture archiving system (PACS)?

Although we are surely moving in the right direction, I believe that we are far from replacing routine projection radiography with 3D CT imaging. Nevertheless, applications of 3D CT imaging will likely continue to expand for specific diagnostic tasks.

Rebuttal

Dr. Mahesh has provided a concise summary of the evolution of CT technology, and has shared his vision of future CT innovations. There is very little in his opening statement to disagree with.

I would like to point out, however, that Dr. Mahesh has limited his discussion of cost to new technology development (buried in the CT scanner purchase price). The additional burden on radiologists, as well as the cost of a technologist to generate 3D views, must also be considered as an incremental expense over the price of obtaining and interpreting plane films. The need for a 3D workstation, an administrative infrastructure to manage the image processing activity, and additional PACS capacity are also nontrivial costs.

Lastly, the increase in radiation dose delivered by CT compared with projection radiography cannot be ignored. Currently in the U.S., concern about radiation exposure from CT exams is focused primarily on children. This concern will eventually extend to adults as well.

Before 3D CT replaces projection radiography, the benefits will need to clearly offset the drawbacks. This will need to be proven by carefully designed and conducted clinical research studies.

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5.4. Free-standing, self referral centers for whole-body CT screening should be closed, or at least restricted to at-risk patients

Richard Morin and Michael Broadbent

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OVERVIEW

Direct-to-consumer marketing of whole-body CT screening is occurring today in many metropolitan areas. Free-standing CT screening centers are being sited in shopping malls and other high-density public areas, and these centers are being advertised in the electronic and print media. Some physicists believe that the benefit:risk and benefit:cost ratios are too low to justify these centers, and they should be closed, or at least restricted to at-risk, physician-referred patients. Others feel that free-standing centers simply reflect a free-market economy, and that the principle of *caveat emptor* should prevail. Free-standing CT screening centers are the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Richard Morin, Ph.D. Dr. Morin is the Brooks-Hollern Professor, Mayo Medical School. He received his Ph.D. from the University of Oklahoma in Medical Physics. His dissertation concerned the use of Monte Carlo Simulation and Pattern Recognition for Artifact Removal in Computed Tomography. He was Director of Physics in the Department of Radiology of the University of Minnesota before joining Mayo Clinic in 1987. He is a Fellow of the ACR and a Diplomate of the ABR. Dr. Morin is a former President and Chair of the Board of the AAPM, and is currently a member of the ACR Board of Chancellors, chairing the Commission on Medical Physics.

Arguing against the Proposition is Michael Broadbent, Ph.D. Dr. Broadbent has been a consulting radiological physicist in the Midwest for 26 years. He received his Masters and Ph.D. degrees from UCLA, and is certified in radiological physics by the American Board of Radiology. He has been active in the RSNA/AAPM Physics Tutorial Program, the Illinois Radiological Society's Mammographic Accreditation Program, and the American College of Radiology's Mammographic Accreditation Program. He is on the Medical Physics staff at Rush University and assists in the instruction of Radiology residents.

FOR THE PROPOSITION: Richard Morin, Ph.D.

Opening Statement

This is America. Individuals are allowed to open any kind of business they wish as long as no law, rule, or regulation is trespassed. How does this freedom apply to self-referral centers for whole-body CT screening? First, such sites are banned by regulation in many states.[1,2] That fact notwithstanding, this controversial issue deserves thoughtful reflection. Medical screening generally implies the application of an inexpensive low-risk test to an entire or large segment of an asymptomatic population.[3,4] Clearly, CT is not inexpensive, and scanning the entire or even a substantial segment of the population is not practical. Hence, even the terminology "CT

screening" is misleading, or at best controversial. So why have such facilities and procedures emerged? The answer is clear: money! Oft-heard responses to this statement are: "Live and let live" and "No harm, no foul." But harm can be done. The results of false positive and false negative studies may cause severe anxiety, or a false sense of security in the individual. In either case, the best interest of the patient has not been served.

The follow-up of false positive findings in CT screening will cost the healthcare system millions of dollars. Screening 100 000 individuals for a disease which has a 1% prevalence, and for which CT has a 95% sensitivity and specificity, will yield about 5000 false positives.[5] Even if the prevalence is increased by an order of magnitude to 10%, the number of false positives will be 4500. The emotional and financial cost of false positives to both the patient and society is substantial. In addition, while the case may be made that the radiation risk is low for a 1–10 mSv examination, such widespread exposure for limited expected benefit is contrary to the fundamental principles of radiation safety.

These observations arise from a very fundamental issue. There is no scientific evidence that whole-body "CT screening" is worthwhile.[6] In fact, the major societies and agencies have issued public statements against the use of whole-body "CT screening." [7,8,9,10] The absence of medical evidence supporting the benefits of "CT screening" often brings this discussion to a boutique level of individual antidotes and aggressive marketing. While an understanding of this issue may not be present yet in the general public, readers of this journal certainly understand these principles. It is precisely in this light that the truth is revealed. Whole-body "CT screening" is a business, not good health care.

We end as we began. This is America. Individuals are free to open any kind of business they wish. Pretending that the business of "CT screening" is good health care is disingenuous at best, and scandalous at worst.

Rebuttal

My colleague has raised several interesting points. I concur with the assembly of statistics regarding the incidence and effects of cancer in the USA.

Unfortunately, the point raised in reference to the Mayo Clinic study[11] overlooked a few important details. First, this study dealt with lung CT screening of a population of 50+ year olds, each with 20 pack-years of cigarette smoking history. It did not consider whole-body CT "screening." Second, over 2200 nodules were followed and 25 were malignant. The authors conceded their concern about the "very high false-positive rate" [11] in this highly pre-selected population, and called for a randomized prospective controlled study. Third, the lead author later stated[12] that it is unclear if CT scanning is an effective screening test,[13] and called for a randomized controlled trial to answer this question.

Dr. Broadbent refers to possible radiation hormesis benefits from whole-body CT "screening." If these benefits exist, then whole-body CT "screening" should be marketed or prescribed on this basis.

Informed individuals are free to accept risks in their daily activities. However, there is serious doubt[14] about the degree of "informed consent" in screening procedures. In this setting, the issues of morality and risks discussed by Dr. Broadbent are questionable.

The analogy of whole-body CT "screening" to screening mammography is flawed. Screening mammography is the most heavily regulated imaging procedure in the USA. Whole-body CT "screening" is not even close. My counterpart has not really addressed the counterpoint. Whole body "CT screening" may be good business but it is not good healthcare.

AGAINST THE PROPOSITION: Michael Broadbent, Ph.D.

Opening Statement

It is estimated by the American Cancer Society that 1 334 100 new cases of cancer will be diagnosed in the United State during 2003. The Society also estimates a death rate from cancer of 206 per 100 000 persons. The leading causes of death in 2000 were heart disease, cancer and cerebrovascular disease, with a total of 1 431 512 deaths (56 percent of all deaths).[15] The use of electron beam and conventional CT scans of the total body for lung cancer, colon cancer, and coronary artery disease could potentially lead to the early detection and cure of many of these patients.

Observational data, particularly for lung cancer, suggest that screening could have a major benefit in outcomes despite the dearth of randomized data. "We know that if people with stage 1 lung cancer are not treated, about 80 percent of them will be dead in five years," says Dr. Brant-Zawadzki, professor of radiology at Stanford University School of Medicine. "Compare this to people with stage 1 lung cancer who undergo surgery-80 percent of them are alive at five years." [16]

A study at Mayo Clinic evaluated the benefit of spiral CT and sputum cytology for early detection of lung cancer in 1 520 patients. Fifty one lung cancers were detected in this study, and 59 percent were stage 1A. In addition to lung cancer, abdominal aneurysms, signs of osteoporosis, and visceral fat were also detected. These findings suggest that full-body CT screening will save lives through early detection of lung cancer and other diseases.[16]

The Health Physics News has stated that "the amount of dose encountered from CT screening with proper equipment is insufficient to present a legitimate concern of any radiation-related health effects." [17]

Radiation effects are frequently computed using the linear no-threshold model. This has been called into question in many reports.[17] There may be no risks involved at low exposures, and perhaps even benefits from radiation exposure.[18] Additional studies need to be conducted to determine the benefits of whole-body CT screening. If legislation is passed prohibiting screening, then the benefits in saved lives and reduced costs of care by early detection may never be known.

It is unreasonable to deny a benefit to someone because there may be an associated risk. Only if the hazard is demonstrably greater than any benefit is it morally correct to deny a practice. The risk is voluntary. We all assume acceptable risks in every activity we undertake.

There has been much thinking and evaluation about mammography and the appropriate signs for a biopsy. The same should be done for CT screening follow up. Improvements in mammography, in the face of a rising incidence of breast cancer, have contributed to a 20 percent reduction in mortality.[19] Total body and heart scanning can save lives by detecting diseases at earlier stages when they are treatable. We do breast screening on women without symptoms. We should be

able to do the same with CT screening. There are recommendations as to when breast screening should start and how often it should be done. We should develop the same for CT screening.

Rebuttal

Dr. Morin says the radiation risk of self-referral CT screening is slight. The issue is strictly a risk-benefit analysis of how the findings are used. If the screening examination is not part of preventative health care, then the findings can be considered as incidental to a normal healthcare program. If these incidental findings cause hardship or excess cost, how does this differ from other incidental findings? Are we to tell radiologists not to look for and report incidental findings that occur during studies within the mainstream of current practice? If there is a problem with self-referral findings, then there is also a problem with incidental findings in general.

As Dr. Morin points out, some states restrict the use of radiation screening. As he also points out, however, the radiation risk is not really the issue here. Using radiation safety rules or arguments to eliminate self-referral CT screening is disingenuous, and compromises the freedom of individuals to make their own choices. There certainly will be some people who will benefit from self-referral screening. There undoubtedly will be others who will not have acquired an overall benefit. Professionals who want to play god and decide what is best for the public would be well-advised to improve their profession's handling of the challenge of incidental findings, and leave the risk-benefit judgment to an informed public. Although we would like to see truth in advertising, the public is not as naive as the would-be protectors of the public's interests would have us believe.

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5.5. It is time to retire the computed tomography dose index (CTDI) for CT quality assurance and dose optimization

David J. Brenner and Cynthia H. McCollough
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OVERVIEW

The computed tomography dose index (CTDI) was introduced over a quarter century ago for optimization of patient protection in CT.[1] By means of a single measurement it was possible to determine, to a good approximation, the average dose for a series of scans in lieu of making multiple measurements for each slice. This advance made great sense at the time because of the slow equipment and small anode heat capacities of early CT units, which made multiple measurements difficult. It has recently been suggested that modern technological developments in CT and dosimetry permit patient doses to be determined in a way that better represents the risk to the patient, and that it is now time to retire the use of CTDI for CT quality assurance and dose optimization.[2] However, others argue that measurements of CTDI (or variants thereof) remain adequate for CT quality assurance and dose optimization, and that replacement is unnecessary. This difference of opinion is the topic of this month's Point/Counterpoint debate.

Arguing for the Proposition is David J. Brenner, Ph.D. Dr. Brenner is Professor of Radiation Oncology and Public Health at the Columbia University Medical Center. He focuses on developing models for the carcinogenic effects of ionizing radiation on living systems at the chromosomal, cellular, tissue, and organism levels. He divides his research time roughly equally between the effects of high doses of ionizing radiation (related to radiation therapy), and the effects of low doses of radiation (related to radiological, environmental, and occupational exposures). When not involved in radiation matters, he supports Liverpool Football Club.

Arguing against the Proposition is Cynthia H. McCollough, Ph.D. Dr. McCollough is Associate Professor of Radiological Physics at the Mayo Clinic College of Medicine. She oversees the technical support for Mayo's 22 CT scanners and directs the CT Clinical Innovation Center. Her research interests include CT dosimetry, advanced CT technology, and new clinical applications. She is an NIH-funded investigator, and is active in numerous organizations. She chairs the AAPM's Task Group on CT Dosimetry and the ACR's CT Accreditation Physics Subcommittee, and is a member of IEC, ICRU, and NCRP CT committees. Dr. McCollough received her doctorate from the University of Wisconsin in 1991.

FOR THE PROPOSITION: David Brenner, Ph.D.

Opening Statement

We have an obligation to reduce, as far as practical, radiation-induced cancer risks in the population who receive computed tomography (CT) examinations. These cancer risks are determined by the organ doses to which individuals are exposed. It is logical for the quantities measured in CT quality assurance and dose optimization (CT QA/DO) to bear as direct a

relationship to organ doses as is reasonably practical. The dose descriptors currently used for CT QA/DO, the computed tomography dose index (CTDI) and its subsequent modifications,[3] bear an increasingly distant relationship to organ doses and thus to risk.[4] The technology now exists to directly, routinely and rapidly measure organ doses from helical CT scans in realistic anthropomorphic phantoms, with about the same amount of technical effort as that required to measure CTDI. Thus, I believe that such measurements represent a more logical basis for CT QA/DO than do CTDI measurements.

Specifically, given 1) the problems in maintaining CTDI as a relevant dose index,[4] 2) the availability of MOSFET (Refs. 5,6) (or TLD, if preferred) dosimeters which are very small, sensitive, quick, and convenient to use, and 3) the commercial availability of heterogeneous whole-body anthropomorphic phantoms such as the ATOM phantoms[7] and the Alderson radiation therapy phantoms,[8] it is time to consider retiring the CTDI/homogeneous phantom approach to CT QA/DO. One might envisage CTDI measurements being replaced by direct simultaneous MOSFET measurements of doses at locations in appropriate organs of a full-body anthropomorphic phantom, perhaps appropriate subsets of stomach, colon, breast, lung, gonads, thyroid, bladder, esophagus, liver, brain, and relevant bone marrow. A typical set of measurements at 20 (simultaneously measured) organ locations should take about 30 minutes, including setup—quite comparable to CTDI measurements.

There is no question that CTDI, and its related quantities, can be used to compare outputs of different CT scanners and different CT models. But given the goal of minimizing unnecessary cancer risks to patients, there is a need for a quantity that is a surrogate of risk, and neither CTDI nor its modifications can be forced into this role. It is now quite practical to measure direct surrogates for cancer risk, with no more technical effort than required to measure CTDI. It makes sense to use these more direct measurements as the basis for CT quality assurance and dose optimization.

AGAINST THE PROPOSITION: Cynthia McCollough, Ph.D.

Opening Statement

The advent of spiral CT caused concern about the use of a discrete axial scan to measure dose for a continuous spiral acquisition. However, both theory and experimental data upheld the validity of extending the CTDI construct to spiral CT.[9,10] The larger problem, both for spiral or sequential acquisitions, was the integration limits established in the early days of CT: ± 7 T, where T was the nominal tomographic section thickness (in lay person language, the slice width). In the case of narrow slice widths (which were not considered in the "early days"), the average dose from a series of scans was underestimated by the ± 7 T limits.[11] Hence a fixed integration length of 100 mm, which purposely matched the active length of the well-established CTDI "pencil" chamber, was adopted in Europe[12] and in International CT Safety standards.[13] This resulted in a CT dose *index* that is easily and reproducibly measured,[3] and that captures the majority of the scatter tails for even wide x-ray beam widths.[14]

Recently, the pitch-normalized metric $CTDI_{vol}$ was required by international standards to be displayed on the user interface prior to scan initiation.[13] The radiology community, through extensive educational efforts, is becoming "calibrated" to typical $CTDI_{vol}$ values for common examinations, thereby allowing users to note scan prescriptions that deliver radiation levels outside of the typical range. Users can use $CTDI_{vol}$ to provide a universal index of scanner output

that can be readily compared across scanners worldwide. This "apples to apples" comparison of radiation doses in CT, where users can check scanner output prior to irradiation (and hopefully modify techniques that are inappropriately different from the above reference values), is a practical and robust method of dose optimization, as the use of reference values has consistently been shown to reduce average dose levels and narrow the dose distribution across imaging practices.[15] $CTDI_{vol}$ is a valuable and necessary tool for this task, primarily because it is so well established and uniformly adopted.

This uniformity in measurement technique makes CTDI an ideal quality assurance tool, as quality assurance requires use of the same methods and phantoms in a consistent manner. So too, does dose optimization. Knowing the dose to my liver or your liver is not the issue in clinical dose optimization. Rather, one must know that a $CTDI_{vol}$ of 18–22 mGy is typical for an average adult abdominal CT. That way, if a wrong parameter is selected leading to a $CTDI_{vol}$ of 59 mGy, the user has a clear indication that something is wrong. Besides avoiding unnecessarily high dose CT exams, the display of a universal, easily- and reproducibly-measured metric on the user console provides the operator with a practical tool to reduce dose from CT examinations to appropriate levels. Thus, I consider it time not to *retire* the CTDI, but rather to *promote its use* in daily CT practice.

Rebuttal: David Brenner, Ph.D.

Professor McCollough cogently makes the point that if the sole object of the exercise is to compare and confirm outputs from CT machines, as they are used in 2006, then the $CTDI_{vol}$ dose index is just fine. There are several reasons, however, why CTDI is not the optimal way forward for CT QA/DO.

First, if the history of CT dosimetry tells us anything, it is that the latest version of CTDI will soon need to be modified due to changes in CT technology.[3] For example, as multi-slice scanners feature increasingly broad beams, the 100 mm ion chamber will no longer characterize enough of the scatter from a single-slice profile.[4,16] To have to base QA/DO on a dose index that needs to be modified as CT technology changes is undesirable. Indeed, there are some imminent changes in CT technology that are so basic that they cannot be accommodated by simply tinkering further with CTDI. As an example, for continuous automated axial tube current modulation, designed to compensate for changes in attenuation by different organs along the patient axis,[17] CTDI measurements simply will not delineate whether or not the dose is being delivered appropriately over the length of, say, a colon scan.

Secondly, Professor McCollough's central implication is that, in order to check that the scanner is operating correctly, all we need for CT QA/DO is some good index of machine output. But if this were so, even the basic $CTDI_{100}$ would be more complicated than needed. In fact, still more complicated, spatially-averaged versions of the $CTDI_{100}$, like $CTDI_w$ and $CTDI_{vol}$, are now the standard.[3] Why? Because they are slightly better surrogate indices for organ dose and thus ultimately for organ risk!

In summary, there is a rationale and a desire in CT QA/DO to measure some quantity that will need to be changed, and that is a better surrogate for organ dose/risk than is CTDI. So why not directly measure organ doses in an anthropomorphic phantom?

Thus my arguments in support of the Proposition are:

1. Multiple organ dose measurements in an anthropomorphic phantom with a set of MOSFET detectors, for example, are no harder or slower to make than CTDI measurements.[5,6]

2. Organ dose measurements provide just as good a check that the machine is working correctly as does $CTDI_{vol}$.

3. The CTDI concept needs to be continuously modified as CT technology changes.

4. Organ dose measurements provide direct, rather than crude, surrogates of organ risk—the quantity we ultimately want to control.

Rebuttal: Cynthia McCollough, Ph.D.

In CT, organ doses are determined by the start and end locations of the examination, scanner output and patient anatomy. From the anatomy of interest, CTDI and scan protocol, organ doses can be predicted with high precision using published Monte Carlo coefficients[18,19] or Monte Carlo code modified for this task.[20,21] Using "virtual phantoms" from actual patient CT scans, dose optimization can easily be performed for patients of varying age, gender, and habitus for countless perturbations of scan parameters.[22] The time, effort, and cost associated with "brute force" measurements of organ doses for the innumerable combinations of detector configurations, pitch values, kVp and mAs settings, beam shaping filters, and multiple child and adult physical phantoms—per scanner model—is simply not practical. Further, physical anthropomorphic phantoms, which are available in limited sizes, may use less-accurate "geometric" organs, and can vary based on manufacturer or date of purchase. In addition to dosimeter precision and calibration issues, such variations will confound the optimization task, especially between investigators. Silicon-based dosimeters (diodes or MOSFETs) can only be used on phantom surfaces (if placed internally, the wires create problematic gaps). Also, they have spectral dependencies that are not easily addressed in CT, where spectra vary between scanners and across the scan field, and they must be used in high-sensitivity mode for adequate precision, which shortens their lifespan and increases user cost. TLDs, which can be placed inside the phantom, require annealing and removal (to read them) between multiple measurements—a time consuming effort. In contrast, CTDI gives a precise and consistent index of scanner output, can be used to quickly measure output for many combinations of scanner settings, and can be used with Monte Carlo tools for dose optimization. I agree that organ doses are important, but physicists should use their time and talents to work smarter, not harder, towards minimizing radiation risk from CT.

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5.6. A major advantage of digital imaging for general radiography is the potential for reduced patient dose so screen/film systems should be phased out as unnecessarily hazardous

Eliseo Vano and Keith Faulkner

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OVERVIEW

In general radiography, the dose to the patient is so low that any biological risks to the exposed individual are considered negligible compared with the benefit received. Because of the enormous number of procedures performed, however, the collective dose to the entire population of exposed individuals is significant. Many organizations, such as the International Commission on Radiological Protection (ICRP), recommend keeping this collective dose as low as possible.[1] Since digital detectors have higher intrinsic radiation sensitivities compared with film/screen systems, one way to achieve this objective may be to replace film/screen radiography with digital imaging. Whether this concept is viable in practice is the premise for this month's Point/Counterpoint debate.

Arguing for the Proposition is Eliseo Vano, Ph.D. Dr. Vano is Professor of Medical Physics at the Medical School of the Complutense University, and Head of the Medical Physics Service at the San Carlos University Hospital in Madrid, Spain. After graduation in physics at the University of Valencia, he worked in Nuclear Spectroscopy in Madrid and Paris, and obtained his Ph.D. degree at the Complutense University of Madrid (CUM). Dr. Vano created a Medical Physics Group at the Medical School in the CUM and, in 1982, became the first Professor of Medical Physics in Spain. He contributed to introduction of quality control and patient protection procedures in diagnostic radiology in Spain, is the current Secretary of Committee 3 of the ICRP (Protection in Medicine), and Vice Chairman of the Medical Working Party of the Group of Experts of the Euratom Treaty. He has published extensively in diagnostic and interventional radiology and cardiology, on topics such as quality control and radiation protection of patients and workers.

Arguing against the Proposition is Keith Faulkner Ph.D. Dr. Faulkner is the Regional Director of Quality Assurance for the breast and cervical cancer screening programs for the North East, Yorkshire and Humber Government Office Regions of the UK. After graduation from Imperial College, London, he trained as a medical physicist at the University of London. He is a Fellow of the Institute of Physics and Engineering in Medicine (IPEM), the Institute of Physics, and the Society of Radiation Protection (SRP) in the United Kingdom. He maintains an active interest in research in radiation protection, and is the coordinator of the European Commission's SENTINEL project. He is the author of over 250 peer-reviewed papers. His awards include the Founders' Prizes of the IPEM and the SRP, and the Barclay Prize and Medal of the British Institute of Radiology.

FOR THE PROPOSITION: Eliseo Vano, Ph.D.

Opening Statement

With appropriate training of users and relevant quality control, it is possible to generate images with the same or lower radiation dose with digital imaging compared with conventional film/screen systems for general radiography.[1] In addition, image quality and diagnostic information (after post-processing) can be improved with digital techniques.[2,3,4] Transmission of images by networks and easy archiving are other fundamental advantages of digital imaging. Networks and digital systems also enable the auditing of patient doses and comparison with reference values in real time.[5] With film/screen systems, errors in radiographic techniques or problems with film processors require repeat exposures whereas, with digital imaging, the inherent wide dynamic range and post-processing capability make most retakes unnecessary. Furthermore, if previous films are not available, additional exposures may be required. Hence the use of film/screen systems should be phased out within the next few years because they are unnecessarily hazardous and less versatile than digital imaging.

Digital radiology can have additional benefits for developing countries. Digital imaging can be less expensive than film/screen techniques. Compared with film processors, the use and maintenance of digital phosphor plates (computed radiology) and personal computers (PCs) is easier. Even if initial funding to install sophisticated networks and image archiving systems is not available in developing countries, users can use PCs to burn CD-ROMs that are cheaper than radiographic films and more easily transported by patients to other hospitals, if necessary.

With film/screen systems, patient doses at the individual level are not so high as to be considered hazardous. However, if we take into account the collective dose for a medium sized hospital with, say, 100,000 examinations per year, and if 30% of the patient dose could be saved with digital techniques and another 10% by avoidance of retakes, a substantial risk could be avoided and potential cost savings could be realized. With a typical mean effective dose per examination of 0.5 mSv (collectively, 50,000 mSv/year), digital imaging, if used properly, could reduce the annual collective dose by 20,000 mSv. This annual reduction in collective dose for the same clinical benefit per hospital, supports the promotion and introduction of digital technology as fast as possible.

The initial effort to train the staff in the use of digital techniques and the development of the necessary quality control program would be offset by the dose reduction and the workflow improvement.

AGAINST THE PROPOSITION: Keith Faulkner, Ph.D.

Opening Statement

There are many valid reasons for introducing digital imaging into general radiography, but the claim that film/screen systems are unnecessarily hazardous is not one of them. Digital imaging for general radiography has many advantages compared with film/screen systems, including a wider dynamic range and the ability to manipulate the images produced. The wider dynamic range means that acceptable images may be acquired at a range of dose levels, and therefore repeat exposures can be reduced. Digital imaging can result in the over use of radiation, however, because there is a tendency for images to be acquired at too high a dose, and for too many images to be obtained, simply because the acquisition process is so easy.

There are two aspects of the Point/Counterpoint proposition that can be challenged. The first is that digital imaging necessarily reduces patient doses, and the second is that film screens should be phased out as unnecessarily hazardous. Each of these is discussed below.

In digital imaging, increasing patient dose generally means improving image quality because of reduced image noise. Digital imaging systems may be set up to produce higher quality images than necessary for diagnosis,[6] and consequently patient doses may be higher than needed. The DIMOND project has proposed that digital radiography procedures should be classified in low, medium or high image quality bands.[7] Advice is given on the speed class of the imaging modality to be used for each of these three bands. In these proposals, the speed class of a film/screen system for a given image quality band is the same as that of a storage-phosphor system, and one band lower than that for flat-panel detectors. The decrease in patient dose associated with the introduction of a flat-panel system for digital radiology lies in the range of 33–50% when replacing a film/screen system.[8,9,10] Thus, even if flat-panels are used properly, the maximum reduction in patient dose is only a factor of two. Hence, screen/film systems should not be considered unnecessarily hazardous.

The ease of image acquisition by digital systems can mean that there is an increase in the number of images acquired. This has happened in digital fluoroscopy.[11] Digital radiology has also led to an unjustified increase in the number of procedures by 82%.[12]

In summary, there is evidence that the introduction of flat-panel detectors leads to a dose-reduction of typically 50%, but can lead to almost a doubling of the number of procedures. Hence, it is not reasonable to conclude that film/screen systems are unnecessarily hazardous, and the Point/Counterpoint proposition is untenable. The International Commission on Radiological Protection also has concerns about dose levels in digital radiology. These concerns are summarized in Publication 93.[1]

Rebuttal: Eliseo Vano, Ph.D.

I agree in part with some of the points presented by Dr. Faulkner.

The wide dynamic range of digital detectors means that acceptable images may be acquired at a range of dose levels and that overexposures may not be detected. But overexposures will be minimized with proper training programs and quality control, including frequent patient dose evaluations.

In digital imaging increased patient dose generally means improved image quality due to reduced noise. Again, I agree that this could be misused if the required image quality is not defined for a specific medical task. With digital imaging, it is possible to select image quality (and radiation dose) using the same detector, which is not the case with film/screen. With this already "old" imaging technology, it is necessary to change the speed class of the film/screen combination and, in practice, more dose than is necessary is sometimes used.

The example quoted by Dr. Faulkner of the European DIMOND project[7] proposing the model of three image-quality bands in projection radiography (and corresponding dose levels of low, medium and high) is a clear advance in patient dose management. The ability to select low image quality for some clinical tasks, leading to a saving of 50% in patient dose, is not so readily available if film/screen systems are used.

Dr. Faulkner points out the tendency in digital radiology to obtain more images than necessary (especially in fluoroscopy), but this again is a matter of appropriate training of the practitioners. Using a digital system and archiving short fluoroscopic sequences, a well-trained radiologist may complete a digestive or urological examination, for example, with fewer images and less patient dose compared with those for non-digital technology.

I agree with Dr. Faulkner that film/screen systems are not "per se" unnecessarily hazardous, but it is clear that the added benefits of digital technology are enormous. These advantages, together with reduced doses, means that we should advise our health administrators to move in this direction.

Rebuttal: Keith Faulkner, Ph.D.

Professor Vano makes a series of important points in supporting the use of digital imaging for general radiography. I wholeheartedly agree with him that digital imaging should result in lower patient doses, provided that the technology is used appropriately. I concur that one of the main benefits of digital imaging is the large dynamic range compared with that for film/screen systems. The wide dynamic range means that it is possible to obtain acceptable images at a range of dose levels, reducing the need for repeat exposures. However, there is a tendency for digital systems to be used at higher dose levels than necessary, as users demand images of the highest quality rather than of a quality needed for diagnosis. Professor Vano is correct in endorsing the role of training; it is critical that users have an understanding of the technology of the system, if the potential for dose reduction associated with the use of digital technology is to be achieved in practice.

Even if it is accepted that digital imaging can reduce doses by up to a factor of two, this level of dose reduction does not imply that film/screen systems are unnecessarily hazardous. There are many areas of radiology practice where local differences result in dose variations that are much greater than two, and several population surveys have shown that doses vary among centers by factors of 10–100.

Placed in this context, film/screens should not be regarded as unnecessarily hazardous. There are valid reasons for replacing film/screen systems with digital detectors for general radiography, particularly for centers where there may be problems with the water supply that could impact on chemical processing of film. Professor Vano has eloquently made the case for change, but the case should not be based upon the proposition that film/screens are unnecessarily hazardous.

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5.7. Within the next five years CT colonography will make conventional colonoscopy obsolete for colon cancer screening

Hiro Yoshida and Albert C. Svoboda, Jr.
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OVERVIEW

In the United States colorectal cancer is second only to lung cancer as a cause of cancer death, despite the fact that screening by colonoscopy can detect colorectal cancer early enough for cure and, by detection and removal of precancerous polyps, can actually prevent cancer.[1] The major reason for this high cancer death rate is that fewer than 20% of at-risk adults are screened.[1] Unfortunately there is not sufficient capacity to screen the entire population at risk, and it has been estimated that it would take 10 years to provide colonoscopies to all these unscreened individuals.[2] Sufficient capacity does exist, however, for screening with CT colonography, which has been demonstrated to be a good alternative to colonoscopy but does not suffer from the "fear factor" associated with having an invasive procedure under sedation.[3] Because of these advantages, it seems possible that CT colonography might soon replace colonoscopy as the screening method of choice, and this is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Hiro Yoshida, Ph.D. Dr. Yoshida received his B.S. and M.S. degrees in physics and a Ph.D. degree in information science from the University of Tokyo. He previously held an Assistant Professorship in the Department of Radiology at the University of Chicago. He was a tenured Associate Professor when he left the university and joined the Massachusetts General Hospital and Harvard Medical School in 2005, where he is currently an Associate Professor of Radiology. His research interest is in computer-aided diagnosis, in particular the detection of polyps in CT colonography, for which he received several awards from the Annual Meetings of the RSNA.

Arguing against the Proposition is Albert C. Svoboda, Jr., MD. Dr. Svoboda received a B.S. (Zoology) (1955) and an MD (1958) from the University of Chicago as well as an M.S. (Physiology) (1954) from the University of Southern California, and completed his internship, residency and fellowship in gastroenterology at the University of Michigan (1958–1963). Subsequently, he became an Associate in Gastroenterology at the Scripps Clinic and Research Foundation (1963–1966) and the Department of Gastroenterology, Sansum Medical Clinic (1966–1996). He is currently a Senior Scientist at the Sansum Diabetic Research Institute and Director of the Internship Program. In the American College of Gastroenterology he has served as the Governor for Northern California, Secretary, and Chair of the Board of Governors. He is a Past President of the Southern California Society for GI Endoscopy. In his spare time, Dr. Svoboda is an ardent orchid enthusiast and is an Accredited Judge for the American Orchid Society and the Cymbidium Society of America.

FOR THE PROPOSITION: Hiro Yoshida, Ph.D.

Opening Statement

Colonoscopy is considered the most accurate test for the detection of colonic neoplasia, and it has recently become a popular screening tool for high-risk patients.[4] However, current screening techniques available to average-risk patients are many, and those who make screening recommendations do not agree as to which test or combination of tests should be performed.[5,6]

Thanks to the rapid advancement of computer tomographic (CT) technology, CT colonography, popularly known as virtual colonoscopy, has been emerging as a promising alternative technique for screening.[1] CT colonography involves performing an abdominal CT scan to create images resembling those seen at colonoscopy for detecting colorectal neoplasms. As CT colonography evolves, the weaknesses of colonoscopy will be exposed.

Colonoscopy is an invasive intervention that carries the risk of perforation or serious hemorrhage,[7] whereas CT colonography is a noninvasive image-based examination of the entire colon, with no report of complications thus far. Furthermore, screening of the entire at-risk population by colonoscopy may not be realistic: approximately 41.8 million average-risk Americans 50 years old or older have not been screened, and 12 million more reach 50 each year. Current and near-future capacity for colonoscopy is severely limited and will be unable to satisfy this huge demand.[2] Cost-effectiveness comparison of colonoscopy and CT colonography is inconclusive; however, it indicates that if the cost of virtual colonoscopy could be reduced to approximately half that of colonoscopy, which is not unrealistic, CT colonography would become the more cost-effective screening tool.[8]

Advocating CT colonography obviously requires formal evidence-based scientific data on its ability to detect polyps. A recent large clinical trial, in which 1,233 asymptomatic average-risk patients were examined by state-of-the-art CT colonography, showed a per-polyp sensitivity of 94% and a specificity of 92% for adenomatous polyps >8 mm.[9] This sensitivity of CT colonography was higher than that of colonoscopy (91%), and this is consistent with the reported average miss rate of 6–13% in colonoscopy.[10] Critics argue that the high performance in the study can be achieved only in ideal circumstances. However, in the next five years, the performance of CT colonography is expected to improve further by use of rapidly advancing new technologies such as computer-aided detection[11,12] and novel views.[13]

CT colonography is now showing results that may lead to its becoming a mainstream screening test, which will make colonoscopy obsolete as the primary screening tool. However, it will not eradicate colonoscopy. Colonoscopy has two separate functions, a diagnostic procedure and a therapeutic technique for removing polyps. A realistic scenario is to perform colonoscopy only selectively, for patients with polyps of clinically significant size detected by primary CT colonography. This scenario would be a more efficient use of endoscopy resources, and it is likely to reduce the incidence of colorectal cancer.[8]

AGAINST THE PROPOSITION: Albert C. Svoboda, Jr., MD

Opening Statement

"*Be not the first by whom the new are tried,*

Nor yet the last to lay the old aside."

An Essay on Criticism, Part II, Alexander Pope (1688–1744)

"*A bird in the hand is worth two in the bush;*

A pound in the purse is worth two in the book."

My seniority brings with it "Remembrances of Times Past" when colon polyps or cancers were detected by single column or air contrast barium enema. Perplexing then as today with colonography was the question of what to do with the smooth polyp of small or moderate size, say 1 cm. Prevailing wisdom then was to repeat the x-ray examination after three months and, if the polyp had increased in diameter by 50%, to offer the patient surgery. Today with colonography are the majority of these patients sent to surgery (e.g., colonoscopy)? Would the high risk patient (strong family or personal history) be better served by referral directly for colonoscopy?

Colonoscopy is clearly superior for therapeutic intervention and pathologic diagnosis, but my task is to evaluate and predict diagnostic improvements.

"*And differing judgements serve but to declare*

The truth lies some where, if we knew but where."

William Cowper (1731–1800)

In recent insights on endoscopic innovations,[14] Dr. P. Jay Pasricha (UTMB, Galveston, Texas) said that any new procedure should (1) meet a large need, (2) be simple and safe, and (3) be of proven efficacy. Colonography must answer questions of radiation safety and ability to detect flat lesions, answer follow-up concerns about small polyps, and try to match the extensively proven safety and efficacy of colonoscopy.

Since the introduction of fiberoptic colonoscopy by Bergein Overholt in 1963, followed by cancer detection in 1966, and endoscopic polypectomy by Wolff and Shinya in 1969, there have been steady improvements in diagnostic and therapeutic capabilities of the instruments, which still continue. In addition to video endoscopy, chromoendoscopy and high magnification, improvements can be expected to mirror the on-going progress of miniaturization and optics.[15]

During these decades the procedure has been proven to be both safe and effective even in the hands of increasing numbers of practitioners with variable training. Both colonoscopy and flexible sigmoidoscopy have been shown to significantly and statistically reduce both the number of cancers and deaths from cancer in the populations followed. Recognizing this, Medicare and most insurance companies cover the costs of colorectal cancer screening including appropriate endoscopy.

Any new procedure advocated to replace colonoscopy must demonstrate equal or greater safety, efficiency, availability, affordability, and patient acceptance.

"*People rather admire what is new although they do not know whether it be proper or not, than what they are accustomed to and know already to be proper; and what is strange, they prefer to what is obvious*."

Hippocrates

Rebuttal: Hiro Yoshida, Ph.D.

As Dr. Svoboda correctly pointed out, any new procedure intended to replace colonoscopy must demonstrate equal or greater safety, efficiency, availability, affordability, and patient acceptance. Current 16-slice multi-detector CT scanners allow efficient acquisition of CT images of the colon in 15–20 seconds with a minimum of patient discomfort and invasiveness. The success of low-dose CT colonography[16,17] is removing the concern about radiation safety. The rapid increase in installed CT scanners makes CT colonography widely available to patients. Advances in visualization and computer-aided detection software are expected to permit efficient interpretation while maintaining high detection accuracy, making CT colonography cost effective. Once Medicare begins to reimburse for screening CT colonography, the procedure will become affordable for elderly patients whose main risk factor is age and who constitute the majority of average-risk patients. The emergence of "prepless" CT colonography with fecal tagging[18] is removing the need for laxatives—the foremost reason for the low patient compliance in colonoscopy and CT colonography—thus increasing patients' acceptance. Unfortunately, the detection of flat lesions is as difficult for CT colonography as it is for colonoscopy.[19]

Rebuttal: Albert C. Svoboda, Jr., MD

To allow an honest debate we must not compare apples and oranges. We cannot compare complications from polypectomy and thermo-elective therapy with screening colonography. We cannot ignore additive radiation effects from repeated surveillance virtual colonoscopy nor ignore the neoplastic potential of undetected or untreated flat or small polypoid lesions. And we cannot extend the good but unmatched detection rate of a single unit to general usage.

The introduction of colonography has been a clarion call for colonoscopists to review and compare rates of complete exams (to cecum), missed lesions and subsequent development of neoplasms.[20,21] Both flexible sigmoidoscopy and colonoscopy have a long history of careful follow-up of patients (e.g., the National Polyp Study) and proven reduction of cancer risk.

A recent review of colonoscopies by a gastroenterology group in Rockford, Illinois[21] should set achievable performance standards and endoscopy goals. All six endoscopists were experienced (had done more than 2000 cases). The cecum was reached in a minimum of 98% of cases by each. Of 16,147 colonoscopies performed there were no perforations from diagnostic procedures. Of 206 patients with colon cancer, eight (3.8%) had a colonoscopy between six and thirty-six months previously and five of these occurred at the site of the previous polypectomy suggesting incomplete removal. The remaining three, all of which were early stage, apparently were missed.

One disadvantage of CT colonography is the radiation exposure required. Although the risk to the individual patient is very low, the cumulative risk to the entire population of screened patients is of some concern.[22] Also, many patients will avoid CT because of their fear of radiation, even though such fear might be irrational.

Dr. Yoshida mentions the risk of complications. I performed many thousands of colonoscopies over thirty years of clinical practice. There were no deaths and very few perforations (less than 0.05%), all of which were related to difficult therapeutic procedures. The complications for colonoscopy quoted by Dr. Yoshida are virtually all related to therapeutic endoscopy and the use of thermal devices. Screening colonoscopy should be essentially free of complications especially in the hands of trained, experienced endoscopists.[21] The technique of cold snaring of small lesions similarly carries almost no risk, probably no different than the air insufflation for CT

colonography. Careful patient monitoring for oxygen saturation, heart rate, and blood pressure should avoid problems from conscious sedation.

The most common cause of medical litigation is failure to diagnose. This is almost as critical in the physician's thinking as the patient's well being. If the criterion for referral for colonoscopy is the detection of polyps as small as 6 mm, four times as many procedures will be necessary than if the lower limit is 1 cm. With a 6 mm limit the false positive rate observed is of the order of 55%. A high false positive rate reduces the benefit of pre-selection offered by virtual colonoscopy in the first place. The number of patients who will require both procedures could be a budget breaker. There is pressure to refer patients for colonoscopy only if larger polyps are found. If you see small polyps and report these but do not refer the patient for colonoscopy and cancer develops, you are liable.

In terms of cost effectiveness, Sonnenberg *et al.*,[23] using a Markov model, concluded that CT colonography would be more cost effective than conventional colonoscopy only if the cost of CT could be reduced to 50% of the cost of colonoscopy. Can CT colonography compete?

Both optical and virtual colonoscopy are evolving rapidly and improving. I end with the final thought: "*It is not the strongest of the species that survives nor the most intelligent; it is the one most adaptable to change.*"

Charles Darwin (1805–1882)

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5.8. For diagnostic imaging film will eventually be of historical interest only

Brent K. Stewart and Frank N. Ranallo
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OVERVIEW

Twenty years ago some radiology savants predicted that film would disappear from radiology over the next decade and was to be replaced by digital technologies for acquiring, storing, and displaying images. Today some (principally academic) radiology departments are committed to this objective, and a few (primarily those in military and VA hospitals that have access to the Federal largesse) have achieved it. But most departments are adopting a ''wait-and-see'' attitude, while using ''mini-PACS'' systems to bridge between specific digital imaging systems. Often individuals in these departments believe that the up-front cost of going ''all digital'' will prevent its widespread adoption. They emphasize that if radiology had evolved digitally, and film were a new discovery, it would be heralded as a major contribution to the quality and cost-effectiveness of medical imaging.

How this controversy is likely to be resolved is the subject of this Point/Counterpoint issue.

Arguing for the Proposition is Brent K. Stewart. Dr. Stewart received a Bachelor of Science in physics from the University of Washington and a Ph.D. in Biomedical Physics from the University of California, Los Angeles, where he was a National Science Foundation fellow. He has over 140 peer-reviewed journal articles, book chapters, proceedings papers, and abstracts. He has been involved in Picture Archiving and Communication Systems (PACS) research for the past fifteen years. He is currently Professor of Radiology, Bioengineering, and Medical Education as well as Director of Imaging Informatics and Director of Diagnostic Physics at the University of Washington School of Medicine in Seattle.

Arguing against the proposition is Frank N. Ranallo. Dr. Ranallo is a clinical medical physicist at the University of Wisconsin Hospital and Clinics and an Assistant Professor (CHS) in the Department of Medical Physics at the University of Wisconsin. He received his Ph.D. in Physics from the University of Wisconsin, and has been working in the field of medical imaging since 1976. He is co-author of a book on MRI and has served in the AAPM as a member of the Diagnostic X-Ray Imaging Committee and its task groups. Dr. Ranallo's research interests include optimization of the design and use of imaging equipment and the development of instrumentation and methods to test the performance of medical imaging systems.

For the proposition: Brent K. Stewart

Opening Statement

Since Roentgen's day, film has been the traditional method for capturing and displaying information in medical imaging. This method has served the discipline well; filmscreen radiography can achieve exquisite spatial resolution and provides a reasonable dynamic range of

optical densities for display of image contrast. Film is a jack of all trades: It serves as image acquisition, display, and storage devices. No other medium can compare with film's multitasking capability, even though film is by no means optimized for any one task.

The greatest attraction of film is that it is analog. We live in an analog world; our everyday experience is continuous, not discrete. Film is very user friendly. We humans are very tactile creatures, and touching makes objects more ''real'' to us. There is nothing in the digital world quite like the solid feel of paging through a good book or passing family snapshots around the kitchen table. Even though I digitize almost all messages crossing my desk, I still print many out for meetings or if there are several complex documents that I need to refer to. There is no paperless office yet, but we are inching towards it daily.

However, film has some severe disadvantages that are becoming increasingly problematic in a busy radiology service. These disadvantages include: the frequency of repeat exposures; films are not immediately available for review; it is necessary to properly dispose of the by-products of film processing; and the inability to spontaneously view a film simultaneously anywhere within an institution, the country or the world. The film library is often the bottleneck in the clinical information workflow constituting an interpretive and consultative medical imaging service. Lost, misplaced and misappropriated films are a constant problem that not only frustrates radiologists and referring physicians, but also compromises the quality of patient care. We will never have a ''cradle to grave'' medical record using paper and film.

The widespread adoption of electronic radiology (aka PACS, IMACS, etc.) is inevitable, just as electric lighting, radio, and television have been. All new technologies, when invented, developed and marketed go through an adoption life cycle. The percent of society adopting the technology over time generally describes a sigmoidal-shaped curve, ironically much like an H&D curve. The evolution of technology adoption follows a fairly predictable course. First the Innovators (2%–4%) break new technological ground. Next come the Visionaries, or the Early Adopters (12%–14%). Between the Early Adopters and the Early Majority lies the ''chasm,'' where many technological innovations become mired. The PACS chasm has been bridged lately and the Early Majority (34%) has begun implementing electronic radiology. The Late Majority (34%) and the Laggards (16%) bring up the rear. We are not too far along the technology adoption curve for PACS, but the next few years will see rapid deployment of these systems.

Eventually electronic radiology will be fully adopted as the standard for patient care, the Laggards will finally capitulate, and film will be relegated to the silver reclamation bin.

Rebuttal

While digital vanguards have been lauding the demise of radiographic film for the past twenty years, the process of filmless radiology has taken longer than expected due to the economic, technological, and human elements involved. In 1983, while a graduate student working on the seminal elements of PACS at UCLA, filmless radiology seemed relatively straightforward. There were many strong and clear motivations. We have, however, had to wait several years for cost-effective technology to catch-up with the vision of PACS. There is much unfinished work to bring filmless radiography to fruition, including information technology solutions that can adapt their functionality based on user work-flow preferences.

The driver for filmless radiology is not anticipated cost or film library space savings, but the economic imperative of practicing medicine, and specifically radiology, at a distance, as well as

providing prompt service to physician customers for use in decision making. The bottom line in medicine is ‘‘more with less,’’ that is fewer personnel resources and in less time. This and a ‘‘cradle to grave’’ medical record is something that cannot be accomplished with film.

Digital technology is currently more expensive compared with its analog counterpart. Digital radiography only makes economic sense at this time for dedicated chest units. Even tabletop computed radiography readers are about twice the price of a film digitizer. Again, the limiting factor for small clinics using radiography is personnel—lack of expertise in radiography and short staffing. Lab techs trained in radiographic procedures are currently performing radiography at our primary care clinics. The wider dynamic range and image processing inherent in computed radiography cures many technical errors. Furthermore, there is no need for a film processor that requires continuous flushing and contributes to toxic waste.

Against the proposition: Frank N. Ranallo

Opening Statement

If technological advances continue at the present pace and the world progresses economically, one could reasonably argue that the use of film in medical imaging will fade in the far future. But, let’s look at the possibilities for the foreseeable future, the next 10–20 years. To try to predict the future, it is best to first look at the past.

In 1980 Capp predicted that: ‘‘Film will be eliminated by 2000 A.D.’’[1] In 1985 this statement was enhanced: ‘‘A few years ago, Capp predicted that all radiology departments would be electronic by the year 2000. A conservative estimate in 1980, it now appears that this change will occur at least 5–10 years earlier than predicted.’’[2] Obviously this has not occurred. In fact, sales of film for medical imaging continue to grow, by about 5% per year in the U.S. While the use of film for screen-film imaging has remained flat, the use of laser film has significantly increased. The boost in laser film use over the last decade has been due to an increased number of inherently digital imaging procedures, principally MRI and CT. This growth in laser film use will continue in the near future with the greater use of digital receptors in conventional radiography.

Past experience also teaches us that clear technological advances do not always totally replace their predecessors, or at least may take quite some time to do so. Radio still exists in spite of TV, audiocassettes are still sold alongside CDs, and I still use pencil and paper in spite of my dependence on my computer. Economics, system performance, convenience, and ease of the human interface usually determine the fate of new technologies. We may be approaching a phase transition in the next 5 years that will allow digital and filmless medical imaging to grow substantially. But will the use of film actually vanish? I think not in the foreseeable future.

CT is a totally digital acquisition technology. From its inception one has always been able to read images from a monitor, with no loss of image quality, and with the advantage of being able to adjust image contrast and brightness. Yet, over these many years the standard for interpreting CT images has been to reproduce the images on film, at fixed contrast and brightness, for viewing on illuminators. The ability to view many images together, at full resolution and with manual random access, has been a great strength of film, since there is no need to zoom or page through a set of images. The acceptance of soft copy diagnosis will need to be prodded by the latest improved technology and by the enticements that its unique methods of image management and manipulation can offer.

Finally the questions of image quality and economics need to be addressed. Strictly looking at MTF and DQE curves, present CR systems offer image quality approaching but not yet equal to screen-film. However CR's other advantages, such as enormous dynamic range and ability to digitally process the image to better visualize useful clinical information, make CR quite competitive to screen-film in clinical image quality. Flat panel (DR) technologies now in development may even surpass screen-film in diagnostic quality. However, DR systems costing hundreds of thousands of dollars per image receptor will find limited initial use. At present, CR can be more economically feasible than conventional film technology, particularly for larger departments, by eliminating the film cost, film viewers, and film processor upkeep, even though CR cassettes and processors are substantially more expensive than their screen-film counterparts. This initial cost, along with the additional costs of fully implementing a totally filmless department employing PACS, may be prohibitive for smaller facilities, for some time to come. This is particularly true for facilities with low throughput or in depressed economic areas.

Rebuttal

I agree with most of Dr. Stewart's arguments. We both agree that the use of filmless digital technology will see a rapid expansion in the next few years. Our major differences may simply involve the time frames we have chosen. I still believe that in 10–20 years the use of film will be substantially reduced but not eliminated. Larger facilities certainly have substantial incentives to go filmless, not the least of which is the convenience of image access to the medical staff and the taming of fileroom problems. However, smaller clinics and medical facilities in less economically and technologically advanced parts of the world will continue to use film in the foreseeable future. For these latter facilities, filmless medical imaging in its present technological state even with advances anticipated for the near future, will not offer enough incentive for change in the next 10–20 years. For them film will remain more economically feasible while continuing to provide quite adequate image quality and user convenience.

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5.9. Lossy compression should not be used in certain imaging applications such as chest radiography

E. Russell Ritenour and Andrew D. A. Maidment

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OVERVIEW

Computational techniques are frequently used to compress image data so that transmission and storage requirements are reduced. If the computational techniques result in no loss in image resolution, the technique is referred to as lossless compression. Greater compression of data may yield some loss in spatial or temporal resolution, and is referred to as lossy compression. In some radiologic examinations [e.g., gastrointestinal (GI) studies], some resolution loss may be tolerable, whereas in others (chest examinations and mammography) it conceivably could result in missed pathology. Without lossy compression, however, data requirements can be overwhelming for transmission, storage and retrieval of images such as chest films. The unanswered question, addressed in this Point/Counterpoint issue, is whether some degree of lossy compression can be tolerated in chest radiography.

Arguing for the Proposition is E. Russell Ritenour. Dr. Ritenour has been at the University of Minnesota since 1989. He is Professor and Chief of Physics, Department of Radiology, Medical School and Director of Graduate Studies in Biophysical Sciences and Medical Physics in the Graduate School. Receiving his Ph.D. in physics from the University of Virginia in 1980, he completed an NIH postdoctoral fellowship in medical physics at the University of Colorado Health Sciences Center, where he remained for nine years and served as Director of Graduate Studies in Medical Physics from 1984 to 1989. His research interests include radiologic quality assurance, distance learning systems, and computer-based instruction.

Arguing against the Proposition is Andrew D. A. Maidment. Dr. Maidment received his Ph.D. in Medical Biophysics from the University of Toronto in 1993. He is currently Assistant Professor of Radiology and Director of Radiological Imaging Physics at Thomas Jefferson University in Philadelphia. He has authored more than 65 peer-reviewed journal articles, proceedings papers and abstracts. He has won several awards, including First Place in the 1994 Young Investigators Competition of the International Union for Physical and Engineering Sciences in Medicine. He is active in the ACR and AAPM, including chairing Diagnostic Imaging TG 16, Standards for Noise Power Spectrum Analysis. His research interests include digital mammography, 3D imaging of the breast, digital radiography detector physics and PACS.

FOR THE PROPOSITION: E. Russell Ritenour, Ph.D.

Opening Statement

At present, the only published medical standard for image quality in the realm of digital image transmission is the ACR Standard for Teleradiology.[1] It states that ‘‘When a teleradiology system is used to produce the official interpretation, there should not be a significant loss of spatial or contrast resolution from image acquisition through transmission to final image

display.'' The phrase ''significant loss'' is sufficiently vague that, until recognized standards-setting organizations, such as the AMA, DICOM, FDA, or the ACR, provide specific guidance in this area, I argue that, for legal reasons, the use of lossy compression is not advisable.

Malpractice cases require both sides to present their evidence in a way that a nontechnical individual can understand. The outcome of this process is particularly difficult to predict when the technology in question (and its accompanying literature) is still at a relatively early stage of development. I maintain that the literature in the area of medical efficacy of the effects of lossy compression is at an early stage. At such an early stage, both sides of a case may be able to use credible expert witnesses to construct convincing cases because individual studies may, legitimately, produce diametrically opposite results. The reasons for disagreement, which include insufficient statistical power, the presence of confounding factors, the difference between correlation and causation, are notoriously difficult to explain to a lay audience.

Some of the issues that relate particularly to the subject of image quality in radiology PACS and teleradiology are also difficult to communicate to a jury of lay people. These issues include differences in image quality among different modalities, the role of display systems, patient data management, and communications infrastructure in the delivery of patient care, and the rapidly evolving technology used in digital storage and transmission. Not the least among these is the difficulty of answering the deceptively simple question: At what point in the imaging chain is the ''original'' image ''acquired''?

As the medical literature on a new technology reaches a higher level of maturity, key issues are recognized and the criteria by which implementation of the new technology will be deemed successful are identified. Multicenter clinical trials often appear at this stage, although not in all cases. When the literature has reached such a level of maturity, it is possible to recognize consensus through the appearance of the reports from government advisory groups, and academic and professional societies.

In summary, I maintain that the use of lossy compression for some imaging procedures is inadvisable at the present time. There is no appropriately citable medical standard. The primary reason for this lack of standards is the relatively early stage of development of medical literature in this area. It is an appropriate time for government advisory groups, and academic and professional societies to begin to set standards in this important area of medicine. But, it is an inappropriate time for individual radiologists to use lossy compression in clinical practice.

Rebuttal

I agree that there is a large and continually growing body of literature showing that lossy compression may be used without significant degradation of image quality. However, I maintain that this issue has two components: technical and legal. A vital link in the chain of events that leads to a medical standard is, as of this writing, missing. This link is the presence of citable reviews and recommendations from medical advisory groups. Without that link, individual radiologists put themselves at legal risk.

I do not suggest that the medical community wait for long. On the contrary, the existence of this issue speaks to a need for action. Fortunately, there are some developments in this area. One example is a project of the AAPM Committee on Research and Technology Assessment.[2] This project seeks to evaluate the effects of compression in musculoskeletal and thoracic images. The committee plans to submit the results of the study to the ACR specifically for the purpose of

extending the current ACR Standard on Teleradiology. As of this writing, NIH funding for this project is being sought. A corollary development is the possibility that a forthcoming revision of the JPEG standard will include wavelet compression, one of the most successful methods of achieving ‘‘substantial equivalence’’ with a high compression ratio. If so, it will probably be adopted by DICOM since they already support JPEG. This would help to standardize procedures and specifications.

Compression standards should be and will be adopted. However, until they are, I will continue to advise the physicians with whom I work to avoid the use of lossy compression in images used for primary diagnosis, particularly in imaging applications such as chest radiography.

AGAINST THE PROPOSITION: Andrew D. A. Maidment, Ph.D.

Opening Statement

Lossy compression (LC) is an indispensable part of medical imaging. The need for LC is clear—image sizes exceed the practical and economic limits of telecommunications and storage devices. Moreover, the initial fears that LC would mask subtle pathology have proven to be unfounded. Study after study is showing that all imaging applications should be considered as candidates for LC, albeit with potentially different techniques and compression ratios.

There is a definite need for LC in the transmission and storage of medical images. A typical radiographic study will be between 20 and 100 MB. If it is necessary to send such data in a timely fashion (i.e., a few minutes), either expensive high speed networks are required (e.g., T1 or faster), or LC must be utilized. When one considers storage of these images for five or more years, even small institutions performing 10 000 cases per year can quickly accumulate multiple terabytes of data. LC reduces both storage hardware and media costs, while speeding retrieval since more image data can remain on fast devices longer.

The most common concern is that LC may suppress relevant details or inject spurious noise into images. Such concerns are largely unfounded. The effect of LC depends upon the compression ratio and method. As the compression ratio is increased, the first noticeable effect is the removal of high frequency decorrelated noise, followed by increased blurring and finally by the introduction of artifacts.[3] Detectability degradation from LC can therefore be treated as being equivalent to SNR reductions from other sources. Zhao *et al.*[4] have shown that detectability is equivalent for 4.5:1 LC images and uncompressed images. They have also shown that 17.4:1 LC images are equivalent to uncompressed images, if the LC images are acquired with 25% higher input SNR. Stated another way, a 200 speed LC screen-film image compressed 17:1 would be equivalent to an uncompressed 300 speed screen-film image. Numerous studies have shown that LC can even improve image quality. For example, JPEG LC has been shown to reduce speckle in ultrasound images. LC has also been shown to offer improvement in the detection of lesions in chest radiographs.[5]

Medico-legally, LC is little different from other forms of image processing. All digital imaging modalities perform image or data processing prior to display. We accept such manipulations through articles of faith and the presumption that FDA approval is an endorsement of the efficacy of the device. In fact, the ACR and FDA both allow LC; they only require that the use of LC and the compression ratio be noted on compressed images. The ACR also suggests that the

compression ratio be user selectable. Trained observers can thus learn to recognize compression artifacts just as they do gridlines or processor artifacts, and compensate for them appropriately.

In summary, not all forms of LC are equal. Some will be better suited to one type of image than another. Moreover, scientific studies must be performed prior to acceptance of specific LC uses. However, there has been sufficient proof in the literature over a sufficiently broad range of applications[6] to demonstrate the universal acceptability of LC.

Rebuttal

It most certainly is not ‘‘an inappropriate time’’ to begin use of lossy compression (LC). I agree that LC lacks an authoritative standard, but there is a DICOM Working Group addressing this exact issue. It is important to realize that radiographic interpretation of LC images occurs daily throughout the world. It is through LC that university medical centers can provide subspecialty radiological expertise to small rural communities that otherwise would be served by people who may not be adequately qualified. Is there a greater loss of information in LC of images or in the unskilled interpretation of images?

In spite of many jokes to the contrary, people should not live their lives in fear of lawyers. Rather, lawyers and the law can be seen to serve a constructive purpose in society. They require us to consider the consequences of our actions. One might argue that in spite of concerns of potential future lawsuits, medical science and in fact all fields of human endeavor continue to develop and grow. However, it is equally possible that legal and ethical accountability subconsciously drives us to continuously improve our existence. Such improvements necessarily take into account societal needs, and the cost that society is willing to pay for such improvements. LC is just one of the many improvements that allows us to implement digital imaging in radiology with the concomitant improvements in image quality, medical care, and the accessibility to such care. I would argue, therefore, that timely adoption of LC in radiology is a priority so long as the conditions that require LC exist. However, as with all innovations in radiology, LC must be properly utilized. Thus, it is important that we educate users of the uses and potential abuses of lossy compression.

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CHAPTER 6

Mammography

6.1. All mammograms should be double-read

Craig Beam and R. Edward Hendrick
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OVERVIEW

Several studies have demonstrated that independent double reading of screening mammograms improves the detection of possible cancers. However, several arguments have been made against double reading, including: (1) a single proficient mammographer should be able to identify virtually all detectable cancers; (2) more false positives and therefore more unneccssary biopsies will be created by double reading; and (3) double reading increases the time but not the reimbursement for mammography. In October 1997, the National Cancer Institute held a two-day workshop which concluded that double reading increases the sensitivity of mammography screening by about 5%. Still, very few centers practice double reading. This Point/Counterpoint series explores the two sides of the issue of double reading of mammograms.

Arguing for the Proposition is Craig Beam. Craig Beam, Ph.D., is Director of Biostatistics, Robert H. Lurie Cancer Center, Northwestern University Medical School. He is also Associate Professor, Department of Preventive Medicine, Northwestern University Medical School. Dr. Beam received the Ph.D. in Statistics from lowa State University in 1989. He was Assistant Professor, Department of Radiology at Duke University from 1989 to 1992. Dr. Beam's research interests are in the evaluation of diagnostic technologies. He has been working for the past 5 years developing methods for the assessment of diagnosticians. He currently is principle investigator on an NCI-funded study of the variability in screening mammogram interpretation.

Arguing against the Proposition is Ed Hendrick. Dr. Ed Hendrick is Professor and Chief of the Division of Radiological Sciences at the University of Colorado Health Sciences Center. He helped develop the ACR Accreditation Programs in mammography, stereotactic imaging, and MRI, and served as Chairman of the ACR MAP Physics Subcommittee from 1987 to 1996. He is also Chairman of the ACR Committee on Mammography Quality Assurance, which wrote the ACR Mammography QC Manuals. He has served as Treasurer and President of the Society for Magnetic Resonance Imaging, as co-chair of the Agency for Health Care Policy and Research Panel on Quality Determinants of Mammography, and as a member of the National Mammography Quality Assurance Advisory Committee. He is a fellow of SMRI, SBI, ACR, and AAPM.

For the proposition: Craig Beam

Opening Statement

The benefits and costs of double reading in radiology has been a much published topic and various forms have been considered. Yerushalmy[1] investigated the use of double reading in mass radiology. In 1952 Groth-Peterson[2] investigated the magnitude and impact of individual variation in the reading of photoflurograms and empirically investigated the value of dual reading. A consequence of this study was that dual reading was implemented in a mass screening campaign against tuberculosis in Denmark. Rimington[3] investigated two forms of double reading (in one form only negative films were initially reread) and concluded that neither form of double reading ought to be implemented in the mass screening of chest x rays because the administrative costs outweighed the slight increase in active cases. A 1976 study[4] of the value of consultation among radiologists found consensual diagnosis to outperform simple majority rule based on independent interpretations. Stitik[5] concluded that the economic burden from double reading might be reduced if nonphysicians could do screening. Hessel[6] investigated the effectiveness and cost of an independent third arbiter in chest radiograph interpretation and concluded that ‘‘the choice between single and multiple interpretations must be evaluated in each clinical setting and should consider expected improvements in accuracy, implications for patient care, and additional costs (p. 589).’’ Anttinen[7] and Thurfjell[8] investigated the use of independent double reading in screening mammography. Both studied two radiologists and found double reading to increase case detection. However, although Thurfjell’s method was limited to the use of independent interpretations, Antinnen’s study included a consultation between the two radiologists whenever a case was considered for recall by one of the radiologists. A recent study of the impact of reader variability in double reading demonstrated that the effectiveness of double reading can vary widely depending on the reading pair.[9]

In reality, double reading has many possible forms, each of which need to be objectively evaluated for their impact to sensitivity, false positive errors, and practicality. Double reading in screening mammography should be treated like other diagnostic adjuncts, such as computer-assisted diagnosis, and developed as a useful technology in its own right.

Rebuttal

Dr. Hendrick raises several important issues related to the use of double reading in screening mammography. Among these are the increased rate of false positives, the increased costs required to implement double reading, and problems associated with the practical implementation of double reading. Of course, none of these problems is unique to double reading, they beset almost every technological innovation in radiology.

Dr. Hendrick cites research I have conducted as an argument against double reading[9] (see also Ref. 10). The results we found in doing this research speak, on average, against widespread adoption of independent double reading for the very reasons pointed out by Dr. Hendrick. However, the study analyzed the extent of variability in the effectiveness of double reading, as well as the average performance in a population of radiologists. We found that the impact of double reading can be highly variable, and possibly advantageous for some pairs of readers. An example given in our paper shows a distinct improvement in the sensitivity of one of two radiologists with a very minimal increase in false positives.

The key point to be underscored is that double reading needs to be evaluated in the many forms that it might take. Furthermore, since human variability can exercise a strong impact on its effectiveness, double reading might be best evaluated at the level of individual practices, leaving the decision whether or not to implement this adjunct up to radiologists.

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Against the proposition: R. Edward Hendrick

Opening Statement

Double reading of mammograms is not common among U.S. mammography practices. Requirement of double reading at U.S. mammography practices would have marginal benefit, would trigger an excessive number of negative biopsies, and would be financially disastrous.

The asserted benefit of independent double reading, an increased sensitivity of approximately 5%, is achieved at the expense of 15% higher call-back rate.[1] Dr. Beam's own research showed that the improvement in sensitivity due to double reading is highly variable and depends on the particular pair of radiologists involved.[2] His research also provided the methods to show that in a screening population where the incidence of breast cancer is 3–6 per 1000, as in the typical U.S. mammography practice,[3] double reading would cause the average radiologist to trigger 167 to 335 additional negative biopsies for each additional cancer found.[2] Thus, double reading by the average U.S. radiologist pair would have a small, highly variable benefit, at tremendous added cost, both economic and psychological, due to the large number of negative biopsies that double reading causes.

Current Medicare reimbursement for screening mammography is $64.73, $44.02 for technical and $20.71 for interpretation fees.[4] At current reimbursement rates, both screening and diagnostic mammography lose money at most mammography sites. MQSA Final Rules going into effect in 1999 will add several dollars to the cost of each woman's mammogram due to added equipment and direct patient notification of results requirements.[5] Requiring double reading of mammograms, whether screening or diagnostic, would add logistic difficulties and unreasonable costs for mammography practices.

Diagnostic mammography already requires a radiologist to be on site during the procedure. Double reading of diagnostic mammograms in a timely manner that might affect the diagnostic decision would require two radiologists to be on site and available to interpret mammograms, a practical impossibility at most sites.

Most screening mammograms are batch-read and would appear to better accommodate double reading. There is still the need, however, to interpret screening exams and to deliver mammography reports in a timely fashion to patients and their referring physicians. Double-reading screening mammograms would require bringing two radiologists to the same place to batch-read films placed on the same alternator or would require delivering films to two different sites for loading on two different alternators. The first alternative might work at some larger practices, but would be impractical at the great majority of smaller, private mammography practices. The second alternative is time-consuming and expensive for any practice. In addition, the standard practice of marking the locations of suspicious findings on films for follow-up or biopsy would have to be eliminated to permit independent double reading.

Who will pay the added costs of a second interpretation, additional film handling, and more complicated reporting caused by double reading? To ask U.S. mammography practices to absorb these added costs within the current reimbursement scheme would spell economic disaster for most sites. To expect Medicare, insurance companies, and women themselves to pay an additional $25–30 per screening mammogram to cover the costs of double reading is unrealistic. When these payers learn that double reading yields a marginal and variable increase in sensitivity, at the price of a tremendous increase in negative biopsies and their costs, their support for double reading is likely to vanish.

Rebuttal

I agree with Dr. Beam that double reading has many forms, each of which needs to be evaluated for its impact on sensitivity, false positives, and clinical practicality. This is far short of agreeing that double reading is ready for implementation in clinical practice.

Currently, direct digital acquisition and computer-aided detection methods are in the process of receiving FDA approval as clinical tools in mammography, with improved methods for acquisition and detection evolving rapidly. This is exactly the wrong time to presume that double reading by human observers is the best or most efficient interpretation scheme to improve mammography outcomes.

Double reading may have some role as a quality assurance measure in mammography, if results of double reading can be used as an effective quality improvement tool. That is far short, however, of accepting double reading as a standard in clinical practice.

The best argument against the clinical effectiveness of double reading comes from Dr. Beam's 1996 paper on the subject:[6] ''Our analyses also show that, because of human variability, independent double reading in screening mammography can have a widely variable effect. Not all radiologists complement each other diagnostically, and some add little, if anything, to the accuracy of the other. Adding the reading from a more experienced radiologist does not necessarily improve the TPR [true positive rate or sensitivity] of a radiologist with less experience.''

As Dr. Beam suggests in his opening statement, various forms of double reading need to be compared to single reading and to different methods of reading with the aid of computer-aided detection methods, preferably in a realistic patient population. This should be done for both film and digital mammography before we can conclude that one interpretation scheme is best for clinical practice. Such assessments should include cost-benefit analyses that compare not only the costs and benefits of the interpretation scheme, but also the costs and benefits of the additional procedures triggered by the specific double reading method. Only if cost-benefit analyses prove favorable for double reading should it be considered as a standard of clinical practice for screening or diagnostic mammography. Then double reading might become one of those rare areas in medicine where appropriate research preceded adoption into clinical practice.

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6.2. Pre-menopausal women should be actively encouraged to seek screening mammograms

Andrew Maidment and Elizabeth Krupinski
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OVERVIEW

The controversy continues over the merits of screening mammography for pre-menopausal women (women<50 years of age). Many persons believe that screening benefits are intuitively obvious, and are well supported by experimental evidence. These individuals endorse screening mammograms for younger women. Others feel that the scientific evidence for screening mammography is inconclusive, and that this uncertainty should be communicated to younger women contemplating mammography. Until now, medical physicists have been relatively silent on the screening issue. But this Point/Counterpoint breaks the silence.

Arguing for the Proposition is Andrew Maidment, Ph.D. Dr. Maidment received his Ph.D. in Medical Biophysics from the University of Toronto in 1993. He is currently Assistant Professor of Radiology, and Chief, Physics Section at the University of Pennsylvania in Philadelphia. He has more than 110 peer-reviewed journal articles, book chapters, proceedings papers and abstracts. He has won several awards including First Place in the 1994 Young Investigators Competition of the International Union for Physical and Engineering Sciences in Medicine. He is active in the ACR and AAPM, including chairing Diagnostic Imaging TG 16, Standards for Noise Power Spectrum Analysis. His research interests include digital mammography, 3-D x ray imaging of the breast, and digital radiography detector physics.

Arguing against the Proposition is Elizabeth Krupinski, Ph.D. Dr. Krupinski received her undergraduate education at Cornell and her Ph.D. at Temple University, both in Experimental Psychology. She has been at the University of Arizona since 1992 in the Departments of Radiology and Psychology. Her interests lie in medical image perception and decision-making, especially in the digital environment. The human-computer interaction is also of interest from the human factors perspective. She is interested in the causes of interpretation error and in developing ways to improve training from an image perception perspective. Dr. Krupinski is also the Associate Director of Evaluation for the Arizona Telemedicine Program.

FOR THE PROPOSITION: Andrew Maidment, Ph.D.

Opening Statement

There is almost complete consensus that routine mammographic screening can reduce the mortality of breast cancer. Recent results indicate mortality can be reduced by 40 to 45%.[1] Controversy continues, however, over whether this reduction is shared by all women or whether it begins after menopause, at approximately 50 years of age in developed countries. This dichotomistic doctrine is fallacious; all women should be actively encouraged to seek screening mammograms starting at age 40.

There is little that distinguishes breast cancer in a woman in her 40s from that in a woman in her 50s. The natural incidence increases only slightly between the two decades.[2] The etiology, pathology and clinical sequelae are virtually identical. Furthermore, while women 40–49 account for only 16% of breast cancer incidence, they account for 40% of the years of life lost to breast cancer.[3] Thus, women in their 40s will potentially benefit most from screening. The meta-analysis of randomized clinical trials (RCTs) by Humphrey *et al.*[4] indicates that the summary relative risk for women of ages 40–49 is 0.80 (CI 0.67–0.96), compared with a summary relative risk of 0.78 (CI 0.70–0.87) for women older than 50. These estimates correspond to one life saved per 1385 women for the younger group and one life saved per 838 for the older group.[4] Thus, the benefit of routine screening for both groups of women is comparable.

Admittedly, there is not universal agreement on this issue. Notably, the Cochrane Report[5] found no benefit for women aged 40–49. However, the Cochrane Report considered only 2 of 8 applicable RCTs. One of these, the CNBSS study, has been the subject of extensive criticism.[6]

That said, mammography is far from perfect. Mammography lacks sensitivity; some cancers are missed. Mammography also lacks specificity; many healthy women endure negative biopsies, resulting in a high monetary cost, as well as physical and psychological costs. Mammography entails the risk of inducing cancers, but this risk must be weighed against the probable benefits. It is estimated that annual screening from age 40 to 49 will induce fewer than 8 cancers per 100,000 women screened.[7] Thus, nine lives would be saved for each woman who suffers an iatrogenic cancer. Mammography may find indolent cancers. Finally, universal screening guidelines are questionable; for example, consider women with genetic predisposition to cancer (e.g., BRCA-1/2). These are not failings of mammography alone, however; they demonstrate the boundaries of our knowledge of breast cancer, and limitations of current diagnostic and treatment methods.

Mammography may have some flaws, but it is the best screening tool for breast cancer available today. Above the age of 50, it is almost universally accepted that the death rate from breast cancer can be reduced at a monetary, physical and psychological cost that society accepts. There is no evidence to support a different approach for women in their 40s. Finally, early mammograms provide a highly valuable baseline for radiologists attempting to interpret mammograms later in a woman's life. Thus, a variety of considerations strongly support extension of the benefits of routine mammographic screening to this younger population. That is, all women should be actively encouraged to seek screening mammograms starting at age 40.

Rebuttal

Even casual readers of both my own and my colleague's opening statements on this topic will remember Leonard Courtney's famous words "lies — damn lies — and statistics." [8] First, I disagree with the assertion that mammography and menopause should be tightly linked. The mean age of menopause in the US is 51, not 45.[9] Menopause is exceptionally rare below the age of 40 or above the age of 59.[9] If menopausal changes had the dominant responsibility for breast cancer incidence, then there should be a stronger correlation with menopause. Yet the strongest correlate of breast cancer risk is age, increasing almost linearly with age from 30 to 75.[9]

Second, the data related to positive-predictive value (PPV) cited by my colleague in this Point/Counterpoint are dated and fail to distinguish prevalence (first) screening from subsequent screenings. Consider for example the Ghent program; PPV = 14.2% for prevalence screens of women in their 40s, while PPV = 28.3% for prevalence screens of women in their 50s. However,

PPV = 19.7% and 16.8% in subsequent screens in 40s and 50s, respectively. The increased PPV of the 50s prevalence screen is due to the fact that screening has been started too late for these women; they already have a significant number of readily-detectable cancers. Moreover, the equal values of PPV in subsequent screenings in both age groups clearly indicate that mammography is equally effective for both.

The assertion that young dense-breasted women benefit less from mammography is also questionable. Kerlikowske[10] has shown that sensitivity in women aged 50 and older is affected by breast density (98.4% fatty vs 83.8% dense; $P<0.01$), yet for women younger than 50 this is not true (81.8% fatty vs 85.4% dense).

Screening will benefit from advances in breast cancer biology, better diagnostic tools and improved treatments. There is little doubt, however, that mammography for women aged 40–49 is not only appropriate, but essential. Likewise, clear, consistent and simple screening guidelines are essential. "Start annual screening on your 40th birthday" fulfills this role exactly; it is the perfect birthday gift for any woman.

AGAINST THE PROPOSITION: Elizabeth Krupinski, Ph.D.

Opening Statement

Although the benefits of mammography for early detection and treatment of breast cancer may seem obvious, there is still considerable debate regarding its overall efficacy, who should be screened and at what age.[11,12] The majority of trials (with findings both for and against screening) have been done with women 40 years of age and older. Although the general consensus is that screening mammography is useful for women over 40 (and more so as women get older), the evidence regarding benefits for women under 40 is scarce. Menopause typically occurs between 45 and 50 years of age, with the last two years of perimenopause starting the accelerated decline in estrogen levels. The incidence of breast cancer, to a large extent, parallels menopause onset. Incidence is very low for women in their twenties, increases gradually and plateaus at 45, then increases dramatically after 50. In fact, approximately 50% of breast cancers are diagnosed in women over 65, and recent evidence indicates that since the 1980s breast cancer incidence rates have increased only in women over 50.[12,13] Invasive breast cancer diagnoses in women over 65 accounts for 45% of all new breast cancer cases, and 45% of all breast cancer deaths are in women over 65.[12]

In terms of sensitivity and specificity, screening mammography is less effective in women with dense breasts, especially younger women.[14,15] The positive predictive value (PPV) ranges from 20% in women under 50 to 60% to 80% in women over fifty.[16,17] The low PPV reflects the higher false positive rate[17] for younger women. Although the psychological effects of false positives are generally short-lived and have few lasting consequences,[12] the immediate experience produces high levels of anxiety, especially since waiting times can be prolonged between initial report and follow-up procedures. In addition to low sensitivity, specificity and PPV in younger women, repeated screening exams starting at a younger age lead to an increased risk of radiation-induced breast cancer.[12,18] This is especially true for women with a family history (i.e., genetic predisposition) of breast cancer, or for women being treated with radiation for other purposes (e.g., radiation treatment, scoliosis progression imaging).

The relative lack of efficacy, and the potential for physical and psychological risks, support the proposition that most premenopausal women should not be encouraged to seek screening mammograms. Younger women who are at risk because of a family history or known genetic predisposition to breast cancer (5–10% of all cancers) should be screened, because their cumulative risk of breast cancer is higher than average.[12] For the average premenopausal woman, a careful analysis of the risk factors associated with breast cancer, and adherence to a healthy lifestyle based on prevention, may be more useful than screening mammography. Although certain risk factors cannot be altered (e.g., age of first menarche, late menopause), there are many others that can be controlled, such as not smoking, having children early in life, increased physical activity, maintaining proper weight, reduced alcohol intake, breastfeeding rather than bottle-feeding, and sticking to a healthy diet.[19] Educating women about these risk-reduction factors, and suggesting other methods of screening that do not involve radiation exposure (e.g., ultrasound, MRI), should be the focus of communication to younger women contemplating the costs and benefits of mammography.

Rebuttal

"Statistics—the only science that enables experts using the same figures to draw different conclusions." [20] Reading the statistics on breast cancer screening often leads one to this very conclusion. The Humphrey *et al.*[21] report does indeed report that the relative risk for women aged 40–49 is 0.80, and 0.78 for women older than 50, based on their meta-analysis of eight high profile breast screening trials. This report brings up several other points, however, that lead one to question the strength and generalizability of the conclusions. Most important is the authors' rating of the quality of original studies used in the meta-analysis. Each of the screening trials included in the meta-analysis had important methodological flaws, and seven of the eight studies were rated only fair in terms of study quality. The eighth was rated poor. Also, the authors state that of the seven trials conducted since 1963 that included women aged 40–49, only one actually planned to evaluate breast cancer screening in this group, and none (even the one that specifically included it as a statistical variable) had sufficient statistical power. The lack of power is due mainly to inadequate sample size once data were stratified into age subgroups. There is also some question[22] about when the benefits of screening mammography actually appear in the 40–49 age group in these trials. The potential survival benefit in women aged 40–49 is typically not observed until the trial has progressed for several years. The women included in the studies are now just in the over-50 age group.

In the end, each woman must make a personal decision by trying to understand the overall picture, including an understanding of absolute risk, relative risk and the factors that contribute to breast cancer risk. No studies have been designed that offer guidance on how an individual woman can assess her lifestyle, family history, and environment in the context of available medical evidence to decide when and how often she should be screened. Clearly there are women at higher risk, for whom this decision may be easier. But for women not at obvious risk, the use of the single variable of age (other than gender of course) to determine when screening should begin may not be sufficient. To improve breast cancer screening outcomes, we need to develop better and more accurate models that include as many risk factors as possible for each individual woman.

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6.3. Computer-aided detection, in its present form, is not an effective aid for screening mammography

Robert M. Nishikawa and Maria Kallergi
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OVERVIEW

An obvious application of computer-aided detection (CAD) systems is in the interpretation of screening mammograms. The intent is to prompt the radiologist to cancers that otherwise might have been missed in the first reading of the mammogram. Indeed, several studies have claimed to demonstrate that CAD is beneficial for screening mammography. For example, in a report on a large prospective study in the US it was concluded that: "*The use of CAD in the interpretation of screening mammograms can increase the detection of early-stage malignancies*."[1] However, recently published results from a similarly large study in the UK have been claimed to show that CAD, in its present form, is not effective in that there was no significant difference observed in cancer detection rates *with* CAD compared with reading mammograms *without* CAD.[2] This claim forms the basis of this month's Point/Counterpoint debate.

Arguing for the Proposition is Robert M. Nishikawa, Ph.D. Dr. Nishikawa received his B.Sc. in Physics in 1981 and his M.Sc. and Ph.D. in Medical Biophysics in 1984 and 1990, respectively, all from the University of Toronto. He is currently an Associate Professor in the Department of Radiology and the Committee on Medical Physics at the University of Chicago. He is a Fellow of the AAPM. His current research interests are in digital radiography, computer-aided diagnosis, mammography, and measures of image quality.

Arguing against the Proposition is Maria Kallergi, Ph.D. Dr. Kallergi received her Ph.D. in Physics and Electrical Engineering from the University of South Florida in 1990. Her background was in digital detectors and semiconductor devices but, in 1991, she started a career in medical imaging as a Postdoctoral Research Fellow at the H. Lee Moffitt Cancer Center & Research Institute and the Department of Radiology at the University of South Florida, where she is currently an Associate Professor of Radiology. Dr. Kallergi's research interests focus on two- and three-dimensional digital breast imaging technologies and computer methodologies for the automated detection and diagnosis of breast, lung, and pancreatic cancers.

FOR THE PROPOSITION: Robert Nishikawa, Ph.D.

Opening Statement

For CAD to be effective, two conditions must exist. Firstly, the CAD system must be capable of detecting cancers that are missed clinically. Secondly, the radiologist must be able to recognize when the computer has found a missed cancer. There is ample evidence in the literature to support the first condition. However, published sensitivities for the detection of clinically missed breast cancers range from 50%–80%.[3,4,5] Hence, there is not conclusive evidence that the second condition is true.

There have been four published clinical evaluations of the use of CAD for the detection of breast cancers.[1,6,7,8] Two of these were inconclusive,[6,7] one because it was only a pilot study,[7] and two showed an apparent benefit for using CAD,[1,8] there was an increase in the number of cancers detected. However, neither of these two studies was statistically significant, probably because breast cancer prevalence in a screening population is low. In one of the two CAD-beneficial studies, clustered microcalcifications were detected in seven of the eight missed cancers that were detected by the computer and only one was a mass.[1] In the pilot study, the only CAD-detected cancer was a cluster of microcalcifications. The two other studies were retrospective temporal comparisons and it is not possible to determine what type of lesions the CAD system helped the radiologists find.

CAD detection of clustered microcalcifications can be effective in helping radiologists find cancers. This is because the sensitivity of the scheme is high—up to 98%. Further, very little normal breast anatomy mimics calcifications in a mammogram. Therefore, radiologists can easily dismiss false detections. However, radiologists do not miss calcifications as often as they miss masses. In two large studies, 30% of missed cancers demonstrated calcifications, while 70% demonstrated masses.[3,4] This implies that radiologists either do not look at the computer prompt for masses, or that they look at the prompted area but do not recognize that a cancer is present. As shown by Zhang *et al.*, one reason why radiologists tend to ignore correct prompts is that the false detection rate of the CAD scheme is too high.[9] The superposition of normal breast structure often mimics a mass. Not only does this increase the false-detection rate of the CAD scheme, but it also makes it difficult for radiologists to determine if the computer is prompting a true or false lesion.

I believe that computer-aided diagnosis will one day be pervasive throughout radiology. However, it is important that we understand its limitations, both technical and clinical. In this way we can improve the technology and this will lead to faster clinical implementation and acceptance. In my opinion, further research is needed to improve CAD for mammography, particularly for mass detection, so that it can truly be an effective clinical tool for radiologists. CAD for screening mammography is not quite there yet.

AGAINST THE PROPOSITION: Maria Kallergi, Ph.D.

Opening Statement

Success depends on a number of factors when assessing the effectiveness of any new medical technology, including computer-aided detection systems for screening mammography.

Firstly, there is the question of whether CAD has fulfilled its initial goal. CAD was intended as an aid to the radiologist. Its primary goal was to help detect breast calcifications and spiculated masses at an earlier stage. There are now several testimonies that current CAD systems meet this challenge with a positive impact on cancer detection rates particularly for masses.[8,10,11,12] In addition, callback rates, a major concern initially, have not been affected[13,14] and the false positive signals, a major turn-off factor in the first generation of CAD systems, have been significantly reduced in subsequent upgrades (by almost a factor of 2) and can now be handled with greater comfort and dismissed easily by the trained reader.[15]

In terms of clinical acceptance, ten years ago, when these systems were still in the research laboratories, the medical community was divided, with unfriendly skeptics being an overwhelming majority. Today, radiologists are still divided but the friendly group has grown bigger and friendlier and many of the skeptics have become converts. This change is a consequence of the clinical implementation of CAD that

has allowed the "learner" to practice and acquire the necessary skills for its use. It is also due to the positive results of recent studies that evaluated the systems clinically.[10] Radiologists now find that CAD has increased their level of confidence and that its role is not only that of a "second reader" but also a "refocusing tool" in the often monotonous and repetitive environment of screening mammography, where external factors cause attention interruption and possible observational oversight.

CAD has also had a positive impact beyond the radiologist: on the patient and the administrator. Patients appear more comfortable with the mammographic procedure, they demonstrate an increased level of security, and are more amenable to radiology decisions. Administrators are more likely to embrace CAD now because it can be seen as a marketing tool that could benefit the institution and, in some practices, it even makes good fiscal sense due to the higher reimbursement rate of the mammography package that includes CAD.

Admittedly, the current commercial systems have problems and limitations. Both are well known and understood. It is also well known, but poorly understood by those outside the CAD community, that CAD requires continued commitment and investment to reach the desired levels of performance. Although far from perfect, today's CAD is steadily shaping its role as part of the standard of care.[16] This is due to its demonstrated success in improving (i) the sensitivity of screening mammography and the confidence of the reader, (ii) the security and comfort of the patient, and (iii) the workflow and financial prospects of the administrator.

Rebuttal: Robert Nishikawa, Ph.D.

My colleague, Maria Kallergi, raises a number of important points. The most important one on which we agree is that further research is needed to improve CAD, because existing systems have problems and limitations. I, however, disagree that these problems are all known and well understood. I think the biggest problem is that experience has shown that radiologists frequently ignore "missed" lesions detected by CAD that turn out to be true positives. As Birdwell *et al.* noted, the cancer detection rate increased by 7.4% in their clinical study, whereas, in their retrospective study, CAD was able to detect at least 27% of "actionable" cancers.[4,11] This difference is one of the principle reasons why CAD is not effective in screening mammography.

Further I do not agree that callback rates remain unaffected by CAD. Studies by Freer[1] (18%), Helvie[7] (9.7%), Birdwell[11] (8.2%) and Cupples[8] (10.9%) all found that the callback rate increased when CAD was used. Further research is needed to understand whether the increase in sensitivity justifies the increased callback rate, although I believe that it probably does.

I do agree that there are intangible benefits of CAD to the radiologist. Higher confidence and less fatigue are just two. However, one would hope that this would result in higher performance. This has not yet been documented conclusively.

Defining the benefits of CAD in screening mammography is difficult because of the low cancer prevalence in the screening population. Clinical evaluations are the only true measure of clinical effectiveness. Retrospective studies, two of which Dr. Kallergi quotes as proof of the benefits of CAD, are not definitive and are often overly optimistic. No clinical study has demonstrated a statistically significant benefit for using CAD.

I believe that CAD systems will improve and become the standard of care in the future, but those CAD systems of the future will necessarily have higher performance than the systems studied to date. Newer versions with higher performance are now available and should be tested clinically.

Rebuttal: Maria Kallergi, Ph.D.

I do not disagree with my esteemed opponent on technical issues or future requirements of CAD systems for mammography. I disagree on the way success is judged. I argue that the usefulness of CAD technology today cannot be judged by diagnostic benefits alone. I further argue that benefits come in small "doses," as is the case for the vast majority of medical technologies, and depend on a variety of factors including practice type and volume, readers' experience, and method of interpretation. But even if we focus on the diagnostic benefits alone, recent studies provide convincing evidence that the two conditions set by Dr. Nishikawa as being necessary to demonstrate that CAD is effective, are met by current systems. Specifically, the work of Brem *et al.*[10] supports the first condition related to the capabilities of CAD, and that of Birdwell *et al.*[11] supports the second condition related to the readers' ability to interpret the CAD results correctly. This was a large prospective study, which demonstrated the clinical benefits of CAD with the surprising outcome that CAD was shown to be helpful in detecting masses that had been missed by the radiologist, whereas previous studies had shown most benefit for the detection of calcifications. These findings, along with results from previous studies,[8] strengthen the arguments against the Proposition and there is now substantial evidence that current CAD systems are effective clinically in more than one way.

If one problem has to be identified that potentially impacts negatively on the current CAD systems, it is that the marketing part of the technology was pursued before the science. The result has been the creation of a negative bias on the side of users, mainly due to high false detection rates. This bias has been, and still is, difficult to overcome. Also, we have been clumsy and unprepared for the training process. This has led to a longer and more difficult learning curve that has generated more bias and skepticism. Taking these two elements into account, it is not difficult to explain the inconclusive and sometimes contradictory results of earlier studies.

It cannot be denied that definitive diagnostic improvements will assuage all doubts regarding the usefulness of CAD in mammography. This, however, should not be our only criterion of success. If all factors are considered, we can conclude that current CAD systems, although not at optimum performance, are useful. This allows us to dream of what it will be like when optimum performance is reached.

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6.4. Film mammography for breast cancer screening in younger women is no longer appropriate because of the demonstrated superiority of digital mammography for this age group

Martin J. Yaffe and Gary T. Barnes

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OVERVIEW

The results of a head-to-head comparison of digital vs. conventional film mammographic screening have been published recently.[1] This was a two-year clinical trial conducted by the American College of Radiology Imaging Network in which about 50,000 women underwent both digital and film procedures sequentially. The authors of the report claim "**. . .** *that digital mammography was significantly better than conventional film mammography at detecting breast cancer in younger women*." These findings indicate that digital mammography is justified for younger patients. Previous studies, however, failed to demonstrate the superiority of digital over film for mammography. These studies, together with the greatly increased cost of digital over film, have led some to suggest that it is way too early to abandon film as the modality of choice for screening young women. Whether or not film is still appropriate for screening younger patients is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Martin J. Yaffe, Ph.D. Dr. Yaffe was born in Winnipeg, Canada, received his B.Sc. and M.Sc. degrees in Physics from the University of Manitoba, and, in 1978, his Ph.D. in Medical Biophysics from the University of Toronto. He is a Professor in the Departments of Radiology and Medical Biophysics at the University of Toronto, and serves as Chair of the Mammography Subcommittee of the AAPM Imaging Committee. His research is focused on creating improved methods for breast cancer detection. Since 1985 much of his work has been directed toward the development and validation of digital mammography, as well as on applications to enhance its value in providing new information to facilitate detection, diagnosis, treatment, and prevention of breast cancer. He and his wife, Robin, a psychologist, live in Toronto, where her skills help preserve his sanity.

Arguing against the Proposition is Gary T. Barnes, Ph.D. Dr. Barnes received his B.S. in Physics in 1964 from Case Institute of Technology (now Case-Western Reserve University), Cleveland, Ohio and his Ph.D. in Physics in 1970 from Wayne State University in Detroit. Following completion of his Ph.D., he received postdoctoral training in Medical Physics at the University of Wisconsin, Madison. In 1972 he joined the Department of Radiology at the University of Alabama at Birmingham (UAB) where, from 1976 to 1987, he was Chief of the Department's Physics Section and, from 1987 to 2002, was Director of the Physics and Engineering Division. In 2002 he became Professor Emeritus. He continues to be involved at UAB part time by chairing the Radioisotope and Radiation Safety Committee and teaching radiology residents. He is also involved with X-Ray Imaging Innovations, Inc., a technology development company he founded in 1998. Dr. Barnes has been active on committees of the AAPM, Southeastern Chapter of the AAPM (SEAAPM), ACR, RSNA, and the ABR, and is past President of the AAPM (1988) and SEAAPM (1979). He is a diplomate of the ABR (Radiological Physics), and a Fellow of the

AAPM, ACR, and the American Institute of Biomedical Engineers. He was the 2005 recipient of the Coolidge Award. Dr. Barnes' research interests are in diagnostic x-ray imaging and mammography and include work on scatter control, screen-film systems, digital radiography, and clinical medical physics. He is the author or co-author of 10 patents and 100+ scientific papers.

FOR THE PROPOSITION: Martin J. Yaffe, Ph.D.

Opening Statement

When I began working with mammography equipment, it was common for images to be recorded on direct-exposure film. Presumably this was because of the extremely high spatial resolution requirements for detecting breast cancer. Doses typically exceeded 10 mGy, timers were mechanical, proper breast compression was a thing of the future, and automatic exposure control and grids for mammography did not exist. We've come a long way—through xeroradiography and dedicated screen-film systems for mammography—and each technical development has improved the ability to detect breast cancer. Only five years ago, following considerable collaborative development by several academic and industrial groups, digital mammography was introduced commercially. The Digital Mammographic Imaging Screening Trial (DMIST)[1] may have been the first time that a new technology for breast imaging was actually put to the acid test to answer the question: "Is the accuracy of digital mammography equal to or higher than that of film?" The conclusion was positive—at least for certain subgroups of women, including those with dense breasts, women under 50, and premenopausal women.

Is digital mammography a mature technology? Of course not—there is ample room for further improvement and refinement. There is room for growth of new applications that will have a much greater impact on accuracy than the existence of digital mammography itself-applications like CAD, tomosynthesis, contrast imaging, telemammography, and dual-energy imaging. Each of these applications has the potential to improve the detection, diagnosis, and treatment of breast cancer in different ways. And the use of PACS in conjunction with digital mammography will improve the efficiency of image management.

So, until we develop something better, digital mammography should become the norm for breast cancer screening. Women with dense breasts will likely benefit from this technology because of its wide dynamic range, improved DQE, and adjustable brightness and contrast through a user-defined lookup table, as well as through sophisticated image enhancement methods that can be readily applied to digital images.

Another thing we learned from DMIST and other studies is that there is enormous inter-reader variability in interpreting mammograms. It is clear that technology is only part of the solution. Just as we have the technology to solve problems like hunger, other factors (like politics and inertia) frequently block our progress. We will gain at least as much in performance of breast imaging by improving and standardizing reader skills as we will in converting from film to digital mammography. What a great idea to do both!

AGAINST THE PROPOSITION: Gary T. Barnes, Ph.D.

Opening Statement

The premise for this Point/Counterpoint debate is based on a paper published in the October, 2005 issue of the New England Journal of Medicine.[1] A cursory reading of the paper supports the premise. However, the statement (attributed by Mark Twain to Benjamin Disraeli), "There are lies, damn lies and statistics," is particularly relevant when one reads the paper more carefully.

Of interest are the sensitivity and specificity values given in Table 3 of the paper and listed in Table I below.

Inescapable in the paper is the authors' bias for digital mammography. They state: "We found that digital mammography was significantly better than conventional film mammography for detecting breast cancer in young women, premenopausal and perimenopausal women, and women with dense breasts. There was no significant difference in diagnostic accuracy between digital and film mammography in the population as a whole or in other predefined subgroups." I find it disturbing that the New England Journal of Medicine reviewers and editor allowed the authors to make such blanket and unqualified statements. If there is no difference between digital and film mammography for all women and there is a significant difference in favor of digital mammography for women less than 50 years old, one might conclude that film mammography must be better for women greater than 50 years old. Although the greater-than-50-years-old group was studied, sensitivity and specificity numbers, or for that matter receiver operator characteristic (ROC) curves, were not given.

Even though sensitivity and specificity values are presented, the majority of the authors' conclusions are based on comparing areas under ROC curves. Comparing ROC curve areas gives excessive weighting to regions that have high false positive rates that are not relevant for screening. For example, the authors conclude that digital is significantly better than film mammography for dense breasts based on ROC area comparisons. This conclusion is not supported by the sensitivity and specificity values presented in the paper.

Another concern is that the paper compares the performance of digital mammography units with existing, and in many instances old and poor performing, film mammography units. The digital units were all new and tweaked to perform at the highest level. The authors looked for differences in the units of the four digital-mammography manufacturers that were included in the study (none were seen), but lumped all film mammography units together. As a reader of accreditation phantom images for the American College of Radiology (ACR) Mammography Accreditation Program (MAP) I, and other reviewers have observed that there are very noticeable differences in image quality of sites that have been accredited by the ACR. There are some mammography units with better scatter control that consistently yield better accreditation phantom images than those obtained with other units. The quality of screen-film processing impacts accreditation phantom and clinical images. The results of the study may well have been different if only state-of-the-art film mammography units with good scatter control and good screen-film processing had been compared with digital units.

In summary, the premise that film mammography is inferior to digital mammography and should not be used in examining young women is built on sand, not stone. The authors of the paper on which the premise is based are biased. They have chosen the statistics that support their conclusions, and they do not adequately discuss other statistics that are less supportive of their bias. It is not clear that the claimed improved diagnostic performance with digital would be realized if a site has a film mammography unit with good scatter control and good screen-film processing.

Rebuttal: Martin J. Yaffe, Ph.D.

I am disappointed that Dr. Barnes has used one of the classic logical fallacies, the "ad hominem" argument[2]—i.e., when you aren't able to attack a position held by a person, attack the person. He suggests that the DMIST researchers were biased. The DMIST results were published under peer review in a highly reputable journal. Is he also suggesting that the reviewers were biased? What is the evidence? In fact, a respected, independent statistical group blinded the researchers to the data until completion of the analysis. Until the investigators saw these results, they expressed concerns that a difference between the modalities would not be detectible because of the large reader variability. While there was hope that digital mammography might prove to be advantageous, there was a healthy level of skepticism as well. Furthermore, while the initial policy was to attempt to match doses between the two modalities, the investigators allowed the doses from digital to drop during the trial based on evidence from physics testing. If anything, this would work against an attempt to make digital mammography look better than film.

Dr. Barnes also suggests that the digital systems operated in peak form while the film systems were suboptimal. Again he provides no evidence for this claim. In fact, study sites were selected for their commitment to high quality and all imaging systems were MQSA compliant. The performance of both digital and film mammography was carefully monitored. In the case of sites using photostimulable phosphor systems, film and digital mammography was performed on the same units. Did the local medical physicists and technologists at all 33 sites work to sabotage film in comparison with digital? Film mammography is a mature technique, while the steep learning curve for both manufacturers and radiologists in understanding how best to use the new technology probably was a factor that could have undermined the success of digital mammography in DMIST.

Probably of greatest concern, however, is Dr. Barnes' inference that because there was no statistically significant benefit of digital mammography across the entire study population, while there was proven benefit for younger women and those with dense breasts, implies that film must have performed better in older women or those with fatty breasts. This is simply not the case. If one thinks about the nature of a statistical test, it involves comparing the difference between two values (in this case, areas under an ROC curve) to the statistical uncertainty in that difference. The analogy in imaging theory is Rose's criterion for object detectability of a signal difference in the presence of noise.[3] In DMIST, it was found that the difference was significant for younger women and those with denser breasts. While the difference was also positive (i.e., consistent with digital mammography being superior) in the overall population, the noise in this difference caused the results to be insignificant. There was no magic and no deception. Furthermore, the investigators did not "cherry pick" the data to obtain a result that was significant. The analyses were preplanned before the study was started. Limitations on article length precluded complete publication of all analyses, but a full subset analysis will be published shortly.

Finally, Dr. Barnes complains that the areas under the ROC curves were computed using the entire curve (i.e., using the standard approach). He suggests that this approach weighs the results inappropriately towards regions of the curve representing low specificity. Although it is conceivable that some other method might be more relevant, I'm not aware of a better method that has been validated. I am encouraged that the ROC curves show clear separation in favor of digital even at low false positive fractions typical of the use of mammography in screening, and that the curves show no indication of crossing at any specificity level.

Digital mammography was developed primarily to address limitations of film for imaging women with dense breasts, frequently younger women. In DMIST, of the 165 cancers in women with dense breasts, 24% were found only on digital compared with 11.5% found only on film.[1] We should be delighted that mammography can now be more helpful for those women.

Rebuttal: Gary T. Barnes, Ph.D.

I agree with my esteemed colleague that mammography has improved markedly in the past 40 years. I also agree that digital mammography is not a mature technology. I disagree that digital should be the norm for screening. As noted in my Opening Statement, Reference 1 is biased. It is not clear that digital is superior to state-of-the-art film mammography. Furthermore, digital is more expensive. The cost of a digital unit and review workstation is four or five times that of a conventional film unit and processor. The greater patient throughput of digital units is compromised by downtime at the sites, at least those I support. Service contracts are expensive and more than offset the cost of service and of film and chemistry consumed in film mammography. One inefficiency of digital is that it takes longer for radiologists to read an exam compared with film. We have a shortage of radiologists reading mammography, and digital aggravates the problem. For these reasons I suspect that a cost-benefit analysis (based on good data and science) would show that state-of-the-art film mammography is superior to digital mammography.

A travesty is that Centers for Medicare & Medicaid Services (CMS) reimburses more for digital than for film mammography. Reimbursing more for the same study and diagnostic performance just because the equipment costs more is an absurdity and is caused by lobbying by manufacturers. Digital mammography is a factor contributing to the spiraling costs of health care with no benefit.

It is disturbing how poor mammography is, either digital or film, at detecting cancer. A sensitivity of <50% is not good. We can do better. Based on our experience with CT and the ability of 3D x-ray techniques to remove superimposed overlying and underlying structures and improve lesion conspicuity, it is my opinion that 3D x-ray tomosynthesis or cone beam CT techniques are the future of breast imaging. These will be available in 3–5 years. In addition to better sensitivity, it is also likely that 3D x-ray imaging will have better CAD performance (computers as well as humans do better with simpler images).

In conclusion, it is not prudent to invest in a digital mammography system today. If one does, within a few years it will be necessary to spend a comparable sum once again to purchase a 3D breast x-ray unit. Be wary of salesmen who promise that a digital unit can be upgraded without documenting the cost. Two-dimensional projection mammography, whether digital or film, is nearing the end of its tenure. Wait a couple of years and buy a 3D x-ray unit. It will be a better investment and worth the wait.

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TABLE

Table I. Sensitivity and specificity values taken from Table 3 in Ref. 1.			
		Digital mammography	Film mammography
All women	Sensitivity	0.41±0.03	0.41±0.03
	Specificity	0.98±0.001	0.98±0.001
Women less than 50 years old	Sensitivity	0.49±0.06	0.35±0.06
	Specificity	0.97±0.001	0.98±0.001
Women with heterogeneously dense or extremely dense breasts	Sensitivity	0.38±0.04	0.36±0.04
	Specificity	0.97±0.001	0.98±0.001

CHAPTER 7

Nuclear Medicine

7.1. Positron imaging with SPECT and dual-head scintillation cameras obviates the need for PET in oncologic imaging

Mark T. Madsen and Beth A. Harkness
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OVERVIEW

One of the principal clinical applications of positron emission tomographic (PET) imaging of 18F-fluorodeoxyglucose (FDG) has been to evaluate malignant tumors throughout the body. However, the use of PET is restricted by the cost of dedicated PET scanners and the limited numbers of PET units (65–70) in the U.S. In place of PET imaging, some centers use single photon emission computed tomographic (SPECT) cameras equipped with 511 keV collimators to image the annihilation radiation from FDG. In other institutions, dual-head scintillation cameras are used for coincidence imaging of the annihilation photons for FDG. One or the other, or possibly both of these techniques, may have the potential of providing a less costly approach to tumor imaging with FDG, when compared with PET.

Arguing for the Proposition is Mark Madsen. Dr. Madsen is an Associate Professor of Radiology at the University of Iowa, Iowa City, IA. His research interests include image processing, internal radiation dosimetry, and quantitative SPECT and PET imaging. Dr. Madsen received his Ph.D. in Radiological Sciences from the University of Wisconsin in 1979. He served as the chair of the AAPM Nuclear Medicine Committee from 1986 to 1989, has participated in and chaired several AAPM task groups, and is the current chair of the AAPM Special Interests Group Committee. Dr. Madsen also organized the 1997 AAPM/RSNA Physics Tutorial for Residents.

Arguing against the Proposition is Beth Harkness. Beth Harkness is a medical physicist in the PET Center and an Assistant Professor of Radiologic Sciences at Wake Forest University School of Medicine in Winston- Salem, NC. Ms. Harkness has a degree in radiation science (M.S. Georgetown University, 1992) and is board certified by the American Board of Radiology in Medical Nuclear Physics. Ms. Harkness has been working in the field of nuclear medicine since 1977. During the first 15 years of that time her primary area of interest was SPECT imaging, but she has been working in PET since she joined the faculty at Wake Forest in 1992.

For the proposition: Mark T. Madsen

Opening Statement

This debate concerns the current and future role of positron emission tomography (PET) instrumentation in diagnosing cancer. The two choices currently available are dedicated PET systems and the SPECT/PET hybrid systems. Dedicated PET systems are specifically designed for coincidence imaging of 511 keV annihilation photons, while SPECT/PET hybrid systems are scintillation camera based SPECT systems with the added capability of coincidence imaging.[1] There are many compelling reasons why the hybrid systems will become the primary instruments used in oncologic imaging:

Efficacy. The current interest in PET imaging is not based on the performance of dedicated PET systems, but on the efficacy of ^{18}F-FDG. This compound is the premier radiopharmaceutical for tumor imaging in nuclear medicine today, with demonstrated high sensitivity and specificity for diagnosing lung, breast, head and neck, pancreatic and colon cancer as well as melanoma and lymphoma.[2] Because ^{18}F-FDG concentrates strongly in these tumors, the performance requirements of imaging systems are not quite as critical as they would be for other radiopharmaceuticals. SPECT imaging of ^{18}F-FDG with high energy collimators has been shown to be effective for lesions >2 cm.[3–5] In a recent study, the hybrid systems operating in the coincidence mode found 93% of the lung lesions and 65%–70% of the mediastinal and neck lesions detected by dedicated PET systems.[6] This performance will likely be improved as hybrid systems evolve with more efficient detectors and better reconstruction algorithms.

Flexibility. Dedicated PET systems can only produce images of positron emitters and will be idle otherwise. The SPECT/PET hybrid systems can be operated as full performance SPECT systems with collimators, or the collimators can be removed for coincidence imaging. For oncologic imaging, there are advantages to both approaches. Because the count sensitivity and spatial resolution associated with high energy collimators are poor, one normally would not resort to collimators if a coincidence option were available. However, collimated systems permit the simultaneous acquisition of multiple energy windows so that ^{18}F-FDG can be imaged along with other radiotracers such as ^{99m}Tc-HDP, a bone scan agent. In addition, the hybrid system could be used as a conventional SPECT system during times when PET studies are not requested or PET tracers are unavailable. The thicker detectors used in hybrid systems provide the added advantage of improved count sensitivity for imaging ^{67}Ga, ^{111}In, or ^{131}I.

Cost. It is clear that one can not make an honest case for the hybrid system from strict image performance arguments. Although hybrid systems operating in the coincidence mode have comparable spatial resolution, dedicated PET systems have much better detection efficiency and count rate performance. Thus, for comparable imaging times dedicated PET systems should allow better detection of small, low contrast lesions. This is borne out by the results of comparison studies that show that hybrid systems miss about half or more of the lesions <1 cm that are seen on dedicated PET systems.

However, the cost of a dedicated PET system exceeds one million dollars, putting its purchase out of reach of many institutions.[7] PET applications in oncology will not thrive until many institutions have access to both PET radiopharmaceuticals and PET imaging systems. Currently there are only 65–70 medical institutions in the U.S. with a dedicated PET system. This is obviously too small a number to serve the healthcare needs of the patient population. It is also

too small to provide referring physicians with direct experience in PET imaging. With the current economic constraints imposed on health care organizations, it is unlikely that enough dedicated PET systems will be sold in the near future to rectify the situation. The cost is simply too high and the risk too large (and also real; several PET centers have stopped operation over the last 5 years). Hybrid systems by comparison are attractive since they deliver 70%–80% of the performance of a dedicated PET system at less than half the cost.

Rebuttal

The superior performance of dedicated PET systems was acknowledged in my opening statement. If that were the only issue, there would be no debate. However, the growth of PET has been painfully slow because of the cost and inflexibility of dedicated positron systems. The success of PET imaging in clinical oncology requires the access provided by the hybrid systems.

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Against the proposition: Beth A. Harkness

Opening Statement

The imaging task must be considered when determining if SPECT with a high energy collimator (HE-SPECT) or camera-based coincidence imaging (Camera-CI) are adequate replacements for positron emission tomography with dedicated scanners (True-PET). In oncologic imaging we are trying to evaluate a known mass for the presence of malignancy (primary or recurrent) and, often, the stage of the disease by identifying new lesions. True-PET has been shown to perform these tasks more reliably than other modalities (CT and MRI) for a number of cancers (e.g., lung, colon, breast, and brain). Do HE-SPECT or Camera-CI perform as well for these clinical tasks? Determining if a known mass represents a malignancy requires high specificity. Specificity is governed by the amount of noise in the image. If an image is noisy, the differentiation between normal and abnormal tissue is more difficult. HE-SPECT and Camera-CI (even with a 5/8 in. NaI(Tl) crystal) have much lower quantum efficiency than True-PET. Additional factors such as the collimator and count-rate limitations of the gamma camera further limit the capability of HE-

SPECT and Camera-CI. The higher efficiency of True-PET produces images that contain lower noise levels and thus higher specificity.

Identification of a malignancy where it is not already identified by another modality, as in the case of metastatic spread to lymph nodes, requires a test that has high sensitivity for small lesions. This is directly dependent on the resolution and contrast. True-PET is equal to or superior to HESPECT and Camera-CI for each of these parameters. The system resolution of HE-SPECT, Camera-CI, and True-PET are about 20, 4.5, and 4.5–6 mm, respectively. The spatial resolution HE-SPECT is inferior to True-PET, and Camera- CI, and investigators have shown that HE-SPECT is not useful for evaluating tumors less than 2 cm in diameter. The spatial resolution of True-PET and Camera-CI are about equal and one may expect the contrast to be similar. Camera-CI uses a three-dimensional (3D) acquisition which increases system sensitivity but results in the acquisition of a large number of scatter and random events. If uncorrected or partially corrected, the scatter and random events appear as background counts, thus reducing contrast. Some manufacturers are now using shields on Camera-CI systems to decrease the amount of scattered radiation detected. This further decreases the number of coincidence events detected and increases image noise.

Where it is important to be able to determine if a mass is benign or malignant, it is at least as important to accurately stage the disease. The ability to identify small foci of increased uptake is a major factor in the success of True-PET. HE-SPECT and Camera-CI have inherent limitations that result in low sensitivity for these small lesions ($\leq$1.5 cm)[1] which is a significant limitation in oncologic imaging. Identification of malignant lymph nodes called normal or indeterminate by CT criteria is where True-PET has excelled and established a role in oncologic imaging.

Rebuttal

The efficacy of ^{18}F-FDG imaging in oncology is based completely on the use of True-PET systems. The sensitivity and specificity are dependent on the ability to identify and characterize areas of increased ^{18}F-FDG uptake. Low resolution and increased noise that are a function of the detection device will decrease the ability to perform these tasks. A truly useful diagnostic test should have both high sensitivity and specificity.

The desire to perform PET imaging with HE-SPECT or Camera-CI at a lower initial cash investment can be tempting but may be unwise in the long run. While these methods are adequate for some limited applications (i.e., detection of large tumors) they are severely compromised in others (staging and detection of small tumors). A particular example is the use of Camera-CI in detection of mediastinal and neck lesions mentioned by Dr. Madsen. He points out that Camera-CI detected 65%–70% of the lesions detected by PET. This might be considered adequate if PET had 100% sensitivity, but in reality the sensitivity of True-PET for lesions in the mediastinum is around 80%. This makes the sensitivity of Camera-CI about 50%–55%. Where the specificity using Camera-CI for these lesions may be very high, we would miss nearly 50% of the metastatic lymph nodes. How long would it take referring physicians to stop using a test that failed to detect significant disease 50% of the time?

The 1–2 million dollars price for a PET scanner is a lot for nuclear medicine equipment, but in reality is quite comparable to the price of CT and MRI scanners. This seems to be a reasonable price for improved diagnostic information for oncology patients.

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7.2. Isotopic labeling with short-lived radionuclides represents the future for clinical PET imaging

Beth A. Harkness and Mark T. Madsen

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OVERVIEW

PET imaging in radiation oncology is performed today exclusively with ^{18}F-deoxyglucose (FDG). The ^{18}F half-life is long enough to permit its delivery from a regional supplier, so that an on-site cyclotron is not required. Many nuclear imagers see FDG as the radiopharmaceutical of choice for oncologic imaging well into the future. Others believe that isotopic labeling with biologically-active molecules tagged with short-lived ^{11}C, ^{13}N and ^{15}O as the real future of PET imaging in oncology. This difference of opinion is explored in this month's Point/Counterpoint.

Arguing for the Proposition is Beth Harkness, M.S. Ms. Harkness is the nuclear medicine physicist for Henry Ford Health System in Detroit, MI. She received a master's degree in radiation science from Georgetown University in 1992, and is board certified by the American Board of Radiology in Medical Nuclear Physics. Her primary areas of interest are PET and SPECT imaging. She was involved in the early development of SPECT as a clinical tool, and has also spent 10 years working as a physicist in a PET center. She has been a member of the Nuclear Medicine (1994–2000) and the Remotely Directed Continuing Education (1998–2002) Committees of the AAPM.

Arguing against the Proposition is Mark T. Madsen, Ph.D. Dr. Madsen is an associate professor in the Department of Radiology at the University of Iowa. He received his Ph.D. degree in 1979 from the University of Wisconsin for investigating positron emitting regional cerebral blood flow agents. He was on the faculty at Thomas Jefferson University in Philadelphia from 1979 until 1988 when he moved to the University of Iowa. He is a current member and a past chair of the AAPM nuclear medicine committee and the current chair of the ABR medical nuclear physics subcommittee. Dr. Madsen's research interests include image reconstruction techniques and quantitative SPECT and PET imaging.

FOR THE PROPOSITION: Beth Harkness, M.S.

Opening Statement

The current trend in nuclear medicine is for departments to purchase PET scanners and use [^{18}F]-2-fluoro2-deoxy-D-glucose (FDG) purchased from a nuclear pharmacy to image patients. Oncologic, neurologic, and cardiac diseases are currently being imaged using this radiopharmaceutical. The boom in PET oncology imaging is due, in part, to the fact that FDG is readily available. For nuclear medicine to emerge as a "metabolic imaging" discipline, however, radiotracers will be needed that are target specific and that follow the physiologic pathway being evaluated. FDG does not meet either of these objectives. In the vascular space, FDG crosses the cell wall via facilitated transport using the glucose transport proteins in a manner analogous to

glucose. In the cell, FDG is converted to FDG-6-phosphate in the same manner that glucose is converted to glucose-6-phosphate. But this is where the similarity ends. Glucose-6-phosphaste proceeds along the glycolytic pathway, but the cell cannot process FDG-6-phosphate. In addition, the uptake pathway is the same for all cells, whether they are normal or cancerous, although there is more radiotracer uptake in the latter. One would describe FDG as a nonspecific radiotracer.

To become the metabolic imaging modality, nuclear medicine will have to use radiotracers that are specific in their uptake mechanisms and that are metabolized in the same manner as their nonradioactive counterparts. The need to use short-lived radionuclides, such as ^{11}C is obvious. Because carbon is found in many biologic molecules, ^{11}C can be incorporated isotopically into these molecules without changing their biologic function. There are numerous examples of this approach, including ^{11}C-acetate for imaging fatty acid metabolism in the heart, and ^{11}C-choline and ^{11}C-labeled amino acids for tumor imaging. Even ^{11}C-glucose would be better than FDG for evaluating metabolic function in different cell types. In tumors, it may be advantageous to classify or stage the aggressive nature of a tumor by evaluating the uptake and clearance characteristics of ^{11}C-glucose, compared with what we are doing now with FDG.

The need to produce short-lived tracers will, in the future, motivate manufacturers of cyclotrons to produce turn-key systems that are easy to operate. History tells us that what is difficult or nearly impossible to do today will become commonplace tomorrow through the work of innovative scientists. The fact that it is difficult to obtain ^{11}C tracers outside the research environment today does not mean that this will remain a problem in the future. As investigators show that short-lived metabolic analogues are indeed better for the evaluation and diagnosis of various diseases, cyclotrons in the nuclear medicine department will become common.

Rebuttal

No one would dispute the statement that the cost of producing short-lived radionuclides such as ^{11}C, ^{15}O, and ^{13}N is high, and that the process of approval for marketing and cost-reimbursement has been long. This statement needs to be examined in the light of trends in medical imaging.

The first issue is cost. It is true that the cost of a cyclotron is about $2,000,000, and that, in addition, personnel are required to operate the cyclotron and produce radiopharmaceuticals. One has to examine this cost relative to other costs in medical imaging. Most high-end imaging equipment costs 2–3 million dollars. A good example is a PET/CT scanner. The nuclear medicine community perceives that combining a CT scanner with PET adds diagnostic value to the PET oncology scan. Thus, nuclear medicine physicians and oncologists are willing to commit the funds needed to purchase a combined unit, and to hire the personnel, at least two technologists, to operate the equipment. Many PET/CT scanners are being purchased even though the reimbursement for the CT portion of the study is unresolved. Why? Because the physician perceives that there is a clear diagnostic advantage to using the CT scan for attenuation correction, and for interpreting the spatially co-registered PET/CT study. Cost is not an issue if the technology is perceived to improve diagnostic accuracy and patient care.

The second issue is the difficulty in obtaining FDA approval of new radiopharmaceuticals. Approval of new radiopharmaceuticals has been a troubled process for the nuclear medicine community for many years. With the FDA Modernization Act of 1997, Congress attempted to address the approval time of pharmaceuticals, including radiopharmaceuticals, that has plagued nuclear medicine for the past 25 years. This act directly addresses problems of PET pharmaceutical approval by instructing the FDA to have different guidelines for not-for-profit

medical institutions that produce them. ^{18}FDG is an example of both the difficulty and ultimately successful approval. It took many years to obtain the first approved application of ^{18}FDG, but now there are several approved applications in oncology. Not every facility now must submit a NDA or INDA. The growth we are currently experiencing in PET is through the combined efforts of many professional organizations to obtain approval for ^{18}FDG.

There is no reason this could not occur for short-lived radiopharmaceuticals. Finally, it is the history of medicine that academic centers lead the way in development of new technology. The future of PET lies in the continued development of PET tracers, including those using short-lived radionuclides.

AGAINST THE PROPOSITION: Mark T. Madsen, Ph.D.

Opening Statement

This is a debate where the economic realities of medical imaging play a decisive role. No one can reasonably argue that there is any disadvantage of exploiting the wide potential of radiopharmaceuticals offered by ^{15}O, ^{13}N and ^{11}C, except that the cost will be unrealistically high with little chance of ever recovering a significant fraction of the expense. Short-lived radionuclides will require onsite production and compounding, and the capital equipment, personnel and regulatory expenses associated with these activities will be very high.[1] Let's examine these expenses.

Capital equipment. Radionuclides with half lives under 1 hour require an onsite cyclotron. Onsite means not just somewhere within the institution, but in close proximity to the imaging facility. In addition to the large capital equipment cost for the cyclotron and the site preparation (on the order of $2,000,000), the recurring costs of cyclotron maintenance and the associated utilities are substantial. Onsite compounding of PET radiopharmaceuticals requires space for, and the installation of, specialized equipment such as hot cells, fume hoods, dose calibrators, gas and high performance liquid chromatographs, shielding, and survey meters. The cost for this equipment can be well over $250,000.[1]

Personnel. Highly trained individuals are required to operate the cyclotron and compound the radiopharmaceuticals. Although cyclotrons are largely computer controlled, they still require a portion of an individual's time to operate them. In addition, there are substantial radiation safety issues associated with a cyclotron that are time consuming. Compounding of the radiopharmaceuticals is even more time consuming, because it includes not only the daily preparation of the radiotracers, but all of the associated quality assurance and paperwork. Combined together these responsibilities significantly exceed 1 FTE.[1]

Regulatory requirements. Radiopharmaceuticals that are used clinically in humans require either the approval of a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) from the Food and Drug Administration (FDA).[2] Preparation of the paperwork for either an NDA or ANDA is extremely time consuming and could easily account for 0.5 FTE of a radiochemist or radiopharmacist. The application fees are substantial (>$200,000 for an NDA) and there are yearly recurring fees that exceed $10,000. Combined with the radiation safety demands, the regulatory burden can easily exceed $50,000/year.[1]

The combined cost of the required capital equipment, personnel and regulatory compliance make it extremely difficult to recover expenses unless there is substantial reimbursement. Obtaining reimbursement for any radiopharmaceutical is often a long and difficult struggle, even when it is approved by the FDA. It took years of intense lobbying to get ^{18}F-FDG reimbursed, in spite of the large body of evidence supporting its efficacy. The April 1991 issue of the Journal of Nuclear Medicine was devoted to clinical PET and the role of ^{18}F-FDG imaging,[3] yet Medicare reimbursement for the first ^{18}F-FDG applications did not occur until 1998.[4] There is no reason to assume that the process will be any easier for other PET radiopharmaceuticals, especially when their initial use will be limited to academic centers that have the equipment and personnel to support the effort.

Rebuttal

I have no disagreement with Ms. Harkness about the potential of short-lived PET radiotracers to provide unique diagnostic information. The likelihood is extremely low, however, that healthcare providers will invest in the equipment and personnel necessary for on-site manufacturing of PET radiopharmaceuticals. Innovations may reduce equipment costs for production of short-lived radionuclides, but are unlikely to have much effect on the recurring costs of personnel and regulatory compliance. Ms. Harkness suggests that useful information may be gleaned from examining the kinetics of short-lived PET radiotracers. Although this is undoubtedly true, the acquisition and processing of these studies require substantial equipment and personnel time. This requirement adds to the already prohibitive expense of PET studies with short-lived radionuclides.

For a facility to overcome the economic burdens of using short-lived PET radionuclides, the following conditions must be met: (1) The labeled compound must have a wide range of applications, as does ^{18}F FDG. Radiotracers that cannot be used on a large patient population cannot recover the development and operational costs and are also unlikely to be reimbursed. (2) If a new radiotracer is developed that does have wide applicability, it will have to be impossible to label it with ^{18}F. Otherwise, market forces will selectively remove the short-lived alternative. For example, interest in ^{11}C choline as a potential clinical agent was significantly dampened when ^{18}F fluorocholine became a reality.

With all these considerations, it is reasonable to conclude that short-lived PET radionuclides are not a viable option for most healthcare providers, neither now, nor in the future.

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7.3. Correction for image degrading factors is essential for accurate quantification of brain function using PET

Habib Zaidi and Vesna Sossi
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OVERVIEW

Quantification of brain function using positron emission tomography (PET) is an emerging research field. For many years, interest in the regional distribution of brain perfusion and metabolism has steadily increased, primarily because many neurological disorders are associated with a decrease of regional cerebral blood flow (rCBF). PET offers the possibility of quantitative measurements of tracer concentration *in vivo*. However, there are several issues that must be considered in order to fully realize this potential. In practice, the measured line integrals must be corrected for a number of background and physical effects, the three most significant being the limited spatial resolution and associated partial volume effect, photon attenuation, and the contribution of events arising from photons scattered in the object and gantry. Many investigators believe that accurate patient-specific correction for these image-degrading factors is essential for quantification of relevant parameters when imaging brain function using PET. Others often neglect them or believe that approximate correction methods can be used with confidence. This difference of opinion is explored in this month's Point/Counterpoint.

Arguing for the Proposition is Habib Zaidi, Ph.D. Dr Zaidi is senior physicist and head of the PET Instrumentation & Neuroscience Laboratory at Geneva University Hospital. His research centers on modeling nuclear medical imaging systems using the Monte Carlo method, dosimetry, image correction, reconstruction and quantification techniques in emission tomography and functional brain imaging, and more recently on novel design of dedicated high-resolution PET scanners in collaboration with CERN. He is Associate Editor for *Medical Physics*, a member of the editorial board of *Computer Methods and Programs in Biomedicine* and the *International Journal of Nuclear Medicine*, and scientific reviewer for several medical physics, nuclear medicine and computing journals. He is affiliated to several medical physics and nuclear medicine organizations and member of the professional relations committee of the IOMP.

Arguing against the proposition is Vesna Sossi, Ph.D. Dr. Sossi is Assistant Professor of Physics and Astronomy at the University of British Columbia (UBC), and head of the physics program of the UBC/TRIUMF PET group. She received her Ph.D. in Nuclear Physics from UBC and changed research fields to PET imaging immediately after her degree. She is actively involved in PET instrumentation and data quantification and reconstruction research, with particular emphasis on quantitative 3-dimensional high resolution brain imaging. She was involved in the early characterization of hybrid PET/SPECT imaging, and was part of the review committee for the 2001 NEMA PET standards. She is a scientific reviewer for several medical physics journals.

FOR THE PROPOSITION: Habib Zaidi, Ph.D.

Opening Statement

During the last decade, neuroimaging has advanced elegantly in the medical and research arenas. PET, with its superior sensitivity and spatial resolution, appears uniquely suited to take the lead in this promising field of imaging. Convincing clinical evaluations and research investigations of PET are providing clinicians and neuroscientists with relevant functional information in various pathologies including cerebrovascular disorders, brain trauma, epilepsy, dementia, Parkinson's disease and brain tumors, and in mental disorders such as depression, schizophrenia and obsessive-compulsive disorders. Within the context of functional brain imaging, the aim of quantification is to provide a reliable numerical measure of brain function. For quantitative analysis of PET images, several image-degrading effects must be accounted for, including poor signal-to-noise ratio, limited spatial resolution, and spatially-varying loss or corruption of signal due to photon interactions with matter. Photon attenuation and contributions from scattered photons reduce the accuracy of measured activities and activity concentrations.[1,2] In addition, limited spatial resolution causes an object to appear enlarged if its true size is less than 2–3 times the system resolution. While the total reconstructed counts within the object are conserved, the count density is decreased from the true value because the data are "smeared" over a larger area. This characteristic is known as the partial volume effect.

Advances in quantification of brain function (blood flow, metabolism and receptor characteristics) with PET, especially for small structures such as the putamen and hippocampus, rely on two improvements: (1) hardware improvements to enhance spatial resolution and sensitivity, and addition of components to correct for degrading factors (e.g., electronically-delayed coincidence windows for subtraction of random coincidences, and transmission scanning for patient-specific attenuation correction); and (2) software improvements to attain better image quality and achieve more accurate quantification of relevant parameters. Significant progress has been made in the design of high-resolution 3D PET units with the capacity to acquire more accurate depth-of-interaction information.[3] Also, improved reconstruction algorithms have been proposed, and some have been incorporated into software supplied by manufacturers to end-users. In spite of improved algorithms for accurate smoothing of random coincidences, attenuation correction and scatter compensation, and partial-volume effect-correction, however, many PET users still do not correct for these factors, either because they lack confidence in the algorithms, or they do not appreciate the importance of the corrections owing to the absence of physics support in their institutions.

Earlier PET studies inconsistently reported aging-induced reductions in CBF, oxygen metabolism, and glucose metabolism. Metzler *et al.*[4] have shown that this observation may reflect the absence of correction for the dilution effect of age-related cerebral volume loss. The traditional approach to accounting for the partial volume effect in the quantification of brain PET images uses anatomical information derived from magnetic resonance imaging (MRI) and the spatial resolution characteristics of the PET unit. Although considered as a limiting factor, MR images are generally available for patients undergoing cerebral PET scanning through hospitals' picture archiving and communications systems. Moreover, it has been shown recently that MRI data can be used for attenuation and scatter correction purposes in 3D brain PET imaging using a transmission less scanning protocol.[2] Reconstruction of PET images without attenuation correction can cause excessive count densities and reduced image contrast in regions of low attenuation. Scatter qualitatively decreases contrast by misplacing events during reconstruction, and quantitatively causes errors in the reconstructed radioactivity concentrations by overestimating the actual activity. All of these effects can introduce artifacts into radionuclide images that complicate visual interpretation and cause profound errors in quantification. For these reasons, it is essential to understand both the physical processes that underlie the data acquisition process, and the methods that can be used to correct images for inaccuracies. These

correction methods are now widely accepted by the nuclear medicine community as essential for achieving artifact-free, quantitatively accurate data.

In general, there is no rational motivation why sophisticated correction methods for all of the physical degrading effects should not be applied to brain PET images prior to extraction of relevant quantitative data in a clinical and research environment.

Rebuttal

I agree with Dr. Sossi that accurate quantification requires extensive technical and organizational efforts that may be unaffordable for a clinical department with limited scientific support. The first question to be answered is "What is expected from such studies?" Investments should be comparable to expectations. The second interesting question is "Would one expect similar results between images obtained with and without correction for the physical degrading effects?" The answer would provide a true comparison of the effect of different correction techniques on relevant quantitative parameters when studying brain function using PET. Such an experiment would be difficult to perform with clinical data but should be easily performed using either experimental phantom measurements or Monte Carlo simulation studies, which have the advantage of being able to generate data sets in a controllable manner and switching on and off the effect of the physical degrading factors. Most studies concluded that correction methods improved the quantitative accuracy compared to the case where no corrections were applied.[1] No one would dispute the statement that significant progress in quantitative PET imaging has been made over the last few years as a result of improved correction methods for attenuation, scatter and partial-volume effect. The specific benefits of transmission-based attenuation correction, in contrast with calculated attenuation correction, are the subject of heated debate.[2] Contribution of scatter from outside the FOV remains a challenging issue that needs to be addressed carefully in whole-body imaging especially with large axial FOV 3D PET units. However, this is a less challenging issue in brain scanning. In PET activation studies characterized by low count statistics, subtraction-based scatter correction methods add considerable noise, which jeopardizes the significance of statistical analysis. This problem has been tackled with iterative reconstruction-based scatter compensation techniques, where the scatter component is modeled within the projector/backprojector pair. This approach results in better noise properties than direct subtraction. Accurate scatter modeling has recently been achieved using computationally efficient fully 3D Monte Carlo simulation-based reconstructions.[5] In addition, correction for partial volume effect might influence the results of statistical analysis in group comparisons. Using Statistical Parametric Mapping analysis performed on subjects with probable Alzheimer's disease and age-matched healthy volunteers, Matsuda *et al.*[6] have shown that the significance of the rCBF decrease in the bilateral amygdala and hippocampi disappeared after correction of partial volume effect, while the significant decrease in the bilateral parahippocampal gyri remained.

Reconstruction methods are continuously being improved, and scanner manufacturers are optimizing the performance of dedicated software by integrating latest algorithmic developments. Maximum *a posteriori* reconstructions using a Bayesian model in combination with a Poisson likelihood function and a Gibbs prior on the image provide images of higher resolution. The value of improved models to correct for attenuation, scatter, and partial-volume effects, performed on raw projection data, preliminary reconstructions, or integrated with the transition matrix of an iterative reconstruction algorithm, is still an open question and remains a good academic problem in functional brain imaging. This question requires further research and development.

AGAINST THE PROPOSITION: Vesna Sossi, Ph.D.

Opening Statement

From an idealistic point of view, absolute quantification is certainly desirable to obtain a truthful representation of the biological process or metabolic function being imaged with PET. In the real world, however, we are faced with a variety of limitations, starting with the observation that PET radioactive decay is statistical in nature and therefore cannot be precisely determined. In addition, photons interact with all forms of matter, instrumentation is capable of only limited spatial, energy and temporal resolution and requires careful calibration, and patient motion during a scanning procedure produces blurred images. Correction algorithms exist for most of these effects. There are, however, three questions that must be addressed: What is the overall cost of applying the corrections, are the available corrections sufficiently accurate to increase the quantitative accuracy of the results, and, most importantly, are the corrections really necessary for every study in order to obtain clinically meaningful results? To answer these questions, four main sources of accuracy loss will be examined: attenuation, scatter, presence of random events and the partial volume effect.

Photon attenuation has been repeatedly identified as the single most important factor in the loss of quantification ability. However, attenuation corrections have also been identified as a significant source of errors because measured attenuation corrections can introduce additional noise in the images, thus reducing the image contrast, which is especially relevant in tumor imaging. Also, a mismatch between the spatial location of the subject during the emission and the transmission scans can introduce significant artifacts into attenuation-corrected images. Finally, the presence of metallic dental implants can introduce artifacts into brain images, not only when CT is used to determine the attenuation correction coefficient, as in new PET/CT scans, but also when a standard positron source is employed for attenuation correction.[7]

Another aspect to be considered is that addition of a transmission scan generally lengthens the scanning procedure and increases the dose of radioactivity that must be administered to the patient. For example, in ^{18}F-flurodeoxyglucose (FDG) PET imaging, a tracer uptake period is generally required after tracer injection and before initiation of scanning. If a post-injection transmission scan is not feasible, the patient must undergo a transmission scan first, and then either lie on the scanning bed for a considerable time before the emission scan is started, or leave the bed and then be carefully repositioned for the emission scan. In addition to reducing the useable scanner time, both options increase the risk of a position mismatch between the emission and transmission scan.

The clinical utility of this correction must also be addressed. Certainly there are PET studies where attenuation correction is essential such as determination of process rate constants with methods that use plasma-derived input functions. There are other applications, however, where attenuation correction is not only unnecessary, but even reported as detrimental. Bengel *et al.*[8] argue, for example, that nonattenuation corrected FDG images yield improved contrast between tumor and background. For head and neck tumors, for example, the contrast in nonattenuation corrected images is approximately twice that in attenuation corrected images.

Detection of scatter events is another major contributor to quantification loss. In 3D brain imaging, the fraction of scatter to total detected events can be as high as 40%. No fully accurate scatter correction methods are currently available. Available methods are based on scatter

modeling using physics principles, and often fail to account for scatter originating from radioactivity outside of the field of view. The scatter fraction depends only on the thickness of material traversed by the photons; it does not depend on the injected dose or radiotracer distribution. Therefore, scatter only minimally affects the comparison of images obtained with the same radiotracer in the same patient.

The detection of random events adds a fairly uniform background across the field of view, and thereby reduces image contrast. In contrast to scatter, however, the number of random events is count-rate dependent. If the objective of the study is to compare between two conditions, the effect of random events can be minimized by maintaining similar count rates among scans.

The limited spatial resolution of the scanner causes the partial volume effect, which affects the estimate of radioactivity concentration for all objects that are smaller than the tomographic resolution element. This is often the case in brain imaging. Several partial-volume correction algorithms exist, but they involve many processing steps and generally require acquisition of an MRI scan to define the anatomical size of the structures involved in the function being investigated with PET. These additional steps are costly in expense and time, and may introduce further errors. For instance, co-registration between PET and MRI images has an accuracy limit of approximately 2 mm, which is fairly large considering that structures of only a few mm are often of interest.

Frequently, PET studies focus on identification of functional differences between subjects scanned under different conditions. In these cases the partial volume effect is approximately constant between the two conditions, since inter-subject comparisons are used, and the distribution of radiotracer may not change greatly. In such studies differences of 10–20% in the kinetic parameters derived from the study are often found to be significant.[9] The magnitude of the partial-volume correction may cause some parameter values to increase several fold, with an associated increase in noise.[10] Application of such a correction, if not exact, would jeopardize the ability to detect subtle biological effects. Finally, the effect of image blurring caused by patient motion on the accuracy of the partial-volume correction remains to be investigated.

Rebuttal

Dr. Zaidi is absolutely correct when stating that better image quantification has dramatically improved the investigative power of PET and has contributed to more accurate biological discoveries. He correctly argues that significant advances have been made both in software and hardware associated with PET scanners that yield far more accurate results. As he points out, many of the correction methods require sophisticated measurements and software techniques. This enhanced sophistication requires a high degree of precision and expertise that may not always be available. If imprecise, the correction methods might introduce additional sources of artifact and noise. Correction methods can be implemented only if all sources of potential errors have been thoroughly investigated in the context of the particular scanning protocol. This includes factors often neglected, such as the effects of patient motion on the accuracy of the corrections.

Another aspect to consider is the practicality of obtaining particular correction factors. For example, most of the partial-volume correction methods require MR imaging, which significantly increases the cost of the scanning procedure and the burden to subjects undergoing a clinical examination. It is important to question how much additional information will be acquired by

implementing the correction methods. The answer is likely to be different for different types of studies or clinical examinations and for different scanning environments.

In summary, pursuit of absolute quantification should undoubtedly continue, because it provides a more truthful representation of the processes being imaged. It is also important, however, to evaluate on an individual case basis if the additional accuracy potentially provided by the quantification procedures will significantly benefit the outcome of a PET study.

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CHAPTER 8

Radiation Protection, Standards and Regulations

8.1. The LNT model is appropriate for the estimation of risk from low-level (less than 100 mSv/year) radiation, and low levels of radon in homes should be considered harmful to health

Daniel J. Strom, John R. Cameron and Bernard L. Cohen

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OVERVIEW

The linear no-threshold hypothesis is at the heart of radiation risk calculations, standards setting, and regulatory philosophy. If the LNT ‘‘theory’’ is correct, then any small amount of radiation constitutes a risk to those exposed. On the other hand, if the ‘‘theory’’ is wrong, and risks are much lower than our present regulations are designed to protect against, then we could save considerable time, effort and expense trying to comply with overly restrictive exposure limits. Application of the LNT hypothesis has literally devastated at least one industry in the United States (the nuclear industry) while, at the same time, it has been responsible for spawning others, such as the home radon-proofing industry. It is also responsible for the employment of large numbers of regulators, inspectors and, yes, medical and health physicists. This is clearly an important issue for medical physicists and we are fortunate to have three of the world’s foremost experts to debate it in our Point/Counterpoint series.

Arguing FOR both the Motions is Dr. Daniel Strom, Staff Physicist in the Risk Analysis and Health Protection Group at the Pacific Northwest National Laboratory, Richland, Washington. Dr. Strom earned his Ph.D. in Environmental Sciences and Engineering at the University of North Carolina, Chapel Hill in 1983. Among his current research interests are risk analysis, and protection against radon and its progeny. He claims to be in the middle of the spectrum of views on dose-response models.

Arguing AGAINST the motion that the LNT model is appropriate for the estimation of risk from low-level (less than 100 mSv/year) radiation is Professor John Cameron. Dr. Cameron earned his Ph.D. in Nuclear Physics in 1952 at the University of Wisconsin, Madison, where he has spent

almost his entire working life and is now Professor Emeritus in the Department of Medical Physics. Also throughout his career, Prof. Cameron has been concerned with protecting people from unnecessary radiation exposure—he ''invented'' the roentgen-area-product concept in order to protect patients, for example. At the same time, however, he has continually expressed concern about over stressing the risks of radiation, which he not only considers stifling to progress (and expensive), but also frightens the general public. He is especially interested in allaying the fears of the public by educating them about radiation and its effects.

Finally, arguing AGAINST the Motion that low levels of radon in homes should be considered harmful to health is Professor Bernard Cohen. Dr. Cohen earned his D.Sc. in Physics in 1950 at the Carnegie Institute of Technology. Since 1958 he has served on the faculty of the University of Pittsburg, where he is Professor of Physics. He is the author of several books, including *A Homeowners Guide to Radon*, as well as numerous publications about radon and radiation. Professor Cohen is considered one of the world's leading experts on the risks associated with radon in homes.

Argument for both motions: Daniel J. Strom

Opening Statement

The linear, non-threshold (LNT) dose-response model forms the basis for all USA and international recommendations and regulations for protection of workers and the public from harmful effects of radiation at low doses. It is not used for high-dose (''deterministic'') effects, for which nonlinear, threshold models are well established.

The LNT model states that radiation detriment increases as a linear function of dose, without threshold, when averaged over all ages and both sexes. Detriment is the expectation of harm, which includes loss of life expectancy or quality of life due to fatal and nonfatal cancers and heritable ill-health. These are stochastic effects, that is, their frequency in a population, rather than their severity, is a function of dose.

Radiation protection is a risk management activity. Science is one of many inputs to risk management. There is no practical way to incorporate everything we know as scientists about radiation-induced cancer into risk management. We know that radiation biology is at least a 16-dimensional problem that includes health endpoint, response and projection model, amount of life lost, portion of organism irradiated, background incidence, who's exposed and who's affected, dose, dose rate, dose fractionation, LET (microdosimetry), sex, age at exposure, age at diagnosis, species, subspecies or genetic predisposition, and other effect modifiers (smoking, oxygen, diet, etc.), so using only two of these (dose and response) cannot possibly be correct.

While there are clearly human data that show a response threshold for some cancers (bone cancer from ingested radium, liver cancer from injected thorium, and perhaps lung cancer in nonsmoking miners exposed to radon progeny), there are many others that show no threshold at doses of concern in radiation protection (solid tumors in the Japanese bomb survivors, lung cancer in smoking miners), and one neoplasm, leukemia, for which the dose-response relationship is significantly nonlinear in the Japanese bomb survivors. There is significant reason to believe that the mechanisms of carcinogenesis differ for these diseases.

Valid scientific arguments supporting the LNT model include the following: Tumors are of monoclonal origin; low-dose radiation is a small perturbation in the effect of other carcinogens

that have already exceeded most thresholds; miner, bomb survivor, and other human studies for most cancer endpoints are consistent with LNT; heritable ill-health probably follows LNT, bomb survivor data are compatible with LNT projections of heritable ill-health from animal studies. Valid scientific arguments against LNT include the following: some cogent radiation data do not show LNT behavior for some cancer endpoints; no statistically significant heritable ill-health is seen in bomb survivors (although this is consistent with the 2 Sv doubling dose from animal studies). Specious scientific arguments against LNT include the following: ''if you cannot detect a health effect, it does not exist''; ''if you cannot detect a health effect, it is of no concern''; bomb survivor and miner studies are ''high dose'' studies that are inappropriately extrapolated to low doses; oxidative damage is the same for radiation and chemicals; adaptive response occurs; threshold analogies make sense (e.g., {high, medium, low} applied to {fall, wind, impact}); hormesis is important; some chemical carcinogens have thresholds; energy imparted, not dose, is the independent variable.

Valid policy arguments for LNT include the following: it errs on the side of safety (it is ''conservative''); it is a politically acceptable status quo; at present, there is no prospect of direct measurements of effects at doses of interest; a practical system based on LNT has protected workers. Valid policy arguments against LNT include the following: it has led to expensive risk-management decisions; optimization has not worked (the ''R'' in ALARA has been ignored); small lifetime fatal cancer risks may result in insignificant life-shortening. A specious policy argument for LNT is that a threshold system is impractical.

''All models are wrong, and some are useful'' (Box, 1979). Use of the LNT model as a basis for setting standards for radiation protection against stochastic effects at low doses still makes good policy sense. The LNT model should not be used for individual risk predictions (either prospectively or retrospectively) or for priority-setting; for these applications, the detailed, unbiased risk assessments that account for all known variables should be used.

Rebuttal to Professor Cameron

Cameron invokes the dose-rate dependency of health effects of radiation, a well-established phenomenon. It has long been known that if pairs of microscopic DNA lesions are sufficiently separated either in time or in space, they do not interact; if they occur close enough in time and space, they may interact.[1] This is accounted for in current versions of the LNT model by using a dose and dose rate effectiveness factor (DDREF).

Three recent reviews[2–4] have confirmed that there are thresholds for some kinds of radiation-induced cancer, and one kind of leukemia has never been seen in excess in irradiated populations. This in no way implies that there are thresholds for all kinds of cancer, especially with evidence to the contrary.

Rebuttal to Professor Cohen

Contrary to Cohen's claim, there are good data supporting LNT in the dose regions low enough to be directly applicable to many important radiation protection problems, including indoor radon. These data are from underground miners,[5,6] indoor case-control studies,[7] and Japanese bomb survivors.[8]

Cohen's free radical argument is irrelevant because oxidative damage by free radicals at single sites is almost completely repaired, whether the free radicals are caused by chemicals or

radiation. The damage of concern from radiation is caused by moderate to large clusters of ionization[9] formed at the end of charged particle tracks (the Bragg peak), for which there is no chemical analog. Understanding such damage does not require postulating an impairment of BDM. One-time inductions of adaptive response (''enhancement of BDM'') take significant doses (e.g., 150 mGy), and like a suntan (also an adaptive response) it fades with a half time of days to weeks. I know of no evidence that adaptive response can be maintained indefinitely, or induced by dose rates on the order of 1 mSv per year. It requires no extrapolation from human data (early radiologists) to conclude that repeated doses of 150 mGy to maintain adaptive response would cause deterministic effects and excess cancer.

Finally, the county-radon-lung cancer ecologic study is not a logically compelling design. Conclusions of an ecologic study are good for hypothesis generation, not hypothesis testing. For ''Principles for Evaluating Epidemiologic Data in Regulatory Risk Assessment,''[10] see www.sph.umich.edu/group/eih/UMSCHPS/epidprin.htm.

Concluding remarks

In the face of conflicting science, the LNT model continues to be a useful basis for radiation protection. It should not be used for individual risk estimates, but it is useful for setting standards.

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Argument against the motion that the LNT model is appropriate for the estimation of risk from low-level (less than 100 mSv/year) radiation: John R. Cameron

Opening Statement

No! LNT is not appropriate to estimate risks to any population at any dose or dose rate. LNT is an unrealistic theoretical model contradicted by much human and animal data. Unrealistic because it is unusual for a biological response to be linear over even one decade. It would be even more unlikely that it would be linear at or near zero when the body must have natural defenses to survive the 40 million radioactive disintegrations per hour inside the average adult. The LNT assumption is alledgedly based on radiation-induced cancer among the A-bomb survivors which showed an apparent threshold of about 30 cGy, even for leukemia. The dose rate to the A-bomb victims was about a million times greater than that encountered by radiation workers. If the dose had been protracted over a few months or years, the apparent threshold would have been much higher. For example, while A-bomb victims had a high leukemia incidence eight years post exposure, Chernobyl victims with comparable doses spread over weeks or months had no significant increase in leukemia. There is good evidence that the body has a protective mechanism referred to as apoptosis. That is, injured cells are programmed to ‘‘commit suicide’’ to protect the organism. Prof. Sohei Kondo[1] calls the low dose rate where all damaged cells are eliminated the apoptosis dose rate. At the higher necrotic dose rate, apoptosis cannot keep up. Tissue repair errors lead to cancer induction. Kondo cites two examples to support his model. Rats exposed to a total of 25 working level (WL) months at rates of 2 WL and 100 WL had markedly different lung cancer incidence.[2] At a rate of 2 WL lung cancer was at the background rate of about 0.5%. At a rate of 25 WL, a necrotic dose rate, lung cancers were about three times the background rate. The skin of mice were irradiated with beta rays to a limited area three times a week for life or until the appearance of skin cancer.[3] At a dose rate of 1.5 Gy/week there was no skin cancer. At a necrotic dose rate of 3 or more Gy/week there was 100% incidence of skin cancer. In humans a similar dramatic effect was seen in radium induced osteogenic sarcomas among the radium dial painters. There was no radium induced bone cancer until the skeletal dose exceeded 10 Gy (200 Sv). From 20 Gy to 500 Gy the incidence of osteogenic sarcomas was essentially constant at 2866%. Bond[4] points out that it is inappropriate to predict individual risks from epidemiological data. He feels radiation is a public health problem.

Rebuttal to Dr. Strom

When scientists argue it indicates a lack of definitive data. I think all of us agree there are no definitive data to show radiation risk at the levels now set for radiation workers and the public. My greatest concern is the use of the LNT model by the news media and others to produce fear. Many science teachers are often unaware of the relatively large amount of radioactivity in their own body—almost 10,000 Bq. Our greatest need is to educate the public about radiation. I suggest that every TV weather map show real time radiation levels in nGy/h for radiation monitoring stations in their area and around the country. The public would see the actual radiation levels near nuclear power plants and far from nuclear power plants in the mountains.

In addition every commercial passenger airplane should have a clearly visible radiation monitor that shows the radiation level continously during flight including its value as the plane flies at high altitude. By this means the public would become familiar with radiation levels and their variation.

The dose from every diagnostic radiology exam should be explained by the RT in terms of the time to get approximately the same dose from background radiation. This can be done by means of a small brochure that gives typical values for common x-ray exams. Medical fluoroscopes should be required to have a dose-area product meter so that these larger doses can also be explained in terms of background radiation.

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Argument against the motion that low levels of radon in homes should be considered harmful: Bernard L. Cohen

Opening Statement

The answer to this question is largely dependent on the validity of the linear no-threshold theory (LNT) of radiation carcinogenesis. There are no *data* supporting LNT in the low dose region; it is based on the following reasoning: Since we believe that even a single particle of radiation hitting a single DNA molecule in a single cell nucleus can initiate a cancer, the number of cancers initiated is proportional to the number of such hits, which is proportional to the dose. It has long been known that there are biological defense mechanisms (BDM) which prevent all but a very tiny fraction of initiating events from developing into a clinical cancer, but it has been tacitly assumed that these BDM are not affected by radiation.

It is now recognized[1] that cancer initiating hits on DNA molecules, indistinguishable from those caused by radiation, occur at a very high rate due to random thermal agitation and chemical attack by free radicals—about 6000 hits per cell each hour, or 50,000,000 per year. Since 1 cGy (1 rad) of radiation causes only about 20 such hits per cell, it is obvious that the latter are inconsequential. How, then, can radiation cause cancer? The only possible answer is that radiation can degrade our BDM. Several biological mechanisms have been proposed to explain this, but none of them give any reason to believe that this degradation is linearly proportional to dose, as required to justify LNT.

On the contrary, there is abundant indisputable evidence that low doses of radiation *enhance* BDM.[2] It has been shown in numerous independent experiments, both *in vitro* and *in vivo*, that low dose pre-exposure substantially reduces the number of chromosome breaks and the number of gene mutations produced by later high dose radiation exposures. It has also been shown that

low dose radiation stimulates the activity of the immune system as measured by various indicators. Thus, the theoretical basis for LNT is completely negated, and there is a clear suggestion that low level radiation may actually be protective against cancer.

Experimental data predominantly support the latter viewpoint, or at least the existence of a threshold below which radiation is essentially harmless. Data on luminous watch dial painters[3] who got radium into their bodies by tipping their brushes with their tongues, shows a clear statistically significant threshold behavior. Leukemia among Japanese A-bomb survivors,[4] and breast cancer among Canadian tuberculosis patients[5] exposed by frequent fluoroscopy, both show statistically significant decreases with increasing dose in the low dose region.

But the data most directly relevant to our question are from a compilation of average radon levels in homes for 1729 U.S. counties, well over half of all U.S. counties and comprising about 90% of the total U.S. population. The results[6] show a statistically indisputable tendency for lung cancer rates, with or without correction for smoking prevalence, to *decrease* with increasing radon level; the slope is discrepant with the prediction of LNT by 20 standard deviations! It was shown that ''the ecological fallacy'' and other weaknesses of ecological studies do not apply to this work. Effects of over 60 potential confounding factors were studied, several other tests were applied, and the data and results have been available for two years, but there has been no explanation for this discrepancy other than that LNT fails in the low dose region, grossly over-estimating the cancer risk from low level radiation.

Rebuttal to Dr. Strom

Strom states that solid tumors in Japanese A-bomb survivors and lung cancer in miners show no threshold at doses of concern in radiation protection, and later states that it is ''specious'' to argue that these ''are high dose studies that are inappropriately extended to low dose.''

The A-bomb survivor data[4] show no statistically significant evidence that there is not a threshold below 25 cSv (25 rem). In fact, using those data, it is easy to show that there is a 30% probability that the risk *decreases* with increasing dose up to 20 cSv. By contrast, EPA and NRC are now squabbling over 0.015 vs 0.025 cSv as a regulatory limit for radiation protection.

If our data showing a strong *decrease* in lung cancer rates for *increasing* radon exposures in U.S. Counties is interpreted directly as risk vs exposure to individuals, there is no statistically significant discrepancy between it and the miner data. This was shown by Ken Kase at the 1997 Milwaukee meeting of AAPM. These data cover a range of radon levels that EPA estimates to be causing over 10,000 deaths per year in the U.S.

I do not understand Strom's statements that it is specious to argue that ''adaptive response occurs'' and that ''hormesis is important.'' There is an indisputable body of evidence, accepted by ICRP and UNSCEAR, supporting adaptive response. There is certainly a great deal of evidence, albeit not conclusive, supporting hormesis; this has been the topic of several large international conferences, at least two books, etc. I see nothing specious about pointing out that adaptive response or hormesis *can* explain why linear no-threshold theory fails.

I take this opportunity to apologize for my misinterpretation of the Billen paper.[1] The ''6000 hits per hour'' are not necessarily cancer initiating events, and there are certainly differences between the damage done by radiation and by chemical attack. The situation is quite complicated, but Billen's paper concludes that ''spontaneous DNA damage *may be* many orders of magnitude

greater than that caused by low radiation doses.'' Billen now says that the ''*may be*'' was over-conservative and can be modified to ''*according to available evidence, should be*.''

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8.2. Exposure to residential radon causes lung cancer

R. William Field and Philippe J. Duport
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OVERVIEW

In many geographic regions, exposure to radon contributes significantly to background radiation levels. According to the linear, no-threshold model, this contribution raises the cancer risk of exposed individuals. Radon levels in homes can be reduced, but often the costs are substantial. Some experts feel that the costs are not justifiable, because epidemiological studies have failed to show a correlation between radon levels and cancer incidence. This debate between experts creates public uncertainty and frustration. It is this debate that is the subject of this month's point/counterpoint.

Arguing for the Proposition is R. William Field, Ph.D. Dr. Field is a Cancer Epidemiologist in the Department of Epidemiology, an adjunct professor in the Department of Occupational and Environmental Health, and a member of the graduate faculty in the College of Public Health at the University of Iowa. He received his Doctorate Degree in Preventive Medicine from the University of Iowa in 1994 and since that time has published over 40 articles, including book chapters, related specifically to radon and environmental radiation. Dr. Field has expertise and extensive work experience in Health Physics, Environmental Health, and Epidemiology. He has served as associate editor for the following journals, *Reviews on Environmental Health, Health Physics, and Journal of Toxicology and Environmental Health*.

Arguing against the Proposition is Philippe J. Duport, Ph.D. Dr. Duport is Founder and Director of the International Centre for Low Dose Radiation Research at the University of Ottawa. Dr. Duport has thirty years of field experience in aerosol physics as well as in environmental and radiation protection in the uranium industry in Canada and France. He became Head of Health and Environmental Effects Research Section of the Atomic Energy Control Board of Canada. He was also a member of the AECB delegation to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and to OECD-NEA specialized working groups on radon and thoron dosimetry.

FOR THE PROPOSITION: R. William Field, Ph.D.

Opening Statement

Radon decay products (radon) are well established lung carcinogens.[1,2] Over 20 occupational epidemiologic studies of radon-exposed underground miners have unequivocally demonstrated that prolonged exposure to radon increases the risk of lung cancer.[3] Pooled studies of 65 000 miners found a linear relationship between radon exposure and lung cancer deaths.[3,4] This relationship was maintained, even among a subgroup of miners that had lower exposures extending into the range for some homeowners.[3,5] These findings suggest that residential radon also carries a risk of cancer.[3,4,5] The National Academy of Sciences (NAS) has developed radon

risk models based on miner studies that project 18 600 lung cancer deaths each year in the United States caused by residential radon exposure.[3]

There is mounting scientific evidence to support the argument that residential radon exposure causes lung cancer. A 1997 National Cancer Institute (NCI) meta-analysis[6] examined the effects of residential radon exposure on lung cancer risks, using data from eight of the previously-published large scale residential case-control studies performed independently in Canada, China, Finland, Sweden, and the United States. The results reveal an excess risk of cancer of 14% at 148 $Bq.m^{-3}$. Subsequent major residential case-control studies in Europe[7,8] and China,[9] as well as preliminary findings from the pooling[10] of North American residential radon studies, which includes 4 081 cases and 5 281 controls, closely agree with the NAS projected risk estimates. Moreover, two recent residential case-control studies in Missouri[11] and Iowa,[12] that used enhanced dosimetry methods, found even higher risk estimates. These findings strongly suggest that previous radon studies may have actually underestimated the risk posed by residential radon, because exposure misclassification was found to bias the studies toward finding no association.[13]

In summary, risk estimates from rigorously designed analytic epidemiologic studies provide compelling evidence that prolonged residential radon exposure increases the risk of lung cancer.

Rebuttal

In theory, a single alpha particle can trigger double strand DNA breaks, leading to cancerous transformation of a single cell.[3] *In vitro* studies show that cells exposed to high-LET radiation send out "signals," which cause chromosomal damage and transformation to nearby unirradiated "bystander" cells as well.[14,15] Thus, based on the radiobiological effects of high-LET radiation,[3,16] low-dose radon exposure can induce cancer.

There are several reasons why one should not use animal studies to address the risk of low-dose radon exposure on the development of lung cancer in humans. First, rats do not develop small cell carcinoma, a common type of lung cancer in people. Second, low dose rate studies in animals may underestimate risk, because the time needed for the development of cancer may exceed the lifetime of the animal. Finally, one cannot extrapolate results species-to-species, because there are differences in dose-response relationships among species. Therefore, the best studies to assess the risk of radon-induced cancer in humans are the uranium miner studies and the rigorously designed residential radon case-control epidemiologic studies.

Duport offers two reasons why indoor radon risk cannot be extrapolated from uranium miner studies. His first reason, that the uranium miners would have been exposed to other sources of radiation, is moot, because lung cancer risk from radon exposure is similar between uranium and nonuranium miners. His second reason, that nonsmoking miners exposed to radon doses less than 400 WLM did not develop lung cancer, deserves clarification. In fact, there were cases of lung cancer in the exposure categories of nonsmoking miners below 400 WLM. The estimated excess relative risk per WLM was higher for never-smoking miners than for smoking miners.[3] This agrees with data from residential radon studies, which indicate that residential radon exposure increases lung cancer risk even in nonsmokers.[10,17]

Duport dismisses the epidemiologic studies of residential radon exposure as confusing. The residential radon epidemiologic studies have generated conflicting findings. Ecologic radon studies are the principle source of confusion in radon epidemiology.[18,19,20] Epidemiologists maintain that the ecologic study design should be reserved for generating hypotheses rather than

estimating risk. Our research group[13] and others[21] have argued that the lack of significant findings of some of the earlier residential case-control studies is attributable to random misclassification of risk factors, primarily from poor assessment of radon exposure, which reduces a study's power to detect an association.

Duport suggests that epidemiologic studies would be more credible if confidence intervals included ALL dosimetric errors and uncertainties. Changing the way confidence intervals are calculated in epidemiology will not change the central estimate of risk. Nonetheless, Duport's statement indirectly addresses the importance of accurate dosimetry in environmental epidemiology, a topic of great priority to our research group.[12,13,22] In fact, substituting less accurate dosimetry data in case-control studies reduces the ability to detect an association.[10,11,12,13,21,22] Furthermore, studies that incorporate enhanced dosimetry methods find higher risk estimates.[10,11,12,13]

In summary, an abundance of scientific evidence has clearly demonstrated that prolonged residential radon exposure increases the risk of lung cancer.

AGAINST THE PROPOSITION: Philippe J. Duport, Ph.D.

Opening Statement

The absence of an effect can never be proven with absolute certainty. Nevertheless, there are experimental, epidemiological and dosimetric reasons to doubt that indoor radon decay products (RDP) cause lung cancer, at least at concentrations below several hundreds of Bq/m^3.

Experiment

It has been shown that rats exposed to a low dose [25 working-level months (WLM)] of RDP at high dose rates of 150 and 100 WL $\approx 6\times10^5$ and 4×10^5 Bq/m^3 show a significant excess of lung cancers. Paradoxically, the same dose given at 2 WL ($\approx$ 8 000 Bq/m^3) has a nonsignificant protective effect.[23] This is consistent with other unambiguous thresholds, at doses up to several grays of α radiation, in animals[24,25] and in humans.[26,27] Only an α radiation weighting factor $w_R(\alpha) \rightarrow 0$ at low dose rates explains the absence of risk.

Epidemiology

1. Wrong assumptions in uranium miner studies.

The risk of cancer in an organ is, theoretically, proportional to the total organ dose. In uranium mines, doses other than from RDP are not negligible. In addition, with $w_R(\alpha) \approx 1$ the relevant lung dose for risk estimation is the *total* absorbed dose. In uranium miner cohorts for which individual doses from each radiation source are available and reliable, the RDP risk is overestimated by a factor of 2 to 4, or more if doses received in "neglected" mines and dose misclassification are also considered.[28] The corrected excess relative risk per working level month (ERR/WLM) is close to that of Chinese tin miners (0.001/WLM),[29] which increases the likelihood of no effect at the lowest exposures.

2. Lung cancer in nonsmoking uranium miners.

The lowest exposure in non-smoking uranium miners with lung cancer is about 450 WLM.[30]

3. Confusing indoor studies.

Upon visual inspection of the data points evenly and widely distributed about the no-effect line, what confidence can be granted to a positive trend in a meta-analysis of indoor RDP,[6] when well-designed studies support either the LNT,[31] a U-shaped response[32] or no effect whatsoever?[33]

Dosimetry

Risk is proportional to dose. RDP dosimetry is very uncertain;[28,34] uncertainties in RDP lung dose are very large and impossible to quantify. RDP epidemiologic studies would be more credible (but would they still appear meaningful?) if confidence intervals included ALL dosimetric errors and uncertainties, in addition to statistical mortality uncertainty. In other sciences, peer reviewers would challenge papers in which error bars take only a fraction of all possible errors into account.

Conclusions

(1) Animal and human studies show, convincingly, that low doses and dose rates of alpha radiation have no health effects on the lung or other organs. Biological arguments should be offered to explain why such effects should exist for indoor RDP alpha radiation.

(2) Indoor radon risk cannot be extrapolated from biased miner studies.

(3) Currently published epidemiologic radon studies give a false sense of accuracy because their confidence intervals, as large as they may be, are artificially narrow: They take into account only the quantifiable (and arguably the smallest) part of all errors and uncertainties.

Rebuttal

Dr. Field's arguments are based solely on an epidemiologic construct that relates risk to radon concentration. However, it is the dose (or exposure), not the concentration, that determines the risk. The dose and the concentration are not rigorously related for indoor radon. Radon risks at low doses and dose rates, as extrapolated from uranium miner studies, are overestimated. This is because significant lung doses from gamma radiation, inhaled ore dust and doses received in "neglected" mines have been systematically ignored. In individual and pooled miner studies, confidence intervals at low exposures accommodate any dose-response shape, including the presence of thresholds. These confidence intervals are also underestimated, and would be much larger if all dosimetry and mortality errors were taken into account.

Dr. Field cites European, Chinese and US indoor case-control studies to support his argument. However, other case-control studies[32,33] tend to support no-effect or threshold arguments. Why does my colleague ignore these studies? With all errors taken into account, the number of projected radon-induced lung cancers in the US would be between zero and a high upper limit.

Low doses and dose rates of alpha radiation, including RDP, are probably not carcinogenic in humans[26,27,29] or in animals.[23,24,25] Dr. Field does not explain why RDP alpha emitters are carcinogenic while other alpha emitters are not. He does not address why the observed ineffectiveness of alpha radiation in humans and animals should be neglected in the interpretation of indoor radon risk. In brief, Dr. Field's arguments would be stronger if they reconciled indoor radon epidemiology (all doses and errors taken into account) with dosimetry and indisputable human and animal data at low dose rates of alpha radiation (including RDP). The noncarcinogenicity of low doses and dose rates of alpha radiation (including RDP) is established more rigorously than the carcinogenicity of indoor radon.[35]

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8.3. A prospective study should be performed to test the hypothesis that an increase in background radiation to residents in the gulf states will increase their longevity

John R. Cameron and Jeffrey Kahn

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OVERVIEW

Radiation hormesis suggests that small exposures to radiation over extended periods improve longevity by reducing the risk of disease. One can envision various prospective studies to test the concept of radiation hormesis. The limitation of these studies is that they may be considered unethical. One such study is proposed in this issue of Point/Counterpoint.

Arguing for the Proposition is John Cameron, Ph.D. John Cameron completed his Ph.D. from UW—Madison in 1952 in nuclear physics and switched to medical physics in 1958. He was a founding member of the AAPM and its tenth president. His research interests were in TLD, accurate bone measurement and instrumentation for QC of x-ray images. He co-authored several books. In 1980 he was the founding chair of the Department of Medical Physics at UW—Madison. Since his retirement in 1986 he has sought to educate the public about radiation. He believes that low dose rate radiation is beneficial and that human research is necessary to determine the optimum dose rate.

Arguing against the Proposition is Jeffrey Kahn, Ph.D., M.P.H. Dr. Kahn is Director of the Center for Bioethics, and Professor of Medicine, University of Minnesota. From April 1994 to October 1995 Dr. Kahn was Associate Director of the White House Advisory Committee on Human Radiation Experiments. Dr. Kahn works in a variety of areas of bioethics, exploring the intersection of ethics and public health policy, including research ethics; ethics and genetics; and ethical issues in public health. He has published over 50 articles in the medical and bioethics literature, and his book credits include *Beyond Consent: Seeking Justice in Research* (Oxford University Press, 1998). He also writes the bi-weekly bioethics column "Ethics Matters" for CNN.com.

FOR THE PROPOSITION: John Cameron, Ph.D.

Opening Statement

Arguments in science indicate a lack of convincing data. Probably no other aspect of radiation protection has been as contentious as the present assumption that even the smallest amount of radiation may cause an increase in cancer. The cost to society of this assumption is staggering. In addition, it has contributed significantly to worldwide radiation phobia. Despite the lack of human data to support the assumption at typical background dose rates, the present policy has been recently iterated once again.[1] It seems likely that the only way to resolve the controversy is a human radiation study, such as that stated in the proposition.[2] Further, I believe that such a study would be entirely ethical.

A study by Jagger compared cancer mortality and background radiation rates in three mountain states with those in three gulf states.[3] The mountain states had annual background rates about three times greater than the gulf states. However, the cancer mortality in the gulf states was about 25% greater than in the mountain states. This suggests that people in the gulf states are suffering from higher cancer rates due to a radiation deficiency. If the proposed study is unethical then it is equally unethical not to warn people that they should not live in a mountain state because of the increased radiation. Nobody warns the public that flying in jet planes increases the radiation dose.

More convincing data on health benefits of increased radiation comes from several epidemiological studies. The best radiation worker study is the nuclear shipyard workers study (NSWS) where cohort and controls were identical except for the radiation exposure to the cohort.[4] In this study the health of 28 000 nuclear workers with the highest cumulative doses (>5 mSv) was compared with the health of 32 500 age-matched and job-matched unexposed shipyard workers. The cancer mortality of the nuclear workers was four standard deviations lower than that of the unexposed workers, and the death from all causes of the nuclear workers was 16 standard deviations ($P<10^{-16}$) lower. The annual dose to the nuclear workers was comparable to that received by residents in the mountain states.

A study of British radiologists from 1897 to 1997 shows a similar health improvement.[5] The high occupational exposures of early radiologists (1897–1920), with annual doses estimated at 1 Gy, were associated with a cancer death rate 75% greater than that of all male physicians in England and Wales. However, their non-cancer death rate was 14% lower than the control group. The death rate from all causes was slightly less than the control group. That is, despite their high doses, radiologists had no loss of longevity. British radiologists who first joined a radiological society in 1955–1979 had a non-cancer death rate 36% lower than the control group, and their death rate from all causes was 32% lower ($P<0.001$). Their annual dose was estimated to be about 5 mSv.

The evidence suggests that there is no increased risk of cancer at low doses of radiation. That is why it is ethical to conduct the experiment suggested in the proposition. The results might settle the low-dose radiation risk issue once and for all.

Rebuttal

I agree with much of Dr. Kahn's statement but I strongly disagree with his assumption that there is an "unacceptable level . . . of risk" at the dose rate found in the mountain states where millions of people live longer lives with less cancer than people in the gulf states. The proposed increase in radiation is about 3% of the dose rate to some people who live in Ramsar, Iran with no obvious increase in cancer mortality. I would be happy to participate in such a study although I would prefer a dose rate of 0.1 Gy/y. It seems odd for Dr. Kahn to accept the LNT assumption as a scientific fact while ignoring the better health of the British radiologists and the nuclear shipyard workers.

AGAINST THE PROPOSITION: Jeffrey Kahn, Ph.D., M.P.H.

Opening Statement

The process for human subject research in the U.S. is predicated on the principle of protection, against which any proposed research must be evaluated. This principle evolved out of a history of exploitation of human subjects, shortcomings in questionable or nonexistent informed consents,

and research that posed significant risk without the potential for direct medical benefit to the subjects. In response to this history, federal rules were created that require prospective review of any research involving human subjects. This review must assure that proper informed consent occurs, and take into account whether the level of risk in the research is acceptable, whether the potential benefit of the research sufficiently offsets the risks entailed by it, and most important, whether the distribution of the risks and benefits from the research is acceptable. So it is not enough for risky research to be justified by the potential benefit that it will yield. It is also necessary that the potential benefit of such research accrues to the subjects accepting the risk.

For example, it would be unethical to test a new form of chemotherapy on otherwise healthy subjects to better understand its toxicity, even though one could argue that the significant harm posed to the subjects would be balanced by the benefit of the information gained. The problem is that the distribution of risks is unfair—all the risks would be born by the subjects, while all the benefits would accrue to others. Similarly, this Point/Counterpoint raises the question of whether research on radiation hormesis produces risks without benefits to those exposed to the research, or, if there are benefits, whether they are sufficient to offset the risks.

The problem with this question is the uncertainty of the risks posed by such research. This uncertainty affects not only the ability to evaluate the risk-benefit balance of the research, but also the capacity to assess the issue of risk distribution. What risks would researchers disclose to potential subjects of such research, and how certain could they be in their disclosure? Without sufficient information about both the risks and benefits of the research, informed consent is impossible. Even if we had more complete information, it is questionable that prospective subjects would receive any disclosure in radiation hormesis research as objective information. Our country's history of intentional research-related radiation exposures and environmental releases, and the ongoing health effects claimed by those exposed, have created an atmosphere of suspicion and distrust with regard to radiation exposures.

Then how might such research proceed? More sophisticated studies of epidemiological data regarding long-term low-dose exposure—potentially of those exposed occupationally—could provide much-needed information and guidance for future studies in humans. If human subjects were intentionally exposed to low-dose radiation, their health would need to be monitored very carefully and frequently to identify and treat negative health effects quickly.

One measure of the acceptability of any controversial research proposal is whether researchers would participate themselves or enroll their children. The answer is often instructive if not definitive. There are likely many research questions that we'd like to be able to answer, but they entail unacceptable levels or distributions of risk, or carry too much uncertainty. For these research questions, the price of the answers is simply too high.

Rebuttal

Research that attempts to assess the health effects of environmental exposures generally proceeds from the assumption that increased rates of exposure bring increased risk of harm. That's why controlled experiments in which otherwise healthy research subjects are dosed with a presumed toxin raise red flags—they pose risk to subjects without offsetting direct potential benefit to them. But the title of Prof. Cameron's statement proposes a study to assess the human health *benefits* of low-level radiation exposure, which would be quite a different matter. Offering subjects the opportunity to participate in research that is intended to benefit their health raises far different

ethical concerns—not about protection, but about who gets to participate, and how we can ensure that they are equitably selected.

The dilemma of this Point/Counterpoint topic is in the suggestion that participating in radiation exposure research offers health benefits. There is overwhelming evidence that higher doses of radiation increase cancer risk, so why not start from the presumption that low doses pose risk, too, rather than the counterintuitive hypothesis that it will be beneficial? Why does this distinction matter? It is critical both for how we think about the risk–benefit ratio of the proposed research, and more importantly, for how prospective subjects would perceive the risks and benefits of their participation.

Even the text that follows the title of Prof. Cameron's statement proceeds from the presumption that such exposure carries risk. He suggests that the only way to resolve the controversy over the "assumption that even the smallest amount of radiation may cause an increase in cancer" is to perform a controlled prospective study of the health effects of intentional exposure to small amounts of radiation. So the proposal is not to assess the benefit, but the risks of low-level radiation. Can we conclude from the range of epidemiological studies offered by Prof. Cameron that low level radiation exposure is actually healthful? Such data cannot show cause and effect—any claim that it did would be to commit the epidemiological fallacy. Before we can begin to measure the potential health benefits of radiation exposure in otherwise healthy subjects, we need to be confident that exposure carries minimal risks of harm. But in an era of increasing protection of human subjects, it will be difficult to perform research with risk profiles that are unknown at best, and pose significant risks of harm at worst.

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8.4. Radiation hormesis should be elevated to a position of scientific respectability

John R. Cameron and John E. Moulder

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OVERVIEW

Hormesis, the pharmaceutical principal that ‘‘A weak stimulus might stimulate what the same, but stronger, stimulus inhibits’’ is traceable to ancient times. All substances exhibit toxic effects at the wrong doses. But virtually all substances exhibit either no or beneficial effects at other doses. Since the discovery of x rays in 1895, many articles have been published demonstrating a hormetic effect of ionizing radiation at low doses. Yet the no-threshold dose-effect model of radiation injury ignores these articles and assumes that any exposure to ionizing radiation, no matter how small, is potentially harmful to human health. This assumption has been challenged over the years and with increased intensity recently, in part because advocates of radiation hormesis insist that the effect is scientifically credible. Others insist that the effect is not credible, in part because no biological model exists to explain radiation hormesis. The issue is controversial and important. This edition of Point/Counterpoint addresses the controversy.

Arguing for the proposition is John R. Cameron. Professor Cameron spent most of his career (1958–1986) in Medical Physics at the University of Wisconsin-Madison. In the early 60’s he helped develop thermoluminescent dosimetry (TLD) and pioneered the photon absorptiometry method of bone mineral measurement. In the 70’s he promoted better quality control of x-ray imaging and gathered distinguished group of medical physicists at UW. In 1981 he was the founding Chair of the Department of Medical Physics at UW. Since his retirement in 1986 he has devoted much time to education about the lack of risk and possible benefit from small doses of radiation.

Arguing against the proposition is John E. Moulder. Dr. Moulder received his Ph.D. in Biology from Yale University in 1972. Since 1978, he has served on the faculty of the Medical College of Wisconsin, where he is Director of the Radiation Biology Program. His primary research interest is the biological basis for carcinogenesis and cancer therapy. He has published extensively in this area, and has served on the Experimental Therapeutics and Radiation Review Groups for the U.S. National Institutes of Health. Dr. Moulder is on the Editorial Board of Radiation Research, and is an elected member of the Committee on Man and Radiation of the IEEE. He has also served on the Wisconsin Radiation Protection Council, and on state and local advisory groups concerned with environmental health, pesticides and nonionizing radiation. Dr. Moulder is actively involved in educating the public on realistic assessment of cancer risks.

For the proposition: John R Cameron

Opening Statement

Many radiation scientists have always believed that radiation hormesis is scientifically respectable. The lack of research funding for radiation hormesis is because it is not ‘‘politically

respectable''—that is, it contradicts the assumption that radiation risk extends linearly to zero dose.

Hormesis—health benefits from small quantities of a toxic substance—is well accepted in medical practice. Obvious examples are medications, hormones, and the 17 essential trace elements. All are poisonous in large amounts but beneficial in small quantities. The best collection of references—over 1300—on radiation hormesis appear in two books by T. D. Luckey: *Hormesis with Ionizing Radiation* (CRC Press, Boca Raton, 1981) and *Radiation Hormesis* (CRC Press, Boca Raton, 1991). An excellent recent review by Luckey appeared in 21st Century, Fall 1996.

Evidence for radiation hormesis appears in NCRP Report No. 104 (1990). On p. 118 it states: ''Maisin *et al.* (1983) have reported a significant decrease in lung carcinomas after exposure to 0.02 Gy of 23 MeV neutrons.'' On p. 119, Fig. 6.10 shows that gamma radiation reduces the incidence of lung adenomas from about 30% for the controls to about 20% at a dose of about 0.25 Gy. Later, on the same page: ''In BALB/c mice, a decreased incidence was found for neutrons in the range between about 0.05 to 0.2 Gy dose levels...'' Data in Miller *et al.* [New Eng. J. Med. **321**, 1285–1289 (1989)] show that breast cancer mortality decreased to 66% of controls (p,0.05) for cumulative fluoroscopic exposures of 10–19 cGy. (See also, Pollycove in Physics & Society News, pp. 6–8, April 1998.)

While radiation hormesis plays a role in reducing cancer its primary benefit to the public is in improved health, probably through a stimulated immune response. Two examples: (1) Japanese A-bomb survivors, despite about 400 radiation induced cancer deaths, are living longer on the average than the unexposed controls. (2) The Nuclear Shipyard Worker Study (Matanoski DOE report, 1991) shows that the 29 000 nuclear shipyard workers with the highest cumulative doses were much healthier than the 33 000 age and job matched workers on non-nuclear ships. The cancer death rate was lowest for the nuclear workers but the really significant result was a 24% (16 std. dev.) lower death rate from all causes compared to the controls. This important study, completed in 1988, and reported in UNSCEAR 1994 has yet to be published in a scientific journal.

Strong scientific support for radiation hormesis comes from cellular studies. Feinengdegen *et al.* ''Low level radiation may protect against cancer'' (Physics & Society News, pp. 4–6, April 1998) present data from studies of rodents and humans to show that low level radiation (<0.2 Gy) is beneficial to health. (See Fig. 1.) The article documents four beneficial effects: (1) **damage prevention** by temporarily stimulated detoxification of molecular radical species; (2) **damage repair** from temporary stimulation of repair mechanisms; (3) **damage removal by apoptosis** which results in cell death in response mainly to DNA alterations; and (4) **damage removal by stimulating the immune response**. While doses in the range of 0.1 to 0.2 Gy appear optimum, very low doses comparable to annual background show dramatic hormetic results. Azzam *et al.* [Rad. Res. **146**, 369–371 (1996)] show that a dose of only 1 mGy to mammalian cells *in vitro* reduced neoplastic transformations 3 or 4 fold below the spontaneous rate. This may explain why people living in the seven states with the highest background have about 15% lower cancer death rates than the average for the US (Frigerio *et al.* ANL/ES-26, 1973).

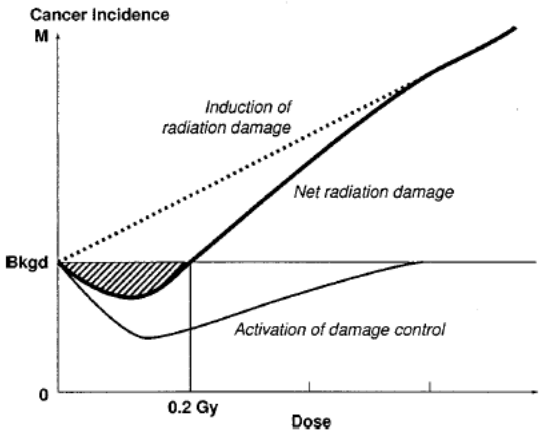

FIG. 1. Hypothetical dose-response curve for cancer induction by radiation illustrating the potential for hormesis at doses below about 0.2 Gy.

Hormetic effects from radon progeny in the lung are suggested in the studies of Cohen (Health Physics, Jan. 1995). The lung cancer mortality in US counties with the highest radon levels (>5.0 pCi/l) is about 40% lower than in US counties with the lowest radon levels (<0.5 pCi/l). This suggests that the radiation eliminates cancers initiated by smoking.

Rebutal

Radiation hormesis is not a model—it is an effect. If a low dose is beneficial, it is hormesis. No scientific definition is necessary. The scientifically respectable position is to report all data even if they contradict current radiation protection dogma. [Radiation biologists have neglected studies of biological effects at low doses (<0.2 Gy) where hormesis is most apt to be observed because research money has been available to look for carcinogenic effects of radiation.]

Against the proposition: John E. Moulder

Opening Statement

The concept of ‘‘radiation hormesis’’ is certainly not ‘‘respectable’’ in health physics circles. It has been condemned as unproven and lacking biological/biophysical plausibility, and criticized because it would require a fundamental change in the basic radiation protection paradigm that ‘‘even the lowest radiation dose is harmful.’’ The concept is, of course, anathema to those who claim that current radiation protection standards underestimate the risks of low dose exposure. But none of these arguments provides a scientific basis for rejecting the concept. The lack of hard evidence and established mechanisms does not make a concept unacceptable, it simply makes it unproven; and the issue of whether a concept is ‘‘politically correct’’ should be irrelevant to a scientific debate.

The only valid criterion for determining whether a concept is ‘‘scientifically respectable’’ is whether the concept is sufficiently well-defined that it can be tested; that is, whether the concept generates unambiguous hypotheses that are capable of being rejected. Here there is a problem with ‘‘radiation

hormesis,'' as the very concept is rather elusive. In a 1987 issue of Health Physics, Jerry Cohen[1] defined ''radiation hormesis'' as the ''process whereby low doses of [ionizing radiation]...could result in stimulatory or beneficial effects.'' However, two pages later Leonard Sagan[2] defined it as the presence of ''effects unrelated to and unpredictable from the [effects of] high dose exposure,'' and still elsewhere Sagan[3] argues that ''radiation hormesis'' could be equated with adaptive response.[4] To another strong proponent of the concept, T. D. Luckey,[5] ''radiation hormesis'' is a specific type of nonmonotonic dose-response function that results in ''beneficial'' or ''biopositive'' effects at doses below 0.5 Gy.

These various statements of the concept are neither well-defined nor entirely compatible. What is a ''low dose?'' What is ''stimulatory'' effect? What are ''beneficial'' or ''biopositive'' effects? What are the criteria for establishing that effects are ''unrelated'' and/or ''unpredictable?'' In fact, the concept of ''radiation hormesis'' is so vague that it is effectively impossible to formulate unambiguous and testable hypotheses based on it. It is this vagueness which makes the concept of ''radiation hormesis'' scientifically unacceptable.

Certainly there are circumstances where exposure to low doses of radiation confers benefits:
• Low doses (by radiation oncology standards) of total body irradiation are beneficial in bone marrow transplantation.
• Some radiation-induced mutations can confer adaptive advantages on cells grown under nonoptimal conditions.
• Doses of the order of 0.01–0.10 Gy can briefly confer resistance to subsequent higher doses of radiation.
All of the above would appear to fit some of the definitions of radiation hormesis, but the researchers who work in these areas see no need to invoke ''radiation hormesis'' to explain their results.

Why is the concept of ''radiation hormesis'' so poorly defined? The answer is that proponents of ''radiation hormesis'' are largely reacting against proponents of the ''linear no-threshold hypothesis,'' and the latter concept is itself essentially untestable at the doses that are of interest in radiation protection. However, these two concepts are not alternatives, since low doses of ionizing radiation could produce no detectable effects without implying hormesis. In fact, we already know that sufficiently low doses of ionizing radiation cause no detectable effects. The argument becomes whether these undetectable effects are beneficial or harmful—an argument that harkens back to the question of ''how many angels can dance on the head of a pin.''

No model—whether it be ''radiation hormesis'' or the ''linear no-threshold hypothesis''—that is based on the shape of dose-response curves for doses below the level where robust effects can be detected should be considered scientifically respectable unless it is backed by well-understood biological and biophysical mechanisms. The scientifically respectable position is to focus on understanding the biological/biophysical basis for radiation effects; and that requires data, not modeling or arguing about ill-defined concepts.

Rebuttal

While Dr. Cameron and I agree that the concept of ''radiation hormesis'' is not politically respectable, we agree on little else. He does not share my concern that the concept of ''radiation hormesis'' is poorly defined, yet he offers two additional definitions of the concept. First, he would define hormesis in terms of ''health benefits,'' thereby restricting the scope to human (or at least to plant and animal) studies.

Still later, his argument implies that the concept of radiation hormesis is equivalent to the claim that ''low'' doses of ionizing radiation can protect mammals from naturally occurring cancer. Neither of these definitions is fully compatible with those of Cohen,[1] Sagan,[2,3] or Luckey.[5] Thus Dr. Cameron further reinforces my contention that the concept of radiation hormesis has not yet been sufficiently well-defined that it can generate hypotheses that are both unambiguous and rejectable.

The remainder of Dr. Cameron's argument is more an attack on blind adherence to ''linear no-threshold'' models than it is an argument in favor of ''radiation hormesis.'' He argues that the general applicability of ''radiation hormesis'' is proven by the observation that some data points on some radiation carcinogenesis dose-response curves fall below the ''zero dose'' levels. This is logically equivalent to arguing that the observation that some points fall above a ''linear no-threshold'' line proves that the conventional ''linear nothreshold'' model underestimates low dose risks. There is far more to risk assessment than arguing about the fit of small data subsets to arbitrary models.[6] It is time to put the modeling aside and focus on understanding the biophysical and biological mechanisms that are responsible for radiation injuries. The modeling and the theoretical arguments about modeling are starting to get in the way of the science.

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8.5. The use of low dose x-ray scanners for passenger screening at public transportation terminals should require documentation of the "informed consent" of passengers

Allen F. Hrejsa and Morris L. Bank

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OVERVIEW

Government agencies are considering use of low-dose x-ray systems to scan all passengers (or perhaps "suspicious" passengers) at transportation terminals. The agencies do not intend to seek passenger consent because the screening dose is low. One can argue, however, that since passengers do not benefit personally from screening, there is not a commensurate benefit to the risk—and therefore passengers should consent before screening occurs. This issue is addressed in this month's Point/Counterpoint.

Arguing for the proposition is Allen F. Hrejsa, Ph.D. Dr. Hrejsa received his Ph.D. in low energy nuclear physics from the University of Notre Dame. He is the diagnostic medical physicist and radiation safety officer at the Advocate Lutheran General Hospital as well as a consultant medical physicist, primarily in the area of mammography. Dr. Hrejsa is certified by the American Board of Radiology in diagnostic and therapeutic radiologic physics. He currently serves as chairman of the governor's Radiation Protection Advisory Board for the state of Illinois. Dr. Hrejsa has served on the AAPM Ethics Committee for many years and was chairman of AAPM ethics committee from 1994 to 2000.

Arguing against the proposition is Morris L. Bank, Ph.D. Dr. Bank received a Ph.D. in Physics from the University of Michigan and completed a postdoctoral fellowship in Radiological Physics at the University of Wisconsin. Presently he is Associate Professor in the Department of Radiation Oncology at Indiana University and Chief Physicist at the VA Medical Center in the Department of Radiation Oncology. He is certified by the American Board of Medical Physics and the American Board of Radiology.

FOR THE PROPOSITION: Allen Hrejsa, Ph.D.

Opening Statement

Currently there are two types of x-ray based body scanners. One type uses low energy backscattered x-rays to produce a surface image of a person sans clothing. This machine can image items concealed next to the skin.[1] The second type is a transmission x-ray scanner which can see objects that might be secreted in body cavities. I will address the backscatter devices which deliver an effective dose of 0.03 μSv per anterior scan and between 0.01 and 0.02 μSv for a posterior scan.[2]

The dose from the scanner is very low. The NCRP estimates that an individual would have to be scanned 2500 times in one year to reach the administrative control limit of 0.25 mSv/year.[2]

Unfortunately the public has an inordinate fear of radiation stemming from information about radiation in the public press and the entertainment media (e.g., Spiderman and the Incredible Hulk). In addition, past mistakes by the government during the Atomic Bomb Testing and Civil Defense era have left lingering fears and mistrust of assurances about the "harmlessness" of small radiation doses.

Since many individuals would be exposed to this small radiation dose, body scanners have the potential to measurably raise the collective dose to the population. We need to be forthright with the public and inform them fully if x-ray scanners are going to be used for security purposes in airports and other transportation venues. To this end, it seems reasonable to seek informed consent from each individual who is to be scanned. If a signed informed consent is obtained, then the individual would not be able to claim years later that he was unaware that he was being exposed to x rays when he was scanned by the security system in the airport.

Another issue has been raised by the American Civil Liberties Union. This group opposes body scans because "passengers expect privacy underneath their clothing and should not be required to display highly personal details of their bodies . . . ."[3] In newspaper stories about the screening trials run at the Orlando Airport, the process was characterized as a "peep show" or "virtual strip search."[4,5] Although privacy is a sensitive issue, an informed consent would describe the nature of the image, how it was made, and any potential risks involved in its production. Manufacturers are now going back to the drawing board and adjusting the software to insert "fig leaves" at appropriate places in the images. Perhaps a concerned individual could be given the choice of an x-ray image or a "pat down". Personally, I prefer the x-ray scan, as do several people I have questioned (see also CBSNews.com July 17, 2003).[6]

Rebuttal

If low dose x-ray scanners are used for security purposes on a large scale, a signed consent would provide a "paper trail" for future research into the effects of low doses of radiation to a large population. Although record keeping would be a challenge, large-scale computing systems are available which would allow collection of the data using "electronic" signatures on a computerized informed consent form. At this stage in the research of low-dose radiation effects in humans (less than 1 cGy per year), the consequences of low-dose radiation 20 years in the future are unknown. So it is not possible to unequivocally state that the increased security outweighs the radiation risk associated with low-dose x-ray scanners.

AGAINST THE PROPOSITION: Morris Bank, Ph.D.

Opening Statement

Government agencies and other institutions are proposing the use of whole body x-ray scanners (WB scanners) for security purposes such as admission to public transportation and detection of contraband in prisons. This use would involve repeated x-ray exposures of large numbers of people with associated hazards. Proposed scanners use a scanning x-ray beam at 60–125 kVp to produce images using backscattered x rays. The images show the skin surface of the person and can identify weapons and contraband concealed under clothing.

There are two classes of WB scanners, General Purpose and Limited Use, with General Purpose scanners proposed for security screening. The whole body effective dose of General Purpose

scanners is very low –0.1 μSv (0.01 mrem) according to the manufacturer and the National Council on Radiation Protection and Measurements.[2] A person could be scanned 2500 times before reaching the recommended administrative control dose of 0.25 mSv (25 mrem) per year [25% of max dose of 100 mrem]. Further, a person would have to experience 1000 scans to achieve the annual Negligible Individual Dose [NID] of 0.1 mSv [10 mrem]. The scanners conform to an ANSI standard for security screening[7] of an effective dose below 0.1 μSv (0.01 mrem) per scan. Such a low WB dose minimizes the radiation risk to persons undergoing exposure. A traveler would require 50 scans per week to accumulate the maximum annual effective administrative dose.

Passengers should be informed in writing of the use of an x-ray scanner, the exposure involved, and the associated risks. However, informed consent and its documentation are not necessary. Record keeping would be impractical considering the many locations of the scanners and the many travelers screened. The benefit of mass scanning in terms of increased security greatly outweighs the individual and collective radiation risk. This opinion is contingent upon instituting additional measures such as shielding to limit radiation exposure to operators and bystanders. Frequent inspection of units to ensure minimum dose levels, and periodic training for operators should be included. Limited Use machines, which have higher effective whole body doses by a factor of 10, are excluded from consideration in this proposal. For these units, record keeping and protocols for limiting annual doses from repeated exposures would be necessary.

Rebuttal

I agree that the public must be knowledgeable and informed about whole body x-ray screening procedures. A choice between a "pat down" and an x-ray procedure is a viable option. If an x-ray scan is chosen, a description of the scanning procedure, the radiation dose and the associated risks must be presented to all persons being scanned. A net benefit to society should result from any x-ray procedure performed on humans. In this case the benefit is the safety of the passengers. This is also the position of the Health Physics Society (HPS)[8] concerning whole body x-ray screening procedures.

Documentation of informed consent is not necessary, however, in order to inform the public of the benefits and low risk of x-ray scans. In fact, screening procedures offer an opportunity to educate the public about the benefits of radiation, and for medical/health physicists to be involved in the discussion. The HPS has a stated position on whole body x-ray scanners, and the American Association of Physicists in Medicine (AAPM) should also consider taking a position.

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8.6. The fetal dose limit for flight personnel should be 1 mSv over the gestation period, rather than 5mSv as recommended by the NCRP

Robert J. Barish and Richard L. Morin
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OVERVIEW

An upper limit of 1 mSv fetal dose over the gestation period is used for employees of European air carriers. This limit, endorsed by the ICRP and the 25 countries of the European Union, is 1/5th of the limit of 5 mSv over the gestation period used by US air carriers based on recommendations of the NCRP. This discrepancy is the subject of this month's Point/Counterpoint.

Arguing for the proposition is Robert J. Barish, Ph.D. Dr. Barish is a medical and health physicist consultant in New York City. He received a B.S. in physics and a Master of Engineering in radiological health from New York University and earned a Ph.D. in Medical Physics from the University of London's Institute of Cancer Research. He was an Associate Professor of Radiology at NYU Medical School, then chief radiotherapy physicist at the Cancer Institute of St. Vincent Catholic Medical Centers of Brooklyn and Queens. His book, *The Invisible Passenger: Radiation Risks for People Who Fly*, is used by airline crewmembers learning about in-flight radiation. Dr. Barish is certified by the ABR, ABHP and ABMP and is a Fellow of the AAPM.

Arguing against the Proposition is Richard L. Morin, Ph.D. Dr. Morin is the Brooks-Hollern Professor, Mayo Medical School. Dr. Morin received his Ph.D. from the University of Oklahoma in Medical Physics. His dissertation concerned the use of Monte Carlo Simulation and Pattern Recognition for artifact removal in Computed Tomography. He was Director of Physics in Radiology at the University of Minnesota before joining Mayo Clinic in 1987. He is a Fellow of the ACR and the AAPM and a Diplomate of the ABR. Dr. Morin is a former President and Chair of the Board of the AAPM, and is currently a member of the ACR Board of Chancellors, chairing the Commission on Medical Physics.

FOR THE PROPOSITION: Robert Barish, Ph.D.

Opening Statement

With regard to radiobiological effects, there is no test that would provide even the most careful scientist with a means for determining whether an individual was exposed to 1 mSv or 5 mSv distributed over a nine-month period. The issue we are debating is not one of demonstrable harm. Rather, it is an examination of the logic used in establishing standards for radiation protection at low levels, in particular for the radiation received in high-altitude air transport. Unlike other occupations, where actual exposures are often considerably below administrative limits, the cosmic radiation dose received by crewmembers in an airliner is an inevitable consequence of

their work environment. For pregnant crewmembers on high-altitude routes, the dose will exceed 1 mSv over the gestation period of nine months, assuming normal work schedules.[1]

At these levels there are no deterministic (non-stochastic) risks. At such low doses, however, the linear no-threshold (LNT) model of radiation risk predicts a greater-than-zero chance of a malignant transformation that might cause a cancer many years after exposure. The LNT model has recently been upheld by the National Council on Radiation Protection and Measurements (NCRP) in Report No. 136.[2] The risk of a radiation induced childhood cancer for the offspring of an exposed crewmember cannot be ruled out.

In Report No. 39 in 1971, the NCRP established dose limits for individuals exposed to ionizing radiation.[3] The dose limit for members of the public was set at 5 mSv per year. In that report the Council specifically stated that: "the maximum permissible dose equivalent to the fetus from occupational exposure should not exceed 0.5 rem." Thus the NCRP recommended an identical exposure limit for the embryos and fetuses of occupationally exposed women as for members of the general public, specifically pointing out the fact that "embryos, fetuses and young children" would be included in that latter category.

When NCRP Report No. 91 appeared sixteen years later,[4] the maximum permissible dose to members of the public was lowered to 1 mSv per year. But the allowed dose to the embryo/fetus of occupationally exposed women was not reduced to that lower level. It was kept at 5 mSv. Thus the categorization of embryos and fetuses of occupationally exposed women was changed, from essentially being members of the public to an in-between status with an exposure limit five times greater than members of the public and ten times lower than an occupationally-exposed pregnant woman. Identical limits appear in a subsequent NCRP Report No. 116.[5]

About the time that the NCRP published Report No. 91, the International Commission on Radiological Protection (ICRP) produced Publication 60 in which a fetal dose limit of 1 mSv was established,[6] a value essentially matching the public dose limit. All twenty-five nations in the European Union accept this value in regulating exposures of pregnant aircrew. The United States Federal Aviation Administration uses it as well in its advisory documents.[1]

It follows from the assumptions that the stochastic risk of radiation exposure at low levels is not zero, that the LNT model is applicable and that the NCRP recommendations permit a five-times-greater risk of childhood leukemia or other malignancy for the child of an air crewmember working for a US air carrier than for a similarly employed woman working for a European airline. I don't think this is appropriate.

Rebuttal

Dr. Morin and I both agree that, at the levels of exposure under discussion, there can be no scientific test of demonstrable harm. He argues that a change in permissible exposure from 5 mSv to 1 mSv for pregnant flight crewmembers would "have tremendous societal and economic impact without justification." But he does not back up this assertion with any statistic on the number of flight attendants and pilots who actually become pregnant each year, nor with the actual economic impact on an airline if they were assigned ground-based activities as an alternative to their in-flight duties. He ignores the fact that all European carriers presently adhere to the lower dose limit yet remain economically viable.

With respect to frequent-flying passengers, it is hard to imagine that any woman would make twenty transcontinental trips or seven intercontinental journeys during pregnancy as leisure or vacation activity. A flight schedule like that would certainly be a consequence of their employment. These women, like the aircrew they travel with, are also occupationally exposed individuals. My arguments regarding aircrew dose equally apply to them!

It is a matter of law that any restriction of radiation during pregnancy requires a declaration by the exposed woman that she wishes to have lower dose limits applied. A woman who does not wish to have these restrictions may simply opt out of the required declaration. So it would not be the airlines that would deny a frequent-flying passenger a ticket. Rather, it would be a matter for employers to put into place for these women (and indeed for their male colleagues) the same type of radiation training required for traditional radiation workers in other settings to help them make informed decisions about their occupational exposures. Business frequent flyers, exposed to cosmic radiation in airliners, should be educated in the same manner as workers who are exposed to ionizing radiation in other occupations.

AGAINST THE PROPOSITION: Richard Morin, Ph.D.

Opening Statement

This proposition suggests that the radiation exposure limit for pregnant airline flight personnel should be lowered. Why? Are there scientific reports of radiation induced anomalies, morbidities, or mortalities for the children of flight personnel? Are there unscientific reports of such occurrences? I believe the posing of such a proposition is simply a manifestation of an overall "lower is better" philosophy regarding radiation exposure. For the sake of discussion, let's ignore the fact that there are no data to suggest current activities require a change in the limit and examine the consequences of such a change.

For an intercontinental trans-polar roundtrip flight from New York to Tokyo, an exposure of about 0.15 mSv is expected[7] from calculations using FAA software[8] that accounts for altitude, latitude, and typical flight time. With the lowered limit, a pregnant employee would be limited to about 7 such trips and no other flights during her pregnancy. Alternatively, about 17 transcontinental New York to Seattle trips[7] with no other trips would be allowed (0.06 mSv/trip) during pregnancy. Restricting flight personnel in such a manner would imply that they could only work about 30 days during their nine-month pregnancies. The consequences would have a tremendous societal and economic impact without justification. However, this is just the tip of the iceberg. If a lower limit is appropriate for safety reasons for flight personnel, then it must also apply to "precious metal" frequently-flying passengers (probably including some reading this column) who easily accrue the same amount of flight time. Who would enforce this restriction? Is it even remotely possible that an airline would deny a passenger a ticket because she had 20 transcontinental trips by day 90 of her pregnancy? Who would then tell her that she couldn't fly for six months?

A "lower is better" philosophy is not supported by science or common sense. It also reflects contorted thinking that perpetuates public misunderstanding and fear of radiation and its biological effects. Unfortunately, when the risks and benefits of ionizing radiation are raised in a public setting, most persons owe their knowledge of this topic to Homer Simpson™!

I argue against this proposition because it has no scientific basis, the consequences to society are enormous, and most importantly, it perpetuates an untruth to the public for no reason at all.

Rebuttal

I compliment my colleague on a scholarly position statement. Academic Theory (somewhat like Legal Theory) is always interesting. However, the topic we are debating is whether or not the current exposure limit should be lowered. Is there evidence for an increased incidence of harm for airline flight crews compared with airline workers who don't fly? I can find none. My colleague has invoked the Linear Non-Threshold Hypothesis (LNTH) for the Biological Effects of Ionizing Radiation. This hypothesis is not without controversy.[9,10,11,12] Not all experts agree with its use at the level of radiation dose experienced by air crews. The fact that the European Union has adopted an ICRP recommendation based on the LNTH doesn't verify the LNTH or establish this course of action as correct. The LNTH is, after all, a hypothesis. Perhaps the European Union has it wrong. It is time for the scientific community to meet its responsibility to demand data in support of regulations. Health care is pushed to provide "evidence-based medicine." We should join together and demand "evidence-based regulations."

I recognize that change is difficult (we still use Roman Numerals to designate Super Bowls). It is time, however, for the scientific community to state unequivocally that the emperor is without clothes. I return to my original statement regarding this proposition. The proposition suggests that the radiation exposure limit for pregnant airline flight personnel should be lowered. Why? To follow this course regardless of scientific knowledge, acumen, or insight, is illogical and potentially of greater risk. As a practical matter, if there are no proven untoward effects, why change and incur the problems and downside risks inherent in such an effort.

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8.7. A pregnant resident physician should be excused from training rotations such as angiography and nuclear medicine because of the potential exposure of the fetus

Edward L. Nickoloff and Libby Brateman

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OVERVIEW

It has been reasonably well documented that a pregnant resident physician can assume radiology rotations, including higher-exposure rotations such as angiography and nuclear medicine, without exposing the fetus to radiation levels that exceed national and international guidelines. Hence, many medical physicists support the contention that rotations should not be altered because a resident is pregnant. On the other hand, many if not most physicists subscribe to the ALARA (as low as reasonably achievable) principle, especially in cases of fetal exposure where increased radiation susceptibility is combined with an inability to decide for oneself. In addition, altered rotations usually can be accommodated by swapping rotations with other residents, with the pregnant resident taking high exposure rotations after delivery of the child. Policies on this issue vary among institutions, possibly because medical physicists have not come to closure on the issue. This issue of Point/Counterpoint is directed toward that objective.

Arguing for the Proposition is Edward L. Nickoloff, D.Sc. Dr. Nickoloff received his Doctor of Science Degree with Distinction from The Johns Hopkins University in 1977 after which he served the Department of Radiology at Johns Hopkins as Acting Director of Physics and Engineering. Currently, Dr. Nickoloff is Professor of Clinical Radiology and Chief Hospital Physicist at Columbia University P&S and the New York-Presbyterian Hospital (Columbia-Presbyterian Center). Dr. Nickoloff is board certified by the ABR, ABMP, and the ABHP, and a Fellow of AAPM, ACMP, and ACR. His research interests include image quality assessment, quality control, radiation dosimetry and radiation shielding, physics instrumentation and technical aspects of CT/mammography/ digital systems.

Arguing against the Proposition is Libby F. Brateman, Ph.D. Dr. Brateman has been a medical physicist for 25 years in private, government, and university-related hospitals and at the former BRH. As a member of the AAPM Radiation Protection Committee, she has championed reasonable radiation protection regulations for x-ray workers at both state and national levels. She is Associate Professor of Radiology at the University of Florida College of Medicine. A member of the ACR Committee on Mammography Physics, she is a five-year breast cancer survivor. As the first adult ventilator survivor in her Bone Marrow Transplant Unit, she understands the dangers of emphasizing statistics in predicting health outcomes for individuals.

FOR THE PROPOSITION: Edward L. Nickoloff, D.Sc.

Opening Statement

Radiation protection criteria for the human fetus are based upon risk estimates derived from limited data on atomic bomb survivors, a few retrospective clinical surveys and animal studies.

These risk estimates contain considerable uncertainty, especially at low dose levels. Nevertheless, the literature does identify a number of risks from fetal exposure to ionizing radiation, such as: leukemia, other cancers, growth retardation, microcephaly, diminished intelligence, mental retardation, genetic mutations, and other effects.

In-utero irradiation of a human fetus tends to affect the Central Nervous System (CNS) rather than to cause the organ and limb anomalies seen in animal experiments. Moreover, extrapolation of animal data to predict human fetal response to radiation has many caveats.

Recent radiation biology studies suggest that cancer can arise from a single cell that has undergone mutations in oncogenes and/or deletion of suppressor genes. Furthermore, fetal cells are more sensitive to radiation damage than other cells because of their increased rate of mitosis, especially during organogenesis. The cancer risk from in-utero radiation exposure has been estimated in NCRP 115 and BEIR V as about 0.025% per cGy. Even at the regulatory limit for the fetus of 0.50 mSv per month, the lifetime cancer risk from fetal radiation exposure would be about 0.01%. Because it is a stochastic process, however, radiation induced cancer could occur even at the lowest exposure levels (no threshold model of radiation injury).

Other potential risks to the fetus from in-utero irradiation include severe mental retardation with an estimated risk of 10%–40% per Gy, diminished IQ estimated at 225 points per Gy, and genetic induced defects estimated at 1% per Gy. Other effects to the CNS from fetal irradiation may be difficult to assess, such as: functional or behavioral defects, emotionality, impaired nervous reflexes, hyperactivity, and various learning deficits.

Unlike patients who receive benefits from medical procedures like angiography that involve significant levels of radiation, the fetus of the pregnant physician is exposed to risk without any benefit. In particular, interventional angiography and cardiac procedures require considerable fluoroscopy and deliver significant radiation dose to patients, and relatively high cumulative scattered levels to staff. Radiation levels involved with these procedures are so large that patient radiation injuries have been reported. Subjecting pregnant physicians to the mental stress and guilt from potential adverse effects to their babies is unconscionable, can easily be avoided, and is not consistent with radiation protection policy.

It is prudent to be conservative and to employ the principles of ALARA. In many facilities, it is feasible to temporarily re-assign pregnant resident physicians to other duties in order to limit the radiation exposure to the fetus, allowing them to complete their high-exposure training rotations at a later date. For these reasons, pregnant resident physicians should be temporarily excused from clinical training rotations that could potentially expose the fetus to significant levels of ionizing radiation.

Rebuttal

Dr. Brateman has raised a number of different issues against the proposition. The regulatory limit of 0.5 mSv per month to the fetus of a pregnant radiation worker is not a magic number below which no detrimental effects could occur. Many of the adverse effects to the fetus are stochastic processes by which a single radiation-damaged cell could result in cancer or other problems, i.e., there is no threshold level. Moreover, the radiation risk is significantly greater to the fetus than to adults. Regulatory limits for the maximum permissible dose for occupational exposure are subject to change and have been reduced over the years from 100 mSv per day in 1902 to the current value of 0.20 mSv per day due to a better understanding of radiation biology.

Indeed, the risks to the fetus from in-utero irradiation may be relatively low. By analogy, the risk of an individual getting struck by lightning is also relatively low. Nevertheless, lightning kills 60–80 persons in the U.S. each year. It is still prudent to use caution both for persons venturing into a thunderstorm and for pregnant residents working in high radiation areas—regardless of the relatively low risk.

It is commendable that Dr. Brateman's clinical facilities utilize radiation protection practices that maintain very low exposures to their staff. Nevertheless, some procedures in radiology can expose staff to high levels of radiation. A single interventional angiography or cardiac procedure may require 30–90 min of fluoroscopy. Moreover, some nuclear medicine facilities are involved with therapeutic radioisotope procedures (labeled antibodies and thyroid ablations) and with cyclotron ''hot labs.''

The social, economic, and political ramifications associated with this issue are indeed complex. The 1991 Americans with Disabilities Act provides protection from discrimination against pregnant workers; and the 1993 Family and Medical Leave Act has provisions for new mothers and fathers. I would also hope that a number of highly publicized lawsuits have sensitized employers to sex discrimination. Dr. Brateman is a highly qualified and competent medical physicist. Although our positions on this topic are diametrically opposed, I do understand and respect her position.

AGAINST THE PROPOSITION: Libby Brateman, Ph.D.

Opening Statement

Excusing pregnant residents from selected rotations is not a recommended policy, because it is not justifiable and potentially disruptive. Data from our institution show physicians performing angiography receive under-apron dose equivalents which are less than 0.5 mSv a month in almost all cases. (The few exceptions have been for fellows who performed interventional procedures for more than 40 h a week.) Attenuated conceptus doses are lower, which could be further reduced with maternity aprons or mobile shielding. Our nuclear medicine physicians never receive measurable monthly doses. Therefore, nearly all physicians receive doses within legal limits for pregnant individuals, without modification to existing practices.

The first implication of excusing pregnant residents from certain assignments is that these assignments pose greater risk than others. Radiation effects have not been demonstrated for doses as low as—or even close to—the occupational limits for individuals with declared pregnancy. Policies and regulations are based on the recommendations of international experts. For a facility to ignore them is difficult to justify from a legal standpoint. If expected occupational radiation doses for certain rotations are considered too risky, even though within guidelines and regulatory limits, what criterion is to be used as the basis for policy?

A second implication of excusing pregnant residents is that these rotations would also be hazardous for potentially pregnant residents. It is not possible to know immediately that conception has occurred. What inference is to be made by the resident already in such a rotation when she learns of her pregnancy? Is there ever a safe time for potentially pregnant residents?

Residencies are organized for residents to complete their training in a general order, with more demanding modalities typically scheduled later in the program. Requested schedule changes may cause negative feelings toward the pregnant resident, which may be reflected in evaluations that affect her career and which put her in jeopardy for having done so— particularly in comparison with a pregnant resident who does not request to be excused.

Excusing pregnant residents also implies that other pregnant personnel (e.g., physicians, technologists, nurses) should be excused. Unlike residents, these individuals may be specialized so that no reasonable substitute assignment exists for them. Difficult to manage, this situation may lead to unlawful discrimination against females because of potential pregnancy.

Regulations are set to reasonable limits. Facilities must ensure that these limits are followed, and they must not discriminate unlawfully. Personnel policies which are justifiable and universally applicable provide the best protection.

Rebuttal

Risk estimates for stochastic effects for pregnant worker doses contain considerable uncertainty and include ‘‘no effect’’ as a possibility. A prudent assumption is that the radiation-related cancer risk is real, even if overestimated. Therefore, following ALARA principles, NCRP Report 116 suggests using a linear dose-response model without threshold for the purpose of radiation protection, with a limit of 0.5 mSv/month to the embryo/fetus. Deterministic effects such as neurological impairment in offspring have not been seen for doses below 0.1 Gy, doses 20 times higher than the limit.

Radiation protection regulations are based on recommendations of the NCRP, which include the concept of justifying and limiting radiation exposure: That is, ‘‘the need to apply individual dose limits to ensure that the procedure of justification and ALARA do not result in individuals or groups of individuals exceeding levels of acceptable risk.’’ NCRP Report 115 states that, even for the highly unlikely maximum dose to the woman (50 mSv), the risk is ‘‘small compared to other risks to the fetus,’’ e.g., 4%–6% of live births with congenital abnormalities.

Cancer is common, with an approximate 41% incidence, which varies by type and incidence among states. For example, lifetime breast cancer incidence (age-adjusted) varies among states from 7.15% to 9.37%. This variability is 177 times greater than the 0.0125% lifetime risk for radiogenic cancers at the maximum allowable dose to the embryo-fetus (0.025%/cSv x 0.5 mSv/month x 10 months).

Every occupation has risks, and everything we do has an associated risk. The probabilities associated with these risks are largely unknown and depend on innumerable factors, many of which are controlled by our choices in living our lives. Some choices are based on reason, with comparisons of risks and benefits (or risks and risks), and some are not. Some of us are more cautious, and what is frightening to some is fulfilling for others. No reasonable person intentionally harms him/herself, family or others. No employer wants to subject employees, pregnant or not, to mental stress and guilt associated with radiation exposure to themselves or their offspring; therefore, appropriate regulations are the standard. As medical physicists, our socially-responsible task is to educate residents, so that they are able to be assured in performing their jobs as radiologists while maintaining ALARA. They will then become better physicians and employers of others, including pregnant staff.

8.8. An occupancy factor of unity should always be used for waiting rooms and other highly-occupied public areas

Douglas R. Shearer and Michael Yester
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OVERVIEW

The linear no-threshold model of radiation injury suggests that a small radiation dose delivered to a large group has the same effect on a population as a large dose delivered to a small group, provided that the person-sievert product is the same to the two groups. According to radiation advisory agencies (e.g., the NCRP), an occupancy factor of one should be used for shielding computations if a single member of the public continuously occupies an adjacent room. However, if the room is occupied by several people over the same period, but no one individual for the entire period, an occupancy factor of less than one may be used. One could argue that this procedure violates the concept of the linear no-threshold model. In fact, one might suggest that an occupancy factor greater than one should be used when the average number of persons occupying the room exceeds unity. This issue is the topic of this month's Point/Counterpoint series.

Arguing for the Proposition is Douglas R. Shearer, Ph.D. Dr. Shearer is an Associate Professor at Brown University and teaches courses in Medical Imaging and Health Physics. He is also the Director of Medical Physics at Rhode Island Hospital. Dr. Shearer is a Fellow in the American College of Radiology. Dr. Shearer obtained an Honors Degree in Natural Philosophy (Physics) at Glasgow University in Scotland and did postgraduate work in Radiation Physics at the University of London where he received a M.Sc. degree with distinction and a Ph.D. He is the author of approximately 100 scientific papers, book chapters and abstracts as well as an article on single-handed ocean sailing.

Arguing against the Proposition is Michael Yester, Ph.D. Dr. Yester is a Professor in the Department of Radiology at the University of Alabama at Birmingham. Dr. Yester is currently Chair of the Nuclear Medicine Committee of the AAPM and serves on the Education Committee and Summer School Subcommittee. Dr. Yester has been active in the Southeastern Chapter of the AAPM and recently served on the AAPM Board of Directors as a chapter representative. Dr. Yester is certified by the American Board of Radiology and is a Fellow of the American College of Radiology and the AAPM.

FOR THE PROPOSITION: Douglas R. Shearer, Ph.D.

Opening Statement

The linear no-threshold (LNT) dose hypothesis when applied to stochastic radiation effects implies three things. Firstly, there is no dose of radiation, however small, which does not carry a risk. Secondly, that risk is linear with dose. Thirdly, the risk is independent of dose rate; thus 30 mSv to one person carries the same risk as 1 mSv to 30 persons. In fact, this concept of

collective dose is explicitly stated in NCRP Report 121. ‘‘The effect or risk of a given dose is identical whether the collective dose is administered to a single individual or distributed over a population of individuals.’’ However, in the application of occupancy factors for radiation shielding design, we depart from the LNT concept.

Occupancy factors are defined rather vaguely in NCRP 49 as ‘‘The factor by which the workload should be multiplied to correct for the degree of occupancy of the area in question while the source is ‘ON’.’’ More precisely, NCRP 127 defines the occupancy factor as the fraction of time that a space will be occupied by any single individual.

The use of this factor can be illustrated by application to a patient waiting room adjacent to a diagnostic or therapeutic x-ray installation. In NCRP 49, waiting rooms are defined as having occasional occupancy and an occupancy factor of 1/16 is suggested. For a 40 h week, this implies that one single person is present in that room for ~2.5 h. This seems rather high and occupancy factors of ~1/40 have been suggested, i.e., 1 h/week. Assuming the permissible exposure to a member of the public is 1 mSv/yr, a dose equivalent to the waiting room space of 16 or 40 mSv/yr would be possible.

However, if we are true to the ideas of LNT, we should consider that for a typical workweek, there is probably at least one person (not the same person) in the waiting room and maybe many more, depending on the capacity of the waiting room—perhaps as many as 10. Thus, the collective dose could lie between 16 and 400 person mSv/yr.

The occupancy factor should then be a function of waiting room capacity and could vary between 1 and 10 or more. This means that shielding requirements would be increased by a factor of 16–400 (a few tenth value layers) to keep the collective dose to the recommended 1 mSv/yr. This would increase the cost of shielding by a significant amount but, according to LNT, there is no alternative.

By assuming the currently accepted fractional occupancy factors, we have implicitly discarded the LNT hypothesis.

Rebuttal

I have little argument with any of Dr. Yester’s points. He is stating the practical and common sense point of view. However, in the first sentence, he states that low levels of radiation are ‘‘safe.’’ The LNT hypothesis states exactly the opposite, i.e., there is no ‘‘safe’’ dose of radiation. There is always some risk.

Based on the LNT and the collective dose concept, we have assigned thousands of cancer deaths to the Chernobyl radioactive releases. The EPA currently informs the public that 14 000 lung cancer deaths/yr (actually somewhere between 7000 and 30 000) are due to the inhalation of small quantities of radon. In fact, by combining a mathematically derived and almost negligible risk with a large population of susceptible individuals, almost any number of deaths can be calculated.

It is not a tenable scientific position to apply LNT and collective dose concepts to some scenarios and tacitly discard them for convenience in others.

The scientific community must adopt a consistent stance to the evaluation of risk from small doses of radiation.

AGAINST THE PROPOSITION: Michael Yester, Ph.D.

Opening Statement

Shielding calculations are a common source of conflict between prudent safety and recognition that low levels of radiation are ‘‘safe.’’ In this conflict, the magnitude of ‘‘low’’ is a major subject of debate. Current guidelines stipulate that the general public should not receive more than 1 mSv equivalent dose in a year over and above background excluding medical procedures. (The typical accepted average background equivalent dose is 1 mSv excluding radon exposure.) In any event, 1 mSv/yr (0.02 mSv/week) represents the target of calculations for shielding calculations. It has been recognized that the limit can be modified by the use of an occupancy factor. Although NCRP guidelines for shielding currently in use (NCRP 49) employ strange combinations of groups and classifications for occupancy factors, these factors represent current practice. The current guideline for a waiting room is an occupancy factor of 1/16 (occasional use).

In this Point/Counterpoint, the linear no-threshold (LNT) model and the concept of collective dose are under scrutiny. Although the use of the LNT model is controversial, it is widely recognized as being conservative. There is significant evidence for other than a linear no-threshold model at low levels of exposure, but the LNT model is the model to be used for radiation protection purposes. If one is making use of the collective dose concept, NCRP 121 states that it should be used with care at low levels of exposure, and the population distribution should be taken into account. In the case being considered, a general waiting room or similar highly-occupied area will consist of a significant transient and variable population. Moreover, the levels of radiation are quite small, so the application of the collective concept is questionable.

In the absence of a good model, it is useful to consider the exposure to an individual for the calculations. Let us consider, then, the shielding from the perspective of an individual. Realistically the time spent by a single individual in a waiting room is short, especially as a typical hospital stay is quite brief these days. In addition individuals would tend to move around within the area. An occupancy factor of 1/16 would represent 2.5 h over a given week, and actual presence in such an area for multiple periods during the year by a given individual would be quite rare. Furthermore, radiation barrier calculations are performed for a point at a distance of 30 cm from the wall, which is again a worst case scenario.

Since there is considerable conservatism already included in the calculations and exposure limits, reasonable occupancy factors should be allowed. Such considerations provide for exposures well within the standard guidelines and in fact contribute minimally to an individual’s annual exposure.

Rebuttal

Dr. Shearer concludes that fractional occupancy factors violate the LNT hypothesis. It is also admitted that following this principle within the current context of debate would increase the cost of shielding significantly. If this is the case, does not this imply that something is wrong when such small exposures are in question? In NCRP 121, it is explicitly stated that the collective dose

concept should be applied with appropriate caution when the population characteristics are poorly defined, or have a high degree of uncertainty, or are subject to significant temporal fluctuations. It was stated that the range of exposure in a waiting room could vary by a factor of 10 or more which would make the uncertainties in the dose quite variable and unreliable. Temporal fluctuations will be significant in common waiting rooms. Thus, it is reasonable to state that the collective dose concept is not applicable in this situation. [It is interesting to note that in 1984 the estimated collective dose equivalent for air travel in the U.S. was 2500 person-Sv (NCRP 93).]

In a final analysis, consider actual shielding practice. The standard material for shielding construction in diagnostic radiology areas is a thickness of 1.5 mm of lead. For a waiting area, the adjoining wall should be a secondary barrier so that only scatter is important. As such, the common thickness affords a significant degree of protection at a modest cost, and the actual exposures in a waiting room are at background level. In my opinion there is little need to use a greater thickness of lead in such imaging situations. However, if the use of reasonable occupancy factors is needed to keep the shielding to a reasonable level, it should be considered rational to do so.

8.9. States should develop regulations to require monitoring of radiation doses during interventional fluoroscopy

Louis K. Wagner and Raymond L. Tanner
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OVERVIEW

Several cases of radiation burns have resulted from excessive use of radiation during interventional fluoroscopic procedures. These cases suggest that some physicians are unaware of the amount of radiation being used. Monitoring of patient exposures during the procedures could correct this shortcoming. It is unlikely that exposure monitoring would be implemented voluntarily. Hence, regulatory action would be necessary. Whether such action is desirable is the subject of this Point/Counterpoint.

Arguing for the Proposition is Louis K. Wagner, Ph.D., Professor of Radiology at the University of Texas—Houston Medical School. Dr. Wagner is a Fellow of the ACR and the AAPM and a member of the NCRP. He has served on many national and international committees, including advisor to the NRC on the medical uses of isotopes. Dr. Wagner has published extensively on radiation effects from diagnostic and interventional radiations. Publications include his books: *Exposure of the Pregnant Patient to Diagnostic Radiations* and *Minimizing Risks from Fluoroscopic X Rays*. Most recently he served as advisor and author on "Skin injuries from fluoroscopically guided procedures"—Parts 1 and 2 that appeared in the July 2001 issue of the *American Journal of Roentgenology*.

Arguing against the Proposition is Raymond L. Tanner, Ph.D. Dr. Tanner is Professor Emeritus of Radiology at the University of Tennessee, Memphis. He is a Fellow of the AAPM and the ACR, served as President of the AAPM when the Centers for Radiological Physics were established, was the first physicist appointed to the ACR Board of Chancellors, and helped found its Mammography Accreditation Program. His 40 year career encompasses college physics instruction, resident and graduate student teaching, provision of radiology planning expertise and consulting in radiation protection and quality control. He served on numerous local, state, regional, and national committees and commissions and examined for the ABR for over 25 years. Directly relevant to this proposition was his six year representation to the CRCPD on behalf of the ACR.

FOR THE PROPOSITION: Louis K. Wagner, Ph.D.

Opening Statement

In 1996, over 700 000 fluoroscopically guided interventional procedures were performed in the United States; more than 1 000 000 are expected this year. The value of these procedures in saving lives is well established.

One of several risks associated with these procedures is radiation. Doses have been sufficient in some patients to induce very painful skin injuries that have lasted for extended periods, from months to years.

About 100 injuries can be documented, but there is a disturbing lack of knowledge as to how prevalent they actually are. The most unsettling fact is that these injuries have been frequently misdiagnosed as contact dermatitis, chemical burn, electrical burn, insect bite, etc. This is due in large measure to the delay between irradiation and the appearance of a lesion. In some severe cases, the progression of the injury was so baffling to physicians that a tenacious investigation was launched. Sometimes years passed before the correct diagnosis was reached. Recently, six cases at a single facility were identified.

Monitoring of radiation skin dose has not been required for fluoroscopy for at least two reasons. In the past, doses from diagnostic procedures have not been sufficiently high to cause injuries. This has led to a false sense of security that fluoroscopy is safe. The second is that technology to monitor skin dose has not been available. Neither of these factors applies today to interventional work.

Several facts make skin dose measurements necessary for some fluoroscopic procedures today:

- Doses to skin can be sufficiently high to induce injury,
- Skin dose depends on the operator's knowledge of how to apply fluoroscopy (and fluorography),
- Commercial fluoroscopic equipment varies tremendously in radiation output and radiation abatement technology,
- Physicians are unaware of how much radiation they deliver to patients,
- Many, if not most, physicians are unaware that fluoroscopy can injure patients.

A regulation that requires interventionalists to estimate skin dose specific to their procedures and equipment is necessary for proper patient care. Clearly this knowledge alone is not sufficient. A quality control review of doses, with establishment of action thresholds, is necessary to prevent excessive doses and injuries to patients. The FDA issued an advisory in 1994, with revisions in 1995, recommending dose monitoring. Few have heeded this advice. Since then, the number of reported injuries has risen dramatically. The time has come to settle the issue. Since voluntary compliance doesn't work, mandating such measurements through regulation is necessary.

Rebuttal

I agree with Dr. Tanner that education, training, quality control, appropriate equipment, and well-designed facilities are the primary elements for fluoroscopic safety. In their 1994 warning, the FDA cited many of these elements as essential. Little progress has been made since then. Most interventional physicians have virtually no training in safe fluoroscopic practices, and they have little appreciation for the amount of radiation they apply to a patient's skin. How can they know when many machines have no dose-monitoring equipment? Even if available, many physicians do not know how to interpret the dose-area-product readout. Consequently, the readout is ignored.

All too often, equipment is inappropriately designed for interventional use. Many machines have too little filtration and no variable-pulsed fluoroscopy. Even when available, physicians do not take advantage of dose-saving measures. Some machines have ill-designed features that defeat dose-saving tools. Patients deserve better than this.

Quality control and administrative rules do not solve the problem either. I applaud facilities that have good quality control programs and require credentialing and training of fluoroscopists. Too few facilities do this.

Therefore, based on a proven lack of success of Dr. Tanner's options (a)–(d), option (e), government regulation, must be implemented. While I agree that a federal agency should oversee such a requirement, no federal agency has the authority to do so. Only state agencies can provide this regulation.

I mostly agree with Dr. Tanner's other comments about the folly of the regulatory process in the United States. Regulators and physicists benefit by over regulation because it creates job security. To support regulation for this reason is appalling and unethical—but it occurs. On the other hand, I cannot support an argument to avoid essential regulation out of fear of over regulation.

The problem with regulation is enforcement, not the rules themselves. Enforcement policies that obsess on ferreting out "violations" while ignoring the overall quality of a program are the primary villain. This binary approach to total compliance or violation is silly. A system that grades the quality of a program with a pass/fail result, together with a list of recommendations and/or commendations, would be more useful.

Both Dr. Tanner and I have complaints about poor and abusive regulatory practices. There is no denying, however, that some regulations are necessary to protect citizens from poor medical practices. Government regulation that requires monitoring of skin dose for interventional procedures is justified.

AGAINST THE PROPOSITION: Raymond L. Tanner, Ph.D.

Opening Statement

Radiation control is achieved by: (a) education and training of users; (b) equipment and facility design; (c) quality control programs; (d) administrative rules; and (e) government regulation (an administrative rule). In other words: A qualified expert, using properly designed equipment and facilities, with continuous quality control, operating within recommended guidelines is an unbeatable combination for safe use of modern technology. The possibilities of (a), (b), and (c) should be exhausted before employing (d) and (e) and these must be kept in order.

Development of regulations requiring monitoring of radiation dose during interventional fluoroscopy may be what is innocently proposed initially. However, this will almost certainly be quickly followed by extension of the regulations to include specification of maximum dose per procedure. (Indeed, it might be beneficial to many more patients if a minimum dose(rate) were required—thus assuring some degree of image quality!) Further extension of dose control to all diagnostic procedures might well follow as the government agencies evaluate the fluoroscopy program and proclaim it successful, without thorough independent analysis. State mandated

mammographic dose and NRC mandated annual public exposure levels are two examples of recent unworkable programs. The proposal for interventional fluoroscopy dose regulations constitutes further undesirable intrusion into the practice of medicine by insufficiently trained persons blindly following cookbook-like rules. The outstanding recent example of this is Managed Care which has not only failed to improve the nation's health care but has actually degraded it.

Technical regulations require that knowledgeable persons be involved both in developing and implementing them. There are not enough professionals willing to work in the poorly compensated bureaucratic establishments to provide this. Moreover, the control of radiation dose in interventional fluoroscopy is possible within existing rules and regulations by means of the recently lowered maximum allowed exposure rates of such units. This can be followed by increased education requirements for physicians authorized to use such equipment and by enhanced quality control programs.

The first quarter of the last century saw the development of fundamental diagnostic radiologic procedures and the beginnings of radiation risk assessment [mostly very small] from such procedures. During this period also the international and national radiation advisory groups were formed. Voluntary programs for radiation control based on the recommendations of these committees worked well for the second and third quarters of the 20th century. The latter half of the century saw an influx of government regulations which have obscured the effectiveness of voluntary programs. Such regulatory mandates are always deemed effective; otherwise the budgets and positions of the regulators would be in question.

If regulations requiring monitoring of radiation dose in interventional fluoroscopy are developed then they should include specific performance standards on new fluoroscopy equipment and periodic testing of such equipment by qualified physicists. Further, such regulations should not be promulgated by states but by the federal government. Otherwise, uniformity will not exist, manufacturers will be confused, quality control programs will suffer and costs will rise. The greater need is one of educating the professional users and the public to better understand how to safely enjoy the great benefit of ionizing radiation and accept the minor, if any, consequent risk when it is used knowledgeably and responsibly.

We must not regulate every aspect of our life style lest we become an Orwellian "Big Brother" society.

Rebuttal

I expected my esteemed colleague to have made the following points: (1) the public interest demands control of dangerous substances, even when used by professionals, (2) exposure monitoring will not be done voluntarily, (3) no standard will be adopted unless government mandated, (4) the risk has been overlooked, (5) voluntary programs cannot enforce compliance. He alluded to points two and four but chose to emphasize an (undocumented) rise in reported injuries from interventional fluoroscopy which may well be due to a heightened awareness of the potential risk involved and/or to increased use of the procedure. Establishment of a rigorous basis for new regulations (which impinge on the practice of medicine) is required prior to initiation thereof.

The approximately 100 injuries cited by Dr. Wagner occurred over several years yielding an incidence of 1 per 100 000 (assuming about 10 million procedures were involved). This is the

same magnitude of risks we accept in our daily lives from activities such as driving, work-site tasks, and leisure pursuits (e.g., boating, skiing, and contact sports). This approach leads to the much more important topic of resource allocation based on a scientific ranking of risks. Where and how we use our private, corporate and governmental funds to reduce risks should not be based on media hype and/or public misunderstanding (fear).

I chose to emphasize the *carrots* of user education, quality assurance, and equipment design rather than the *stick* of government control in speaking to the five points above.

8.10. Reference values are de facto regulatory limits for patient exposures

Mary E. Moore and Priscilla F. Butler
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OVERVIEW

Reference values (sometimes called investigational levels) are patient exposure levels that trigger an institutional response because they are set at the upper limit of expected exposures for patients undergoing specific procedures. When a reference value is exceeded, institutions are expected to initiate corrective action to prevent a reoccurrence (see report of the AAPM Radiation Protection Committee). Hence, some physicists consider reference values to be *de facto* regulatory limits for patient exposures. Other physicists disagree with this interpretation. This disagreement in interpretation is explored in this month's Point/Counterpoint.

Arguing for the Proposition is Mary E. Moore, M.S., M.Ed., DABR, DABMP. Ms. Moore has both a M.Ed. in Science from Temple University, and a MS in Radiological Health/Environmental Sciences from Rutgers University. She has been a hospital health physicist, a medical physicist in radiation oncology, a diagnostic imaging physicist and a system-wide radiation safety officer. She is the radiation safety officer for the Philadelphia VA Medical Center. Ms. Moore is a past Treasurer and member of the Board of Directors of the Health Physics Society, and a member of the American Board of Medical Physics Panel of Examiners for Medical Health Physics. She continues in her appointments to the NJ Commission on Radiation Protection (since 1987), and the NJ Radiologic Technology Board of Examiners (since 1991).

Arguing against the Proposition is Priscilla F. Butler, M.S., FAAPM, FACR. Ms. Butler is the Senior Director of the Breast Imaging Accreditation Programs in the Standards and Accreditation Department of the American College of Radiology. She is also an adjunct associate professor at the George Washington University Medical Center. Prior to joining the College she spent over 13 years as a medical physicist and faculty member in the Department of Radiology at the George Washington University Hospital. Ms. Butler also served as a commissioned officer in the US Public Health Service (Food and Drug Administration) and participated in the start-up and conduct of their Breast Exposure: Nationwide Trends (BENT) program. Ms. Butler received her graduate degree in medical physics at the University of Florida in 1974 and was certified by the American Board of Radiology in Diagnostic Radiological Physics in 1982.

FOR THE PROPOSITION: Mary E. Moore, M.S., M.Ed., DABR, DABMP

Opening Statement

Are Reference Values "*de facto*" regulatory limits? The key word in this question is "*de facto.*" Reference Values are "*in effect*" regulatory limits with the inherent requirement of mandatory compliance.

Whenever professional organizations publish standards or recommendations for issues not addressed in state or federal regulations, they become the "accepted rule" or current standard of practice. For example, prior to the Mammography Quality Standards Act (MQSA),[1] the American College of Radiology's (ACR)[2] voluntary mammography accreditation program instituted a maximum mammography mean glandular dose limit of 0.3 rad. At that time, this Reference Value was a *de facto* regulatory limit: If exceeded, corrective action was (and is) required. The applicant facilities empowered the ACR with the authority to impose this dose, and other *de facto* regulatory limits, in order to receive the recognition of accreditation.

Other accreditation bodies such as the Joint Commission on Accreditation of Health Organizations also have standards that are "*de facto"* regulatory limits. JCAHO accreditation is essential for hospitals. If JCAHO were to adopt Reference Values as one of it's required performance standards, the accredited facilities would consider it as a new regulation and ensure its implementation.

Current regulations do not establish patient exposure investigation limits. However many medical physicists use the FDA Center for Devices and Radiological Health's Nationwide Evaluation of X-Ray Trends (NEXT)[3] data as a quality control guide. Measured patient skin entrance exposures for designated studies are compared with relevant NEXT data to identify unacceptable patient exposure levels. Establishing trigger levels and requiring corrective action to prevent reoccurrence is the next step in preventing unnecessary patient exposures. This process is the essence of the Reference Value program, which also parallels the required response when state and federal regulations are violated. However, implementing Reference Values does not require regulatory agency notification.

In summary, voluntary implementation of Reference Values effectively establishes self- imposed patient exposure limits which are "in reality" regulatory limits.

Rebuttal

The interpretation of reference values as *de facto* regulatory limits is a perception based on the effective result of adopting action trigger levels. This interpretation issue is different from the question of whether reference values should be formalized and incorporated into state and federal regulations.

The *de facto* regulatory aspect of voluntarily establishing investigational limits occurs when an action level is exceeded. The facility is expected to investigate, to identify the cause, and to implement corrective action that will prevent a reoccurrence. This is the same process followed when a state or federal regulation is violated. Consequently some medical physicists perceive reference values as *de facto* regulatory limits for patient exposures.

Different professional organizations have proposed investigational levels based on expected patient exposures for specific procedures. Each facility is free to adopt or establish the exposure levels that they feel are appropriate as reference values. Prior to implementation, each facility should ensure their exposure limits are adequate for good image quality. While the appropriateness of a numerical value selected as an investigational limit is a very important issue, it is different from the question of whether reference values are perceived as *de facto* regulatory limits.

A significant difference between *de facto* and state or federal regulations is that the numerical values of the *de facto* investigation limits are not cast in bureaucratic stone. Individual facilities should review, and if necessary, change their investigational limits periodically to ensure they continue to be appropriate for newly acquired technology.

Voluntary implementation of reference values has the same operational effect as mandatory federal and state regulations. A limit is set. If it is exceeded, corrective action is required to prevent a reoccurrence. In effect, the process is the same for both voluntary reference values and mandatory regulations. Hence, the interpretation of voluntary self-imposed mandates as *de facto* regulations is in reality accurate.

AGAINST THE PROPOSITION: Priscilla F. Butler, M.S., FAAPM, FACR

Opening Statement

Reference doses for diagnostic radiology have been discussed internationally (for over 10 years) by the International Commission on Radiological Protection (ICRP).[4,5,6] Although not specifically addressed as "reference," in 1978 the US Food and Drug Administration (FDA) published Radiation Protection Guidance to Federal Agencies for Diagnostic X-rays, including recommended maximum entrance skin exposures for 10 examinations.[7] In more recent years, the AAPM's Task Group on Reference Values for Diagnostic X-Ray Examinations has drafted a report for publication; the Conference of Radiation Control Program Directors (CRCPD) Committee on Quality Assurance in Diagnostic X-ray has drafted a revision to its Patient Exposure and Dose Guide; and the American College of Radiology (ACR) approved an ACR Standard for Diagnostic Reference Levels in Medical X-ray Imaging at its annual meeting this year. Although the terms used for these reference doses differ (e.g., the ICRP and the ACR call them "reference levels," the AAPM calls them "reference values," and the CRCPD refers to them as "guides"), there is one unifying theme: these numbers should not be used for regulatory purposes. To understand why, we must first look at how the numbers will be implemented.

Reference values are established by various organizations for selected examinations and projections, defined patient sizes and, for automatic exposure controlled (AEC) x-ray equipment, with specific phantoms to simulate the patient. If the examinations are performed properly, clinical image quality will be generally acceptable at exposures and doses below the values defined as reference. Consequently, medical physicists should investigate and identify the causes of doses that exceed reference values under prescribed conditions. The medical physicist must consult with the physician and assess his or her image quality needs as actions are taken to reduce the radiation dose. If the physician determines that there is a clinical need for higher radiation exposure, then the level in use should remain unchanged.

Many imaging facilities, particularly those not under radiology control, do not require a routine survey performed by a medical physicist, or may only request a survey that does not include exposure or dose measurements. Medical physicists should inform their clients of the usefulness of dose measurements and reference values for their clinical practice and their patients. They must also be sure to obtain measurements under the same conditions for which the reference values are defined.

Adopting reference values as regulations by state or federal agencies, or using them as *de facto* regulations, could significantly interfere with their successful implementation. The major

concern is the potential degradation of image quality that may result if dose reduction measures are put into place by individuals not trained or experienced in the evaluation of image quality. Reducing dose without a concurrent assessment of image quality by a physician would be detrimental to patient care.

Turning reference values into regulations could also hamper the widespread adoption of new x-ray techniques that may require additional dose. Mammography is a case in point. Since 1988, the average mean glandular dose for a 4.2 cm breast (as measured by state and FDA inspectors) has slowly increased from 1.33 (Ref. 8) to 1.76 mGy in 2002. This increase has resulted in significant image quality improvement primarily due to the use of grids, less noisy film and higher film optical densities to improve contrast. Under the Mammography Quality Standards Act (MQSA), the FDA wisely established a regulatory limit of 3.0 mGy.[9] There is no need for mammography to be performed at doses above this level, and facilities will be issued a noncompliance if it occurs. However, this limit is not a reference value. Should a medical physicist investigate the reason for an exposure that is just below 3.0 mGy? Absolutely. Could there be consensus on a mammography reference value that is lower than the regulatory limit? Most likely. But the value would have to be routinely re- evaluated and revised to allow for image quality improvement trends. Regulations do not allow for that.

Rebuttal

On October 1, 2002, the ACR Council approved the 2003 ACR Standard for Diagnostic Reference Levels in Medical X-Ray Imaging. When publishing standards, recommendations or guidelines, professional organizations carefully explain that their publications are not intended to serve as the "accepted rule." For example, the ACR includes the following cautionary statement on each ACR Standard: "The standards of the American College of Radiology (ACR) are not rules, but are guidelines that attempt to define principals of practice that should generally produce high- quality radiological care. The physician and medical physicist may modify an existing standard as determined by the individual patient and available resources." These standards should not be treated as *de facto* regulations.

Unfortunately some facilities will erroneously treat reference values as *de facto* regulatory limits. The real danger exists that many of these facilities will take the easiest measure possible to cut patient dose below the reference value without assessing their action's impact on image quality and patient care. These facilities may not invest the necessary time and resources to research their entire imaging system in order to determine the true cause of the high doses or to assess the higher doses' impact on patient care. It is essential that these facilities consult with experienced medical physicists and diagnostic radiologists to make that determination.

Reference values should be treated as "trigger levels." But, as described by the ICRP and other organizations, exceeding reference values should trigger an investigation, rather than action to correct the high dose. Corrective action should only be taken if the radiologist determines that there will be no reduction in image quality or that the reduction in image quality will not interfere with appropriate patient care.

Finally, reference values and regulatory dose limits (or accreditation pass/fail limits) serve different purposes. Patient dose regulations and accreditation pass/fail limits are intended to be maximum values beyond which there is no demonstrated clinical benefit. Reference values are investigational levels set to encourage quality improvement. Both can coexist.

In summary, reference values are an important tool for improving the quality of radiologic imaging but should not be treated as *de facto* regulations.

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8.11. Federally mandated imaging standards (e.g., MQSA) serve the best interests of patients

John McCrohan and Richard L. Morin

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OVERVIEW

Since October 1, 1994, all mammography facilities in the U.S. (except those of the Department of Veterans Affairs) have been required to be certified by the U.S. Food and Drug Administration (FDA). This requirement is a consequence of legislation entitled the Mammography Quality Standards Act of 1992 (MQSA) enacted by the U.S. Congress. The goal of the legislation is to assure that mammography is safe and reliable, and to allow the detection of breast cancer in its earliest, most treatable stages. The key features of MQSA are: To operate lawfully, a mammography facility must be certified by the FDA as providing quality mammography services. For a facility to be certified, it must be accredited by a federally approved private nonprofit or state accreditation body. To be accredited, the facility must apply to an FDA-approved accreditation body; undergo periodic review of its clinical images; have an annual survey by a medical physicist; and meet federally developed quality standards for personnel qualifications, equipment quality assurance programs, and record keeping and reporting. The facility must also undergo an annual inspection conducted by federally trained and certified federal or state personnel.

The MQSA legislation addresses an issue (breast cancer detection and diagnosis) that is fraught with emotion, and reflects in part an intense lobbying effort by groups concerned with women's health. Whether or not it represents the most effective path to improvement of breast cancer detection and diagnosis was controversial at the time of the passage of the legislation, and remains controversial today. This edition of Point/Counterpoint addresses the controversy.

Arguing for the proposition is John McCrohan. Capt. Mc- Crohan, an officer in the U.S. Public Health Service since 1974, holds a Masters degree in Radiological Sciences from the University of Washington. He is the Acting Director of the Division of Mammography Quality and Radiation Programs in FDA and has had a major role in directing the implementation of the Mammography Quality Standards Act. Involved in mammography since 1976, Capt. McCrohan was instrumental in the Nationwide Evaluation of X-ray Trends assessments of mammography in 1985, 1988, and 1992. He has served on numerous mammography committees of the ACR, NCRP, and the Conference of Radiation Control Program Directors.

Arguing against the proposition is Richard Morin. Richard L. Morin is a Consultant in the Radiology Department, Mayo Clinic Jacksonville, Professor of Radiologic Physics, and member of the graduate faculty, Mayo Graduate School. Dr. Morin earned his Ph.D. degree from the University of Oklahoma in Radiological Sciences in 1980. His current research interests include computer applications in the radiological sciences with particular emphasis in electronic imaging, medical imaging detectors, transmission, display, and analysis technologies. He has been active in the ACR Mammography Accreditation Program and has served on the Standards and Accreditation and Government Relations Committees of the ACR Commission on Physics and Radiation Safety.

For the Proposition: Capt.John McCrohan

Opening Statement

The federally mandated MQSA imaging standards are clearly in the best interests of patients. Breast cancer is a life threatening disease and a major source of morbidity and mortality. Mammography is the only proven means of early detection and the best hope for those at risk from breast cancer. Therefore the focus on mammography is justified.

Mammography is a difficult imaging technique and one in which high quality is extremely important in breast cancer detection. A significant investment is necessary to achieve the high quality required. In 1985, the Nationwide Evaluation of X-ray Trends showed that mammography image quality was quite variable,[1] demonstrating that the investment necessary to achieve high quality was not being made consistently. Subsequent standards-setting efforts by the American College of Radiology (ACR) and state regulatory agencies were only partially successful at addressing this problem and resulted in a ''patch-work'' of inconsistent requirements. Federal standards were necessary to assure that all facilities would make the required investment in quality.

The federal imaging standards mandated by MQSA provide a nationally uniform baseline for performance, improving image quality, and thus the effectiveness of mammography, particularly among facilities where image quality was poorest. MQSA standards are risk-based,[2] addressing those aspects of mammography essential for quality. The standards are also performance-based, allowing flexibility. The standards setting process is open, providing opportunities for the public and the mammography community, directly and through the mandated advisory committee, to help define the standards assuring balance between high quality and access, between the benefits to patients and the burdens on facilities. In fact, the MQSA standards embody, to an extraordinary extent, the consensus imaging standards developed for the ACR's voluntary Mammography Accreditation Program. As a result the MQSA standards are reasonable, achievable, and enforceable.

In addition to mandating federal imaging standards, MQSA also requires annual facility inspection and enforcement of the standards. Both significant effort and the will to invest that effort is necessary to achieve the quality required by the standards. While initial inspection results were quite positive [30% of facilities had no findings and 2% had serious findings] and have continually improved [most recently 55% of facilities had no findings and <1% had serious findings], they also show that meeting the MQSA standards continues to be difficult for some. Without inspections many facilities would not make the investment necessary to assure quality.

MQSA had improved quality nationwide without reducing access[3] and its federally mandated imaging standards assure women of high quality mammography. Clearly MQSA is in the best interests of patients.

Rebuttal

Dr. Morin asks if standards and enforcement should come from the same source. In fact they must. The federal government cannot enforce nongovernmental standards. The MQSA ''interim'' regulations incorporated standards developed within the radiology community into comprehensive federally mandated standards. The MQSA ''final'' regulations were developed in

an open process involving the National Mammography Quality Assurance Advisory Committee and 1900 members of the radiology community whose 8000 comments yielded a much improved federal standard. With MQSA providing a baseline, the radiology community can, and perhaps should, ‘‘raise the bar,’’ developing more stringent standards. However, MQSA standards are federally enforced, providing a high level of assurance that all facilities meet this baseline.

Dr. Morin states that patients need assurance that their examinations are competently performed and interpreted. However, neither professional standards nor federally mandated standards assure competence. What MQSA assures is that all facilities undergo periodic peer review (including clinical image evaluation) and annual inspection. Through these mechanisms, federally mandated standards are enforced on all mammography facilities, assuring that equipment performs appropriately, quality control programs are adequate, personnel meet substantive initial and continuing qualifications, and examination results are appropriately communicated to patients. The inspection results [1995, 32% ‘‘no-findings’’ inspections; 1997, 56% ‘‘no-findings’’ inspections] show both the need for, and the benefits of, inspections.

It is quite true that the best interests of patients are tied to good facilities, personnel, and practices. However, these can only be encouraged, not assured, by professional standards. Poor facilities, personnel and practices can only be discouraged, not eliminated. Good facilities can be assured by appropriately developed federally mandated standards. Patients should not have to search for a quality mammography facility. They should expect that all mammography facilities provide quality services.

MQSA is arguably the best example to date of the synergy that is possible between the radiology community and the government. The results are clearly in the best interests of patients.

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Against the Proposition: Richard L. Morin

Opening Statement

How could anyone oppose federal standards to assure high quality patient care? How could anyone oppose federal standards to assure all mammography imaging systems are evaluated in the same way? Interestingly, these are very different questions. The issue is the degree of involvement of the federal government in the type, nature, and evaluation of imaging standards. Opposition to standards is not the issue, but rather, who should set the standards and should both standards as well as enforcement come from the same source.

Actually, in this arena, the standards must be formulated by the regulated community since only they possess the expertise and training to separate good practice from bad practice. The point here is that unlike other areas of regulation, specifications of technical factors alone are necessary but not sufficient. Standards set responsibly by professionals in the field will

inevitably be higher than those set by government bodies concerned with regulatory consistency and inclusion of the least common denominator. Standards set by professional bodies address all areas of practice and provide the baseline for Continuous Quality Improvement, Critical Pathways, and other techniques of practice assessment. It is the nature of these standards that their development involves input from a large number of professionals (e.g., Radiologists and Physicists) involved in an area (e.g., mammography). The incentive in this setting is competent patient care, not compliance. Professional standards continue to emerge for Radiology, Radiation Oncology, and Medical Physics. These standards are becoming more robust and inclusive, ''raising the bar'' in each area of practice.

Let us return to the central point—the best interest of the patient. A patient needs to be assured that a facility is able to competently perform the required examination and provide a competent interpretation. The best interest of the patient is tied closely to good facilities, systems, practice, and physicians. The patient is best served by the best medicine. Hence, for mammography, that means the best from all aspects of practice: the RIS, the mammography and processing systems, patient positioning, radiographic technique, image evaluation, interpretation, and communication to the patient. Standards must therefore involve all aspects of practice.

The federal government has a legitimate role in mandating adherence (and possibly linking reimbursement) to professional standards. The role of establishing, reviewing, and revising professional standards belongs with the professionals.

Rebuttal

I fear perhaps a central point was missed. The issue under discussion is ''Federally mandated imaging standards.'' While the Mammography Quality Standards Act was posed parenthetically as an example, the issue is certainly much broader, bringing into question the nature and relationships of agencies involved in standards, regulations, and enforcement. The point here is not that high quality standards and accreditation programs can save lives; the point is how and by whom are the standards to be formulated.

However, let us examine the case of mammography. The standards were formulated by the American College of Radiology with the consultation of a large body of Radiologists, Medical Physicists, and Technologists. The subsequent accreditation program grew from an early program administered by the Illinois Radiological Society (a chapter of the ACR). The standards and programs were developed without regulatory compliance in mind and centered on the professional competence of personnel and the technical performance of the equipment. These efforts were focused on the best interest of the patient, in this case, the early detection of breast cancer. Subsequent legislation and rules certainly provided more prescription in both testing and compliance. However, it is not self-evident that prescriptive checklists for staff and equipment improved the prior use of professional judgment. One of the fundamental reasons for the success of this program lies in the fact that the infrastructure of these standards had been built by a body independent of the regulatory body. In fact, a strong case can be presented that accreditation agencies ought to be separate and independent of regulatory agencies. This not only avoids potential conflict of interest but assures independent professional and patient-centric though during standard development.

The federal government has a legitimate role in mandating adherence (and possibly linking reimbursement) to professional standards. The role of establishing, reviewing, and revising professional standards belong with the professionals.

8.12. The AAPM should develop protocols generically, and avoid documents that are too strict and prescriptive, to facilitate their adoption by regulatory agencies like the Nuclear Regulatory Commission and States

Cynthia G. Jones and Bruce Thomadsen

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OVERVIEW

Clinical physicists have the most knowledge about specific calibration and quality control protocols needed to assure the optimized use of ionizing radiation for diagnostic and therapeutic purposes. Many individuals, including some in regulatory agencies, believe that physicists should develop these protocols without concern for extraneous influences such as rules and guidelines from regulatory agencies. However, development of a protocol without concern for regulations creates an enigma for the practicing medical physicist, because following the protocol could result in noncompliance with regulations. This enigma could be resolved if regulatory agencies were willing and able to respond quickly to new protocols, but bureaucracy of the agencies may interfere even if the agencies wished to respond rapidly. Hence, most protocols in medical physics are built to encompass regulations rather than to optimize the procedures they are designed to address. This issue of Point/Counterpoint addresses the intrinsic conflict between existing regulations and protocol development.

Arguing for the Proposition is Cynthia Jones. Cynthia Jones is the Senior Assistant for Materials, Office of Commissioner Dicus, Nuclear Regulatory Commission (NRC). Before joining the Commissioner's staff in July 1999, she was the Senior Level Advisor for Health Physics at the NRC. In that position, she helped develop an NRC Management Directive on the Development and Use of Consensus Standards. Ms. Jones will receive her Ph.D. in nuclear engineering from the University of Maryland in September 2001. Before working at the NRC, she was a physicist at NIST, and a medical and reactor health physicist at UCLA.

Arguing against the Proposition is Bruce Thomadsen, Ph.D. Dr. Thomadsen, a member of the Medical Physics Department of the University of Wisconsin, specializes in radiotherapy physics and radiation safety. He has participated in the development of task group recommendations (compromising as necessary), and with the development of new radiation regulations for the State of Wisconsin. One of the main thrusts of his work has been in quality achievement and error prevention in patient treatments.

FOR THE PROPOSITION: Cynthia Jones

Opening Statement

Since the enactment of the National Technology and Transfer Act of 1995 [Public Law ~P.L.! 104-113] on March 7, 1996, all Federal agencies are required to use standards developed by a consensus body. Although one could argue that the AAPM is not listed as one of the ''official'' standards consensus bodies that are identified on the National Institutes of Standards and

Technology website [like the American National Standards Institute (ANSI)], the protocols it develops use a consensus process within its professional organization. An interesting aspect to this law is that if a Federal agency uses its own standards (i.e., a regulation developed by an agency for its own use) in a regulation, instead of using an existing consensus standard, it must justify the reason for not adopting the standard and provide a yearly report from the head of that agency to the President's Office of Management and Budget (OMB).

In order to effectively communicate how this law was to be implemented at Federal agencies, OMB issued its revised Circular A-119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment,'' on February 19, 1998. In that circular, OMB also requires that when promulgating a proposed rule, a Federal agency must include a statement that identifies when a voluntary consensus standard is being proposed for use, or when a government unique standard is proposed instead of a voluntary consensus standard. In the latter case, the agency must provide a preliminary explanation of why use of a voluntary consensus standard is inconsistent with applicable law, or is otherwise impractical (Note: OMB defines ''impractical'' as including circumstance in which use of the consensus standard would fail to serve the agency's program needs; would be infeasible, inadequate, inefficient, or inconsistent with the agency's mission; would impose more burdens, or would be less useful than the use of another standard). In addition to this statement, Federal agencies must now also invite public comment as to whether or not the public knows of an existing standard which should be used in lieu of the proposed regulation.

In developing its proposed regulations since the enactment of P.L.104-113, NRC staff now consistently reviews the technical literature for determination of any consensus standards or technical professional societies guidance documents, such as AAPM protocols, that may be used in lieu of the proposed rule or referenced in a proposed regulation or guidance document. Considering the subject at hand, if AAPM were to have developed protocols which could be viewed as suggested recommendations, for example, for calibration and quality control use that were not in conflict with an existing national consensus standard (such as an ANSI), there would be incentive indeed for the NRC to use that instead of development of a new rule, or at a minimum, add that protocol to the list of references which would provide licensees with guidance in this area. In an era of ''rightsizing'' government, it makes good sense to not reinvent the wheel, but rather to use already existing professional societies' protocols for use in new regulations.

Rebuttal

The intent of P.L.104-113 and OMB Circular A-119 is to use *already existing standards* (or protocols in AAPM's case) in lieu of an agency drafting new regulations. If NRC incorporates a standard or protocol into a regulation in its entirety, it would not be able change any ''shoulds'' to ''shalls,'' because that would require a change to the standard itself. I am not proposing, as the opposition states, that the AAPM, or any other standards developing organization, write minimalist standards. Indeed, I am recommending that these bodies more carefully consider what is essential, versus what is purely optional for licensees to do in the course of a particular practice. Perhaps wording such as ''Suggested Best Practices'' in protocols would clearly delineate those ideas that could improve a practice, but yet are nonessential. Without suggested good practices from societies like AAPM, regulatory agencies would be at a great disadvantage in having to expend resources to develop their own guidance documents, which is exactly not what was the intent of P.L. 104-113. Carefully consider what is required of licensees in any AAPM protocols. Through the use of OMB Circular A-119, you'll get what you asked for.

AGAINST THE PROPOSITION: Bruce Thomadsen, Ph.D.

Opening Statement

In many AAPM documents we walk a fine line that never quite gets resolved in the organization: Whether recommendations should describe minimum acceptable standards of practice or something better. As the technology and our understanding improve, we, as a community, like to believe that the level of care we can provide our patients also improves. Although the previous minimum standard usually remains safe and as efficacious as before, we like to suggest that our members hold their practice to the improved level. We also like our documents to be comprehensive, covering all possible aspects of a problem.

AAPM protocols for calibration and quality assurance serve two basic functions: (1) to provide guidance for members performing specific functions, and (2) to improve the state of practice. For both of these functions, the protocols often contain recommendations considered absolutely necessary, demarcated by the use of ''shall,'' and other recommendations that would improve patient care but remain dispensable, indicated by ''shoulds.'' The ''shoulds'' help refine a practice and often provide layers of safety or assurance in treatments, at the cost of additional time and resources. Leaving these recommendations optional, the AAPM recognizes that few or no programs can afford the dedication of personnel or funds to perform all suggestions. Nor do all suggestions apply to all situations. Compliance with all recommendations in the reports of Task Groups 40, 53, 56, 59, and 64 alone requires more staffing than reimbursements allow. Yet, the suggested recommendations frequently help practitioners deal with specific situations, and avoiding inclusion would leave members without valuable guidance.

Regulatory bodies often cannot use the word ''should'' in rules as the AAPM does. In translating recommendations into regulations, some agencies simply change all ''shoulds'' to ''shalls,'' adding requirements to perform certain actions uselessly in many situations. Adopting a protocol en bloc, such as, ''User shall follow AAPM TG#...'' can be interpreted as requiring all precepts.

To avoid this unpleasant consequence of good intentions, the proposition suggests writing minimalist protocols such that no one could object to performing all parts. Unfortunately, this approach not only eliminates guidance though suggestions, but also loses opportunities to raise the quality of patient care. Such an approach also means that no protocol document would collate all relevant information, leaving members to comb through the literature themselves.

Although possibly uncomfortably increasing the workload for some practicing medical physicists, the inclusion of some or many protocol recommendations into regulations often provides the justification for increasing the staffing levels in some programs.

To serve best the AAPM membership and patients under our care, the Association should continue to draft protocols addressing the state of the art, including necessities and suggested ''niceties.'' During comment periods in regulation formulation, the Association must lobby for inclusion of the necessary concepts, without adoption of the optional suggestions. To follow the proposition would set all standards to the lowest common levels.

Rebuttal

In an era of ‘‘right-sizing,’’ it does make sense not to reinvent anything (or at any other time for that matter). It would serve the society as a whole well for regulatory bodies to make use of AAPM protocols. However, simply copying over the protocols into regulations is a case of good advice making bad laws. One suggestion to avoid mass adoption of AAPM recommendations into regulations might be to keep official protocols very basic, and move all optional recommendations into less official formats. In many cases, though, such a procedure would gut the true substance of the protocol, and certainly make links between the two documents more difficult. Nor would that prevent agencies from incorporating the less official documents. Examples of misdirected good intentions abound (such as Minnesota's establishing an exposure limit for the general public of 0.054 mR/y), and some state legislator may think that incorporation of all the bells and whistles would benefit their constituency.

Thus, with no guarantee of control over the fate of our documents, we could prepare for the worse, creating only minimalist recommendations that everyone (and their mother or father) could satisfy. This approach would put the AAPM out of the science business, leaving us as a self-serving professional (or unprofessional) organization. Or we could continue to write protocols we consider in the best interest of the patient and society, reflecting the state-of-the-art and improving the state-of-the-practice, and diligently comment during regulation generation. All AAPM documents go through extensive review in the Association, from the task group, through committee and council, and often by the Board and journal reviewers. This process usually leads to high quality, thoughtful recommendations. We should trust ourselves enough to continue this course.

8.13. NRC restrictions on the packaging of radioactive material should be expressed more explicitly than simply in terms of "apparent activity"

Michael S. Gossman and Beth Felinski-Semler
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OVERVIEW

As promulgated by the Nuclear Regulatory Commission, packaging regulations for radioactive material are confusing (e.g., "activity" vs "contained" activity vs "total" activity). As a consequence, medical physicists are forced to second-guess the intent of the regulations. This dilemma is the subject of this month's Point/Counterpoint. These authors wish to remind the readers of Point/Counterpoint that the views presented here do not reflect the views of any regulatory body mentioned.

Arguing for the proposition is Michael S. Gossman, M.S. Beginning academically at Indiana University, he furthered his education by attaining a Master's Degree at the University of Louisville. Pioneering in atomic physics, he eventually published a book on scanning tunneling microscopy in 1997. Mr. Gossman attended Vanderbilt University, where he studied medical physics and worked as a health physicist. His current focus is research and planning for special procedures in the area of high dose-rate brachytherapy. Mr. Gossman is certified in Therapeutic Radiologic Physics by the American Board of Radiology (ABR) and is a clinical medical physicist at Erlanger Medical Center in Chattanooga, TN.

Arguing against the Proposition is Beth Felinski-Semler, M.Sc. She received her B.A. in Physics from LaSalle College (University) in 1976, and her M.Sc. from Temple University in 1977. She began working in medical physics in 1977 at Cooper Hospital/University Medical Center in Camden, New Jersey, first in nuclear medicine and later in radiation therapy. She has instructed both radiation oncology residents and therapists in physics and dosimetry. She is certified in radiation therapy physics by the ABR. Beth is presently the senior clinical radiation therapy physicist at the Department of Radiation Oncology, South Jersey RMC in Vineland, New Jersey.

FOR THE PROPOSITION: Michael S. Gossman, MS, DABR

Opening Statement

There are troubling inconsistencies in the practice of transporting sealed radioactive sources in the United States. There are currently no uniform guidelines governing the proper disclosure of radioactive sources in transit. The purpose of such disclosure is to enable both receivers and response teams to properly assess situations involving damage to packages containing radioactive material. Unfortunately, physicists are left to use their own interpretations as to the method for labeling such packages and determining which values to disclose. Without specific guidelines, many questions remain unanswered. Notably, which activity level should be used for labeling packages—the apparent activity or the contained activity? In many instances there is a great

disparity between the two. Currently, a survey including twenty brachytherapy source manufacturers revealed half are labeling according to the apparent activity rather than the contained activity.[1] My discussions with some of our collegial society members on how they transport radioactive materials validate the breadth of the problem.

Consider, for example, the inconsistencies in the shipment of prostate seeds. The (contained activity to apparent activity) conversion factors for all prostate seed manufacturers range from 1.30 to 1.78 for iodine-125 and from 1.80 to 2.20 for palladium-103. Depending on which activity the physicist chooses for labeling, the value could differ from what another might label by as much as 78% for iodine-125 and 220% for palladium-103. There is a potential for a source encapsulation to break open and leave a bare source with a higher exposure rate than that which would occur if the encapsulation did not break. Currently, response personnel are not equipped with enough information to know the worst-case scenario when radioactive materials are damaged. This deficit could have devastating results.

Clearly we need uniformity to ensure all avenues of safety. Regulations governing the shipment of radioactive material, however, do not specifically address this troubling issue. No guidance regarding proper labeling criteria is available from the Nuclear Regulatory Commission, the U.S. Department of Transportation, the U.S. Department of Energy, the International Atomic Energy Agency or the International Air Transport Association.[2,3,4,5] Explicit guidelines need to be promulgated and followed to govern the process for labeling radioactive material. To do so, the conversion factors for apparent to contained activity need to be determined and published for all sealed sources. Using this information, a guideline should be produced by the Nuclear Regulatory Commission to indicate what the explicit labeling standard will be. Furthermore, it should be uniformly recognized by the other supervisory agencies and departments.

Rebuttal

Modern treatment planning systems use air-kerma strength and other appropriate factors inclusive of apparent activity for source specification.[6,7] For older models, source specifications come from the activity and gamma factor stated by the vendor. As my worthy antagonist affirms, some vendors maintain they do not indicate whether the activity is "contained" or "apparent," and some do not even provide the conversion factor.

The FDA requires that manufacturers of radiological devices specify how the source encapsulation (and substrate) influences the output.[8] The physical quantity of activity is also to be listed as "apparent" or "contained."[8] These data were not required for sources made long ago. Still, conversion factors can be determined experimentally. The method has been published, and results were provided for sources currently used in intravascular brachytherapy treatments.[9,10] The method involves assaying the output of the encapsulated source and then assaying the material again when the encasement has been chemically digested with an acid.

Guidelines from no regulatory body specify to label radioactive material shipments according to apparent or contained activity. This implicit wording is nothing short of permission to do either. It is my suggestion to have regulations explicitly state "apparent activity" when the activity rating in shipments is used. Furthermore, it is my suggestion that the shipper make the conversion factor for that source model readily available by presenting it in the clear pouch external to the package.

To attain uniformity, the NRC should first require manufacturers to provide the conversion factor for each source model. This information should be available, since it was originally requested by the FDA for medical use approval. For sources that are no longer available, documentation may be obtained from the FDA or in the files of the applicable former manufacturer. If factors are not available, they can be identified using the method discussed previously. Moreover, the factors must be made available before these proposed regulation changes are introduced.

I agree that such a change in shipping regulations will affect the wording in other regulations. It will affect and should affect regulations like those from the IATA internationally. Regardless of the inconvenience associated with change, we need to endorse strictness and uniformity. Only by establishing a standardized method for classifying and monitoring radioactive material, can we appropriately account for what is transported.

AGAINST THE PROPOSITION: Beth Felinski-Semler, MSc, DABR

Opening Statement

In the field of medical physics, definition and consistency of procedures have always been important. These are the foundation for our field today. We improve and make things better and clearer, but are always able to trace back to the foundation. We now have an inconsistency in the shipping and receiving of brachytherapy "sealed sources." The confusion occurs because of the specification of source strength. Source strength has been defined in one of four ways: the contained activity, the apparent activity, the equivalent mass of radium, and the exposure rate at a specified distance.[11] Three of these methods depend on the inherent filtration associated with source construction. It is this filtration that gives rise to the term "apparent activity" for clinical use, because the apparent activity is less than the contained (actual) activity due to source filtration. The exposure to persons handling the sources, and the dose to the patient, are not dependent on the actual (contained) isotope activity, but instead on the "filtered" activity outside of the source walls. Hence the problem: which activity, apparent or contained, should be used when describing sealed sources in transit.

The NRC (Part 20 appendix A) establishes activity levels and their shipping requirements for specific sources. In Part 71 the NRC defines and establishes shipping container requirements. Then the DOT and IAEA take over and establish labeling requirements based on the exposure level at the surface of the package and at one (1) meter. The purpose of all these regulations is to set universally known safety standards. Are any of these regulations affected if the apparent activity or the contained activity is used, even if in some cases such as palladium-103 the difference could be as much as 200%? I think not. The difference in activity only comes into consideration if a source is ruptured in some type of accident. In this situation, one would hope the outer shipping container that the sources are housed in will still be adequate to contain the activity at the required level. If contamination is the concern, first and foremost to the emergency response personnel is the qualitative knowledge of what the exposure rate in the area is, then what the specific isotope is, what type of radiation is involved, and what the physical form is. What the labeled activity states is not the primary concern in this situation.

So, should the use of apparent or actual activity be causing so much concern? No! Is there a problem with not establishing which of the two should be used? Yes! As stated previously, consistency has always been a mainstay for our field. Therefore the answer is simple: we should use apparent activity. The source has inherent filtration which is an intrinsic part of the source

itself. The filtration is not removed when the source is used clinically. All clinical documentation, such as the written directive, describes the source in terms of apparent activity. All computational systems use apparent activity.

In closing I have one last thought. If it were to be decided that contained activity should be the standard for shipping, then it will be necessary to alter the departmental paperwork to state this activity. Who will supply the factors to convert all of the available sources? What about long-term existing sources whose manufacturer no longer exists? I have called several of the companies who supply seed sources. Several of them do not supply this information.

Rebuttal

I agree with my colleague's desire for uniformity, as evidenced in my opening statement—definition and consistency are a foundation for our field. But I do not believe that if actual activity is not used, we are putting ourselves and emergency response personnel at risk. Have there been hospital incidents where seeds have ruptured? Yes, mostly due to errors in judgment. With proper handling, these incidents would not create dangerous exposure levels. "Time, distance, shielding and containment" are the keys to radiation safety. Policies and procedures are in place in all institutions using radioactive material; we just have to read them!

What about the public arena? There are policies and procedures there also. The federal government and individual states have emergency response policies, a section of which covers radiation emergencies. In my home state of New Jersey, the state[12] has a radiation response team under the jurisdiction of the State Police. There are two levels of response: an awareness group and the HAZMAT technicians. The awareness group is the first responder to a site. They know how to evaluate and recognize a hazardous situation, and they have responsibility for defensive measures—the protection of life and property including evacuation of an area and its security when called for. They also are responsible for notifying the HAZMAT team when warranted. HAZMAT is responsible for measuring, containing, and removing dangerous materials. In case of an accident involving radioactivity, the exposure level at the site is the controlling factor.

My knowledgeable opponent states that if actual activity is to be used, the conversion factors from apparent to actual activity need to be supplied. We are of like minds here: I just posed the question "Who" should supply the information. This is no trivial matter. The easy answer would be the NRC. They have written the guidelines for activity levels and shipping requirements, and they license the manufacturing of sources and their use in institutions. But this is true only for reactor-made products. What about accelerator-produced isotopes? For these materials the States are in control. In addition we must not leave out the DOT. This agency has definitions and areas of control of their own, which may agree with the NRC and States, but are not limited by them. These are only three of the multiple groups who are responsible for defining activity. All of these groups will have to be involved. So perhaps my simple question "Who should supply the information we need?" should be rephrased to, "When will this issue be resolved?"

I agree that a guideline is needed for all to follow, when describing the activity of a sealed source. We simply cannot continue to use both actual and apparent activity. I doubt that much will happen soon. In the meantime, the use of apparent activity is the best way to proceed when dealing with sealed sources. In the event of an accident, we can put our minds at ease by knowing that the exposure level is the controlling factor in how the event is dealt with, not a number written on a slip of paper.

I wish to thank Daniel Januseske, M.S. for the information and time he shared with me during the past month.

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8.14. In addition to the current byproduct materials, it is important that the Nuclear Regulatory Commission take over regulation of naturally occurring and accelerator-produced radioactive materials

Kevin L. Nelson and J. Frank Wilson

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OVERVIEW

Senator Hillary Rodham Clinton recently introduced a bill into the US Senate (Bill No. S.2763) to *"... amend the Atomic Energy Act of 1954 to redefine "byproduct material" to include: (1) any discrete source of Ra-226 produced, extracted, or converted after extraction, for use in a commercial, medical, or research activity; (2) any material that has been made radioactive by use of a particle accelerator and is produced, extracted or converted after extraction for use in such activities; and (3) any discrete source of naturally occurring radioactive material, other than source material, that the NRC determines would pose a threat similar to that posed by a discrete source of Ra-226 and is likewise extracted or converted after extraction, for use in such activities."* The bill also instructs the NRC to promulgate final regulations and standards to achieve this and to cooperate with States in formulating such regulations.

This is a controversial issue, especially as regards the medical use of these radioactive materials, when one considers that, in 1996, the National Academy of Science's Institute of Medicine proposed to Congress[1] that *"... Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses"*. The assumption of regulation of all radioactive materials by the NRC is the subject of this month's Point/Counterpoint debate.

Arguing for the Proposition is Kevin L. Nelson, Ph.D. Dr. Nelson received his Ph.D. from the University of Minnesota in health physics. He has been employed as a medical health physicist at Mayo Clinic in Jacksonville, Florida since 1995 and is an Assistant Professor of Radiology in the Mayo Clinic College of Medicine. He is certified by the American Board of Health Physics. Dr. Nelson has served on the Board of Directors of the Health Physics Society from 2002–2005. He also served as an Associate Editor of the Health Physics Journal for eleven years.

Arguing against the Proposition is J. Frank Wilson, M.D. Dr. Wilson is Professor and Chairman of the Department of Radiation Oncology and Director Emeritus of the Cancer Center of the Medical College of Wisconsin. He has served as the President and Chairman of the Board of the American Society for Therapeutic Radiology and Oncology, and as President of the American Radium Society. In addition, he has served as Chancellor and as Vice President of the American College of Radiology. He is the PI of the ACR Quality Research in Radiation Oncology (Q-RRO) project. Dr. Wilson is a member of the National Council for Radiation Protection (NCRP).

FOR THE PROPOSITION: Kevin Nelson, Ph.D.

Opening Statement

Should the oversight of accelerator-produced radioactive material and certain naturally occurring radioactive material (NARM) be unified? I would argue that centralized control is better, even though, in the past, these materials have been under some form of federal agency oversight or state control. To better answer this question, it is useful to review the history of regulatory oversight of radioactive material in the United States. In 1946, the Atomic Energy Commission was created as part of the Atomic Energy Act.[2] No mention was made of accelerator-produced or naturally occurring radioisotopes. With time, demand for these isotopes increased due, in large extent, to the interest in medical applications. With the advent of this technology, standards were required for both reactor and accelerator-produced radioactive material. In the late 1950's–1960's, the U.S. Department of Commerce issued a series of radiation standards. Accelerator produced materials, including ^{18}F, were included.[3] Since the 1970's individual states have been allowed, pending approval from the Nuclear Regulatory Commission (NRC), to create regulatory programs compatible with federal regulatory standards. To date, thirty-three such agreement state programs exist,[4] all with slightly different regulatory wording. Most agreement states, however, regulate accelerator-produced materials and naturally occurring radioisotopes using the same guidance given to NRC-regulated materials.

There is concern that additional regulations may be required to adequately safeguard all radioactive material, including generally licensed devices and that additional security measures are necessary to ensure these materials do not fall into the wrong hands. The Department of Homeland Security is tasked with providing centralized control and more efficient and effective regulatory processes to better safeguard this country.[5] It is in this context that Congress has attempted, since 2002, to pass legislation to address the unification of regulatory control over NARM materials. Language in the congressional bills introduced in the 108th Congress, S. 1043 and S. 2763, addressed three types of materials: (a) ^{226}Ra (b) other naturally occurring radioactive material viewed to pose a similar threat to ^{226}Ra, and, (c) accelerator-produced radioactive materials.[6] Of course, if similar legislation passes, details regarding compatibility with existing regulations will need to be resolved. Allowing for proper disposal of NARM material under existing legislative and regulatory mandates would need to be addressed. The Organization of Agreement States and the Health Physics Society have issued a joint position statement in support of this initiative.[7]

Some may argue that the existing level of regulation is sufficient. However, the United States is one of the few nations in the world that does not regulate NARM from a centralized perspective. Under centralized regulation current agreement states would be minimally impacted since they already regulate accelerator-produced radioactive material and NARM in a similar fashion as NRC-regulated material.

I agree with remarks made by NRC Commissioner Diaz before the American Radiation Safety Conference and Exposition on June 11, 2001, "One of the fundamental reasons to have regulation is to decrease the uncertainty in the implementation of a nation's interests, without undue burden to society."[8]

Centralizing regulation of these materials is appropriate.

AGAINST THE PROPOSITION: J. Frank Wilson, M.D.

Opening Statement

My position *against* the proposition serves the dual imperatives of maintaining optimal medical care and unfettered biomedical research in the future. Expanding the NRC regulatory mandate risks moving in the opposite direction. In fact, all aspects of the NRC's Medical Use Program 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20, as applicable to medical uses, should be eliminated, as was recommended to Congress in 1996.[1] Intervening world events since that time, and growing awareness and concern about potential nuclear terrorism, do not mitigate against such a restructuring. These unfortunate developments, on the contrary, argue emphatically for a more effective, cost efficient, alternative regulatory system for the low risk situations in which ionizing radiation is used for medical purposes; not for propagating the old one. Establishing an overarching regulatory framework that considers all radiation sources used in medicine in their entirety deserves a high priority and broad based support. This would be the best way to achieve reasonableness in regulatory applications so that medical progress is not impeded while, at the same time, a maximum level of public safety is ensured.

Currently, regulatory authority over the medical uses of ionizing radiation is widely distributed among numerous governmental agencies at federal, state and local levels.[9] These entities and their complex roles and relationships need not be detailed here. While it can be argued that this "system" somehow seems to "work," it is cumbersome and difficult to cope with. Inconsistent regulatory requirements may contain security loopholes that go unrecognized. Expanding unequal treatment of the radiation sources used in medicine, might aggravate the existing situation. In addition, resources that would be expended to develop and promulgate a new federal program, and especially later by medical and research facilities trying to comply with it, would not yield equivalent benefit in terms of patient protection or increased national security. This time and money would be better directed to enhancing medical care and research, including the development of new radiopharmaceuticals.

With specific regard to regulation of naturally occurring radioactive materials, Ra-226 and its derivatives are surely the most prevalent and dangerous NORM that could be used malevolently.[10] Planning long term regulation of a substance that outlived its usefulness, is clinically obsolete, and has no significant future role in biomedical research is not necessary.[11] Needed instead is a high profile national action plan to rapidly identify and finally dispose of all remaining radium sources. Built-in rewards and incentives, both positive and negative, would gain wide cooperation with the plan. A worldwide effort of this sort should be undertaken. In the USA, the states, with the leadership of the Conference of Radiation Control Program Directors, are best prepared to organize and carry out this task. They are those closest to and the most knowledgeable of possible remaining repositories within each locale of these dangerous materials.

I look forward to responding to the viewpoint expressed by Dr. Nelson favoring the proposition under consideration.

Rebuttal: Kevin Nelson, Ph.D.

Dr. Wilson and I agree on the central point of this discussion—inconsistent regulatory requirements can create problems. The Health Physics Society, for example, has expressed a similar concern as far back as 1992 when a position statement on this issue was first created.[12] Dr. Wilson has eloquently discussed the theoretical detriment to medical and research activities if an overarching regulatory framework were to be created. The NRC and agreement states have increasingly attempted to work with key stakeholders on legislation that may impact them. Under

this working relationship, I am of the belief that with input from state programs that already regulate these materials, the final result could truly benefit the end user. I would also agree that most radioactive material used in medicine and research poses a low risk according to most international and national radiation safety experts. However, it is important to remember that the intent of terrorism involving radiation is not so much radiological as it is psychological. Not regulating NARM and certain naturally occurring radioactive materials uniformly above certain exempt quantities is, in itself inconsistent, as these materials could cause harm if used for nefarious purposes. In addition, creating a unified regulatory structure would also benefit non-Agreement State medical licensees who must now navigate a regulatory quagmire and often pay a fee to the state for licensing NARM and to the NRC for licensing by-product material. I would also agree with Dr. Wilson that having a national plan to dispose of all unused or unwanted radium sources would be beneficial. However, given the fact that we continue to struggle with the disposal of low-level waste in this country, even after the passage of the Low-Level Radioactive Waste Compact Act of 1980, I am uncertain when such legislation would be passed. In the meantime, these sources still pose a risk and need to be properly controlled. I believe this initiative is important in maintaining regulatory consistency and the benefits will far outweigh the perceived burden.

Rebuttal: J. Frank Wilson, M.D.

Apparently, Dr. Nelson and I completely agree on key points that surface when considering the Proposition. First, is the paramount obligation to provide for the national security. Other agreement areas are as follows: a) uniform regulatory control of sources of ionizing radiation is prudent; b) the existing regulatory framework is highly complex and may contain unreconciled incompatibilities; c) proper disposal of NARM material should be definitively addressed.

Where, if at all, do we disagree? First, asserting federal control over NARM does not create a new *alternative*, non NRC-based, regulatory framework encompassing *all* radiation sources used in medicine. Such a framework would, I believe, be a more coherent, cost efficient system than that proposed, which would avoid overregulation of low risk medical and research situations. Enlarging the NRC mandate to achieve security objectives without imposing new administrative burden and costs on healthcare and biomedical research downstream seems unlikely. New unfunded mandates imposed on these vital activities can no longer be afforded. Whether public concern is for protection against "nuclear weapons" or "dirty bombs," federal agencies under mandate must carry out enforcement to a zero risk level. Many recall that until quite recently reactor produced radioactive materials used in medicine were regulated at the same intensity level as nuclear plants themselves and the severe consequences of noncompliance.

I had read the joint statement of the Organization of Agreement States and the Health Physics Society, as an individual never involved in either organization. It struck me that, although new legislation is endorsed, the sponsors also indicate seven conditional "principles for enactment" reflecting background concerns similar to those I expressed. Some of these principles are mentioned, but not addressed in detail, in pending legislation. At this writing, the legislative bill has survived Joint Conference Committee review. With Congressional endorsement presumably imminent, further preliminary discussion of these issues will be moot.

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8.15. The current NRC definitions of therapy misadministration are vague, do not reflect the norms of clinical practice, and should be rewritten

Howard Amols and Jeffrey F. Williamson
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OVERVIEW

Application of the concept of therapy misadministration, as interpreted by the Nuclear Regulatory Commission, has confused many medical physicists. This confusion has caused some physicists to rail against the definition, and to declare that the concept is unworkable in specific clinical situations. Others believe that recent changes in the interpretation have made the concept of therapy misadministration manageable in the clinical setting. This difference in perspective is examined in this month's Point/Counterpoint.

Arguing for the Proposition is Howard Amols, Ph.D. Dr. Amols received his Ph.D. in Nuclear Physics from Brown University in 1974, followed by post-doctoral training at Los Alamos National Laboratory. He has held medical physics positions at the University of New Mexico, Brown, and Columbia Universities. He is currently Chief of the Clinical Physics Service at Memorial Sloan Kettering Cancer in New York City, where he dutifully reports a few misadministrations every year, his personal reservations on the regulations notwithstanding. He is certified by the ABMP, and is a Fellow of the AAPM. He has over 100 serious publications in addition to his numerous infuriating letters and editorials. Although Dr. Amols recently became AAPM President Elect, the views expressed here do not represent those of the AAPM or any other reputable society.

Arguing against the Proposition is Jeffrey F. Williamson, Ph.D. He is currently Director of Medical Physics and Professor of Radiation Oncology at Virginia Commonwealth University/Medical College of Virginia Hospitals. While working as a dosimetrist, Dr. Williamson completed his Ph.D. in Biophysical Sciences at the University of Minnesota. He has been a member of the faculty of the University of Minnesota and Arizona and of Washington University. He is a member of the NRC's Advisory Committee on the Medical Uses of Isotope (ACMUI), Immediate Past Chair of the Radiation Therapy Committee (RTC), and Chair of RTC's Subcommittee on Photon-Emitting Brachytherapy Dosimetry. Dr. Williamson wishes to remind "Point-Counterpoint" readers that the views presented here are his alone and do not represent those of the ACMUI or the U.S. NRC.

FOR THE PROPOSITION: Howard Amols, Ph.D.

Opening Statement

According to most regulatory agencies a medical misadministration[1] in radiation therapy means (give or take a few words from state to state) the administration of "a therapeutic radiation dose such that errors in computation, calibration, time of exposure, source activity or placement, treatment geometry or equipment malfunction result in a delivered total treatment dose differing from the prescribed total dose by more than 10%; or a single fraction dose differing from the dose ordered for that fraction by more than 50%." Further, "when a misadministration is discovered the licensee or registrant shall immediately investigate the cause and take corrective action."

I believe this definition is unrealistic because: (1) The threshold values (10 and 50%) are arbitrary, because they are unrelated to expectations of significant clinical consequences, and they are not based on any analysis of whether such errors reflect the standard of care (i.e., do "good" clinicians rarely make such errors while "bad" clinicians do?). (2) The definitions are vague. What, for example, does "error in source placement" or "treatment geometry" mean? Does: "prescribed dose" refer only to the target volume, and if so what fraction of the target volume. Are incorrect normal tissue doses also misadministrations? Is a 5 mm error in collimator setting a misadministration if it slightly underdoses a sliver of the target and/or overdoses a sliver of the spinal cord? For an I-125 seed implant to the prostate, does a single seed implanted in the rectum constitute a misadministration? Space does not permit a complete list of such ambiguities, but we leave it to the reader (as a homework exercise) to come up with five similar examples. (3) For most misadministrations, which in my experience result from garden variety carelessness, the edict to "take corrective action" often results in little more than banal busywork. What kinds of corrective action are expected, for example, when a misadministration results from someone punching the wrong number into a calculator or computer program? Is "our staff has been instructed to be more careful" an adequate response? Does such action really accomplish anything?

In a recent editorial in the journal Brachytherapy[2] it was suggested that a more logical definition of a misadministration is to identify only events where, because of some error or lapse in judgment by the medical team, the dose delivered, or volume irradiated is outside the norm of acceptable clinical practice and/or likely to cause clinical harm. Revising current definitions along these lines would require: (1) A survey or analysis to determine the distribution of treatment errors. Are 10% and 50% dose errors within or outside the normal variation of delivered-vs-prescribed patient doses when practiced in a "reasonable manner" by "careful and experienced practitioners"? (2) A survey or analysis to determine if a consensus exists regarding a dose threshold for adverse clinical consequences to the patient.

Further, we suspect (but cannot prove) that: (1) Misadministrations occur far more frequently than is reported, due in part to the vagueness of the definitions, and to the fact that many clinicians fail to see their utility. (2) There is little consistency among institutions in this country on the interpretation of a misadministration, and whether or not certain types of errors meet or do not meet the definition of a misadministration.

Finally, a law that cannot be enforced, much less understood, generates only contempt for the law. Until the rules for misadministration are modified to reflect clinical reality they will remain ineffective.

Rebuttal

Dr. Williamson states that the definition of a Medical Event (ME) must be " . . . decidable . . . unambiguous . . . and . . . relevant." I agree, but maintain that current NRC definitions of ME fail on all counts. I've yet to see any evidence suggesting that the current dose threshold values are anything more than numbers picked at random, nor am I convinced that even the new definitions of ME are unambiguous. The recent revisions of CFR 35 helped, particularly for brachytherapy, but still do not set unambiguous criteria for such things as error in source placement, fraction of target volume that must be correctly irradiated, etc. Dr. Williamson limited his discussion to brachytherapy, but did not discuss NRC rules for teletherapy ME which are even more confusing. I will return to brachytherapy shortly, but first would like to remind readers that NRC ME rules still apply to Co-60 teletherapy, and that these rules have filtered down in one form or another to state regulations for linear accelerator teletherapy, even though this technology is not directly regulated by the NRC. Much of my opening statement was focused on the particularly ambiguous definitions of ME for teletherapy. Since Dr. Williamson did not address teletherapy, I will assume that he agrees with me.

So let me return to brachytherapy. Dr. Williamson correctly argues that a major purpose of having ME regulations is to identify programs that have seriously flawed QA programs. But how can one quantitatively determine whether a QA program is seriously flawed? If a center performs 100 brachytherapy procedures per year, and implants an incorrectly-calibrated seed in one patient during the course of the year that results in a 20% dose error to one patient, is this a flawed QA program? How about another program, also doing 100 brachytherapy procedures per year that discovers a systematic error that resulted in all 100 of their patients receiving a 9% dose error? Which, if either of these program is seriously flawed? Current regulations say the former, with the latter program getting off free. I disagree!

Finally, Dr. Williamson challenges me to review his list of FY 2002 NMED ME and point out recently reported MEs that did not warrant investigation. Space is limited so I'll focus on reported MEs for intravascular brachytherapy (IVB), of which there were 10. I note first that prescribed doses for these procedures ranged from 8 to 23 Gy, and that in 5 of these procedures the delivered doses to the prescribed volumes were in fact within the same range, although they differed by more than 20% from the prescribed dose for the particular patient being treated. This is admittedly a simplistic argument that ignores different prescription doses for different isotopes; the point is that errors in delivered doses for these MEs were of the same magnitude as the uncertainty in what optimal prescription doses should actually be. In other words we're punishing the occasional klutz but not the perpetually ignorant. Second, I note that in most of these MEs, device failure played a significant role, and devices are regulated by the FDA, not the NRC. So if we really want to do this right, there also needs to be better coordination in Washington (what else is new?).

In conclusion let me state that I am not against having rules, watchdogs, or minimum acceptable standards. Quite the contrary! I'm simply arguing that the current NRC regulations need to be improved.

AGAINST THE PROPOSITION: Jeffrey Williamson, Ph.D.

Opening Statement

The misadministration or medical event (ME) reporting requirement is intended to capture avoidable technical errors on the part of the caregiver that result in erroneous or unintended

delivery of radiation to patients or human subjects. Premature termination of an implant by the patient, seed migration, or other factors beyond the control of the caregiver that give rise to dose delivery errors are neither misadministrations nor medical events. The U.S. Nuclear Regulatory Commission (NRC) has recently replaced "recordable event" and "misadministration" with the revised concept of "medical event." An ME (10 CFR 35.3045(a)),[3] is any event, excluding patient intervention, in which administration of byproduct material or radiation therefrom that yields a dose (a) that differs from the prescribed dose by at least 50 cSv to an organ; and a total delivered dose differing from the prescribed dose by 20%, or a dose delivered by a single fraction differing from the prescribed dose/fraction by 50%; (b) that exceeds 50 cSv to an organ involving the wrong patient, wrong mode of treatment or a leaking source; (c) to a tissue or organ other than the treatment site that exceeds by 50 cSv and 50%, the dose expected from the treatment, had the written directive been followed. Permanent seed migration is specifically exempted.

Since agreement states are obligated to adopt an adverse-event reporting rule that meets the essential objectives of 35.3045 by October 24, 2005, I will confine my remarks to the revised reporting rule.

The ME threshold is intended to approximate levels of clinical relevance or at least clinical concern. NRC's goal is to capture not only those errors with potential for patient injury, but also those that suggest that the Licensee's radiation safety or technical QA programs are deficient[3] (p. 20330). NRC uses ME incidence both to assess the effectiveness of its overall nuclear materials regulatory program[4] and as a key performance endpoint in its new "risk informed, performance-based" regulatory paradigm. Essentially, MEs are used to identify both individual Licensees and generic treatment situations that need more prescriptive regulatory attention.[3]

If the ME reporting program is to identify flawed QA and safety programs, its definition must be (a) decidable, i.e., provide criteria for unambiguously distinguishing between medical events and nonevents; and (b) relevant, i.e., identify only significant "QA failures" warranting review and possible modification of the associated QA program.

Determining whether a treatment is an ME under conditions such as the wrong patient or modality is straightforward. A dose delivery error in excess of 20% is also straightforwardly decidable. Most of the 23 MEs reported in NRC's Nuclear Material Event Database (NMED)[3] for FY 2002 involved incorrect source strengths, unit conversions, or decay corrections; inaccurate reference point localization; dwell times from the wrong catheter; gross source-train mispositioning; or intravascular brachytherapy device failure. NRC's Medical Policy Statement[5] effectively limits patient safety oversight to assuring that the physician's written directive is followed. For ME decisions, the difference between the delivered treatment and that intended by the authorized user is to be evaluated based on the treatment site and dose-specification criteria chosen by the radiation oncologist and documented in the written directive. So long as the prescription quantity (e.g., D90 for prostate brachytherapy) is within 20%, local discrepancies between the planned and delivered dose distributions exceeding 20%, caused by limited precision of seed positioning, do not constitute medical events. Finally, dose-calculation or estimation techniques that have uncertainties approaching 20% are irrelevant to ME classification, so long as these procedures adhere to the appropriate standards of practice.

Do the ME criteria identify significant QA events? As current QA practice standards are based upon a target dose-delivery accuracy of 5%,[6] discovery of an avoidable 20% dose-delivery error is clearly grounds for re-assessing the effectiveness of one's QA program. While many MEs may not have immediate clinical consequences, there is ample evidence that 15%–20% errors do

measurably alter clinical outcome in many settings.[7,8] Previously, I have argued[6] that the ME definition significantly improves upon "wrong-site" misadministration by specifying a dose threshold (at least 50 cGy and a 50% dose-delivery error) which eliminates many meaningless events. Records of past MEs are perhaps the best measure of ME relevance. In this spirit, I challenge my opponent to identify just one FY 2002 NMED ME that is undeserving of investigation as a potential QA program flaw.

Rebuttal

In his first point, Dr. Amols attacks misadministration-reporting levels as arbitrary because they may not lead to unfavorable changes in clinical outcome. The principal regulatory role of the ME reporting rule is to identify licensees with deficient safety programs, with the assumption that the best defense against avoidable patient injuries is a functional QA program. The patient reporting requirement is a secondary consequence: once an error has been reported to the government that may have health consequences, ethically and legally this information must be shared with the patient. I agree that treating ME as a potential patient harm index undermines its value as a QA performance index, and makes ME reporting unnecessarily disruptive of the patient-physician relationship. Dr. Amols' assertion is probably true that geometric uncertainty in treatment delivery may make 20% or even 50% errors to small tissue volumes a routine consequence of radiation therapy. However, ME assessment is based upon compliance with the written directive, and not assurance that the dose at every point in a complex 3D dose distribution is delivered within 20%.

Dr. Amols' second point is that ME fails the decidability criterion. Some of his concerns are specific to the about-to-be obsolete misadministration concept. "Treatment site" and "prescribed dose" are defined not by the regulations but by the planning and delivery team themselves. For prostate brachytherapy, these may be "prostate with specified margins" and "D90." In addition, the authorized user has the option to revise the written directive in light of source positioning errors at any point prior to treatment completion. The "wrong site" ME criterion could be problematic, however. A single seed unintentionally placed outside the prostate capsule could deliver a dose in excess of 50 cGy and 50% of the planned distribution to some non-target tissue. My hope is that the NRC will temper its decisions with a modicum of clinical judgment, and accept the authorized user's signature on the post-implant plan as indicating clinical acceptance of these unavoidable deviations.

Dr. Amols' final point is that mandated corrective actions following an ME are meaningless, and that errors must be accepted as inevitable. This view is clearly contrary to prevailing standards of care, both as practiced and as codified in AAPM's Task Group reports.[9] Clearly, anyone has a finite probability of "punching in the wrong numbers:" the challenge is to develop a system of redundant checks that minimizes the probability such errors will go undetected. TG-40 (p. 585)[9] clearly states that errors in excess of specified thresholds should be viewed as failures of the QA system.

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8.16. Medical technologies should pass performance and cost-effectiveness review in Centers of Excellence before being released for diffusion in the clinical community

Charles A. Kelsey and Gerald Cohen
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OVERVIEW

In 1987 W. Schwartz stated in an article in JAMA: ‘‘Long term control of the rate of increase in (healthcare) expenditures thus requires that we curb the development and diffusion of clinically useful technology.’’ More recently, the National Cancer Institute announced (NIH GUIDE 26, No. 28, August 22, 1997) a new initiative to establish a single national network of investigators to perform multi-institutional clinical trials in diagnostic imaging related to cancer. The goal of the initiative is ‘‘the creation of a Network that will serve as an instrument for the expert clinical evaluation of discoveries and technological innovations relevant to imaging. Its activities will result in the following: (1) the expeditious, reliable, and comprehensive clinical evaluation of new imaging modalities; (2) the facilitation of technology development and translational research relating to imaging in academia and in industry; and (3) development of improved clinical trials methodology specifically related to imaging and the early detection of cancer. Although the NCI initiative may or may not be intended to address Dr. Schwartz’s concern, it is conceivable that it could be used for that purpose by regulators and payers of healthcare services. This is one of several controversies surrounding the NCI initiative. This edition of Point/Counterpoint addresses these controversies.

Arguing for the proposition is Charles A. Kelsey, Ph.D. Professor Kelsey received his Ph.D. in Nuclear Physics in 1962 from the Notre Dame University. In 1965 he joined the University of Wisconsin Radiology Department. In 1975 he accepted a position with the University of New Mexico as Chief of Biomedical Physics and Professor of Radiology to work on the Los Alamos Pion Cancer Therapy Project. Since 1985 he has been working in diagnostic radiology and radiation safety. He has served on the National Cancer Institute’s Radiation Study Section and numerous other government advisory agencies. He is intimately familiar with government regulatory actions and procedures.

Arguing against the proposition is Gerald Cohen, Ph.D. Dr. Cohen was born in New York City, earning his B.A. degree at Queens College and his Ph.D. in Physics at Purdue University. Feeling the attraction of Medical Physics, he trained for a year with Dr. Kereiakes at the University of Cincinnati Medical Center. The advent of the CT scanner started his career in diagnostic imaging at Allegheny General Hospital in Pittsburgh in 1975. He moved to the University of Texas Medical School-Houston in 1978, publishing over 50 papers and book chapters on various aspects of diagnostic equipment and image evaluation. Dr. Cohen has been at General Electric Medical Systems since 1984 in various roles involved with advanced applications and technology development in diagnostic imaging.

For the Proposition: Charles A. Kelsey

Opening Statement

I write in favor of the proposition for two major reasons. First, it will help to base decisions about the acquisition of new medical equipment on a sound scientific basis rather than on a hodge-podge of individual preferences. Second, it will reduce health care costs.

Centers of Excellence will be able to develop performance criteria and evaluate the cost-effectiveness of new technologies in a much more scientifically exact manner than can any one user or combination of users. Centers of Excellence will provide a firm scientific foundation for the clinical applications of new technologies. If Centers of Excellence had been in existence in the early 1970s they would have undoubtedly shortened the path that CT technology followed into the clinical arena. Even today we have few strictly scientific studies which show that costly CT examinations are superior to more conventional examinations in the sense that patients experience better outcomes with CT. I only need mention spiral CT as another example of an unproven, unevaluated, technology, even though most clinicians ''feel'' or ''believe'' that it is immensely valuable.

The use of Centers of Excellence to evaluate technologies before they are allowed to be purchased by the end-user will reduce medical costs by eliminating the not-so-good products. The current system of allowing the ultimate user to decide whether or not to adopt a new technology based on anecdotal evidence is clearly inefficient and costly. Centers of Excellence will reduce costs to the government and managed care organizations because the Centers will perform the scientific experiments and evaluations needed to establish purchasing criteria and regulations. Third party payers, managed care organizations and regulatory agencies will save the money they otherwise would have had to spend to develop these data. Saving money is good; therefore, Centers of Excellence are good.

There are those, misguided but of good heart, who may disagree with my point of view. They may argue that large organizations are not efficient in making good choices. As examples, they may point to the response of the big three automakers to the introduction of smaller, more efficient cars; to the response of IBM to the introduction of personal computers; or to Kodak's decision not to purchase the Xerox technology. They may do this to disprove my point. These examples, however, actually prove my point, because even in the face of less than desirable decisions, these companies have survived. The combination of Centers of Excellence, watchful government agencies, and frugal third-party payers will help ensure that technologies are allowed to diffuse into clinical medicine in a thoughtful, cost-effective manner.

Those of us who believe there is substance to Dr. Schwartz's words: ''...we must curb the development and diffusion of clinically useful technology'' are favorably disposed to the establishment of Centers of Excellence.

Rebuttal

Dr. Cohen comes out strongly for reducing cost through cost effectiveness studies and raises some valid questions regarding performance evaluation of new technologies. He wants to know which procedures should be used in assessing a new technology, when in the technology's development to begin the assessment, what are the real costs of a technology and who will pay for the assessment. These are legitimate concerns, but ignore the question of whether such assessment should be required before the technology is released for diffusion into the medical community. Is it better to allow the present laissez faire free market system to determine which

medical technologies survive, or have a scientifically sound evaluation system in place to ensure that only technologies that have been reviewed for performance and cost-effectiveness are allowed into the medical community? I believe it is better to have a firm scientific foundation justifying a technology before its introduction. This foundation can best be established by centers of excellence established solely for this purpose. History shows that once government entities make a decision or establish a program they can be ruthlessly efficient in working toward that goal. And efficiency is good. Large entities such as the Post Office, the Department of Defense, and the Internal Revenue Service all serve as examples of what we can look forward to in the coming years if these Centers of Excellence are established. Any and all small steps toward an improved technology will be thoroughly studied and their improvement verified before being introduced. We will all rest easier knowing the Centers of Excellence are watching out for us.

Against the Proposition: Gerald Cohen

Opening Statement

It is clear that the revolutionary advances in medical imaging since the invention of the CT scanner in the early 1970s have, until recent years, occurred against a backdrop of rapidly rising healthcare costs. The high cost of some medical imaging technologies, such as CT and MRI scanners, have made them highly visible cost-increasing targets. As a result, there have been voices raised calling for prior review and testing of the ''performance'' and ''cost-effectiveness'' of such systems before diffusion in the medical community.

Such an approach raises many thorny questions and issues, such as:

• What are the appropriate clinical procedures to assess on new imaging technologies? In most cases, these can only be developed by the medical community through clinical development in a variety of clinical environments. Could anyone have predicted 25 years ago that the CT scanner would become the workhorse for diagnostic imaging of the body? Prior restraint on diffusion would become a classic ''chicken and egg'' situation, with the result that the most potentially clinically useful and cost-effective procedures might never see the light of day. Experience has shown that the marketplace is smarter than the experts in predicting the future.

• At what stage in development should assessment be performed? Medical technology, unlike drugs, is a continuously evolving and dynamic process, using constant feedback from clinical users for development. Too early or limited an evaluation would hinder innovation and inhibit useful technologies. In addition, if each new model or upgrade needed evaluation, this would make improvements cost-prohibitive.

• What do we assume for ''cost''? Assumptions regarding the clinical environment, allocation of overhead costs, system throughput, system price, etc. will greatly impact the results obtained. ''Charge'' is often used as a surrogate, but this is often an artificial number for billing purposes. Do we assume the performance and throughput of a first generation system, or do we assume future developments? Do we use the ''costs'' at a teaching medical center, a community hospital, or an outpatient imaging center?

• Who pays for the trials? These potentially significant added costs have the potential for making imaging technology less, rather than more, cost-effective.

Physicians and providers have responded to the healthcare systems' cost-sensitive environment by demanding higher patient throughput, expanded versatility, greater quality, and decreased unit costs, and manufacturers have responded accordingly. Physicians have judged medical imaging to play a valued, cost-effective role in patient management, as reflected by its growing utilization over the past four years, at the height of healthcare cost sensitivity. Processes such as appropriateness criteria, practice guidelines and disease management should be supported and encouraged to help guide physicians in the best use of imaging for the care of the patient. Increased productivity should be sought everywhere. Cost-effectiveness studies should be supported and encouraged, but should not become a regulatory barrier to diffusion.

Rebuttal

I think that Dr. Kelsey's final remark captures the essence of the debate. If one agrees with the remarks attributed by Dr. Kelsey to Dr. Schwartz, that ''...we must curb the development and diffusion of clinically useful technology,'' then I agree that the establishment of the Centers of Excellence, as envisioned by Dr. Kelsey, can be a useful element in achieving that goal. However, if one feels that the development of clinically useful technology is an important element in improving the quality of healthcare, then perhaps we should examine alternative approaches.

Centers of Excellence can be a useful means for developing an infrastructure capable of performing selected clinical trials, technology assessments, and outcome studies, in a scientific and efficient manner. Such research can serve as a useful guide for physicians, equipment purchasers, and third-party payers in their purchasing and reimbursement decisions, and should be supported. However, if such studies become a regulatory requirement before new technology is ''allowed'' to be offered to the clinical community, then the supporters of curbing the development and diffusion of new technology will have achieved their goal. Requiring a limited number of Centers of Excellence to ''approve'' all new technology will severely narrow the base of scientific and clinical research, slow the rate of technology development, and significantly increase the cost of development.

CHAPTER 9

Education

9.1. Medical physics graduate programs should focus on education and research and leave clinical training to residencies

Gary T. Barnes and Timothy K. Johnson
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OVERVIEW

Traditionally, medical physics predoctoral and postdoctoral educational programs have provided a mixture of didactic instruction and on-the-job training in a clinical environment. Graduates of these programs have taken jobs where usually, but not always, their work is supervised by an experienced medical physicist. Many, perhaps most, of the leaders in medical physics have followed this pathway into the field. Residencies in medical physics are a relatively recent innovation. With their advent, the Commission on Accreditation of Medical Physics Education Programs, Inc. (CAMPEP) has chosen to emphasize didactic training in medical physics educational programs. Programs that place too much emphasis on clinical training, and not enough emphasis on didactic training, are not granted accreditation. CAMPEP's position has jeopardized the future of some medical physics educational programs that have produced credible graduates over several years. Whether this position reflects the best interests of the medical physics profession is the subject of this Point/Counterpoint issue.

Arguing for the Proposition is Gary T. Barnes, Ph.D., Professor and Director of the Physics and Engineering Division of the Department of Radiology at the University of Alabama at Birmingham Hospital and Clinics. Dr. Barnes is a past president of the AAPM, served on the AAPM Commission on Accreditation of Educational Programs for Medical Physicists for five years (1991– 1995). He assisted in transition of the AAPM Commission's responsibilities to the current independent Commission, and in 1996 chaired the CAMPEP Graduate Education Review Committee.

Arguing against the Proposition is Timothy K. Johnson, Ph.D. Dr. Johnson is Associate Professor in the Department of Radiology, and Director of the Graduate Program in Medical Physics at the University of Colorado Health Sciences Center. He is the author of the MABDOSE internal radionuclide dosimetry software [see *Medical Physics* **26**, 1389–1403

(1999)], and has high hopes for radioimmunotherapy as a supplement to external beam and chemotherapy in the treatment of cancer.

FOR THE PROPOSITION: Gary T. Barnes, Ph.D.

Opening Statement

The careers that medical physicists embark on are many. The majority involve the clinical support of radiologists, radiation oncologists, and other medical disciplines. Many work in large medical center departments and have additional responsibilities involving postgraduate physician training, research, and/or medical physics graduate education. A smaller percentage work in industry in the areas of product development, support, sales or marketing. A requirement of all areas is a sound didactic foundation. This can only be achieved with extensive and comprehensive formal course work. Such a foundation is a prerequisite to cognitive problem solving and facilitates intellectual growth following matriculation. In addition, in the hospital environment one must have a good understanding of medical physics clinical responsibilities. These responsibilities take time to assimilate to the level that they can be performed in a professional manner without supervision.

Medical imaging and radiation oncology have become more complex in recent years as have medical physics and its subdisciplines. In 1960 imaging consisted mostly of radiography and conventional fluoroscopy. In larger departments nuclear medicine imaging was done with rectilinear scanners.

Radiation oncology was limited for the most part to cobalt-60 teletherapy, orthovoltage units and implants. The picture in 1999 is much different. Imaging utilizes radiography, fluoroscopy, planar gamma camera images as well as CT, ultrasound, MRI, SPECT and PET. Highly complex digital heart catheterization and interventional radiology laboratories are commonplace. Medical centers are making significant investments in digital radiography and PACS. Dual modality linear accelerators, high dose rate brachytherapy, CT simulators, computerized 3D treatment planning, and conformal radiation therapy are commonplace in radiation oncology. Intensity beam modulation and stereotactic radiation therapy are being utilized at larger medical centers.

The knowledge and experience that a clinical medical physicist must have to function as a professional is much greater today than it was in the 1960s. This knowledge and experience cannot be achieved with two years of graduate school and the writing of a thesis or even with additional years devoted to research and a Ph.D. dissertation. It requires additional hands-on working experience under the supervision of experienced medical physicists. This fact is readily apparent to the certifying boards which require three or more years of working experience before one can sit for an exam in one of the subdisciplines of medical physics. To date recent graduates have obtained this experience by either taking a junior level position or by entering a medical physics residency. The advantage of the latter is that it provides a broad level of structured working experience under a group of medical physicists. Claiming that a two year graduate program can provide this level of experience, and that at the end of the program the individual is a professional and can work independently and without supervision, is not realistic. Based on the experience requirements of the American Board of Radiology and the American Board of Medical Physics, it is misleading.

In summary, for an individual to be a clinical medical physicist, both a good didactic graduate education and extensive hands-on experience are required. Both requirements are recognized by the American Board of Radiology and the Board of Medical Physics. The time it takes to achieve this level of competence should be formally recognized and is best accomplished by a structured medical physics residency following the completion of graduate school. Salaries in medically-related professions are related to supply and demand, and also to the time it takes to obtain the necessary hands-on experience. In the medical field working experience is achieved initially and formally in structured residencies. This model works well, is accepted by the medical field and should be employed in clinical medical physics.

Rebuttal

Dr. Johnson and I are in agreement on several points. We agree that it is important for a medical physicist to have a sound didactic background. We also agree that professional skills are necessary for a medical physicist to function successfully (and independently) in the clinical environment, and that these skills are not learned in the classroom. A difference in our positions is that he views the Master of Science degree in medical physics as a professional degree, whereas I view it as an academic degree. A more fundamental difference in our positions is that he argues that a sound didactic foundation and satisfactory level of professional skill can be obtained in a master's degree program. It is my position that this cannot be accomplished in the time typically required to obtain a master's degree (i.e., one and one half or at most two years). The recommended course work outline in AAPM Report No. 44 ''Academic Program for Master of Science Degree in Medical Physics'' is extensive and will completely occupy a student's time unless it is watered down and taught without appropriate rigor and mathematical sophistication. Furthermore, AAPM Report No. 44 does not mention computer courses or a formal course in the mathematical methods of medical physics. I consider these courses to be essential to permit students to adapt to the current clinical and alternative (i.e., research, product development, etc.) job climate, and to future advances in the field.

Dr. Johnson argues that several medical physics programs incorporate the development of clinical skills into their curricula. He believes it would penalize graduates of these programs to subject them to additional years of indentured servitude, and that this procedure is just plain wrong. However, the course work requirements fully occupy the student's attention for the time typically required to obtain a master's degree. Adding the development of a significant level of clinical skill into the curriculum can only be accomplished in one of two ways: either water down the course work or extend the degree time. Although watered-down courses are easier to teach, they short-change students and limit their future growth. Dragging out the time for a student to obtain a degree is, in my opinion, extending the student's indentured servitude under far less satisfactory conditions than spending time in a structured residency. In a medical physics residency the pay and fringe benefits are the same as physician residencies, and are significantly better than the pay and benefits of a graduate student.

AGAINST THE PROPOSITION: Timothy Karl Johnson, Ph.D.

Opening Statement

Medical Physics is a professional degree based on an applied science. When individuals train for the field, it is with the reasonable expectation that they will be employed in a clinical setting possessing certain skills. This is, after all, where the jobs are: A quick scan of the AAPM's monthly Placement Service ''blue book'' demonstrates that the majority of employment

opportunities are in Radiation Oncology, and that the professional skills desired are (1) Machine and source calibration; (2) treatment planning for external beam and brachytherapy sources; and (3) checking treatment charts. These skills are not learned in the classroom.

While a background knowledge obtained through didactic course work is necessary for a broad-based understanding of radiation, it is hardly sufficient for the majority of tasks that evidently are expected from the degree. This being the case, it appears irresponsible to provide a program where didactic lectures are emphasized at the expense of the very skills that make one employable.

Reserving clinical training to the residency appears to be motivated by two considerations: (1) an effort to place Medical Physics education within the same framework as the Radiology residency for reasons of professional stature and parity; and (2) a lack of uniformity in Graduate program curricula that prevents a standards committee like CAMPEP from avoiding subjective evaluations. The medical school curriculum, however, has evolved to a natural division between basic skills learned in the first four years, and specialized clinical skills imparted in a residency. In contrast, a number of medical physics programs incorporate the development of clinical skills into their curricula. To penalize graduates of these programs to additional years of indentured servitude is just plain wrong.

With respect to the second point, a certain amount of diversity exists among medical physics graduate programs. Diversity always plays havoc with standards, because an unintentional outcome of standards is often homogenization. Standards make evaluation easier on the part of examiners charged with overseeing individual program compliance; they do not allow for programs that supercede the standard's baseline to be recognized for any excellence that goes above and beyond the published standard.

One needs to ascertain whether there are alternative means for distinguishing graduate programs in Medical Physics. A more natural metric for distinguishing ''ability' might be a two-tier accreditation. The two-tier evaluation would allow CAMPEP to categorize the major differences in graduate medical physics programs. Graduates having a clinical component would have a different level of competence associated with their degree. Depending on a student applicant's professional goals and aspirations, they could opt for a clinical residency depending on the tier their graduate school prepared them for. When the clinical training occurs should not matter: only that it occurs.

Rebuttal

Dr. Barnes reiterates the general argument for a sound foundation in didactic course work, namely that it facilitates general problem solving skills and fosters intellectual growth. This is followed by statements regarding the value of clinical experience. Neither are in dispute. However, he goes on to state that the knowledge and experience of a clinical medical physicist cannot be achieved within a typical two-year medical physics graduate school program, and that the advantage of the clinical residency is that it provides a broad level of structured work experience under a group of medical physicists. This sounds very much like the advantage of our graduate program, in which the hands-on experience is taught in concert with related didactic learning. I encourage prospective students that are reading this to apply
to our program.

Dr. Barnes states that in the medical field, working experience is achieved initially and formally in structured residencies. For physicists, the initial work experience is typically gained within the framework of a graduate program, followed by supervised positions in the field. The need to separate the work experience from didactic lectures is not the defining model of residency programs. In fact, radiology residents are usually exposed to a core lecture series that includes a didactic physics course concurrent with their clinical experience.

Upon talking to the few Colorado graduates that chose to complete a clinical residency, the ‘‘new skills’’ that they ‘‘mastered’’ to a large extent centered on learning to use a different interface for a treatment planning computer. This was not substantive new knowledge, but rather the consequence of their taking a job that employed a treatment planning system different from the one they trained on. The physics of ionizing radiation interacting with matter did not change—just the appearance of how to manipulate it. Moreover, these skills were gained within several weeks, not one year of concentrated effort. An unbiased observer would probably conclude that this was the period of time that any medical physicist (board certified or not) would require to master a new dosimetry system.

I do not think anyone believes that a two-year graduate program provides a level of experience whereby a graduate can work independently and without supervision. It does provide a level of experience whereby a graduate should be able to command an entry-level professional salary without being subjected to the penury associated with student status.

9.2. Physicists directing training programs should cooperate to align student enrollment with market demand for medical physicists

Don Tolbert and James A. Zagzebski
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OVERVIEW

Many persons believe that the market demand for medical physicists is bound to diminish as a result of growing fiscal constraints imposed by the increasingly competitive environment of managed care. Some would say that the market demand for physicists has already begun to sink. They might argue that it is unwise for the discipline and unethical for the training programs to graduate more medical physicists than the market can absorb. They would endorse an agreement among training program directors to limit student enrollment so that it is aligned appropriately with the market demand for physicists. Opponents to this point of view might suggest that market demand is impossible to predict, and that one should be optimistic that the growing sophistication of diagnostic imaging and radiation oncology will require more medical physicists in the future. They also might propose that an academic discipline such as medical physics has no right to deprive interested young people from pursuing studies in the field, and that no discipline guarantees employment to its graduates. This debate is the subject of this month's Point/Counterpoint issue.

Arguing for the Proposition is Don Tolbert, Ph.D, FAAPM, FACR. Dr. Tolbert earned his Ph.D. in Nuclear Physics at the University of Kansas in 1968. Following two years as a Post Doctoral Fellow at Florida State University, he accepted a Post Doc Re-Trainee position with the Medical Physics Division of Radiology at the University of Wisconsin in Madison. After seven years on the faculty he moved to Hawaii where he became Director of a Radiological Physics Outreach program. From 1981 through 1990 he was Managing Partner of Mid-Pacific Medical Physics and since 1991 has worked at Tripler Army Medical Center in Honolulu, HI.

Arguing against the Proposition is James A. Zagzebski, Ph.D. Dr. Zagzebski is chairperson of the Medical Physics Department of the University of Wisconsin. He teaches courses and conducts research in diagnostic ultrasound physics. Currently he and his students are working on tissue feature extraction with ultrasound, flow measurements using ultrasound contrast agents and problems in 3-dimensional imaging. Dr. Zagzebski received his Ph.D. in Radiological Sciences in 1972 and has been with the University of Wisconsin since that time.

FOR THE PROPOSITION: Don Tolbert, Ph.D., FAAPM, FACR

Opening Statement

I write in favor of the proposition. Two conditions are necessary however. The planned objective must benefit (a) both the state and federal government, and (b) the medical physics profession.

Item (a) is necessary to avoid antitrust litigation. We should petition federal and state authorities having jurisdiction over medical physics to help arrive at the appropriate number of program

positions to ensure an adequate supply of graduates while conserving increasingly scarce public resources.

How does this benefit medical physics? Talent and experience from basic science pursuits have traditionally been important to the profession. Our founding fathers began not only the research and development aspects of medical physics, but also the clinical applications. Medical physics training programs accredited by the Commission on Accreditation of Medical Physics Education Programs (CAMPEP) Are now the preferred choice of most students pursuing a medical physics career (Bhudatt Paliwal, Chairman of CAMPEP, personal communication). While research and development aspects of medical physics may continue to benefit from individuals entering directly from the basic sciences, the clinical aspect of the profession does not.

In all aspects of our profession the standard has been raised considerably. Employers now expect medical physics graduates to function at a level comparable to physicians and other professionals. The influence of managed care however, has enabled economic factors to outweigh professional competence in hiring. When the output from medical physics training programs does not meet market demand, entry into the field occurs through the side door where the benefit of medical physics training is not structured per CAMPEP accreditation criteria. Entry through the side door disadvantages the medical physics profession and exposes institutions to greater liability.

Program directors must make decisions based on accurate numbers representing dynamic variables in the marketplace. Much information could come from the membership data gathered and maintained by the AAPM Headquarters. For example, if the AAPM membership in the categories of Canadian, Student, and Honorary are subtracted from those for the Total membership, a linear regression analysis shows an increase of approximately 126 members per year (Sal Trofi, Jr., AAPM Executive Director, personal communication). Does this increase represent market demand? CAMPEP accredited training programs graduate an average of approximately 100 per year (Bhudatt Paliwal, personal communication). If the market demands 126 per year and the average accumulated total from accredited training programs is 100 per year, then non-accredited programs must be making up the difference, or, the difference must be entering through the side door.

Rebuttal

I agree that excellence must continue to be a priority in our training programs. This has provided much leadership in medical radiological applications and is certain to play an increasingly important role in non-radiological efforts.

Cooperation by program directors would have to include consideration of the dual nature of training programs. At the risk of oversimplification, some graduates are employed in research and development while others are employed in the clinic. Jim states that the medical physics job market is ‘‘ . . . a market whose demands have a time constant that seems shorter than the training period for students.’’ An examination of (a) student membership and (b) salaries for all degrees (certified) with primary employment in radiation therapy[1] suggests otherwise.

Student AAPM membership enrollment from 1990 through 1999 is distinctly bimodal. From 1990 through 1995 a linear trend line (R^2=0.925) shows an increase of over 55 students per year, while from 1995 through 1999 a linear trend line (R^2=0.909) shows a decrease of over 25 students per year. The same analysis applied to average ‘‘Primary Income’’ salaries for all

degrees (certified) employed in radiation therapy show similar results. From 1990 through 1994 a linear trend line (R^2=0.976) indicates a salary increase of $4,710 per year while from 1994 through 1998 the same analysis (R^2=0.998) indicates a salary increase of only $1,950 per year.

These numbers are only suggestive. The ''student'' membership category is subject to error because it can take a few years to have the membership category accurately reflect passage from training to non-training status. The ''all degrees'' category was used only because it was continuously used from 1990 through 1998. The numbers above suggest that the market trend may remain constant for a period of four to five years. I believe this is long enough to allow program sizes to adjust to market demands.

A model should be developed that uses membership, salary survey, etc., information as input data for suggesting when market cycles may change.

AGAINST THE PROPOSITION: James A.: Zagzebski, Ph.D.

Opening Statement

Directors of Medical Physics training programs certainly owe it to the profession to be attentive to the medical physics job market as they do long range planning. However, they should not attempt to fine tune program enrollments to respond to ups and downs of the medical physics job market, a market whose demands have a time constant that seems shorter than the training period for students. Instead, directors should focus on maintaining high quality programs, programs that are responsive to the needs of the field, and most importantly, programs that foster discovery.

Five years ago a graduate of our program approached me and expressed dismay that medical physics training programs had not reduced their output of graduates. It seemed the ''flood'' of new medical physicists into the job market at the time, along with pressures on the health care dollar, were reducing opportunities for established physicists. Luckily, few programs cut enrollments at that time. Had they done so, employers in today's market would be even more pressed to find well-trained physicists than they currently are.

While market demands eventually will influence the size and breadth of all training programs, directors should work for excellence in these programs rather than try to outguess job market pressures. Men and women choose medical physics as a career because they enjoy the ''physics approach'' to discovery, and they have a keen interest in leaving this world in slightly better shape than it was when they entered. The physics profession, the medical physics community, and society, has benefited greatly from the thousands of fine individuals who have been trained as medical physicists. Who doubts that their contributions will continue?

If we impose constraints on the size of medical physics programs, then, in a sort of self-fulfilling prophecy, we also will be constraining growth in our field. Some of the most important discoveries in medical physics have been fostered within our training programs, with graduate students working alongside faculty. Technology such as Cobalt 60 machines, computerized treatment planning, DSA, digital imaging, bone densitometry, SPECT, PET, TLD, CT, MRI, and 3-D ultrasound have emerged from our academic programs. Today their atmosphere of discovery is spawning MRI angiography, biomagnetism, tomotherapy, thermal therapies, and molecular imaging. It is important to foster this

atmosphere—which is creating the jobs for tomorrow's medical physicists—rather than thwart it. Great things happen when medical physics programs expand their enterprise, and along the way create the technology that will be needed in tomorrow's medical practice.

Rebuttal

Don is correct in noting that CAMPEP accredited programs are the preferred entry into our profession. The premise, however, that the number of graduates can be coupled to the medical physics job market ignores key factors in training medical physicists. Interestingly, these factors also are linked to the high professional standards required of medical physicists, also noted by Don.

The first factor is that there is keen competition among graduate programs in attracting well-qualified applicants. Most medical physics programs compete not only with each other but also with graduate physics programs for outstanding undergraduate physics majors. If only a handful of qualified individuals applies to a program, should admissions standards be lowered to fill professionally-based quotas? Of course not! Vice-versa, if a program is blessed with an unusually large number of highly qualified applicants, and faculty have means of supporting these students, shouldn't these young physics majors be given the same opportunities to contribute to the field that we have enjoyed? This might not occur with mandated enrollment limitations.

The second factor is space limitations and limited training resources in graduate medical physics programs. Programs have finite laboratory and equipment resources to provide training at the quality required to assure success in today's complex environment. Ramping up training slots to fill immediate job quotas would cause chaos within a training program, as this may require additional faculty and additional equipment. Vice-versa, why would a program waste precious training resources, and deny entry to a competent student when the job market happens to be tight (assuming program directors are not misrepresenting the job market to their applicants)?

Manpower needs in medical physics must be dealt with at the professional level, while programs should be allowed to respond to market demands as they see fit. Individual physicists can do much to introduce qualified undergraduates to our field and to encourage them to apply to CAMPEP training programs. It is surprising how many undergraduates are still not aware of medical physics as a career option. Professional organizations such as AAPM can continue to support training with fellowships, reduced registration fees for students, etc. When we enjoy an overabundance of graduates, these activities can be curtailed. But medical physics training programs should concentrate on maintaining high quality programs, enrolling the number of students they can support, and continuing to provide outstanding training experiences.

REFERENCE

1. AAPM Professional Information Survey Report.

9.3. All medical physicists entering the field should have a specific course on Research and Practice Ethics in their educational background

David Switzer and Nicholas Detorie
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OVERVIEW

There can be little disagreement with the premise that medical physicists must function ethically in all endeavors, including research, practice and education. How ethical principles are best instilled into medical physicists can be argued, however. Some would say that every physicist should take a specific course on ethical principles and their applications. Others believe that ethical behavior is best learned through association with ethical teachers, mentors and colleagues. Still others might argue that ethical behavior is culturally-instilled, and a separate course in ethics is not needed. How ethical principles are assimilated by medical physicists is the topic of this month's Point/Counterpoint.

Arguing for the proposition is David Switzer, MS. Mr. Switzer received his Masters Degree (Major Physics, Minor Mathematics) from Saint Louis University, his thesis dealing with thermionic emission using x-ray crystallography, high vacuum, high voltage, and electron diffraction studies in completion of the research. He began his career in Medical Physics at the University of Missouri in 1969. He has served as Chairman of the Ethics Committees of the AAPM and the ACMP. His place of work for the past seventeen years has been the Northern Rockies Cancer Center in Billings, Montana. Mr. Switzer is certified by the ABR (TDRP) and ABMP (ROP) and is a Fellow of the ACMP.

Arguing against the proposition is Nicholas Detorie, Ph.D. Dr. Detorie is the Interim Director of Medical Physics in the Department of Radiation Oncology at Johns Hopkins University and is the Director of the Medical Physics Residency Program at JHU. Dr. Detorie has served as Chair of Public Education for the AAPM and as Chair of Continuing Education for the ACMP. Currently, he Chairs the Medical Physics Standards Committee for the ACR Commission on Physics and is the AAPM representative to the AIP Media and Government Relations Committee. He is also a member of the Editorial Board for the AAPM Newsletter.

FOR THE PROPOSITION: David Switzer, M.S.

Opening Statement

Medical physics emerged in the modern era as an outgrowth of innovations fueled by technological advances made during World War II. These advances included the emergence of microwave technology, the creation of artificial radioactive material, and the use of computers powered by solid-state devices. In the late 1940s, the embryonic nucleus of our present field came into being. Pioneering medical physicists were supported, encouraged, and challenged by their physician colleagues to assist in diagnosis and treatment with the innovative use of new

technologies. Those physicists were well served by their strong scientific education, training, and experience.

The preparatory training of medical physicists has traditionally not included ethics. I am not alleging that medical physicists lack ethics. Ethical issues accompany many medical physics applications, such as calculations to determine the radiation dose to critical organs or a fetus. Medical physicists are well aware that the future holds other roles requiring ethical applications of our knowledge.

Medical physics services often include the provision of advice on whether or not to provide treatment, the use of curative versus palliative courses, the potential occurrence of early and late effects from radiation treatments, and the loss of function or changed morphology related to the disease and/or its treatment. Medical physicists know that physicians, nurses, radiation therapists, administrators, and attorneys take formal courses in ethics. As physicists we could further our professional standing if our credentials included ethical courses equal to those taken by our colleagues. Training in ethics would expand the respect we have for each other and for our practice as part of a professional team.

Ethical behavior is closely connected to our cultural background and heritage. It is honed by our work with mentors and colleagues. Medical physicists could benefit by having an initial introductory course in ethics, which would provide a uniform basis for establishing soundly-based ethical positions. Medical physicists would then be better prepared for the many professional dilemmas that inevitably arise. In a recent article, N. Reed Dunnick said, "It is not enough that each of us individually tries his or her best to practice ethical behavior. We must include it in residency training."[1] This is also appropriate for medical physicists who have not had an ethics course in their graduate education. The first guideline in the AAPM Ethics Guidelines is "Medical physicists should strive continually to improve their knowledge and skills . . . . ."[2] We should strive to improve our ethical decision-making skills.

Concerns which might be addressed in a formal ethics course would include: self-respect and professional respect; collegial communications; professional respect for each other; pursuit of our work as professionals; and ethical challenges in employment situations.[3] Ethical positions could be developed on issues such as relations with patients and medical colleagues, allocation of medical resources, and relations with vendors.[4,5,6] A short course at the RSNA, AAPM, ACMP, or ASTRO meetings could be held for those of us now in the field.

Rebuttal

During preparation of this paper, honesty, ethical behavior, and integrity have been part of the business news. There are calls within the professional business community to teach ethics in order to set standards and guides for improvement. For example, "Common features of an effective ethics and awareness training program include: (1) live instruction, (2) small class sizes, (3) significant group interaction, (4) at least 4 hours of training, and (5) separate courses for compliance areas. . . . In any organization, a good business ethics process is the first and most important line of defense against unethical or illegal activities. . . . Training also helps improve their (employees) decision-making capabilities in the presence of ethical dilemmas as well as establish goal congruence between employees and the organization."[7] Societal expectations have increased in recent years for all medical professionals. Medical Physicists' professional colleagues have chosen to include ethics courses in their curricula. There is a need to meet the public's expectations.

The Ethics Committee of the AAPM has dealt with issues of acknowledgement of corporate support for research work, review of others' work, etc., and issued formal statements included in the Directory.[2] Disputes have occurred between Medical Physicists who could have been served by a formal ethics course. Conflict, heartache, and animosity could have been averted.

In many Medical Physicist's careers there have been exceptional physicists, medical physicists, physicians, and other colleagues who have provided significant insight, mentoring, and leadership. In many cases these colleagues were innovators of a technique, method, or device. These colleagues did not take a course in the topic for which they were the initial expert. Mother Teresa is rightfully an example of an individual—a pioneer—who was sainted for her devotion to the cause of the poor, the sick, and the hungry. May we all look to her as an example for ethical behavior.

AGAINST THE PROPOSITION: Nicholas Detorie, Ph.D.

Opening Statement

Mother Teresa did not, to the best of our knowledge,[8] have a specific course in ethics. Would anyone doubt that she was an ethical person? This 20th century icon exhibited behavior based on the fundamental building blocks of ethics: honesty and integrity. She specifically illustrates that a course in ethics is not required for ethical behavior or even sainthood! We may not all be like Mother Teresa, but her example brings into focus two important issues related to the requirement of a specific educational "ethics" course: purpose and need.

From our professional perspective, what would be the purpose of such a course? Surely, it could not instill honesty and integrity, since these attributes are not learned by short-term exposure to discourse and dialogue in a traditional classroom setting. Honesty and integrity are assimilated over the long-term by association with individuals that behave in like manner. The purpose of a specific course would be acquisition of knowledge *per se*. Acquired knowledge in any profession requires a priority process. Becoming a Medical Physicist requires curricula that develop professional skills. Consequently, knowledge priorities are established emphasizing the technical aspects that help us contribute to better patient care. With knowledge *per se* as purpose, the ethics course yields little patient benefit. Does this mean that "ethical knowledge" is unimportant? No. It means that ethics is not a training priority compared with other knowledge that must be mastered in order to be professionally effective.

The second issue to consider is need. Think about various ethical issues that may arise in our professional practice. Plagiarism, data falsification, conflict of interest, software piracy, confidentiality, and author acknowledgement are just some that may come to mind. Have we not demonstrated an ability to deal with these issues? Is it possible that as a professional group, physicists are not behaving properly, and therefore need a course with a specific ethics focus? To address this question a National Science Foundation Grant was awarded to Wylo and Thomsen to conduct a survey of the physics community. They asked the question: Should physics students take a course in ethics?—Physicists Respond.[9] Survey results indicated that most physicists thought such a course would be helpful, but approximately only one third of the physicists in any given category thought an ethics course should be required. The perceived need for such a course is not strong.

A simple test may reveal your own bias regarding this issue. After reviewing the resume of two applicants for a medical physics position in your radiation oncology department—all other items and issues being equal—do you want to pursue the candidate that has the additional course in: (a) Physical Techniques for IMRT Planning and Delivery or (b) Research and Practice Ethics in Medical Physics. Picking (a) indicates your implicit agreement that a specific ethics course is not warranted at this time.

There is a role for ethics education in our profession that can be met by seminars and symposia that may sensitize us to current ethical issues. However, there is no well-defined purpose or documented need indicating that medical physicist entering the field should be required to take a specific ethics course.

Rebuttal

Mr. Switzer's asserted purpose for a specific ethics course for medical physicists includes: enhanced professional standing, uniform basis for ethical decision making, improved "respect" for self and colleagues and improved ethical knowledge. He has tried to identify a need for a specific course by enumeration of specific instances involving ethics: fetal dose calculations, advice to physicians regarding treatment, probability of radiation effects, employment relationships, and relationships with patients, medical colleagues, and vendors. His "ethics" purpose identifies only peripheral priorities and his need lacks validity.

The Medical Physicist is to the Radiation Oncologist/Radiologist as the Anesthesiologist is to the Surgeon. We improve patient care and aid our medical colleagues by providing professional competence, judgment, and technical consultations hewn from physics training. Behaving this way automatically enhances our professional standing amongst colleagues and patients and develops relationships of "respect." This behavior cannot be learned in a specific course. Mr. Switzer tacitly admits that ethical behavior is accrued over the long term via "background and heritage." The additional purpose, to improve knowledge via AAPM guidelines, realistically means Medical Physics knowledge, not knowledge of other subjects.

Regarding need, Mr. Switzer concurs that he is not claiming AAPM medical physicists lack ethics. I support his claim. My inquiry with the past and current chairs of the Ethics Committee, Dr. Hrejsa and Mr. Freedman,[10] indicates the yearly number of ethical "cases" has remained flat and may be decreasing. About 1 "case" per year potentially requires action. With almost 5000 AAPM members, the demonstrated need for a specific ethics course is practically nonexistent.

Without a better-defined purpose and need, medical physicists entering the field should not be required to have a specific course in their background. We should not consider surgery when a band-aid will do. Educational symposia are sufficient for our needs.

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9.4. Physicists are better educated for a career in medical physics if they graduate from a specialized medical physics graduate program rather than from a more traditional physics graduate program

Ervin B. Podgorsak and David W. O. Rogers
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OVERVIEW

Persons entering the practice of medical physics today are more likely to have graduated from a graduate program in medical physics than from a traditional physics graduate program. Some might say this is a good trend because entering physicists have a greater knowledge of the practice of medical physics. Others might say that to be a good medical physicist, one must first be a good physicist, and a graduate degree in traditional physics helps ensure the latter. They would claim that knowledge about the practice of medical physics can be acquired during postgraduate residency training. These opposing points of view are debated in this month's Point Counterpoint.

Arguing for the Proposition is Ervin B. Podgorsak, Ph.D. Dr. Podgorsak graduated in physics from the University of Ljubljana in Slovenia in 1968 and then obtained his M.Sc. and Ph.D. degrees in Physics from the University of Wisconsin in Madison. During 1973–74 he held a post-doctoral fellowship at the Ontario Cancer Institute in Toronto. Since 1975 he has been employed at McGill University in Montreal, where he currently holds positions of Professor of Medical Physics, Director of the Medical Physics Unit in the Faculty of Medicine, and Director of the Medical Physics Department at the McGill University Health Centre. He is board certified by the CCPM and the ABMP.

Arguing against the Proposition is David W. O. Rogers, Ph.D. Dr. Rogers has just taken up the Canada Research Chair in Medical Physics in the Physics Department of Carleton University. He has been part of the graduate program in Medical Physics at Carleton since 1986. Previously he worked at the National Research Council of Canada where he headed the Ionizing Radiation Standards group since 1985. His research is centered around radiation dosimetry-related measurement standards, clinical dosimetry protocols and the development and application of Monte Carlo techniques to medical physics problems.

FOR THE PROPOSITION: Ervin Podgorsak, Ph.D.

Opening Statement

During the past two decades medical physics has undergone a tremendous evolution, progressing from a branch of science on the fringes of physics into an important mainstream discipline that can now be placed on an equal footing with other more traditional branches of physics. To be productive in any of the traditional specialties of modern physics, physicists must not only possess a solid knowledge of general physics and science, but also a rigorous didactic graduate training in the specialty.

Many believe that medical physics is exempt from the requirement of didactic M.Sc. or Ph.D. training in medical physics, and prefer a model in which physicists with a graduate degree in a "straight" physics discipline can become a medical physicist through on-the-job academic and clinical training in medical physics. For practical reasons, this approach was historically the standard path to entering the medical physics profession. Now, however, this entry model should be discouraged in favor of a model that provides a well-defined and rigorous four-step progression to becoming a qualified medical physicist. The four steps are:

(1) Undergraduate degree in physics.

(2) Graduate degree in medical physics from a Commission on Accreditation of Medical Physics Educational Programs (CAMPEP)-accredited program.

(3) Residency in one of the medical physics specialties (e.g., radiotherapy physics, diagnostic radiology physics, etc.) at a CAMPEP-accredited institution.

(4) Certification in the particular medical physics specialty by an appropriate certification body (e.g., American Board of Radiology (ABR), American Board of Medical Physics (ABMP), Canadian College of Physicists in Medicine (CCPM)).

The sophistication of modern medical physics, as well as the complexity of the technologies applied to diagnosis and treatment of human disease by radiation, demand this stringent approach to becoming a member of the medical physics profession. On-the-job training simply does not provide, with the same degree of efficiency and quality, the depth and breadth of knowledge required of physicists entering the medical physics profession today.

Pioneers and early workers in medical physics came from traditional branches of physics such as nuclear physics, high-energy physics, solid-state physics, etc. By chance they ended up working in nuclear medicine, radiology or radiotherapy, and developed the necessary skills and knowledge through on-the-job training. In addition to clinical work, they also promoted medical physics as a science as well as a profession, and developed graduate medical physics educational programs, first through special medical physics courses offered as electives in physics departments, and later through independent, well-structured medical physics programs that lead directly to graduate degrees in medical physics.

Many graduate programs are now available to an aspiring medical physicist and progression through the four steps is feasible, albeit still somewhat difficult because of the relatively low number of accredited academic and residency programs in medical physics. The number of these programs is growing, however. We are now in a transition period and, within a decade, progression through the four steps will become mandatory for physicists entering the medical physics profession. The sooner broad-based didactic training through graduate programs in medical physics becomes the norm, the better it will be for the medical physics profession and for the patients the profession serves.

Rebuttal

"What does being educated for a career in medical physics mean?," asks Dr. Rogers, and answers with two essential elements: a physicist's approach to problem solving and having research experience. He then points out that these two elements can be obtained by progressing through a B.Sc. degree in physics to a graduate degree in any traditional physics discipline. However, Dr.

Rogers ignores one additional essential element of medical physics education: having the basic knowledge of all aspects of medical physics and a rudimentary knowledge of fields related to medicine such as anatomy and biology. Today, this knowledge is best attained from a well-structured academic graduate program in medical physics, rather than from on the job experience while working as a medical physicist.

Dr. Rogers points out that AAPM awards generally go to those who have come into medical physics from other branches of physics. This, of course, does not prove that coming into medical physics from elsewhere is better or even equivalent to coming from a graduate program in medical physics. It only highlights the fact that the award recipients are senior medical physicists who entered medical physics years ago from other branches of physics. In the past, didactic medical physics programs did not exist and medical physics and technology were far less sophisticated than today. I predict that AAPM awards in the not-too-distant future will start shifting to medical physicists educated in dedicated medical physics graduate programs.

Organizations offering medical physics certifications already recognize the importance of academic as well as clinical training in medical physics by insisting on a broad basic knowledge of medical physics during various components of the examination process. This basic knowledge is difficult, although, as Dr. Rogers points out, not impossible, to attain on the job where one is heavily involved with acquiring clinical experience and providing service to patients. Of course, a physicist trained in another branch of physics can become a medical physicist; the transition is not trivial, however, and is far less efficient than coming from an accredited graduate program in medical physics, cross-fertilization and diversity of backgrounds notwithstanding.

Another option, not debated here yet of some relevance to the debate, is entry into medical physics through an undergraduate B.Sc. program in medical physics. While in principle this may give the student an advantage in a subsequent medical physics graduate program, the early undergraduate concentration on medical physics occurs at the expense of general undergraduate physics as well as mathematics courses. This concentration adversely affects the students' subsequent graduate career in medical physics.

While other options remain open, presently the most efficient path to a career in medical physics is through the well-defined and rigorous four-step progression: (i) B.Sc. in physics; (ii) graduate degree in medical physics; (iii) residency; and (iv) certification.

AGAINST THE PROPOSITION: David Rogers, Ph.D.

Opening Statement

I have been involved with Carleton University's graduate program in medical physics since 1986. I feel strongly that good graduate education in medical physics is valuable. I am also one of a large number of medical physicists who joined the profession via other graduate degrees in physics, in my case nuclear physics. When my friend Ervin Podgorsak and I were approached to take part in this "debate," the original wording was "Medical physicists are better trained if . . . " rather than "educated." I would not debate the earlier proposition, which is obviously true. What we are actually debating in this Point/Counterpoint is the difference between "educated" and "trained."

What does being educated for a career in medical physics mean? It involves two essential elements. The first is having a physicist's approach to problem solving. The second involves having research experience to gain the ability to tackle new problems in a systematic way, beyond solving problems in a course or textbook.

Having a physicist's approach to problem solving is a characteristic learned in any good undergraduate physics education. A colleague who runs a large molecular biology laboratory with a half-dozen physicists and a dozen biologists makes the point that the physicists and biologists attack problems in completely different ways. We all recognize this fundamental aspect of our undergraduate education as physicists.

What we learn in graduate school is how to work independently on a problem. The question is, are we better educated if the problem is related to medical physics? There is no evidence that this is the case. In fact, I believe that medical physics is well served by physicists from other areas of physics joining the profession, because the variety of backgrounds is valuable. This diversity leads to strength and robustness in the profession. Those with other physics backgrounds must be properly trained before they work independently in a clinic, but we are debating education, not training. Medical physics is such a broad field that even someone with a graduate degree in the field must still learn most of the necessary specific knowledge and skills by working or training in a clinic.

At the AAPM awards ceremony every year, most of those receiving honors and awards have come from other branches of physics. These backgrounds can lead to very productive careers in medical physics. This is not just a generational issue which is now different for the younger generation. There are outstanding contributions to our field by those who were trained in other branches of physics in the last ten years.

Note that I am not arguing that physicists from other disciplines are better educated, only that they are equally well educated. I also recognize that a graduate degree in medical physics may be the most efficient path for someone to enter the field, but it is not the only path. Our field is well served by the breadth and diversity of the physics backgrounds of those entering the field. The fact that individuals with nonmedical physics degrees will take longer to become fully qualified to practice clinical physics should be seen as one of their personal contributions to medical physics. This diversity of backgrounds adds a distinct strength to the field, and I would argue strongly against restricting our discipline to those graduating from medical physics graduate programs.

Rebuttal

I concur with much of what Professor Podgorsak has written and certainly agree that the most efficient route for entering the profession is via a graduate program in medical physics (I will even agree it should be accredited once Carleton's program attains that status!). But I disagree that a well-educated physicist from any subdiscipline is limited to the field of their degree. Given time, a well-educated physicist can pick up the specific skills required to work in most other sub-fields, so long as individual talents are respected (i.e., most theorists are incapable of becoming experimentalists and vice versa). Making the switch may be inefficient for the individual involved, but all branches of physics benefit from cross-fertilization. For that reason I reject the notion that a degree from an accredited program is an essential step to becoming a certified medical physicist. Such a step would limit the breadth of experience of physicists entering the profession. The examination process for certification must be adequate to assess that an

individual has attained the necessary knowledge in medical physics. That said, I certainly agree that the easiest and fastest way to enter the profession is via a graduate education in medical physics.

9.5. Medical physics education programs should include an in-depth course in statistics and mathematical modeling of human anatomy and physiology

Donald E. Herbert and Gary A. Ezzell
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OVERVIEW

Medical physics is an experimental science based on data acquired with an imprecision that is quantified by statistics. Further, the applications of medical physics are expressed increasingly through the use of mathematical models of human anatomy, physiology, and pathology. Many claim that understanding and using these principles is essential to professionalism in medical physics. Others believe that these principles are peripheral to medical physics, and should not occupy prime time in the medical physics curriculum. These differing viewpoints are discussed in this issue of Point/Counterpoint.

Arguing for the Proposition is Donald E. Herbert, Ph.D. Dr. Herbert is Professor, Department of Radiology, College of Medicine, University of South Alabama; Director, COM Biostatistics and Epidemiology Core Unit, and Director, Biostatistics and Epidemiology Support Group, Comprehensive Sickle Cell Center. He was a member of the Committee on the Biological Effects of Ionizing Radiation of the National Academy of Sciences and a co-author of the committee's BEIR V Report (1990). He is a Fellow of the AAPM and has chaired several AAPM committees and task groups. He studied at Carnegie-Mellon University and Northwestern University (BS in Physics) and at Johns Hopkins University and the University of London (Ph.D. in Physics), and taught Physics at Colorado College.

Arguing against the Proposition is Gary A. Ezzell, Ph.D. Dr. Ezzell began practice as a clinical physicist in 1977 in Atlanta after receiving an M.S. from the Georgia Institute of Technology. In 1979 he moved to Mount Sinai Medical Center in Cleveland. He joined Harper Hospital and Wayne State University in Detroit in 1984, working clinically and teaching in the academic program. He received his Ph.D. in medical physics from Wayne State in 1994. In 2000 he joined Mayo Clinic Scottsdale as section head for physics in radiation oncology.

FOR THE PROPOSITION: Donald E. Herbert, Ph.D.

Opening Statement

Persuasive arguments in support of the proposed enrichments of medical physics academic programs can be found among the epigrams of the 1993 AAPM Report 43: 1) "Statistics is the theory and practice of matching theory to data." Since "matching" is what we do every day, it is important to be good at it. Moreover, 2) "It is possible to maintain ⋯ that statistics in its broadest sense is the matrix of all experimental science and is consequently a branch of scientific method, if not Scientific Method itself; and hence, that it transcends the application of the scientific method in sundry fields of specialization. The scientist should know statistics as he knows logic and formal language for communicating his ideas." [All science is either statistics or it's stamp

collecting! (Apologies to Lord Rutherford).] Furthermore, in our changing world medical physicists must become 3) *scientific generalists* who can "practice science—not a particular science," i.e., become more problem oriented and less discipline oriented. (The more insistent—and more interesting —problems rarely respect disciplinary boundaries.) A knowledge of statistics will equip medical physicists to become 4) "inference experts," i.e., "universal experts whose specialty is not so much a subject matter as a method of inference applicable to all subject matters." They can perform better as 5) "purveyors of the scientific method" to the medical profession, an increasingly important role. After all, "the product of a statistical analysis is not a posterior distribution, or a decision, or a *p*-value, or other summary of the data, but rather what a statistician produces is an argument . . . the whole argument, including the assumptions, the logical steps involved, and the conclusions . . . the role of diagnostics and sensitivity studies becomes central; we need to study how the argument is affected by changes in all the assumptions.[1]" Providing such arguments fall within the ambit of what can be expected of a physicist by his colleagues in medicine and administration as we continue through A. Relman's "Era of Assessment and Accountability[2]" with Evidence-based Medicine, Technology Assessment, Outcomes Research, the JCAHO's probabilistic definition of "quality," etc.

And surely not least are the ethical arguments: "So what is the relation between statistics and ethics? . . . Stated simply it is unethical to carry out bad scientific experiments. Statistical methods are one aspect of this. However praiseworthy a study may be from other points of view, if the statistical aspects are substandard then the research is unethical.[3]"

The case for including mathematical modeling (including nonlinear dynamical models)—for *insight* as well as for *prediction*—can be made just as easily: "Philosophers and historians of medicine identify and physicians themselves attest to two major . . . schools of medical thought." *Realism*, which "asks ontological questions, builds **deterministic models** and engages in . . . bench science," and *Empiricism*, which "asks epistemological questions, and offers **probabilistic models**" . . . "Probabilistic medicine eschews the questions of why, . . . and calls up the odds . . . .[4]" The medical physicist must be able to provide expert support and instruction in both schools.

Our world is changing fast. "Those who do not respond to their changing world will have decreasing influence in it.[5]"

Rebuttal

Dr. Ezzell presents the view that Statistics is not sufficiently important to warrant a required course in place of the current mélange of a few ad hoc disjoint, adjunctive, albeit crucial, techniques. But the need to apply appropriate statistical principles and methods arises as insistently and as frequently in the routine as in the research practices of medical physics, and is encountered as regularly by the M.S. as by the Ph.D. (although the need is too often either not recognized—"We see what we know"—or is ignored). Moreover, it now appears that the physicist may confront the need to teach Statistics to radiology residents for ABR examinations.

Unfortunately, Statistics is a broad and deep subject. Although fascinating, it demands considerable study to perform at the professional level of the medical physicist. It involves not only study design and data analysis but also the analysis of rival methods of design and analysis and the exercise of well-informed judgment in the selection of the most defensible and robust method, given the problem, context in which it arises, data (regrettably, data are never "given,"

but must be "gotten," and they are invariably biased by the presence of outlying, influential, and missing observations) and prior information available, and purpose(s) to be served.

The most efficient way to impart such knowledge is in a formal course. A required formal course also enforces the perceptions of both the difficulty and the importance of Statistics to medical physics practice. A formal course also teaches what remains to be learned and thus provides an effective beginning to the lifelong commitment to augmenting one's statistical knowledge that distinguishes the professional scientist. Otherwise, the physicist, like the physician in Shaw's *The Doctor's Dilemma,* risks drawing " . . . disastrous conclusions from his clinical experience because he . . . believes, like any rustic, that the handling of evidence and statistics needs no expertness." It happens, as a close reading of the literature attests.

AGAINST THE PROPOSITION: Gary A. Ezzell, Ph.D.

Opening Statement

There is no denying the importance of understanding the statistical principles fundamental to so many parts of our field. Examples are ubiquitous: Poisson statistics in radiation detection, ROC analysis in imaging, survival curves in therapy, *p*-values everywhere. The question is where to put the information in the curriculum. Is it better to have a separate course, as proposed, or to include those statistics that are relevant to each subject in the material for that unit?

The problem with the one course solution is that some of the material is so basic that it needs to be introduced early (e.g., counting statistics in nuclear medicine), and other topics are more naturally discussed later (survival curves). Would such a course be placed at the beginning of the program, along with such staples as radiation interactions, displacing some other introductory class? As a matter of curriculum design, one need only look at the web sites of CAMPEP-approved programs to see the preferred solution: None *requires* such a course, although several offer comparable electives.

This observation leads to the most persuasive argument against the proposition. Educational programs that are designed for people who want to finish with a Master's degree and go into clinical practice face a difficult dilemma. The number of credit hours needed for the degree remains more or less constant, but the knowledge that must be taught keeps increasing. Consider radiation therapy physics. Twenty years ago, students learned tissue-air-ratios, Clarkson integrations, and wedge pair techniques. Current students still need TARs, Clarkson, and wedges, but also need to understand pencil beam algorithms, dose-volume-histograms, and radiosurgery. In imaging physics, entirely new modalities such as MRI and PET have developed. Teaching is a zero-sum game in an expanding universe.

This is the key point: Requiring students to take a statistics course effectively requires them not to take something else. For example, in the Wayne State University program, after all the required courses are taken, a therapy-inclined M.S. student typically chooses two of three potential electives: External beam treatment planning, brachytherapy physics, or medical statistics. They have had some of each in the core curriculum, but now have the chance to go deeper. Very few choose statistics, simply because the other classes are more directly relevant to their anticipated needs.

The situation is very different for Ph.D. students, for whom such a course is likely to be pertinent and necessary. A researcher must master statistical concepts and modeling tools that underpin the techniques applied in the clinic. That such a course should be offered makes complete sense, but to require it of all students does not.

To make such a course available to all of us, students, recent graduates and established practitioners, makes even more sense. The proper response to expanding knowledge is life-long learning, and so would it not be good to have a series of CAMPEP-approved, remotely-directed classes in statistics, modeling, human-factors engineering, etc., available to the community? Program directors take note: Build it (on the web), and we will come.

Rebuttal

Dr. Herbert argues that all science has a statistical foundation, and so perhaps a working knowledge of basic statistical methods should be a prerequisite for any graduate work in our field. If we require calculus, perhaps we should require statistics.

I certainly grant the importance of clear analysis in the work that all medical physicists do. Most of us have quality assurance as a major component of our jobs, and deciding test frequencies and action levels is inherently statistical. Most of us do measurements, and every measurement report should have an error estimate. We certainly should be in the habit of thinking in these terms, and we should teach our students to do so. Our publications should exhibit more statistical rigor. Routinely we read of various factors expressed to one part in a thousand, but much less routinely is that precision explicitly defended. Our board exams should test candidates' ability to reasonably estimate accuracy and precision and to make justifiable decisions based on those estimates.

Does each educational program need to have a required course in statistics, or is it sufficient to imbue each course with the necessary statistical framework? I would argue that the latter is crucial, and the former optional. On average, anyway.

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9.6. Educational programs for imaging physicists should emphasize the science of imaging rather than the technology of imaging

Paul M. DeLuca, Jr. and Mitchell M. Goodsitt

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OVERVIEW

Some imaging physics educational programs focus on the cross-cutting principles of imaging, with specific technologies presented as applications of these principles. Proponents of this approach believe that it provides a solid foundation for trainees to work in any imaging field. Other educational programs emphasize knowledge of specific imaging technologies and their applications in the clinical setting. Advocates of this pathway feel that imaging physicists invariably confine their practice efforts to a specific technology (e.g., x ray and CT, medical, nuclear, ultrasound or MRI), and their educational experience should support this concentration of effort. This controversy is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is Paul M. DeLuca, Ph.D. Dr. DeLuca received a Ph.D. in nuclear physics from the University of Notre Dame, and immediately joined the University of Wisconsin as a Research Associate. Presently Dr. DeLuca is Professor of Medical Physics, Radiology, Human Oncology, Physics and Engineering Physics. He served as Chair of Medical Physics from 1987 to 1998. In 1999 he assumed a role in the Medical School as Associate Dean for Research and Graduate Studies, and his administrative role was expanded in 2001 with an appointment as Vice Dean. His research interests have concentrated on fast neutron production and dosimetry, determination of elemental neutron kerma factors, and application of microdosimetry to radiation dosimetry. He currently is Vice Chairman of the International Commission on Radiation Units and Measurements (ICRU). From 1999–2003 he served as a Chair of the Nonproliferation and International Security (NIS) Division Review Committee (DRC) at Los Alamos National Laboratory (LANL) and currently is a member of the LANL Threat Reduction (TR) Directorate Program Review Committee (PRC).

Arguing against the Proposition is Mitchell Goodsitt, Ph.D. Dr. Goodsitt received his M.S. in radiological sciences and Ph.D. in medical physics from the University of Wisconsin, Madison. After graduating in 1982, he became an Instructor of Radiology/Assistant in Physics at Harvard Medical School/Massachusetts General Hospital. From 1986–1992, he was an Assistant/Associate Professor at the University of Washington. In 1992, he moved to the University of Michigan, where he is presently Professor of Radiological Sciences. His primary areas of research are quantitative CT, mammography, and ultrasound. He presently directs a course on the physics of diagnostic radiology for residents and graduate students, guest lectures in the nuclear engineering department, and co-teaches an x-ray physics/CR lab for a biomedical engineering course. He is certified in diagnostic radiologic physics by the ABR and was recently elected a fellow of the AAPM.

FOR THE PROPOSITION: Paul DeLuca, Ph.D.

Opening Statement

As a confirmed experimentalist, my first instinct is to change places with Dr. Goodsitt! In any case, the previous 40 years of unimagined creativity in imaging science, demands an examination of the field of medical image science. Following the 1895 discovery by Roentgen, transmission radiography and fluoroscopy, fully conceptualized and partially developed by 1896, rapidly reached a mature state of affairs. The next 70 years showed modest advances in image receptors, source design, HV generators, and other aspects of image acquisition. New medical imaging modalities developed slowly in a methodical manner, including ultrasound and radionuclide-based imaging. By the early 1970s, however, one could sense an impending revolution.

Computer processor speeds increased at a prodigious rate, transistor gate densities increased exponentially, and processing power put early Cray-level computing power on desktops. Computed tomography started the onslaught of modern volume-image science. Magnetic resonance imaging devices added enormous capability to volume imaging and complemented CT imaging. Changes after 1980 were dramatic. High performance electronics, smart control systems, and enormous advances in large-area, fully-digital image receptors led to a broad range of imaging devices with ever more elegant capabilities to provide very high resolution, 4D image acquisition with highly adaptable acquisition strategies. Finally, modalities started to fuse to permit concurrent acquisition of physiological and anatomical information—the determination of function.

How then shall we prepare scientists (i.e., medical physicists), to work and perform research in this developing area? Traditionally, image science curricula were founded in the modalities, the physics of image acquisition. They usually commenced with so-called diagnostic imaging (transmission radiography), nuclear medicine imaging (often not including PET), ultrasonic imaging, thence volume imaging (CT and PET), and perhaps aspects of specialized digital imaging (e.g., DSA). While satisfactory 30 years ago, this curriculum fails to capture the underlying common image formation concepts and mathematics. The principles of image formation are quite general and apply to all modalities. In fact, the underlying mathematics (the inverse problem), is widely applicable across volume imaging. This was first recognized by an early publication of the ICRU,[1] and more recently in the outstanding text by Barrett and Myers[2] (2004). Casual reading of the latter's table of contents emphasizes the broad nature of the math and statistics of image formation. With this foundation, a curriculum built on these overarching principles can with confidence proceed to a discussion that builds on determining the underlying biological functionality, while including the prerequisite anatomical information in the broad context of the underlying math and physics. Modality-based discussion is presented in the context of the interrelation amongst modalities and their concomitant ability to determine function. This is precisely the direction of the recent recommendation of the AAPM guidance documentation.[3]

Rebuttal

As expected, Dr. Goodsitt and I are actually rather close in our thinking as well as our shared concerns about learning, namely can instruction and learning realistically be bifurcated into theory and practice without compromising understanding. It truly is a matter of degree!

However, this conundrum is more or less exactly the situation encountered in undergraduate physics or engineering. Quite often introductory physics courses, even for physics majors, are taught without a solid foundation in calculus, differential equations or special functions. These courses often include electricity and magnetism or classical mechanics. In these situations, and as correctly noted by Goodsitt, in some manner or other the underlying math is taught concurrently with the physics! Time and time again, this process has resulted in less than adequate preparation

for graduate level physics—perhaps adequate for a B.S. degree, but deficient for Ph.D. level courses. In comparison, when calculus through differential (or partial differential if possible), special functions, and linear algebra are well understood, mechanics and electromagnetic fields take on the beauty and symmetry that truly makes them forever understood. Coming from the former process, I still struggle with even modestly complex electromagnetic field theory having first learned E&M without the needed mathematics.

Even so, the contrary view, defended by Goodsitt, has clear merit when the understanding of the imaging process is very tightly coupled to the modality under study. In fact accepting that viewpoint leads exactly to the problem. Namely, students, after a year or so of modality-based instruction, are now challenged to understand the broad common footings that underpin all modalities. Frustration sets in, or even worse the student never clearly grasps the common underlying elements of the image formation process. Image processing in astrophysics or space science starts from the first principal approach for exactly this reason. Goodsitt makes exactly this point when he states "When students start out in a medical physics program, many have not yet decided which modality or modalities to specialize in ⋯ this can change later in their careers ⋯ research in multimodality and multiscale imaging has a promising future. Thus, it is beneficial for the students to learn the fundamentals of each imaging modality to a substantial depth, because they may eventually use those modalities in their research." These remarks embody the compelling need for a common underpinning in training and on this point we agree!

AGAINST THE PROPOSITION: Mitchell Goodsitt, Ph.D.

Opening Statement

I do not think this is an either/or proposition. Rather, I believe that to produce well-rounded imaging physicists, the education curriculum should emphasize both the technology and the science of medical imaging. The debate, as I interpret it, is more a choice of which to emphasize first, the physics and technology or the generalized mathematics of medical imaging. I believe it would be a great disservice to the majority of imaging physics students if the education programs first emphasized the generalized mathematics and cross-cutting principles of imaging (e.g., impulse response functions) at the expense of the physics and technology. I base this opinion on my experiences as a student, teacher, and researcher. There is a great diversity of skills and backgrounds of students who enroll in medical physics educational programs (e.g., students with undergraduate majors in physics, biophysics, bioengineering, biology, computer science, mathematics, etc.) Having a curriculum that starts with courses on the physics and technology of each major modality would benefit the majority of these students. First and foremost, it teaches the students the fundamentals of each modality to a sufficient depth that the students can better appreciate the meanings of the equations they will learn in imaging mathematics courses. Second, in many cases the physics courses provide students with introductory and conceptual treatments of imaging topics such as Poisson statistics, the sampling theorem, convolutions, Fourier transforms, etc. that many of the students will need to better comprehend the far more in-depth treatments of such topics in imaging mathematics courses. When I was a student at the University of Wisconsin, our curriculum followed this approach, and it worked very well. Since then, in my teaching experience, I have observed the results of the opposite ordering of courses, wherein students first take a class devoted to generalized mathematics of imaging science. These courses typically involve very brief introductions to topics followed by derivations of fairly complex mathematical equations related to the topics. For example in Macovski's excellent

Medical Imaging Systems textbook,[4] which is employed in many of these courses, 31/2 pages are devoted to deriving the generalized transmission equation for a parallel grid:

$$T(\theta) = \left\{ \frac{1}{s}[(n+1)s - h\ \tan\ \theta]e^{-n\mu t/\sin\ \theta} + (h\ \tan\ \theta - ns)e^{-(n+1)\mu t/\sin\ \theta} \right\},$$

$$\tan^{-1}\left(\frac{ns}{h}\right) < \theta < \tan^{-1}\left[\frac{(n+1)s}{h}\right],$$

where $T(\theta)$ is the transmission at angle θ relative to the normal, n is an integer that takes on values between 0 and infinity, t is the thickness, h is the height, μ is the linear attenuation coefficient, and s is the period (= 1/frequency) of the grid strips.

All of us can appreciate the elegance of this equation and other equations that appear in this text. The problem I have witnessed is that the students and instructors frequently concentrate on the mathematics of imaging science to the detriment of basic principles such as knowing the purpose of grids and their effects on image quality and patient dose. Such concepts are best taught first in a less mathematically rigorous course devoted to the physics and technology of x-ray imaging.

When students start out in a medical physics program, many have not yet decided which modality or modalities to specialize in. Even after they've decided on a specialty, this can change later in their careers. Furthermore, as described at the 2003 Biomedical Imaging Research Opportunities Workshop,[5] research in multimodality and multiscale imaging has a promising future. Thus, it is beneficial for the students to learn the fundamentals of each imaging modality to a substantial depth, because they may eventually use those modalities in their research. Once this is accomplished it is logical to progress to the generalized mathematics of medical imaging courses, where as stated by Macovski in the preface to his textbook, "a formal mathematical structure is provided, which should prove useful for the reader interested in further more detailed analysis."

Rebuttal

I hate to be the old fogey here, but what worked in medical physics education 30 years ago can still work very well today. It just has to be updated to include new technology (e.g., DR, multidetector helical CT, MRI, PET, image fusion, etc.) The AAPM Report[3] that Dean DeLuca cites doesn't disagree with my thesis — it recommends for image science, "modality-driven material as well as overall materials such as the inverse problem, signal processing, etc." The AAPM report promotes freedom in curriculum design such as combining and redistributing topics, but the core curriculum that is outlined is basically the same as it was 30 years ago with the updates mentioned above. The new textbook *Foundations of Image Science* by Barrett and Meyers[2] that is recommended by Dean Deluca does appear to be outstanding. It contains over 1500 pages of text, with probably about as many equations, covering topics such as linear vector spaces, eigenanalysis, singular-value decomposition, pseudoinverses and linear equations, etc. I still fear that students using this as their first textbook in medical imaging will be overwhelmed by the complex mathematics and lose sight of the general principles. While there may be a few exceptional students who would do fine, the majority would be better off the old way, starting with the basic imaging physics for each modality and ending with unified imaging theory and mathematics.

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9.7. Engineering is preferred over physics as an undergraduate preparation for diagnostic and nuclear medical physicists

John D. Hazle and Charles R. Wilson

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OVERVIEW

Diagnostic and nuclear medical physicists are engaged in the application of science and engineering principles to solve technical challenges in medical imaging. Graduate educational programs for medical physicists usually cover the science (especially physics) principles, but the applied science (i.e., engineering) principles often are not emphasized. For that reason, some physicists prefer to hire graduates of medical physics programs who have an engineering background at the undergraduate level. This issue is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is John D. Hazle, Ph.D. Dr. Hazle is Associate Professor and Chief of Imaging Physics at The University of Texas M. D. Anderson Cancer Center. He is a past president of the Southwest Chapter and was recently elected as an at-large member of the AAPM Board. Dr. Hazle actively participates in the M. D. Anderson graduate program in medical physics and is Director of the Imaging Physics Clinical Residency Program. His research is focused on developing temperature sensitive MR imaging techniques for monitoring minimally invasive thermal therapies, and on developing a small animal cancer imaging research program. Dr. Hazle has been an ABR oral examiner and was a member of the ABMP MR Physics Examination Development Committee.

Arguing against the proposition is Charles R. Wilson, Ph.D. Dr. Wilson is Associate Professor in the Department of Radiology at the Medical College of Wisconsin. He is head of the Medical Physics & Imaging Science Section of the Department. He has served the AAPM on a number of committees and currently is Chair of the Diagnostic X-ray Imaging Committee. He is certified in Radiological Physics by the American Board of Radiology and is a fellow of both the AAPM and the ACR.

FOR THE PROPOSITION: John D. Hazle, Ph.D.

Opening Statement

Medical imaging is nearing the end of the digital revolution. Digital solutions are available for most imaging modalities. Ultrasound, x-ray computed tomography (CT), nuclear imaging, digital subtraction angiography (DSA), and magnetic resonance (MR) are inherently digital. Digital chest projection x-ray systems (using computed radiography and direct digital technologies), and full-field digital mammography are now FDA approved. So what does this evolution have to do with proper undergraduate preparation in medical imaging physics? In my opinion, everything.

Not so long ago, we were concentrating on using our knowledge of radiation interactions with matter to develop detectors optimized for imaging applications. Achieving adequate image quality at acceptable patient and personnel doses presented significant challenges. An

undergraduate education in physics provided the best foundation for addressing these challenges. However, the clinical problems confronting the imaging scientist today are focused more on optimizing system performance, and less on radiation dose. Dose is still important, but is at a more manageable level than 10–20 years ago.

Medical imaging technologies are more mature today, and an array of digital systems is available to replace screen-film technology. Imaging physicists are increasingly asked to address problems created by the complex data pathways of modern imaging equipment. These problems include the application of image filtering algorithms to achieve better signal-to-noise and/or latent image properties (e.g., optimizing edge enhancement filters for digital chest imaging), the use of transfer functions to convert typically linear response functions to functions matched more closely to the human visual system (i.e., logarithmic functions for hardcopy filming or soft copy reading on computer display monitors), and employment of post-processing algorithms to further optimize or condense data into a presentable format (i.e., calculating functional MR maps from thousands of source images). The proliferation of digital imaging equipment and PACS will increase these demands. A background in electrical engineering provides a firmer foundation in practical mathematics, signal processing and systems optimization techniques for solving these problems. Computer science/engineering is also a significant skill requirement in support of PACS. To be honest, computer engineering as it exists today probably does not include enough rigorous math and physics education for clinical imaging physics.

Functional imaging is a new frontier for medical imaging. As molecular imaging agents become more available, we will be less concerned about the shapes (morphology) of organs or tumors and more interested in their functional properties. Nuclear imaging (PET and SPECT) and MR will lead the way in functional imaging. A bioengineering background provides a better foundation in physiology and biology for this imaging application.

In summary, engineering is becoming a preferred *undergraduate* preparation for graduate work in medical imaging physics. Undergraduate physics programs are not preparing students as well for graduate work in medical imaging physics, and ultimately as clinical scientists. Imaging physics graduate students with physics undergraduate degrees seem to have more difficulty learning physiology, systems theory, computer and communications sciences compared with engineering students. Finally, the diminishing numbers of students entering undergraduate physics programs is of concern. If we accept that engineering undergraduate preparations are good for medical imaging physics, then we should forge closer relationships with undergraduate engineering programs to promote medical imaging physics as a profession.

Rebuttal

Dr. Wilson and I agree that the practices and technologies associated with medical imaging physics will be substantially different in five years. We also agree that undergraduate engineering is more "focused on problem solving and practical solutions" than conventional physics undergraduate training. However, we disagree as to whether this is an advantage or disadvantage. I believe it is an advantage.

As we move into the next decade, the role of the clinical medical physicist will continue to evolve as an expert technical problem solver. We are increasingly asked to dissect complex systems and solve practical problems in digital imaging, signal processing, and systems integration. While it is intellectually stimulating to consider the "spherical chicken," clinical

medical physics is very much an applied science. A significant fraction of our value to the healthcare enterprise is our ability to develop solutions to complex problems. Our value as researchers is not only basic technology development, but bridging the gap between the clinician (radiologist, radiation oncologist, neurosurgeon, etc.) and the imaging equipment in support of translational and clinical research.

In summary, physics undergraduate degrees served our generation well, and will probably serve our successors well in the future. However, an undergraduate engineering curriculum will likely serve future medical imaging physicists better than physics as an undergraduate degree in the next millennium.

AGAINST THE PROPOSITION: Charles R. Wilson, Ph.D.

Opening Statement

A restatement of the proposition posed in this month's Point/Counterpoint feature is: "Given equivalent graduate medical physics training, an individual with an undergraduate background in engineering will be a better medical physicist than one who was a physics major." I am speaking against the proposition because I believe that engineers and physicists approach problems differently and that these differences are established during the undergraduate years. In my opinion, the individual with a physics background is better equipped to deal with future advances in medical imaging. The practices and technologies of medical imaging will be substantially different in five years, and the individual best equipped to deal with those changes will be one with physics training and a broader perspective of the physical world.

Graduate programs in medical physics cover the physical and mathematical principles underlying medical imaging. Graduate courses deal with the production and detection of ionizing and nonionizing radiation and their applications to medical imaging. Mathematical tools and concepts such as MTF, DQE, noise, and ROC for the quantitative analysis of images are included in the medical imaging physicist's graduate training program. Whether an individual has an undergraduate background in engineering or physics makes little difference in his/her ability to master this body of knowledge. In either case, students will have had courses in calculus, statistics, physics, electricity, magnetism, mechanics, etc. However, the fundamental approach to problem solving is very different between engineering and physics.

I have first-hand knowledge of the differences between undergraduate physics and engineering. During my first two undergraduate years, I was an engineering student and took core engineering courses. In my third year, I switched from engineering to physics. In engineering, the curriculum was focused on problem solving and practical solutions. In physics, on the other hand, we focused on understanding the physical world. We were interested in solving problems, but the solution was not the primary goal. The contrast between the disciplines was apparent in the way professors approached their subjects. In the engineering course on electricity and magnetism (E&M), I analyzed many circuits and learned how to design a transformer. In the physical E&M course, when the professor presented Maxwell equations and their applications he would often begin by saying, "Let us postulate a spherical chicken . . . ." While I enjoyed solving practical engineering problems, I found the physics approach to understanding the physical world to be more satisfying.

I believe the differences in approach make individuals with a physics undergraduate background better able to find unique, innovative approaches to medical imaging challenges. When confronted with a problem, the individual trained as an engineer may not recognize the forest for the trees. An individual with a physics background is better able to step back and see both the forest and the trees. It is this ability to see the larger picture that I believe makes medical physicists with undergraduate physics training better positioned to the future challenges and opportunities of medical imaging.

Rebuttal

Dr. Hazle argues that specific problems confronting the medical imaging physicist in image and signal processing, PACS system administration and functional imaging require training and background specific to the problems. He believes that electrical engineering provides a better foundation for dealing with image processing algorithms than does an undergraduate physics background. He also feels that biomedical engineering provides a better background than does physics for individuals working in the field of functional imaging.

While I agree with Dr. Hazle that certain engineering backgrounds are useful for preparing an individual to work in specific medical imaging fields, I believe that the mathematical and computer skills of individuals with a physics background are comparable to those of persons with an engineering background. Furthermore, I believe that the individual with a physics background who has been trained in the scientific method has superior analytical skills and is better prepared to handle new challenges in medical imaging. What happens when the current specific problems in medical imaging are solved or replaced by problems with new imaging modalities? Will the medical imaging physicist with an engineering background be versatile enough to handle the challenges presented by new technologies? I believe that undergraduate physics training with its emphasis on scientific methodology better prepares the medical imaging physicist to handle current and future medical imaging challenges.

In Dr. Hazle's summary he states that imaging physics graduate students with a physics undergraduate degree seem to have more difficulty learning physiology, system theory, etc., compared with students with an engineering background. In my experience with graduate students in both medical physics and biomedical engineering the capability to grasp certain concepts depends more upon the individual's ability rather than on the student's background and training.

9.8. With the expectation that cancer detection and treatment will occur increasingly at the molecular and gene levels, medical physics trainees should take courses in molecular biology and genetics

Barbara Y. Croft and Colin G. Orton

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OVERVIEW

The National Cancer Institute is making a major investment in research at the molecular and genetic levels with the expectation that, in the future, cancer diagnosis and treatment will occur at a more fundamental level. This occurrence is expected to replace, to a large degree, current ''half-way treatment technologies'' such as radiation and drugs that are extraordinarily expensive and often less effective than desired in curing cancer. In anticipation of this development, one could argue that medical physicists should be knowledgeable about molecular biology and genetics through coursework taken during their training. On the other hand, medical physics is a highly sophisticated discipline, and the curriculum for educating physicists is already overloaded with technical courses and required training and research experiences. None of these courses or experiences can logically be dropped to make room for new courses that anticipate future needs but do not address present knowledge requirements for physicists. Whether molecular biology and genetics should be added to the curriculum for medical physicists is debated in this issue of Point/Counterpoint.

Arguing for the Proposition is Barbara Y. Croft, Ph.D. Dr. Croft is a Program Director in the Biomedical Imaging Program of the National Cancer Institute. Prior to joining the NCI, she was a member of the Radiology Department of the University of Virginia. She is best known for a SPECT book and a radiopharmacy textbook. She has served on national committees concerned with the use of ionizing radiation in medicine. Since joining the NCI, she has been working with all aspects of funding medical imaging research, especially small animal imaging.

Arguing against the Proposition is Colin G. Orton, Ph.D. Dr. Orton is the Director of Medical Physics and Professor of Radiation Oncology, Karmanos Cancer Institute and Wayne State University in Detroit. He is Director of one of the first accredited medical physics graduate programs, with over 150 M.S. and Ph.D. graduates. He has practiced radiation oncology physics for the past 35 years. Throughout his career one of his major research interests has been radiobiological modeling and he has taught courses in radiation biology annually to residents, therapists, and physicists. He is a Past President of the AAPM, Past Chairman of the ACMP, and is currently President of the International Organization for Medical Physics.

FOR THE PROPOSITION: Barbara Y. Croft, Ph.D.

Opening Statement

Medical Physics trainees should take courses in molecular biology and genetics.

The world is changing as molecular and cellular biologists and geneticists learn more about processes that hold cells together, occur inside cells, and transmit properties from one cell generation to the next. At some level all biology is chemistry and all chemistry is physics. We are moving from an era in which biology was a descriptive science to one in which chemical and physical processes will dominate.

The effect that this has on the medical physicist is that he/she can expect to interact daily with biologists whose background in the physics of imaging is scant, but who wish to apply imaging to biological models because of what it can reveal about animal models of disease. The mouse genome is 95% similar to the human (the remaining 5% is the mouse's whiskers and tail and our skin pigment, for example). Because of this similarity and because mice are small, breed rapidly, and live their lives quickly on a human scale, mice are a convenient model for human disease, whether it be cancer, renal or heart disease. The possibility of studying a model of human disease through the life cycle of an individual mouse, and to use that model for testing treatments, excites molecular and cellular biologists and geneticists. The animal can be kept intact if the biological processes can be imaged. In turn, imaging methods used to validate mouse models and treatment methods can be applied to human sufferers of disease. The medical physicist cannot be a fully contributing partner with the biologist in this work unless he/she has a basic knowledge of the principles employed.

This is not to say that the medical physicist forsakes training in his/her own field of interest in deference to molecular and cellular biology and genetics. Instead, I suggest that too great an adherence to the purity of physics and engineering means that the physicist will have great tools but no co-investigators and be of little interest to others. It is very exciting to contribute to advances in medical physics and simultaneously in medical science.

In the future, the medical physics curriculum will need to be periodically re-examined with respect to biology as well as physics. The biological sciences will need to be integrated with the practice of medical physics in the hospital and medical laboratory.

As for the issue of a place in an already-crowded curriculum, we have to make room for courses that inform the trainee about the circumstances to be faced in his/her future. These are additional opportunities for learning beyond core courses, including short courses, seminars planned around a theme, visiting professorships, etc. Trainees seem to find time to learn the computer languages they need, for example, even though they are rarely part of the core curriculum of a medical physics program.

Rebuttal

Dr. Orton's position is that what was good enough for us when he and I were growing up is good enough for current and future generations. It is my contention that there is a new day dawning, not only in cancer diagnosis and treatment, but in all medical specialties that depend on imaging. That new day is typified by a complete knowledge of the human genome, of the use of this knowledge in the examination of normal and abnormal gene expression, and of the ability to apply molecular biological principles in the treatment of disease.

I do see the likelihood for greatly increased use of medical imaging, and, in particular, what is called ''molecular imaging,'' in diagnosis and treatment of disease. I see a great potential for the principles of molecular biology to be used in the service of imaging for treatment planning, for

treatment follow-up, and in treatments themselves, in radiation therapeutic methods as well as those based on ultrasound and optical principles.

It is said of the army that they train their recruits for the last war. We want to prepare our trainees for diagnosis and therapeutic methods of the future. It is shortsighted for us to decide that the current curriculum is sufficient for the challenges our trainees will meet.

And of course, I am not advocating making molecular biologists out of medical physics students, but of educating them in the principles of molecular and cellular biology and genetics, so that they can work with scientists who think in these terms.

AGAINST THE PROPOSITION: Colin G. Orton, Ph.D.

Opening Statement

As with any profession, knowledge is everything. Medical physics is no exception. The problem is where do we draw the line. Life is too short to learn everything. I have no doubt that molecular biology and genetics research will play increasing roles in cancer prevention, detection and treatment over the next several decades. It might even be argued that some specialists of medical physics such as radiotherapy may become obsolete if cancer can be prevented by genetic intervention. Personally, I do not buy that argument, however, because it reminds me of over 30 years ago when I first started my career as a radiation oncology physicist when colleagues told me I was crazy to specialize in cancer treatment now that genetic research was about to conquer the cancer problem. Certainly molecular biology and genetics research have come a long way since that time, but cancer incidence and mortality, and the concomitant use of radiotherapy, have continued to *increase*, not decrease.

I strongly doubt that medical physicists will be less able to perform their duties if they have not taken complete courses in molecular biology and genetics. Indeed, I believe that being required to take such courses will be detrimental, since this will mean that other, more appropriate courses will need to be excluded from the curriculum at a time when technological developments are forcing medical physicists to become even more specialized than ever in order to practice effectively. As director of a graduate medical physics program for many years, I can think of several other courses more appropriate than molecular biology and genetics that we would like to add to our list of required courses if they could be included in the students' already busy schedules. I believe that it is our primary responsibility as educators to provide our students with a thorough knowledge of the basic principles of medical physics and how to apply them. This should be the major consideration in the design of courses for our teaching programs. There are numerous peripheral topics that deserve some attention, but not complete courses.

I think molecular biology and genetics could be included in this category. In the radiobiology course that I teach, for example, we devote one two-hour lecture to these topics. Complete courses on these subjects are available in other departments should individual students want to include them in their electives. However, few students have been able to take advantage of these opportunities because they either have too little time or, more importantly, they do not have the prerequisites in biology and biochemistry to enable them to understand, or even be allowed to take such courses.

In summary, I believe that trainee medical physicists have enough to learn without having to take extra courses in topics such as molecular biology and genetics that are interesting but not

essential to their practice, and for which they are unlikely to have sufficient background knowledge to appreciate.

Rebuttal

I feel that I must respectfully disagree with all of Dr. Croft's arguments. She states that, because medical physicists have somehow found time to learn computer languages, they will also find the time to learn molecular biology and genetics. She is mistaken. Most medical physicists have learned that it is smarter to leave programming to programmers. What we have done is learn to use computers, and we have been able to do this readily because we understand the basic mathematics behind them. Unfortunately, the same is not true for molecular biology and genetics, because few medical physicists possess sufficient basic biology and biochemistry knowledge to be able to benefit significantly from trying to learn these topics without extensive preparative study in the basic biological sciences.

Dr. Croft further argues that medical physicists need to know molecular biology so that they can collaborate with biologists to image biological processes in experimental animals like mice. Frankly, I think most medical physicists would abandon their profession if they thought this was their destiny.

Finally, let me respond to Dr. Croft's assertion that, if they do not learn molecular biology and genetics, ''...physicists will have great tools but no co-investigators and be of little interest to others.'' Dr. Croft, physicists have developed x-rays, radiology, radioactivity, nuclear medicine, PET, RIA, CT, MRI, and IMRT, to name but a few. Some tools? Some interest?

9.9. The concepts of transient and secular equilibrium are incorrectly described in most textbooks, and incorrectly taught to most physics students and residents

William R. Hendee and Daniel R. Bednarek

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OVERVIEW

Many medical physicists believe that transient equilibrium between parent and progeny radionuclides occurs when both are decaying at the decay rate of the parent. They also believe that secular equilibrium occurs when the half-lives of parent and progeny are greatly different, and the activities of the two are equal. These beliefs are explored in this Point/Counterpoint from mutually opposing points-of-view.

Arguing for the Proposition is William R. Hendee, Ph.D. Dr. Hendee received the Ph.D. degree in physics from the University of Texas. He joined the University of Colorado, ultimately serving as Professor and Chair of Radiology for several years. In 1985 he moved to Chicago as Vice President of Science and Technology for the American Medical Association. In 1991 he joined the Medical College of Wisconsin, where he serves as Senior Associate Dean and Vice President and Dean of the Graduate School of Biomedical Sciences. His faculty appointments are Professor and Vice Chair of Radiology, and Professor of Bioethics, Biophysics, and Radiation Oncology. He also is Professor of Biomedical Engineering at Marquette University.

Arguing against the Proposition is Daniel R. Bednarek, Ph.D. Dr. Bednarek received his doctoral degree from the University of Chicago in 1978 and is certified in Radiological Physics by the ABR. He is a Professor in the Department of Radiology at the State University of New York at Buffalo and clinical medical physicist at the Erie County Medical Center. He was a charter member of the AAPM Commission on Accreditation of Educational Programs for Medical Physicists and has served the ABR as an oral examiner and as a member and chair of the diagnostic radiology physics written examination committee.

FOR THE PROPOSITION: William R. Hendee, Ph.D.

Opening Statement

In thinking about radioactive equilibrium, let's start with definitions. According to Webster's International Dictionary: Equilibrium: a state of balance between or among opposing forces or processes resulting in the absence of acceleration or the absence of net change; a state of dynamic balance (as of a liquid at the boiling point) in which two or more simultaneous opposing processes (as vaporization and condensation) proceed at the same rate and thereby cancel each other's effects. Transient: impermanent, transitory, short-lived, momentary, ephemeral. Secular: of or relating to a long enduring process; requiring or taking ages.

In the context of radioactivity, equilibrium defines a balance between the rate of formation of a radioactive product, and its rate of decay. When equilibrium (state of balance) is achieved, these

two rates are equal, and no change occurs in net radioactivity. At equilibrium, the activity of the product is constant, and is at its maximum level.

Transient equilibrium defines an equilibrium condition that exists for only a moment in time. Before this moment, the product activity is growing more rapidly than it is decaying, and the net activity of the product is increasing. After the moment of equilibrium, the product activity is decaying more rapidly than it is growing, and the net activity is decreasing. It turns out that this net activity decreases with an "apparent half-life" equal to the half-life of the radioactive parent, because it is the decreasing amount of parent that causes a diminution in the activity of the product. There is, however, nothing "in equilibrium" associated with this apparent half-life. It is also true that at the moment of transient equilibrium, the activity of the parent and product are equal for situations where all of the parent decays to the product. This observation in itself also does not connote an equilibrium condition.

Secular equilibrium defines a special case of transient equilibrium in which the half-life of the parent is very long compared with that of the product. In this case the product activity approaches but never truly achieves equilibrium. After a time, however, the rate of change of product activity is so small that the activity of the product appears almost constant (i.e., neither increasing nor decreasing over time). This condition satisfies the meaning of "secular:" of or relating to a long enduring process.

Many texts have obfuscated the meaning of equilibrium by statements such as "In equilibrium, both activities decay with the parent's half-life." [1] "When the ratio of the activities of daughter to parent is constant, a particular type of radioactive equilibrium exists. This is spoken of as transient equilibrium." [2] "In the state of equilibrium . . . the daughter radioactivity decays with an apparent half-life of the parent radionuclide rather than its own." [3] "In transient equilibrium, parent and daughter decay together, with the half-life of the parent." [4] "The daughter nuclide . . . reaches a maximum, and then achieves the transient equilibrium decaying an apparent half-life of the parent nuclide." [5]

However, some texts get it right. For example, "In the ^{132}I–^{132}Te example, transient equilibrium occurs (1) at only one instant in time; (2) when ^{132}Te reaches its maximum activity; (3) when the activity of ^{132}Te in the sample is neither increasing nor decreasing; and (4) when the activities of ^{132}I and ^{132}Te are equal." [6] As another example, "After approximately 23 hours the Tc-^{99m} activity reaches a maximum, at which time the reproduction rate and the decay rate are equal and the parent and daughter are said to be in *transient equilibrium*. Once transient equilibrium has been achieved, the daughter activity decreases with an apparent half-life equal to the half-life of the parent." [7] And some texts are ambivalent, for example, "The second segment of the (activity) curve traces what is called the period of equilibrium, during which time the amount of daughter nuclide decreases as the parent nuclide decays." [8]

I will admit that all of this is a bit academic; most of us understand the applications of radioactive equilibrium even if we may not define it properly. But then again, definitions in medical physics really should be aligned closely with scientific principles.

Rebuttal

I appreciate the thoughtful and succinct position statement prepared by my colleague in response to this month's Point/Counterpoint. There are, however, several points in his position statement that I take issue with.

First, I agree that "terminology is used incorrectly when its use is contrary to a generally accepted meaning." That is the reason for my reference to definitions for "equilibrium," "transient," and "secular" available in Webster's International Directory. It is important that uses of words in medical physics not wander from the established definition of those words in science and literature.

Those of us who write textbooks know of the possibility of fallible information in such sources. Often this fallibility is a product of extrapolating concepts and definitions across several references. Citing several textbooks as justification for a definition is risky: the authors may simply be reading and using each other's publications.

I take issue with the comment that the definitions of transient and secular equilibrium offered in my position statement represent "deviant" definitions. They are "deviant" only insofar that they attempt to return the definitions of these concepts to well-accepted meanings in the wider world of science.

The National Council on Radiation Protection and Measurements is an invaluable resource for establishing radiation protection guidance, and it does view its mission as "representing the consensus of leading scientific thinking" in this arena. I am an honorary member of the Council, having completed 16 years of service on the Council in 2002. In none of the Council discussions in which I participated do I recall any effort to establish definitions of fundamental concepts such as radioactive equilibrium. I don't believe the Council would extend its mission to such activities.

As stated in my position statement, the subject of this Point/Counterpoint is a bit academic. A reader who has followed the discussion certainly will understand the concept of radioactive equilibrium and its applications in medical physics—which is, of course, the most important objective to achieve.

AGAINST THE PROPOSITION: Daniel R. Bednarek, Ph.D.

Opening Statement

The question of whether the concepts of transient and secular equilibrium are incorrectly described and incorrectly taught is not one that can be answered by mathematical proof or scientific fact. This question is answered by defining what is meant by "incorrect." I would submit that terminology is used incorrectly when its use is contrary to a generally accepted meaning. To use the terms transient and secular equilibrium in a manner that is inconsistent with what is described in most textbooks would be incorrect usage. The proposition then is an inherent contradiction since in language, common usage determines the meaning of words.

What definition could the terms transient and secular equilibrium have other than as generally taught? I could find only two sources[6,9] where these terms have been unambiguously defined differently than in the above overview. In those references transient and secular equilibrium are described as existing "only at a single moment in time at which the rate of formation and the rate of decay of the daughter are exactly equal." [9] In both sources, no supporting documentation for this deviant definition is given. In fact, this moment has been identified by Evans[2] and by Marmier and Sheldon[10] as "ideal equilibrium." Both Khan[11] and Andrews *et al.*[12] have strongly refuted the concept of single-moment transient and secular equilibrium.

As the proposition acknowledges, the majority of textbooks utilize the definition of transient and secular equilibrium described in the above overview. Where does this currently accepted usage come from? It comes from historical precedent and from acceptance by authorities in the field. Makower and Geiger[13] as early as 1912 provided a definition for transient equilibrium that is consistent with current teaching. R. D. Evans, a recognized authority, explicitly defines transient and secular equilibrium in this manner,[2] while Andrews *et al.*[12] give a list of ten classic references that support "the generally accepted definition and understanding of these terms." Furthermore, this meaning is as defined by the National Council on Radiation Protection and Measurements,[14] which has a mission to "represent the consensus of leading scientific thinking." Even the Oxford English Dictionary[15] contains this definition for transient equilibrium.

If this description of the concepts of transient and secular equilibrium is supported by authorities and recognized experts in the field, if this meaning is broadly understood by a majority of individuals in the discipline and is as defined in a dictionary and by a scientific body chartered by the U.S. Congress, if it can be traced to the earliest days of the science of radioactivity, then what reasonable justification can there be to say that it is incorrect?

Rebuttal

Dr. Hendee bases his definitions of transient equilibrium and secular equilibrium on the definitions of the individual words in these terms as presented by Webster's dictionary. It is entirely understandable how one could arrive at his conclusion if one only had Webster's dictionary to use as a reference. Fortunately, the majority of textbooks and scientific literature, as well as the Oxford English Dictionary, contain a common meaning that has historical precedent and almost universal agreement. Although it may be unfortunate that a more literally descriptive terminology was not originally coined to describe the process, using these terms as historically understood is not incorrect.

In Dr. Hendee's interpretation, equilibrium exists when "no change occurs in net radioactivity" and such equilibrium exists "only for a moment in time." Classically, transient and secular equilibrium have referred to the state of equilibrium when the ratio of activities of progeny to parent is constant, while that moment of no change in net radioactivity has been known as "ideal equilibrium." Most texts do not "obfuscate the meaning" but are clear in using this classic definition. Dr. Hendee says "some texts get it right" but only quotes two[6,7] neither of which gives supporting documentation for a definition that is contrary to most other texts. Although he quotes some texts as "ambivalent," [8] those texts may simply reflect the confusion wrought by previous editions of Refs. 6 and 7. It is hard to understand how a condition that exists "only for a moment in time" or "appears almost constant" can be a better description of a "state of balance." It would indeed be unfortunate if this proposed definition were to be adopted since we would then be left without terms to describe what has been generally understood as transient and secular equilibrium. These are valuable concepts that serve to communicate important relationships between parent and progeny radionuclides.

I agree that definitions "should be closely aligned with scientific principles." However, there is no contradiction with scientific principles in the generally accepted definitions. The principles are the same no matter what words we choose to call them. What is important is consistency in communication. Attempts to unilaterally redefine recognized terms simply bring about confusion in understanding the scientific principles involved.

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9.10. Physics concepts that cannot be explained from a clinical context should be omitted in physics courses for radiologists

G. Donald Frey and Robert L. Dixon

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OVERVIEW

Radiologists should understand the physics concepts that are important to the practice of radiology. When these concepts are presented from a clinical context, they are understandable to most radiologists. When they are described as more abstract physics concepts, however, many radiologists find them incomprehensible. Primarily this is because the radiologists then have to translate abstract concepts into their clinical applications. Some believe that this translation should be the responsibility of the physics instructor—and that topics that cannot be translated should be deleted from the course. This issue is the topic of this month's Point/Counterpoint.

Arguing for the proposition is G. Donald Frey, Ph.D. Dr. Frey attended Canisius College in Buffalo, NY. He received a B.S. degree in physics in 1965. He then attended the University of South Carolina in Columbia, SC. He and Dr. Dixon were students there at the same time. He received the Ph.D. degree in 1970. For the past 30 years he has been on the faculty of the Medical University of South Carolina in Charleston, SC. He is presently a Professor of Radiology and Director of Diagnostic Physics.

Arguing against the proposition is Robert L. Dixon, Ph.D., Professor of Radiology (physics) at Wake Forest University School of Medicine in Winston-Salem, NC. Dr. Dixon is certified in Therapeutic and Diagnostic Radiological Physics and Medical Nuclear Physics by the ABR and has been teaching Radiological Physics to radiology residents for more than 25 years. In 1985, he received the James L. Quinn, M.D. award for teaching excellence from his department. Dr. Dixon currently practices and teaches in the area of Diagnostic Radiological Physics, but also has previously practiced and taught in Radiation Oncology. He is a former AAPM president, RSNA third vice president, and a current ABR examiner.

FOR THE PROPOSITION: G. Donald Frey, Ph.D., FAAPM, FACR

Opening Statement

There is an old story that tells of a farmer whose chickens have stopped laying eggs. The farmer calls the agricultural school but since it is Friday afternoon only the resident physicist is available to take the call. The farmer explains the problem. The physicist says, "I think I can help you. First let us postulate a spherical chicken." This story reminds us that we all have preferred modes of thinking and that the mode that is good for one discipline is not necessarily the best for another. Experience has shown that residents have neither the time nor the inclination to learn how to solve clinical medical physics problems directly from physics concepts, but they can readily grasp and apply a concept when it is presented in a clinical context. The physicist, trying to understand the pattern of scatter around an x-ray machine, would likely start with the Klein-Nishina formula. I know from experience that this is a poor approach for residents. To make the

concept understandable for residents it has to be put into clinical terms with drawings of equipment, graphics, and perhaps actual measurements. Thus I propose, in support of the proposition, that the appropriate model for teaching resident physics is one where all material that is taught derives from and applies to the clinical practice of radiology.

For this to take place, the physicist must make the "translation" from physics to the clinical situation. The best teachers have the knowledge of both the physics and the clinical situation so that they can easily make the "translation." Poor physics teaching is more often the result of a lack of clinical knowledge, than it is an ignorance of the physics.

Teaching from a pure clinical prospective has several advantages. Having the physicist teach from the clinical context increases the amount of material that can be covered in the limited time available, since time is not wasted on physics principles that are interesting but not relevant. In preparation for resident teaching, physics material that has no clinical relevance should be removed from the course of instruction, to make room for materials that are more clinically important and interesting. In the extreme of this position we could, in homage to Ernst Mach, ban any concept that cannot be applied in a clinical context. This would remove much of the material in medical physics books and examinations for residents, since the material is present because it is interesting to the physicists who teach the material, not because it is useful or interesting to the students.

A second advantage to the clinical approach is that the resident is more likely to retain the material and be able to reason, at least by analogy, through equipment and image quality issues that occur in practice.

A final advantage of this method is that it preserves the image of the physicist as possessing valuable and occult knowledge. While resident education should prepare the residents to reason through the common problems they encounter, they should remain aware that when more complex situations arise they need to consult with their medical physics colleagues.

Rebuttal

I would agree with Dr. Dixon that in depth knowledge of physics is better than a superficial one, and that the well-motivated radiology student can learn physics to a considerable depth. If the ABR announced that radiologist candidates for the board had to be able to solve the Schroedinger equation for a square well potential they would soon all be able to do so.

However, there are limitations on the time available for the instruction of radiology residents. This limited time is better spent ensuring that the resident understands the relation between physics principles and clinical applications, rather than requiring the resident to have a deep understanding of physical principles. As an ABR examiner, I have encountered physics candidates who have a superior in-depth knowledge of physics, but who could not apply that knowledge to clinical situations. It is much the same with radiologists. An in-depth knowledge of physics may broaden their cultural horizons, but if they cannot easily apply their knowledge in clinical situations, their patients will suffer.

Dr. Dixon makes the point that a broad knowledge of physics prepares one for future innovations. Again I agree with the principle, but I doubt that many students retain much of this additional material. Most of my residents have taken a calculus-based physics course prior to

entering medical school, but after four years of concentrating on their medical education, they retain little of that knowledge. Frequently, they even have difficulty with algebra.

Finally, we agree that the ABR ultimately controls what must be learned as a minimum. We need to prepare residents for this examination, but we also should prepare them to meet the requirements of clinical practice. And as medical physicists, we should encourage the ABR to have a clinically-relevant examination in physics.

AGAINST THE PROPOSITION: Robert L. Dixon, Ph.D.

Opening Statement

In my teaching career I have been privileged to teach physics to two very bright groups of individuals whose primary interest was not physics, *viz.*, officers selected for the navy nuclear power program in its early days and radiology residents. If we were to apply the premise of this debate to the first group, we would have said that "physics concepts which cannot be explained in terms of operation of a nuclear submarine should be omitted from the course." Fortunately, Admiral Rickover was more enlightened than this in designing a course for these officers, and we taught physics starting with classical mechanics, progressing through atomic and nuclear physics, diffusion and Fermi age theory, transport theory, and finally reactor physics, with parallel courses being taught in mathematics, thermodynamics, and electronics. I don't remember mentioning the word "submarine" when I was describing the Bohr atom, although I could have said there are no Bohr atoms on board a submarine (or anywhere else for that matter). My point is that in physics one has to build a basis of fundamental ideas before one can progress to applying physics to clinical (or engineering) problems. To try to relate every concept along the way to a clinical situation would be a tremendous nuisance. Furthermore, a good basic background gives students the ability to master new concepts later in their careers. For example, in the 1970s who would have thought that nuclear spins would play any role in Radiology. Indeed, many physicists from medical physics training programs, which stressed only the practical, were clueless about NMR, and those with traditional physics backgrounds stepped to the forefront.

In my experience, one can keep the attention of these bright students, even if a concept does not appear to be clinically relevant, if it is taught in an interesting manner. One of the favorite lectures of my students is on relativistic effects. Eyes get big when I tell them that a cocked bear trap weighs more than the same bear trap when sprung by W/c^2 where W is the work required to cock it. Similarly, the mass of the constituent particles of a nucleus is greater than the mass of the bound nucleus by W/c^2, where W is the work required to pull the nucleus apart piece-by-piece. Now I do advocate relating the concept being taught to a clinical situation where possible and useful. For example, when discussing the interactions of x-ray photons with matter, I first show a normal diagnostic radiograph, and then ask the question: "What happens if I turn off photoelectric absorption?" I then show a similar radiograph taken with 10 MV photons illustrating that an understanding of the photoelectric absorption process goes a long way toward understanding the production of a good image. If a physical principle can be illustrated with an image, then by all means it should be done since radiology residents are used to this medium. I utilize heavily the images from the ACR teaching film file (principles of imaging module) in my course, as well as many of my own images, e.g., contrast-detail CT phantom images made at various dose levels.

A final (and practical) consideration: If the writers of the ABR exam do not also buy into the premise as stated, then the students will not have been properly prepared. The structure of the physics course for radiology residents is largely left to the individual physicist with only the time allotted, the ABR exam, and student interest (attendance) as constraints or boundary conditions. I have no doubt that many physics faculty members would welcome more guidance in structuring such a course.

Rebuttal

Dr. Frey is evidently confused about which came first—the spherical chicken or the spherical egg. The problem with our students is not that they can only reason in some arcane "clinical mode" as Dr. Frey implies (they have all had pre- med courses in physical science which requires thinking in terms of models). Instead, the problem is that they are very busy learning a lot of things which they know they will use in their careers. Many of these students see little use in learning any physics except to pass the board exam. It is the same with my son (the artist), who cannot see how his high school chemistry course will have any possible application in his life (and, I suspect that his teacher has little interest in proving such relevance). The naval aviator must take a course in aerodynamics which contains many physics concepts and equations, when all he really wants to do is to learn air combat maneuvering (the text book attempts to show relevance with pictures of jet fighters interspersed in the text). It is an age-old problem for teachers of theoretical material, not just medical physicists.

I do agree with Dr. Frey that if the medical physicist has little knowledge of the ultimate clinical application of the subject matter, then he/she cannot be an effective teacher. I always have a "lab session" with my students in which I take them into a fluoroscopic room and illustrate the previously-taught concepts of contrast, noise, dose, resolution; and the dependence of these parameters on machine settings, which the operator (radiologist) can select.

9.11. To prepare radiology residents properly for the future, their physics education should be expanded in breadth and depth, and should be more quantitative and mathematically-based

Michael Dennis and Mark Rzeszotarski

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OVERVIEW

The future of radiology includes greater technical complexity of existing imaging techniques, and extension of imaging methods into the subcellular realm of molecules, biochemical mechanisms, and genes. To participate in this future, radiology residents should learn more about physics and its quantitative, mathematical approach to biology. On the other hand, one can argue that radiology must become more of a partnership between radiologists and basic scientists such as physicists, because only through such partnerships will the discipline be able to fully exploit the opportunities presented to it by expanding technology and basic science knowledge. In this approach, radiologists will not need to know much physics, but they will need to know some physicists. This controversy is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Michael J. Dennis, Ph.D. Dr. Dennis received his B.S. degree in physics from Xavier University, followed by an M.S. in Radiological Physics from the University of Cincinnati in 1973 and a Ph.D. in Medical Physics from the University of Texas Health Science Center at San Antonio in 1979. He has worked in community teaching hospitals and corporate settings and has been a diagnostic medical physicist at the Medical College of Ohio in Toledo for the past ten years. He has served on several AAPM committees and task groups, and has chaired the Medical Physics Education of Physicians committee for the past four years.

Arguing against the Proposition is Mark S. Rzeszotarski, Ph.D. Dr. Rzeszotarski is an Associate Professor of Radiology and Biomedical Engineering at Case Western Reserve University. He is certified in Diagnostic and Medical Nuclear Physics by the ABR and has been teaching medical physics to radiology residents for twenty years, first at Mount Sinai Medical Center and currently at MetroHealth Medical Center, both in Cleveland. He has been active in AAPM and RSNA committees on resident education, and is the coordinator for the annual AAPM Diagnostic and Therapy Physics Review Courses.

FOR THE PROPOSITION: Michael J. Dennis, Ph.D.

Opening Statement

The technology of radiology is expanding, and so should the technical knowledge of those responsible for the use and interpretation of this technology. Diagnostic imaging is no longer film-screen systems, image intensifiers, scintillation detectors and single-crystal transducers. It now employs a wide array of sources and detectors, alternative data acquisition methods, and a variety of techniques for image processing, display, transmission, and storage.

The increased technology of radiology is apparent not only by walking through the department, but also by changes in imaging physics texts used by residents. Over the eight years between editions of one text, for example, a 25% increase in the number of pages is found.[1] These changes reflect the growth of technologies such as PET, 4D and harmonic ultrasound, computed radiography, digital detectors and multiple-detector spiral CT. Added to this is the expanded knowledge required for effective use of MRI with its multiple pulse sequences, suppression and enhancement techniques, parallel acquisition methods, and spectroscopy.

The operation of imaging equipment is becoming increasingly specialized. In this environment the radiologist, if technologically unsophisticated, cannot control the applications of the technology. He or she becomes a consumer of the equipment's output rather than a director of its application and use. This can limit the clinical benefit of the technologies, and decrease the contribution of the radiologist as an imaging specialist.

In AAPM report #64 on teaching physics to radiology residents,[2] the rationale for a physics education program is related to: (1) the safety of patients and personnel, (2) clinical expertise, (3) technical communication skills, (4) equipment decisions, (5) radiologists as radiation specialists, and (6) certification and licensure. Safety issues are a growing concern, because of the high dose levels found in CT and fluoroscopy. Clinical expertise is linked to knowledge of disease processes, but the diagnostic task is integrally tied to the technology used to reveal these processes. Specific technical knowledge of imaging systems facilitates the acquisition and interpretation of images. The radiologist must be able to convincingly communicate the technical reasons for what should be done, why, and how. The radiologist is often the primary decision-maker in the acquisition of imaging equipment, and must be able to analyze technical capabilities and understand what is sales "fluff." Radiologists are frequently challenged by clinical specialists who feel that they are equally capable of image interpretation within their narrow specialty. In-depth knowledge of the technology and its applications is one of the unique aspects in the radiologist's training. This should be enriched rather than diluted. Also, certification and licensure of the radiologist is one of the major assurances to the public that radiological exams are conducted safely and knowledgably.

Regarding the physics content of the American Board of Radiology exam for radiologists, the opinion of some examinees is that the physics exam is becoming more difficult. This seems reasonable, because the technology of the discipline is becoming more complex. It appears that the ABR is incorporating more practical, problem based questions in the exam in place of the rote recall of specific facts. In preparing for this exam, AAPM report #64 recommends 100 to 200 hours of physics training. In an informal survey of nine institutions, Zink and McCollough[3] found a range from 21 to 100 hours, and an average of 66 hours, of physics taught in residency programs, covering all diagnostic modalities. This is the equivalent of a single four semester-hour college course, and is inadequate for the effective understanding and use of the wide range of technologies encountered in clinical imaging.

Rebuttal

How do we teach residents with regard to the increasing complexity of diagnostic imaging? Many programs provide considerably less than the recommended hours of instruction. The fact that a typical resident has had only minimal math and physics makes it imperative that sufficient time is applied to develop an understanding of diagnostic imaging technologies.

I agree that a solid physics, mathematics and statistics foundation is the goal, and that clinicians should be able to recognize when and where to seek out expert assistance. They also require a higher level of knowledge and expertise to deal with the increasing technical complexity of day-to-day operations. The radiologist is the consultant to primary care physicians. The radiologist must understand the application and technical specifics of the various imaging tools used, and communicate the relative benefits and risks to his or her peers. These decisions and communications are usually made without the availability of a physicist. This is especially true outside of major medical institutions where diagnostic physics support is likely provided on a part-time basis. Even in modality accreditation programs requiring physics guidance, the radiologist has the ultimate responsibility, including technical compliance. The radiologist need not be a physicist, but he needs a very firm technical foundation in an increasingly complex subject.

AGAINST THE PROPOSITION: Mark S. Rzeszotarski, Ph.D.

Opening Statement

Each year, the practice of radiology becomes more complex as a result of advances in technology and ever-increasing medical knowledge. New regulatory and accreditation requirements continue to be imposed, placing further demands on the time available for training. Meanwhile, the average number of radiologic examinations performed per resident continues to increase.[4] The complexity and number of images per procedure are also increasing.

I follow the recommendations of AAPM Report No. 64, by teaching a comprehensive physics course annually.[2] Ninety hours of physics lectures are provided each year, supplemented by lectures on continuous quality improvement, critical reading skills, using electronic media, radiation safety, regulatory compliance, reimbursement compliance, how to conduct research, and radiation safety lab activities. Residents also attend orientation and an annual education day of training as well as didactic lectures on the recently revised ACGME general competencies.[5,6] These lectures compete with the clinical and case conference lectures to fill the fixed number of available time slots for didactic presentations.

My goal in teaching residents is to instill a sound conceptual basis for the physics of radiology. While I would like to provide in-depth mathematics-based physics instruction, there is simply no time. In addition, medical schools selectively exclude individuals who would be best suited for advanced study in physics.[7] Most medical schools require undergraduates to take a single course in physics, and less than 20% of the schools require college level mathematics or calculus. Undergraduates who major in physics, mathematics or engineering collectively constitute less than 6% of all students admitted to medical school. Most medical students have poor mathematics and physics backgrounds.

Mathematics is an essential tool for the physicist. Just as an auto mechanic relies on tools to fix a car, mathematics provides the tools for understanding physics. While a physicist is comfortable working with integrals and exponentials, these incite fear and anxiety in most residents. Unfortunately, there is insufficient time to teach the fundamentals of mathematics along with the essential physics. Instead, one is relegated to teaching physics using basic mathematics, incorporating analogies and metaphors whenever possible to help residents understand difficult physical principles.[8] One can also use the knowledge that radiologists are visual learners. They comprehend concepts more easily from a graph, image or sketch than from an equation.[9] My role

as a teacher is to explain physics concepts using methods residents can understand and relate to in clinical practice. This takes considerable time and further reduces the breadth and depth of coverage of all important topics.

Radiologists routinely consult with physician specialists and physicists. This partnership is essential in today's integrated technology environment where no single individual can know everything. In the future, radiologists will also need to include mathematicians, statisticians and biologists in the intellectual pool of clinical consultants. The real challenge will be to provide residents with a solid physics, mathematics and statistics foundation so they recognize the need to seek out assistance from experts when necessary.

Rebuttal

I agree with Dr. Dennis that the technology of radiology has expanded substantially. In an ideal world, residents should receive medical physics training which is commensurate with the complexity of the technology. However, our clinical understanding of radiology has also increased significantly, through both improvements in technology and a better understanding of medicine. There is a fixed amount of time available during a diagnostic radiology residency. Limits on duty hours, and mandated accreditation, regulatory and competency evaluation requirements, further restrict the available time for learning. The time spent understanding medical physics and clinical radiology must be carefully balanced to produce a well-rounded radiologist with good clinical skills along with a solid foundation in medical physics. As technology continues to increase in complexity and sophistication, the radiologist will have to rely increasingly on consultant experts like medical physicists. This is the standard of care in radiology today.

I also agree that the American Board of Radiology physics examination has become more oriented toward clinical, problem-oriented medical physics, requiring interpretive skills beyond rote recall of facts. This is good for radiology. We must remember, however, that the exam is a test of minimum competency. I focus on providing my residents with a solid foundation in clinical medical physics, rather than just enough physics to pass the boards. I teach residents how physics principles can be used to understand and improve images. Once they comprehend these principles, they have no problem scoring well on the boards. Teaching is performed using qualitative nonmathematical methods that are both understandable and pragmatic. These methods require more preparation time by the medical physicist, but the end result is improved comprehension by the resident. They learn to apply their knowledge of physics to clinical practice, which is the single most important outcome of medical physics training.

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CHAPTER 10

Professional Issues

10.1. Medical physicists should position themselves as institutional resources in expanding areas such as healthcare informatics and information networking

Jon H. Trueblood and Kenneth R. Hogstrom
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OVERVIEW

All healthcare institutions are faced with the expensive and technically challenging demand to continually improve their informatics capability and their infrastructure for information networking. The demand includes the need to provide Electronic Medical Records and Picture Archiving and Communications Systems (PACS), and their integration with Radiology (RIS) and Hospital (HIS) Information Systems. In many institutions, one of the problems in meeting this demand is the lack of skilled personnel who understand both the technical and the clinical aspects of information systems and networks. Medical physicists have this understanding, and could be a major resource in helping institutions meet their informatics and networking needs. But assuming this responsibility would divert medical physicists from their more traditional roles in diagnostic and therapeutic radiology, where they also have unique responsibilities. Whether to offer to help resolve information systems and networking challenges presents a dilemma for medical physicists. How this dilemma might be resolved is examined in this issue of Point/Counterpoint.

Arguing for the Proposition is Jon Trueblood, Ph.D. Dr. Trueblood is Professor and Director of the Medical Physics Section of the Department of Radiology at the Medical College of Georgia. Dr. Trueblood is the past Chair of the AAPM Education Council and is currently Vice Chairman of CAMPEP and Chairman of the ACR/CMP Committee on Physics Education. In 1993 he was co-director of the AAPM School on the topic of ‘‘Digital Imaging.’’ For more than a decade he was co-director of the AAPM annual Diagnostic and Therapy Physics Review Courses. He has been instrumental in establishing the Medical Physics Continuing Education Credit (MPCEC) Program under the auspices of CAMPEP. In 1998 Dr. Trueblood received the AAPM Award for Achievement in Medical Physics.

Arguing against the Proposition is Kenneth R. Hogstrom, Ph.D. Dr. Hogstrom is Professor and Chairman of the Department of Radiation Physics in the Division of Radiation Oncology at The University of Texas M. D. Anderson Cancer Center, where he holds the P. H. and Fay Etta Robinson Professorship in Cancer Research. Dr. Hogstrom has over 25 years experience in the research and development of dose algorithms, PACS, and other software tools used in radiation therapy. He is director of a medical physics graduate education program, member and previous chair of the CAMPEP residency education program review committee, and AAPM President for 2000.

FOR THE PROPOSITION: Jon Trueblood, Ph.D.

Opening Statement

Outside of reviewing radiation therapy treatment charts, medical physicists, in general, have not been significantly involved in the business of patient medical records (charts). However, along with the transition to filmless radiology, the analog methods used by medical record departments are also rapidly making the transition to electronic (digital) records. The process of integrating the patient's electronic medical records and digital medical images has not only generated a huge hospital information software industry but is also resulting in the formation of institutional wide healthcare informatics and information networking service departments.

The expertise included in hospital informatics departments is necessarily multidisciplinary in nature and generally includes some combination of computer system, database and network engineers, telephone/cable technical personnel, business and technical managers (coding, typing, billing, etc.), representative specialty physicians, and, in some academic institutions, a medical informatics scientist. Frequently, the medical physicist is not included in the initial constitution of such medical informatics service groups. This is unfortunate because, within the aforementioned typically included specialists, who among these specialists has a perspective on the content, format, communication and display requirements, and storage and retrieval requirements of the following medical record entities: medical images obtained from the digital imaging modalities (MR, US, CR, CT, etc.) and from the digitization of film and analog video displays (fluoroscopy, video cameras, etc.); 3-D visualization images created to assist radiation therapy, surgery and diagnosis; and CT simulation and electronic portal images? Who among these specialists understands image quality issues in the context of lossy compression and greyscale and color display monitor characteristics? Which specialists understand how these images are acquired and how they need to be distributed? Which specialists are most aware of the DICOM standards? These rhetorical questions represent an abridged list of digital medical image entities which are outside the expertise of most medical informatics groups.

It should be obvious that, at a minimum, a medical physicist should be included as a consultant to the institutional group charged with oversight of medical informatics. The extent to which such duties detract from the more traditional role of the medical physicist will be situationally variable. Even if it requires adding medical physics personnel, is it a bad thing for the institution to need this service from the medical physicist? What other health professional possesses the knowledge to properly integrate digital medical images into the patient medical record?

Rebuttal

My opponent has provided an excellent referenced definition of academic medical informatics and information networking. Note that the proposition states that the medical physicist should be

an institutional resource in these expanding areas of healthcare. This does not mean that the medical physicist need be an expert in the academic discipline of medical informatics or computer networking. In the context of my opponent's radiotherapy accelerator analogy, medical physicists have certainly been a resource in the design requirements for this sophisticated instrument without being expert in the fields of electronic circuit design, mechanical and electrical engineering or computer device control technology. Just as the medical physicist has been the best resource for advice on the performance and functionality requirements in the development of the accelerator, the medical physicist is the best institutional resource for consultation on the performance and functionality of medical image acquisition, display, archival and network systems. The important question is ''Do the medical informatics professor and the computer network engineer possess more knowledge about radiology and radiotherapy medical information and images than the medical physicist?'' If the answer is no, then the medical physicist who does not become an institutional resource in these expanding areas of healthcare has missed an important professional opportunity.

AGAINST THE PROPOSITION: Kenneth R. Hogstrom, Ph.D.

Opening Statement

My position is that the scope of healthcare informatics is enormous and an area in which the medical physicist has little to no training, and hence, one in which medical physicists should not assume responsibility. Fueled by advances in computer technology, medical informatics is the logic of healthcare, and according to Coiera,[1] the role of medical informatics is to help develop solutions as to (1) how rational structures can be used to specify how clinical evidence is applied to patient care, (2) how organizational processes and structures can be used to minimize use of resources and maximize patient benefit, and (3) how tools and methods can be developed to best achieve these roles. Information networking, which in the present context can be thought of as a collection of computers connected together and sharing data and programs, is a tool of healthcare informatics.

Undoubtedly, through research and development the medical physicist has contributed to the technical sophistication and functionality of picture archiving and communication systems (PACS) in diagnostic imaging[2] and radiation oncology.[3] Nonetheless, the medical physicist should not be responsible for the development, operation, and maintenance of a PACS, which requires a well-staffed group of computer informatics professionals that have adequate goals and resources. Furthermore, should medical physicists perform such duties related to PACS and information systems, then they should have a joint title indicating their increased responsibilities, and that portion of their effort should be recognized as nonmedical physics for staffing determinations.

The medical physicist is responsible for acquisition, commissioning, procedure planning, quality assurance, and safety of radiological equipment. The breadth and complexity of this has increased significantly in recent time due to the influx of new technology for patient care, e.g., MRI, SPECT, PET, digital imaging, and functional imaging in diagnosis and IMRT, gated therapy, image guided therapy, and stereotactic irradiation in therapy. Therefore, the medical physicist should participate in acquisition, commissioning, and quality assurance of image quality, spatial linearity, and functional operations of the PACS, i.e., those functions for which the medical physicist is typically responsible, but not in its development, operation, and maintenance. A similar analogy in therapy has been the radiotherapy accelerator. Radiotherapy accelerators are highly sophisticated medical instruments

whose developments were stimulated by physics and whose uses have been improved through medical physics research and development. The medical physicist assists in acquiring, commissioning and providing ongoing quality assurance of the dosimetric properties of the machine. However, radiotherapy accelerators are developed by engineers, manufactured by industry, and operated and maintained by other non-medical physicist professionals.

Rebuttal

The questions raised by Dr. Trueblood are typical of most emerging medical technology, and I concur that it would be acceptable for a medical physicist to be a consultant to an institutional group responsible for medical informatics. Both of us clearly recognize the contributions and the knowledge of the medical physicist in digital technology applied to radiology. However, in response to Dr. Trueblood's question, it could be a bad thing for the medical physicist to become overly involved and responsible for medical informatics. Historically, too often the medical physicist has had to solve ''computer problems,'' that were not related to medical physics. Although such actions may benefit the institution, and even provide short term recognition of medical physicists, they are seldom accompanied by increased medical physics personnel, and as a result, distract from other duties of the medical physicist. Therefore, I will assert my earlier point that if medical physicists perform such duties, then their effort should be recognized as non-medical physics for staffing determinations.

Medical physics is a maturing profession whose demands are increasing because of increased patient demand, more sophisticated technology, and an increased range of applications to medicine. Because of this, physicians are becoming more dependent upon medical physicists. Therefore, we need to focus on refining our proficiency as practicing professionals and not be expanding into areas that are clearly not medical physics.

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10.2. Medical physicists should assume PACS responsibilities

James R. Halama and Walter Huda
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OVERVIEW

The implementation of Picture Archiving and Communications Systems (PACS) is a challenging and costly project being addressed in some form by every radiology department. Some physicists believe that this implementation presents an obligation and an opportunity for medical physicists to increase their contribution to the clinical service of the department. Other physicists feel that PACS is outside the knowledge and skill set of medical physicists, and would distract them from their responsibilities in quality control and equipment monitoring. These opposing points of view are debated in this Point/Counterpoint.

Arguing for the Proposition is James R. Halama, Ph.D. Dr. Halama is an Assistant Professor of Radiology/Section of Nuclear Medicine at the Stritch School of Medicine at the Loyola University Medical Center. Dr. Halama is currently the Chair of the Nuclear Committee of the AAPM Science Council. He has spent many years working with image processing techniques in nuclear medicine, and pioneered bulletin board communication methods on the world-wide-web through development of the Loyola University Nuclear Information System (LUNIS). He currently manages the radiology imaging network, and serves as chairman of the PACS selection committee at Loyola.

Arguing against the Proposition is Walter Huda, Ph.D. Dr. Huda obtained his Ph.D. in medical physics at the Royal Postgraduate Medical School (Hammersmith Hospital) at the University of London. Dr. Huda worked for five years at Amersham International, a commercial company specializing in radioactive products. In 1982 he moved to North America, and worked in medical physics at the Manitoba Cancer Treatment and Research Foundation (Winnipeg) and the University of Florida (Gainesville). Dr. Huda is currently a Professor of Radiology at SUNY Upstate Medical University (Syracuse), and Director of Radiological Physics. His research interests are in medical imaging and radiation dosimetry, and he is certified in Diagnostic Physics by the CCPM and ABMP.

FOR THE PROPOSITION: James R. Halama, Ph.D.

Opening Statement

In many radiology departments today a gap exists in integrating information technology and PACS. In a very short time, all radiological imaging will be digital and connected within a PACS. Departmental administrators understand cost and workflow issues; information technology personnel understand computer networks, databases, and message exchange; technologists know how to produce images, but lack the technical understanding of image production; and few physicians look at image quality beyond what is presented on the video screen. Because of their technical training, orientation, and understanding of images from production to presentation, medical physicists are the persons who can bridge all of these gaps.

Medical physicists have the opportunity and the responsibility to adapt to the new PACS environment.

The starting point in gap bridging is having an understanding of images and the data that are stored along with images. It is clear, as previously argued by Trueblood and Hogstrom,[1] that medical physicists are the specialists who have a perspective on image content, format, communication, display, storage and retrieval. Medical physicists understand image quality in the context of glossy image compression, and grayscale and color display characteristics.

The DICOM standard, that enables PACS to exist, is open to interpretation by both imaging and PACS vendors. Critical nonimage data elements in the DICOM headers may not be interpreted correctly across vendor platforms, and may not be stored at all in a PACS. Increasingly, PACS are being used as the data repository for imaging modalities. Expertise is needed not only to solve cross-platform connectivity issues, but also to validate the vendor's interpretation of DICOM data elements. This expertise is critical because of the increasing demand for 3-D visualization tools in PACS workstations, the emergence of image-guided therapy, and image fusion between CT, MR, and PET. DICOM, although viewed by many as complete, is still an emerging standard, and validation of procedures will be required for many years to come.

In planning for, or extending the reach of PACS, questions arise almost daily concerning image storage and bandwidth requirements for transferring images to and from on- and off-site locations. The input of a medical physicist in departmental planning and PACS committees will help the department select the proper PACS and network configurations. In addition, good technical input often keeps the department from over-specifying performance criteria.

Assumption of PACS responsibilities by physicists enhances the quality of patient care and helps the radiology department operate more efficiently. PACS responsibilities, however, require that physicists are knowledgeable in this area. We must provide more continuing education programs for physicists who are being called upon to work with PACS.

Rebuttal

Unfortunately, PACS is being narrowly viewed as merely a tool for improving the operational efficiency of Radiology departments. We must remember that PACS archives, transmits, and presents *images* to physicians. In Radiation Oncology, PACS is used to archive, transmit, and present radiation treatment plans. Medical physicists should, at a minimum, have sufficient knowledge of DICOM, computer networks, interfaces to modalities, and databases to ensure that the integrity of image and related data are maintained from production to presentation. This responsibility for image and data integrity is being coded into federal regulations. For example, the revised NRC Part 35.41 states "For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that . . . at a minimum . . . address . . . verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600.[2] DICOM RT was developed recently to standardize the transfer of radiation treatment plans to therapeutic devices. I would be very uncomfortable in suggesting that a computer scientist take on this responsibility.

Yes, there will be individual medical physicists who have sufficient knowledge to become PACS administrators and oversee the total PACS operation. The fact remains that most medical physicists, at some time in their careers, will be called upon to perform PACS responsibilities

insofar as the integrity of image and related data is concerned. The AAPM should initiate continuing education programs to raise the level of competence of medical physicists in PACS, and medical physics training programs should incorporate PACS into their curricula. By offering these programs, medical physicists will not need to seek education and training from other societies and professional groups.

The underlying issue is: Do medical physicists *remain* the imaging specialists? Or do they hand over increasing bits and pieces of new technology to computer scientists who have no knowledge of the specialized requirements of Radiology?

AGAINST THE PROPOSITION: Walter Huda, Ph.D.

Opening Statement

There will be *individual* medical physicists who may develop an interest in PACS and acquire the necessary skills to assume PACS responsibilities. My contention, however, is that *most* medical physicists working in radiology departments will not and should not assume PACS responsibilities. Diagnostic physicists currently have their hands full dealing with issues of radiation dose and image quality In most radiology departments, responsibility for PACS should be assumed by computer scientists with informatics expertise.

Medical physicists usually have undergraduate degrees in physics, and they gain their medical physics training with an M.S. and/or a Ph.D. level degree. A typical training program in diagnostic physics includes interactions of radiation with matter, radiation biology and protection, and medical imaging for the major modalities currently encountered in radiology (i.e., radiography, fluoroscopy, DR & CR, CT, Ultrasound, MR and Nuclear Medicine). Although virtually all physicists are knowledgeable about computers, most have little direct experience of the DICOM standard, interfaces to imaging modalities, network issues, or databases. Certification boards such as the American Board of Radiology and the Canadian College of Physicists in Medicine do not cover PACS in a substantial way in their written and oral examinations.

The advent of PACS is dramatically changing the way that Radiology departments operate. With PACS, radiographic images are digitally acquired, processed, transmitted and archived. In the near future, the radiologist's report will be dictated using voice recognition dictation systems. Radiology Information Systems (and Hospital Information Systems) will then permit the end product of the radiological examination (i.e., report + images) to be available on line to referring physicians in a matter of minutes or hours. This is a huge improvement over film-based imaging systems where the median time to produce a verified report is measured in days! PACS is primarily about improving the operational efficiency of radiology departments, which is *not* the domain of diagnostic medical physics. To introduce PACS into radiology requires detailed technical knowledge about DICOM, interfaces, networks, and databases.

Imaging physicists serve an important role in monitoring technological trends such as the recent introduction of multislice CT scanners. Keeping the department at a state of the art level requires joining appropriate societies (e.g., American Association of Physicists in Medicine), attending relevant meetings (e.g., SPIE Medical Imaging), and reading pertinent journals (e.g., Radiology). To be knowledgeable about PACS requires joining the American Medical Informatics Association, attending the Healthcare Information and Management Systems Society (HIMSS)

meeting, and reading the Journal of Healthcare Information Management. Most medical physicists are not even aware of the existence of these entities, and are certainly not active participants. Therefore they are not equipped to assume the primary responsibility for PACS in a radiology department.

Rebuttal

My colleague makes the claim that a gap exists in integrating information technology and PACS; expert personnel are required to address cross-platform connectivity, validate the vendors interpretation of DICOM data elements, and tackle issues of communication, storage and retrieval requirements. All of these PACS issues are important. But they are beyond the expertise of most diagnostic physicists. The AAPM is the professional home of medical physicists, *Medical Physics* is the journal we read, and there is an annual meeting that we normally attend each summer. A review of the contents of the journal and annual meeting shows that there is virtually no mention of PACS topics. It is doubtful that more than a small percentage of diagnostic medical physicists would feel comfortable in bridging the gap between information technology and PACS.

I fully agree that medical physicists have a special understanding of dose and quality issues in medical imaging. There is little doubt that we will continue to have an important role in providing 3-D visualization tools, image guided therapy and image fusion. However, as I argued in my opening statement, PACS is primarily about the improvement of the operational efficiency of radiology departments. Efficiency will be achieved by the effective management of images and reports, and integration of PACS with RIS and HIS systems. Individuals who do venture into the PACS arena will most likely have little time left to devote to the traditional diagnostic physics tasks (specification, acceptance testing, quality control, and clinical use). The success of a radiology department depends on a team effort consisting of radiologists, physicists, technologists, manufacturers, *as well as* PACS personnel.

It is of interest to contemplate to what extent medical physicists who operate outside of the larger academic medical centers will become involved with PACS. A substantial percentage of radiology centers do not employ full time physicists, and many diagnostic physicists operate in private practice to provide consultation services to the medical imaging community. To guide a radiology group through the difficult transition from a film based enterprise to the all digital world requires an individual knowledgeable about PACS issues, and not a medical physicist *per se*. I believe that most private medical physics groups get very little PACS business, and I doubt that they are positioned to successfully move into this area, *unless* they expand by recruiting computer scientists and information technologists with the necessary expertise.

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10.3. It is important that medical physicists be involved in the development and implementation of integrated hospital information systems

George C. Nikiforidis and George C. Kagadis
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OVERVIEW

It is becoming increasingly difficult to operate a hospital without an integrated hospital information system (HIS) that streamlines the collection, management, and distribution of information necessary for health professionals to function efficiently. Such electronic data processing systems are used to manage information from such diverse sources as laboratories and radiology departments. Laboratories typically do not have staff that is highly knowledgeable about data collection and exchange. On the other hand, radiology departments often have medical physicists experienced in managing PACS systems, and it has frequently been these medical physicists who have evolved into local HIS experts. Some hospitals realized the importance of hospital information systems early on and employed dedicated medical informatics specialists for the development and implementation of their information systems. In these hospitals, medical physicists have often been only marginally involved in information technology, and some have suggested that this marginal involvement is detrimental to our profession. They have recommended that medical physicists should spend more time and effort developing their expertise in medical informatics so as not to relinquish this responsibility. Others have suggested, however, that medical physicists do not, and should not, take on these extra duties because they have neither the training nor the time for such endeavors. This controversy is the topic of this month's Point/Counterpoint debate.

Arguing for the Proposition is George C. Nikiforidis, Ph.D. Dr. Nikiforidis received his Laurea in Physics and his M.Sc. in Atomic and Nuclear Physics both from the University of Milan, Italy in 1973 and 1980, respectively. He received the Ph.D. in Medical Physics from the University of Patras, Greece in 1981. He is currently Professor of Medical Physics and Director of the Department of Medical Physics at the University of Patras, where he is also the Dean of the School of Health Sciences and director of the postgraduate course on Medical Physics. He has been the principal investigator or been involved in a variety of national or European research and development projects.

Arguing against the Proposition is George C. Kagadis, Ph.D. Dr. Kagadis received his Diploma in Physics from the University of Athens, Greece in 1996 and both his M.Sc. and Ph.D. in Medical Physics from the University of Patras, Greece in 1998 and 2002, respectively. He is currently a Research Fellow in Medical Physics and Medical Informatics at the Department of Medical Physics, University of Patras. He is a Greek State Scholarship Foundation grantee, and a Full AAPM member. He has been involved in European and national projects, including e-health. His current research interests focus on medical image processing and analysis as well as studies in computational fluid dynamics. Currently he is a member of the AAPM Imaging Informatics Subcommittee and an Associate Editor of *Medical Physics*.

FOR THE PROPOSITION: George C. Nikiforidis, Ph.D.

Opening Statement

Hospital information systems have become key elements of the infrastructures of modern hospitals in the developed world. Their role in a hospital's main function of providing health services is twofold: they act both as a tool for managing the entire spectrum of activities within the hospital organization, and as mechanism for integration of newly acquired data and knowledge into clinical routines.[1,2,3,4,5] With regard to the former, a medical physicist (MP) has little to contribute. Information technology scientists are natural protagonists in fields where technological development in hardware and software is so rapid. The latter, however, forms a new dimension of development for an HIS. Its dynamic character lies in the process of continuously including new types of data emerging from new diagnostic methodologies. This continuous updating of HIS constitutes a challenge for modern medicine. First, technological advances offer the opportunity to perform diagnostic examinations at increasingly subtle levels of pathology; from the organism to the tissue, the cell and—nowadays—the molecule. Extrapolating present trends, it is quite probable that in the ensuing years a diagnostic procedure might simultaneously include data originating, for example, from multislice CT, PET, microarrays, and proteomics.[6,7] Second, a new need is formed for combining data optimally and maintaining a holistic approach to clinical problems. Approaching the clinical problem from diverse diagnostic aspects should strengthen our perception of the problem at hand without leaning towards technological fetishism.

Medical physicists can play significant roles in this framework. Their firm scientific knowledge of the physical principles of data acquisition from a number of diverse diagnostic modalities (making use of ionizing as well as nonionizing radiation) can assist them not only in filtering out sources of noise convolved to the measurements, but also in bringing out the additional value of specific diagnostic methodologies over others.[8] As the hospital environment becomes more molecular, new entities such as microarrays and molecular imaging are emerging. The fragmentary character of information calls for integrative initiatives that will combine the scientific backgrounds of basic sciences such as physics, chemistry, and biology.

Exploiting their background knowledge of the mechanisms of data acquisition, medical physicists are able to perform data reduction in the form of extracting characteristic features from the data, i.e., variables that contain summaries or inferential information from highly complex raw data. The MP can thus be actively employed in the process of learning from data originating from heterogeneous sources of information and aiming at various groups of end users. Medical decisions are intrinsically of statistical character, and pursuing plausible hypotheses involves inference from complex data structures.

HIS can become an indispensable tool for such tasks, and MPs can act as moderators for diverse medical needs met through inference inside the hospital. Their role among end users can provide better exploitation of the knowledge gathered in a medical setting, and can serve as an effective inter-science collaboration between physicians and physicists. I strongly believe that by playing an active role in the ever-evolving HIS environment, MPs can exert a positive influence in hospital organization. This gives MPs the opportunity to offer better services to the hospital and to patients.

AGAINST THE PROPOSITION: George C. Kagadis, Ph.D.

Opening Statement

The development and implementation of integrated hospital information systems is a very interesting issue. Getting involved with this task requires a strong background in medical informatics science and is highly work-intensive. My position is that medical physicists have neither an adequate background in this science nor the time to devote to it, and hence should not assume such a responsibility. Medical physicists usually have an undergraduate education in Physics and an advanced degree in medical physics. According to AAPM Report Number 79, there should be a core curriculum in which all medical physics trainees should be well grounded. In addition, there should be subsequent training in the more specific aspects associated with subspecialties such as imaging or radiation therapy.[9] Medical physicists have a variety of obligations such as acceptance tests, shielding design, radiation dosimetry, treatment planning, image quality, etc. Being either a diagnostic or therapy physicist demands devotion and responsibility in everyday practice. Medical physicists' obligations have significantly increased recently with the advent of new technological advances such as multidetector CT, PET, IMRT, MLC, and Gamma Knife, as well as hybrid machines CT-SPECT, MR-PET, etc.[10] Thus specialization and dedication are crucial if medical errors are to be avoided.

Development and implementation of an integrated HIS alter the way clinical enterprises operate, and require specialists who have a solid background in medical informatics. These individuals should have in-depth training in PACS, database design and management, interfaces to imaging modalities, communication protocols DICOM, TCP/IP, as well as higher-layer HL7 protocols, etc. An HIS will make the outcome of a radiological, laboratory, or other physical examination readily available to referring physicians. A well-developed and implemented HIS will increase the operability and consequently the performance of the healthcare enterprise.[11,12,13]

The current medical physics curriculum does not provide sufficient tools to enable medical physicists to have a key role in the development and implementation of an integrated HIS. Additionally, medical physicists have little (or at best, fragmentary) knowledge of medical informatics issues, and thus any attempt to be involved in the development and implementation of an integrated HIS would distract them from their specialized work and thus decrease productivity and efficiency in their daily clinical practice. The partnership of medical physicists with radiologists, other physicians, and medical informatics specialists is essential in an integrated HIS, where each individual has a discrete role and cannot have knowledge of everything.[14]

Rebuttal: George C. Nikiforidis, Ph.D.

It would be unrealistic not to admit the need for greater specialization of MPs in individual aspects of medical physics so that they can embrace the new technologies and methodologies that enter our everyday practice in the hospital. If, however, this were not accompanied by efforts to link the physicist's routine work to the broader goals of modern medicine, then the very act of specializing would cause their marginalization. Their role would become ancillary and MPs would undoubtedly narrow their scientific role to one of simply striving to follow continuous technological advancements.

Hospital information systems are the means for a solid attachment of MPs to the roadmap of advancement in medical science, as they are the key factor for the integration of scientific knowledge. Giving MPs the opportunity to be involved in the development and implementation of an HIS makes them active contributors to this roadmap. Registration and fusion of medical

images constitute good examples for such integration. Taking advantage of the HIS infrastructure, the information is combined to produce fused images. Interpreting them comprises a challenging task for the clinicians, since they are required to evaluate a new, unfamiliar representation of the information. It calls for collaboration among experts, opinion exchange and, frequently, argumentative reasoning. The MP, aware of the physical principles involved in the image acquisition mechanisms, can effectively assist the clinicians in this task.

Being able to take part in such schemes undoubtedly requires proper education in fields that lie at the interface between scientific disciplines. Knowledge of the mechanisms of novel acquisition methodologies, as well as aspects of computer science, is only a part of the technologies necessary to allow MPs to perform information integration and implement statistical learning procedures. Armed with such qualifications, the role of MPs as knowledge facilitators would be enhanced. This would promote the importance of medical physicists in the hospital environment.

Rebuttal: George C. Kagadis, Ph.D.

I agree with my colleague that hospital information systems have become key infrastructures of modern health care enterprises. I also agree that the role of the current medical physicist is expanding to new fields according to medicine's development. However, I disagree with his statements that the medical physicist can act as a moderator for the diverse needs for medical inference in the hospital setting. Such an approach would add more tasks to the daily workload of medical physicists and would divert them from their important duties. They have to be efficient in their daily clinical work as well as stay up-to-date with new technological developments in either imaging or radiation therapy. These tasks demand devotion in order not to decrease productivity and efficiency.

I also agree that active participation of medical physicists in either the development and/or implementation of an integrated HIS may positively influence both their status (strategic role) and the clinical enterprise function. On the other hand, medical physicists are evaluated and acknowledged for their services as medical physicists, and any possible recognition with regard to HIS services might just be transitory. Additionally it is not likely that this new involvement would lead to an increase in medical physics department personnel. This means that if medical physicists do assume HIS responsibilities in either development and/or implementation, they will inevitably have less time to dedicate to their traditional tasks and thus compromise their quality of service or, in the worst case, leave them more vulnerable to making errors.

For these reasons I believe that medical physicists should not be directly involved in the development and implementation of an integrated hospital information system but should be active participants in this environment. They should, however, collaborate with other healthcare professionals serviced by the integrated HIS in order to refine their occupational proficiency and meet the challenging applications of new technical advances.

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10.4. There is no legitimate role for an applications service provider in radiology

Paul G. Nagy and Charles E. Willis
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OVERVIEW

Image management is becoming a major challenge in radiology as the specialty migrates to an all-digital format for recording, retrieving and networking images. Some radiology leaders believe that image management is too great a technical challenge to be handled internally, and that contracting with an external applications service provider is the best way to proceed. Others feel strongly that image management is key to effective radiology services, and that quality can be ensured only by internal management of radiology images. This controversy is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Dr. Paul Nagy. Dr. Nagy is a medical physicist at the Medical College of Wisconsin whose expertise is in imaging science and information technology. He is a recognized voice in the PACS community advocating the third generation of PACS where the integration of information systems focuses on the clinical workflow of Radiology. His research includes developing the next generation of storage technology through storage area networks, distributed file systems, and load balancing clusters. He has developed open-source applications to monitor the performance of a PACS. He has been an invited speaker on Integrated Healthcare Enterprise at the annual meetings of SCAR, AHRA and RSNA.

Arguing against the Proposition is Dr. Charles Willis. Dr. Willis is Associate Professor in the Department of Radiology at Baylor College of Medicine and a member of the Medical Staff of Texas Children's Hospital in Houston, Texas. He is a diplomate of the American Board of Radiology in Diagnostic Radiologic Physics and licensed to practice Diagnostic Radiological Physics by the State of Texas. He serves as the Chief, Section of Electronic Imaging for Texas Children's Hospital. He is a member of AAPM Task Group 10 for Computed Radiography and Task Group 18 for Electronic Display Devices. He has authored numerous publications on practical aspects of Computed Radiography and PACS.

FOR THE PROPOSITION: Paul G. Nagy, Ph.D.

Opening Statement

The business case for the remote application service provider (ASP) model is a reaction to the market's slow adoption of picture archival and communications system (PACS). However a truly competitive third generation of PACS has emerged that employs inexpensive off-the-shelf hardware. This PACS generation uses robust software based on DICOM standards, and focuses on radiology workflow. The remote ASP model does not provide economy-of-scale cost savings compared with a third generation PACS, and adds performance bottlenecks as well as

vulnerabilities by running services from a remote location. The total cost of ownership for an off-the-shelf PACS is estimated to be between $4 and $8 an exam, whereas the cost of an ASP PACS is between $10 and $14 an exam. Radiology departments do not typically have in-house information technology leadership to articulate the benefits and risks of different ways to implement PACS. I believe that this is a role ideally suited for the diagnostic medical physicist.

PACS has a large appetite for storage. Fortunately, storage is also the fastest-moving segment of the computer industry, even surpassing Moore's Law. The areal bit density of magnetic hard drives has grown by 60% each year since 1987, and by 100% each year since 1995. From 1988 to about 1994, PACS was the driving force behind the entire storage market, and we paid bleeding edge prices for it. Today highly rack-dense multiterabyte storage-area networks can achieve a storage solution at a cost of $10–20 per Gigabyte. The in-house cost of storing a typical CT study (100 MB) on RAID is $1, and on tape is less than $0.25. There is no economy of scale by going to a data warehouse offsite for any department generating more than 40–50 k procedures per year.

Another concern with the ASP model is the security and performance of the network transmission line connecting your facility with an ASP data center. In disaster recovery, transfer rates are insufficient across a wide area network. Even with an expensive OC-3 high-speed 155 MBit network connection, the time to restore one terabyte of data is just under two days! Local area networks can now run at gigabit speeds on existing CAT 5 cabling at one-third to one-fifth the cost of sending data over a wide area network and restore the same data in two hours.

Lastly, ASPs have a big hook attached; they have your data. Without stringent stipulations in a contract, you may have to buy back your own data in order to migrate to another PACS solution. Moving 10 s of terabytes of data accrued over a few years by a reasonably sized institution, could be cost prohibitive as well as take weeks to months of dedicated network transmission time to get back.

Most diagnostic medical physicists coming out of programs today have the necessary computer skills to understand, implement, and support a PACS in a hospital environment. There is a real need for PACS professionals in today's modern radiology department. This need presents a real opportunity for medical physicists who understand image quality and information technology to make a significant impact on patient care.

Rebuttal

Dr. Willis is correct in his assertion that an "on-site" ASP model is just a business decision based upon the financial model the hospital prefers. The term ASP is ubiquitous and overloaded, making comparison confusing. I would like to suggest using the term "fee for use" as opposed to "on-site" ASP. The "fee for use" model has the identical technology and architecture as a capital PACS and as such I have no problems with it. If a hospital has difficulty procuring the capital necessary, the "fee for use" model is a legitimate way to go.

The remote ASP PACS is a difficult sell compared with other industries where the ASP model has been successful. Modality and workflow integration requires considerable customized work that needs to be done onsite. The file size of radiographic data is also atypical of the ASP industry. In the banking industry, the transaction size is on the order of kilobytes (KB) whereas in radiology that transaction size is easily 1000 times larger. This larger data size drives the transmission costs up over a wide area network at even minimally acceptable performance rates.

The ASP model has validity when a facility is too small to support the salary of an administrator. That threshold is well under 50 000 procedures per year and can be calculated by looking at the total cost of ownership between the two models. But I believe it is a Faustian bargain to rely upon your ASP vendor for IT expertise. Computer technology is a disruptive industry and vendors do not always pass on the benefit of lower cost technology. The physicist, who frequently acts as the technology officer of the department, could justify the cost at even a modest sized institution.

It is very desirable for a hospital to have a physicist who can understand the entire imaging chain, from image generation to image transfer to image review. Piggy backing PACS responsibilities onto the physicist's role is a great opportunity for recent graduates looking for a way to break into the industry and make a difference. The salary of a physicist can be easily cost justified compared with the cost of not being an educated consumer in the PACS industry.

AGAINST THE PROPOSITION: Charles E. Willis, Ph.D.

Opening Statement

An ASP is a business model used extensively in banking and other industries to obtain up-to-the minute information technology (IT) without investing in capital equipment and skilled IT personnel. The application service provider assumes the costs of hardware, software, maintenance, personnel and connectivity, and provides services that are critical to a customer's business. This model has been proposed as a way for hospitals to obtain a PACS without making a significant initial investment.[1,2] The fee for an ASP PACS service would appear in the institution's operational budget as an incremental cost of doing business, instead of as a combination of capital budget items and operating expenses. In many ways, the ASP model resembles leasing, which is used widely to obtain medical imaging equipment.

The notion that an ASP has no legitimate role in radiology reflects the idea that an institution must retain control over medical images. However, most radiology operations outsource their long-term archives of images offsite. Few departments have sufficient space onsite to maintain even two years of films. The expanding availability of electronic imaging and low-cost, high-volume storage paves the way for a return to the ideal of retaining image archives entirely within the institution. This return would require an expanded radiology IT staff, which would be a challenge considering the current demand for skilled personnel in the IT industry.

An ASP does not have to provide total IT support for a radiology department. It can play a more limited role, such as supplying the radiology information system (RIS) while the institution maintains the PACS system. An ASP could supply an offsite archive that serves as long-term image storage or as a disaster recovery system. The ASP could staff and operate the complete electronic imaging system, at the direction of the radiology department on the premises of the hospital. This would be an example of an "on-site ASP."

Some early adopters of PACS are now facing substantial investments to avoid technological obsolescence, in the sense that equipment and software cannot be reliably maintained. The ASP model can be considered as a way for hospitals to avoid technological obsolescence, because the responsibility for maintaining the IT system is transferred to the ASP. The operating cost for the system is negotiated and can be budgeted appropriately.

There are many community hospitals that do not enjoy the capital resources to purchase IT systems for radiology. They also lack the personnel to operate such systems. The ASP model is often an attractive option for these smaller hospitals.

Demonstration of an ASP as a viable business choice depends on several factors. The first is whether ASP can be cost effective. For an off-site ASP, broad–band connectivity to the hospital is crucial. Frequently, hospitals that would find ASP attractive are underserved in terms of network infrastructure. The specific terms of an ASP contract are especially critical, including performance, reliability, and exit clauses. The hospital is responsible for the quality and reliability of imaging operations: Whether an ASP can meet or exceed what the radiology department can provide on its own must be carefully examined.

Rebuttal

Dr. Nagy claims that an offsite ASP will cost more to operate than will a "third generation, off-the-shelf PACS." Because of numerous hidden costs, I remain skeptical of all PACS cost estimates, but recent studies[3] suggest that fee-for-use leasing has the greatest potential for cost-effectiveness in smaller hospitals. Who is going to operate, train, maintain hardware, software, and supplies for an "off-the-shelf PACS" system? Who is going to assure that the in-house archive is still functional when its end-of-life occurs before statutory requirements for retaining images are reached? Off-the-shelf systems eventually become obsolete and unsupportable, so replacement costs should be considered.

Dr. Nagy's analysis of bandwidth limitations from an offsite archive is flawed. To maintain continuity of clinical operations, it is only necessary to retrieve relevant prior images as needed, and not to immediately retrieve the entire archive. The archive could be completely restored by physically transporting magnetic media, rather than by "dedicated network transmission."

While I agree that most diagnostic physicists have the computer skills to understand PACS, I strongly disagree that implementing and supporting PACS is an appropriate role.[4] While the physicist can act as a valuable consultant to the hospital, this should not include performing economic analyses for hospital administration or managing an electronic image distribution system. "Medical physicists must utilize their training and expertise in the physics of imaging to continue to provide the highest quality diagnostic information to the radiologist with the least possible radiation or other safety risk to the patient, staff, or public." [5]

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10.5. The provision of consultative physics services as commodities undermines the professionalism of medical physics

Robert Kriz and Lincoln B. Hubbard
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OVERVIEW

Medical physicists have traditionally been full-time employees of hospitals or healthcare organizations. In this capacity, physicists have contributed to professional needs such as staff training, equipment acquisition, policy development and procedure evaluation, in addition to technical concerns such as equipment calibration, quality control and radiation safety. Increasingly, these technical concerns are outsourced to consultants who offer physics services as commodities on an as-needed basis. This approach decreases opportunities for physicists as full-time employees of institutions, and undermines the professionalism of medical physics.

Arguing for the proposition is Robert J. Kriz, M.S. Mr. Kriz received his M.S. from DePaul University in 1976, and recently retired from the University of Illinois Hospital and Clinics in Chicago. He spent the last 20 years working in diagnostic radiology writing purchase specifications, doing bid evaluations and acceptance testing of radiological imaging equipment. He also developed and ran the physics and radiobiology training program for radiology residents at the University of Illinois, and taught the diagnostic physics course for over 20 years. He still teaches diagnostic radiological physics at Rush University.

Arguing against the Proposition is Lincoln B. Hubbard, Ph.D. Dr. Hubbard is a radiological physics consultant in the Midwest. A physics B.S. at the University of New Hampshire preceded a Ph.D. in theoretical nuclear physics from M.I.T. A postdoctoral at Argonne National Lab under Warren Sinclair was followed by 6 years of college teaching along with research at Oak Ridge National Lab. In 1974 Dr. Hubbard changed from academic to clinical work, and he joined Fields and Griffith in their consulting group the following year. He is certified by both the ABR and the ABHP, and has been active with the ABR since the 1980s as an oral examiner and as a contributor to the physics written exams. In the 1980s he assisted Dr. Lanzl in creating the medical physics teaching program at Rush University. Also in the 1980s he was the lead physicist in the Illinois Radiological Society's mammography accreditation program which became, in 1987, the ACR MAP program. He and Nancy, his wife of 41 years, have two daughters and two granddaughters.

FOR THE PROPOSITION: Robert J. Kriz, M.S.

Opening Statement

Several trends that began some time ago are reducing medical physics to a commodity service and seriously eroding the profession. A physics report is a commodity when its accuracy and relevance cannot be judged by the administrator paying for it (e.g., a safety report on an x-ray

facility). However, if the state accepts the report, it is considered adequate. This can be especially problematic if the agency is more likely to accept the report if written by a former state employee who is now in the private sector.

I am chagrined at the diminishing number of diagnostic physicist positions in medium to large hospitals. Where such positions do exist they tend to be in academic institutions dedicated to research. Research is important, but it doesn't address the common problems of a large radiology department. The issue is that the diagnostic physicist does not generate revenue, and therefore is expendable so long as regulatory requirements are met.

Writing performance specifications and acceptance tests into bid documents is happening less frequently, partly because of the formation of large purchasing groups. At my former institution, there were several large purchases made without any physics input at all. In one case several units were combined into a single purchase to force vendors to be more competitive. Because of the size of the purchase, university management took charge of the negotiations, with disastrous consequences. Price was the only consideration in these negotiations, and systems were downgraded, needed options were dropped, less powerful generators were acquired, and low-end imaging chains were substituted, all without the knowledge or advice of the physicist.

My state allows the bid procedure to be bypassed if the preferred vendor has contracted (with large specified discounts) to a buying group. Often a vendor is preferred simply because the selection reduces paper work and avoids complicated analyses of competing systems. In this approach, physics advice is eliminated entirely. This is happening despite the advance of technology and the increasing complexity of equipment. In these situations the physicist is relegated to safety surveys, shielding calculations and distribution of film badges. Even in these areas, especially surveys of x-ray equipment, the work is often transferred to nonphysics personnel.

Safety surveys of x-ray equipment require strong (and formal) education in physics. Modern R&F and especially special procedures/cath labs, have become enormously complex. Adjustable filtration and automatic brightness stabilization that is contrast dependent is in use. A cookbook inspector filling out forms, measuring HVLs and checking collimator accuracy may entirely miss the point. But who educates the administrator? If the credentials and reports of the inspector are accepted by the approval agency, and the financial investment is low, the administrator is happy.

Standards makers and regulators have also contributed to the problem. The Joint Commission on Accreditation of Healthcare Organizations seldom reviews the credentials of physicists performing equipment safety surveys. As a result, many of these surveys are performed by RTs who purchase a dosimeter and fill out forms. Often the selection of physics support is made by a chief technologist or business manager with more concern about cost than about expertise. We need the help and support of our radiology colleagues to ensure that the standard of care is not reduced. Many radiologists are not aware of this problem.

The FDA under MQSA has contributed to the problem by not insisting on high standards of education, and by allowing the states to approve inspectors of mammography equipment. In many cases states have decided that an RT with a short training course and some experience is equivalent to an advanced degree in physics. This situation has improved somewhat recently but needs much more improvement.

Rebuttal

I strongly agree with my colleague that the consulting medical physicist adds to the professionalism of the discipline. But how is the decision made to go "outside," and who makes it? In today's competitive and cost-cutting environment, a request for a consultant may be looked upon as a shirking of responsibility. In actuality, it is more likely to be the opposite, especially as technological sophistication increases. Can all hospitals perform IMRT, TIPS, digital mammography, etc.? Competition demands they must. Costs may demand otherwise. Physics support for these services is viewed by some as purely a cost without significant benefit (i.e., income). Radiologists understand these services cannot be performed without strong physics support, but they are in their own financial battle.

Credentialing of medical physicists has become more important than ever. Statutory credentialing may become necessary. Administrators are more likely to respect the credentialed physicist as a professional. Once they are aware of Board Certification, for example, administrators are less likely to accept reports from uncredentialed "look alikes."

When a regulatory agency accepts reports from less than fully qualified medical physicists, they severely damage the profession.

AGAINST THE PROPOSITION: Lincoln B. Hubbard, Ph.D., FACR

Opening Statement

In 1902 there were no radiation physicists routinely working in the clinical environment. The physician radiologist was a jack-of-all-trades who could manufacture photographic plates, generate high voltage, get a gas x-ray tube to conduct, position a modest patient, and interpret results. Fifty years later, radiologists had specialized assistants—including those jack-of-all-trade medical physicists who are the colossi of our professional heritage.

Specialization is a major contributor to the "professional success" of radiology, both for the "professionals" (radiologists, physicists & technologists) and for the population served. Specialization occurs in many fields; in economics it is viewed as one of the wealth producing engines of modern society. Specialization in medical physics is no exception. The diverse offering of modern medical physics requires too may skills for a single jack-of-all-trades to be a professional expert in all areas.

With a fragmented and highly specialized field, how are all of the special offerings to be covered? The jack-of-all-trades cliché includes "master of none." That is, a full-time physicist who limits medical physics services at an institution to his/her expertise is probably acting in an unprofessional manner. On the other hand, a full-time physicist who performs services beyond his/her professional capability is certainly unprofessional. The full-time physicist should encourage the most appropriate medical physics services for his/her facility. If additional expertise or effort is needed, then it should be provided by either additional full-time physicists or by consultants. The choice between the two depends on efficiency. Does the use of a consultant negatively impact a full-time medical physicists? Certainly not, if the use is appropriate and properly integrated into the physics services of the facility. For example, infrequent tasks such as shielding design, beam data acquisition, or acceptance testing might be beyond the physicist's expertise, or involve too much effort to be handled by the regular staff. Certain routine tasks may also be better handled by consultants than by full-time staff, due to time, interest or expertise limitations.

Mammography physics is one area where physics professionalism has grown rapidly in the last decade. Here specialization with extensive first-hand experience is recognized as essential both within the clinical area and by regulatory and accrediting bodies.

There is nothing unusual about reducing a highly specialized professional service to a commodity; this is simply fee-for-service. The professional paragons: medicine, law and accounting, make widespread use of fee-for-service. Services delivered without fee-for-service, i.e., only by employees, such as military officers and bureaucrats, are usually considered less "professional." When fee-for-services exists, so do consultants. It is the consultants who set the professional standards and fees. It is the market activity of consultants that allows a balance between a client's needs and the professional's service. Economics tells us that goods and services produced under conditions far removed from the free-market situation are inferior in the long run. Medical physicists whose standards and/or fees are set without significant marketplace input deliver inferior (and thus, intrinsically unprofessional) value. If medical physicists as a group manage to follow such a course, they will achieve an inferior professional status in the long run.

Rebuttal

My colleague is correct in stating that a problem with physics professionalism is the presence of self-proclaimed physicists who know little about actual physics, and yet act as consultants. But my colleague errs in suggesting that eliminating consultants will eliminate the problem. As with most multifaceted endeavors, some routine tasks carried out by legitimate physicists could be handled by technicians with less training. As with nurse-physician or paralegal-attorney relationships, these technicians need adequate supervision to ensure that conditions are not mishandled because they are misunderstood. It is the independent and unsupervised activities of the inadequately trained that usually lead to services of poor quality.

To a considerable extent, well-trained physicists are to blame for this situation. We have burdened ourselves with protocols designed to make our tasks straightforward. To the uneducated, these protocols make the tasks look easy. Often we end up with an approach that mandates one method, even though alternate methods may yield satisfactory results. In many imaging evaluations, for example, four repeat measurements are required to determine a coefficient of variation. This number is not derived from statistics, but is a purely operational technique to allow the statistically incompetent to make valid "judgments."

My colleague is also correct in his other major point that medical physicists are often underutilized. He identifies part of the cause of underutilization as the commodity nature of consulting. The remainder of the cause can be attributed to misguided or under applied standards of accrediting and regulatory bodies. I agree with the comment about underutilization, but believe that the cause of this problem does not lie primarily with organizations such as the JCAHO or ACR. We medical physicists have not defined the core services that we have a unique capability to perform. Until we define these services, and market ourselves as being defined by them, they won't sell very well to organizations whose interest in medical physicists is less consuming than our own. AAPM committees spend too much time with the promulgation of protocols and too little time defining why and how we can make clinically important and cost-effective contributions to health care. And almost no time is spent developing arguments to describe why our training and experience gives us the legitimacy to provide these contributions. If we really want a profession, we must define it, legitimate it and sell it.

10.6. The growth of biomedical engineering is a major challenge to medical physics

Randell L. Kruger and Bruce H. Curran
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OVERVIEW

Educational programs in biomedical engineering are rapidly establishing and growing, in large measure because of funding from the Whitaker Foundation and National Science Foundation. In these programs, the most popular instructional track is imaging. Some diagnostic physicists feel that this pipeline of imaging-trained biomedical engineers is a major challenge to physicists in imaging. Others think that this influx of engineers is an opportunity that should be capitalized on. This difference in perspective is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is Randell Kruger, Ph.D. Dr. Kruger is the Medical Physics Section Head in the Radiology Department of the Marshfield Clinic. Dr. Kruger received his Ph.D. from the Medical College of Ohio and completed a post-doctoral medical physics residency at the Mayo Clinic. Prior to his doctoral program he earned a master's degree in mechanical engineering from Arizona State University. He has seven years of engineering work experience with the U.S. Air Force and Allied-Signal, Inc. He is certified in Diagnostic Physics by the ABR and is president of the North Central Chapter of the AAPM.

Arguing against the proposition is Bruce Curran, ME, MS. Mr. Curran received his Masters Degrees from Dartmouth College (Engineering Science-Biomedical Engineering) and Northeastern University (Computer Science). He is Clinical Assistant Professor of Radiation Oncology at the University of Michigan and responsible for clinical physics within the Department of Radiation Oncology. He currently serves as chair of the Meeting Coordination Committee of the AAPM and co-chair of a task group on clinical implementation of Monte Carlo dose calculations. He is a fellow of the AAPM and the ACMP.

FOR THE PROPOSITION: Randell L. Kruger, Ph.D.

Opening Statement

Can an engineer become a medical physicist? I am a personal testimonial that engineers can and do migrate into medical physics, after receiving the proper educational and clinical training. During the 2003 AAPM Annual Business Meeting in San Diego the topic of changing the academic requirements for AAPM membership was discussed. The proposed amendment adds two words to ARTICLE IV, Section 4 of the Bylaws—they are ("or Engineering" added to the existing text of Physical Science). This change would add engineering degrees to the criteria for AAPM Membership eligibility. The motivation for the change is the need to create consistency between current practice and the bylaws. However, some diagnostic medical physicists are concerned that imaging-trained biomedical engineers would challenge the role of, and seek to replace, the diagnostic medical physicist.

The clinical and research applications of medical imaging in bioengineering have contributed to the explosive growth of biomedical engineering jobs.[1,2,3] Of the more than 100 college and university programs that offer academic programs in biomedical engineering, more than half offer imaging educational or directed-research programs.[1] Significant job growth and interest in biomedical imaging has been accelerated with the lure that "all teaching hospitals, have a growing need for bioengineers trained in imaging methods." [2] The U.S. Labor Department's Bureau of Labor Statistics projects that the number of biomedical engineering jobs will increase by 31.4 percent through 2010.[1] Are all of these imaging-trained biomedical engineers planning to work for industry or in research? The National Institutes of Health Bioengineering Consortium provides a definition of bioengineering, which does not include the word "imaging" anywhere in its 59-word statement.[4] Yet the rapid development of a biomedical imaging curriculum and career field in biomedical engineering indicates a shift in focus of the biomedical community.

The roles of the medical physicist in diagnostic imaging have been well documented and comprehensively defined by the AAPM, the American College of Radiology (ACR), and the European Federation of Organisations for Medical Physics.[5,6,7] These organizations have described and defined the diagnostic medical physics professional role, and the practice, training, and qualification requirements in the field. A primary responsibility of the diagnostic medical physicist is the development and supervision of a quantitative quality control program. However, the diagnostic medical physicist has several other responsibilities and duties (such as: radiation safety; compliance activities; radiobiological, shielding and equipment evaluations; educational activities; and research, to name just a few). An imaging-trained biomedical engineer is not prepared or trained to perform these duties and responsibilities. Most members of the biomedical engineering and medical physics communities understand the differences between a diagnostic medical physicist and a biomedical engineer. The concern is that other members of the medical community might assume (or be misled to understand) that an imaging-trained biomedical engineer can perform the duties and responsibilities of a diagnostic medical physicist. This would jeopardize the quality of diagnostic imaging services provided to the medical facility and its patients.

Rebuttal

I agree with my colleague that medical physics is an applied branch of physics that deals with the application of physical principles to the diagnosis and treatment of human disease.[8] However, I disagree with his statements that link engineers and medical physicists. The logic he employs to support the equivalence of biomedical engineering and medical physics is flawed.

Medical physics is a focused field of study that requires clinical training or preceptorship. Biomedical engineering is a broad interdisciplinary field of study with little or no clinical training. A description of biomedical engineering provided from a large state university biomedical engineering department[9] states "the Biomedical Engineering Graduate Program is an interdisciplinary program designed to provide broad familiarity with the interactions among the engineering, biological and medical sciences and in-depth training in one of the traditional engineering disciplines." Medicine in general is an application of science to the treatment of human disease and health, and its practitioners are educated and trained specifically for expertise in their field. It appears my colleague proposes an exception to this rule for biomedical engineers. Medical physics is significantly influenced by the technological advances, as is all of medicine. An individual with broad familiarity would lack the specific training and experience necessary to provide the required clinical services.

I think it is important to consider the fundamental factors driving this issue. The Whitaker Foundation's funding has significantly accelerated and expanded educational programs in biomedical engineering. The expansion of biomedical engineering into medical imaging, interestingly, comes at a time when the medical physics profession is experiencing a shortage of practitioners and a limited number of training programs. Donald Frey's statement[10] "one of the more serious problems facing the profession of medical physics is the shortage of practitioners" highlights this problem. The laws of supply and demand cannot be ignored.

Can an engineer become a medical physicist? The answer is yes, provided he or she obtains the proper academic preparation and clinical experience.

AGAINST THE PROPOSITION: Bruce Curran, ME, MS

Opening Statement

According to the AAPM, medical physics is "an applied branch of physics concerned with the application of the concepts and methods of physics to the diagnosis and treatment of human disease." [11] This definition focuses on the application of training and experience to the diagnosis and treatment of patients. There are few (if any) medical physicists engaged in pure research without thought to its future implementation, which distinguishes us from many of our colleagues engaged in more theoretical branches of physics (defined, at least from one source, as "the science of matter and energy and of interactions between the two, . . . ").[12] An interesting observation on these definitions is that, for many universities, education in the field of "Applied Physics" often appears under the domain of the College of Engineering.[13]

Appropriate to this discussion is a look at the profession of engineer. One dictionary defines an engineer as "one who is trained or professionally engaged in a branch of [engineering] the application of scientific and mathematical principles to practical ends such as the design, manufacture, and operation of efficient and economical structures, machines, processes, and systems." [12] Since physics is clearly a member of the sciences, it appears that engineers are individuals who can also be considered to be involved in the application of physics to the solution of a certain class of problems such as the diagnosis and treatment of human disease. It would thus seem that, with a slight twist on the origins of the phrase, "We have met the enemy and he is us." [14]

For the majority of medical physicists today, technological advancements in imaging and therapy have led to a new role for the medical physicist, namely that of manager of the complex equipment necessary to our profession. We are no longer expected only to understand how different radiations interact with materials and patients. Today, physicists must also be knowledgeable about computer systems, networks, and the myriad of new technologies essential to current clinical practice. The influx and influence of individuals with advanced training that includes an in-depth understanding of the technology itself is helpful, perhaps even necessary, to effectively carrying out our duties, as well as advancing state-of-the-art patient care. A collaborative environment that includes professionals with skills both in physics and engineering appears to be the best of all worlds.

Patients benefit from having a team of individuals with a broad range of skills available for designing, building, testing, and monitoring the techniques and equipment needed in the practice of medical physics. These skills require significant education, training and experience, and it is

unlikely that any single individual will master all aspects. The inclusion of biomedical engineers, with their strengths in equipment and biological/equipment interfaces, in the profession of medical physics will strengthen our profession and allow it to grow. This in turn will improve our stature and acknowledgement as key individuals in the diagnosis and treatment of patients.

Rebuttal

One might as well ask "Can a theoretical nuclear physicist become a medical physicist?" The answer of course, is yes, as many of our colleagues can attest. Did their initial education completely prepare them for our field? Probably not. As Dr. Kruger notes, proper education and clinical training is necessary for most individuals entering our field, whatever their educational background.

Does an education in biomedical engineering prepare individuals less well for entering our field? It certainly prepares them differently. A biomedical engineer specializing in biomechanics would be no more suitable for clinical practice than the theoretical nuclear physicist. A review of the course offerings in a biomedical engineering program reveals courses in anatomy, instrumentation, physiology, radiological health, imaging (radiation, MR, optical), and medical imaging systems,[15] all appropriate to our profession.

So how do we "separate" those engineers (and physicists) not appropriately qualified to practice medical physics from those who are? Ideally, the certification/licensure process would ensure that only qualified individuals attain the title of medical physicist. The reality is, however, that many individuals are given the title long before they acquire the skills necessary for practice. This is mostly a result of history; the small number of educational programs in medical physics, the lack of appropriate residence and training programs that give us the time to acquire needed skills before certification, and the rapid increase in the need for properly trained professionals in our profession.

Medical physics as a career will continue to attract a polyglot of engineering and scientific professionals. It offers the alluring combination of interesting, challenging problems, the satisfaction of helping humanity, and good salaries and benefits. The incorporation of such diverse backgrounds has helped to keep the field fresh and innovative. We should continue to encourage entry into medical physics of persons with diverse backgrounds, while striving to improve the processes by which we identify those individuals who have earned the title of medical physicist.

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10.7. Through their preoccupation with new technical developments, physicists have lost sight of the realities of cancer care and statistics.

Robert J. Schulz and James A. Deye

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OVERVIEW

The history of radiation oncology is a marvelous story of technical developments leading to improvements in the care of cancer patients. Many of these developments have increased the precision of treatment and the (tumor)/(nontumor) dose ratio to yield higher cure rates with fewer side effects of irradiation. There may be, however, a point beyond which the biological variability of patients, rather than the imprecision of treatment, becomes the dominant influence on treatment success. Whether we have reached, or gone beyond that point, is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is Robert J. Schulz, Ph.D. Dr. Schulz is a Charter Member and Fellow of the AAPM, Fellow of the American College of Radiology, and Diplomate of the American Board of Radiology. He delivered the Earle Gregg Memorial Lecture and has twice been a recipient of the Farrington Daniels Award. He was the Chairman of the Subcommittee on Radiation Dosimetry (SCRAD) and of Task Group 21 for high-energy photon and electron dosimetry. His professional career began at Memorial Sloan-Kettering (1952–1956), developed further at the Albert Einstein College of Medicine (1956–1970), and concluded at Yale University (1970–1992). His retirement to rural Vermont has enlarged his perspective on radiation oncology.

Arguing against the Proposition is James A. Deye, Ph.D. Dr. Deye is Program Director and Expert in medical physics with the National Cancer Institute, Radiation Research Programs. His Ph.D. is from Vanderbilt University based upon nuclear physics research completed at Oak Ridge National Laboratory. He has been a member of numerous committees within the AAPM, ACR, and ACMP and chaired the AAPM Professional Council in the mid 1980s, where he founded and hosted the first Tri-lateral Committee meeting. He is a Fellow of the AAPM and board certified in radiation oncology physics by the ABMP and in radiological physics by the ABR.

FOR THE PROPOSITION: Robert Schulz, Ph.D.

Opening Statement

Although originally applied to stock brokers, the term "irrational exuberance" is also appropriate for some medical physicists. By suggesting that IMRT is the holy grail of radiation therapy, it appears that these physicists have lost sight of the realities of cancer and its management. Although highly profitable for manufacturers and good for the employment of physicists, it is unlikely that IMRT will reduce overall cancer mortality.

The rationale for IMRT is simple: a) the achievement of local control will reduce mortality; b) the likelihood that this achievement increases in some unspecified way with tumor dose.

Although local control is likely to reduce local recurrence, about 70% of cancer deaths are due to metastatic disease despite aggressive treatment of the primary. This is clearly the case for breast cancer where local control is readily achieved but mortality has not changed in 70 years. And in cancers in which death is caused by failure to achieve local control, e.g., brain and ovarian tumors, there is little reason to expect better outcomes by simply increasing the dose. As with surgery, the goal of IMRT is to "resect with negative margins" while avoiding the trauma and mortality of operative procedures. However, surgical resection fails for many cancers. Why should we expect more from IMRT? Surgical resection with adequate margins is standard therapy for esophageal cancer, for example, but five-year survival remains a dismal 12%. The achievement of local control has been a mantra for cancer therapy for many years, but relatively static mortalities suggest that newer, more sophisticated, systemic therapies will have to be developed before significant improvements are obtained.

In the U.S. this year, cancers at twenty specific sites will account for over 93% of the estimated 1.27 million new cases and 91% of the 553 thousand deaths. Surgery is the primary therapy at eleven of these sites and chemotherapy at three, with radiation primary or competitive with surgery at only six. Excluding skin, the remaining five (uterine cervix, endometrium, oral cavity, brain and prostate) account for 24% of incidence and 12% of mortality (with the prostate responsible for 15.6% and 5.7% respectively). As IMRT is mainly envisaged as replacing or supplementing conventional radiation treatments, it is unlikely to change the distribution of therapies, so what gains may be realized by IMRT will have to be made at those five sites. If, and this is a very big "if," IMRT could reduce the 12% level of mortality by one tenth, and assuming that it is employed for all patients in four of the five sites and for half of all prostates, then the overall number of deaths would be reduced by about 4900. To realize this gain, each of the approximately one thousand radiation centers in the U.S. would need one IMRT system. Each of these systems would at best extend the lives of five patients per year. How can this huge capital investment and operational expense be justified?

Rebuttal

It appears that Dr. Deye may be amongst those who "have lost sight of the realities of cancer care and statistics." At no point in his argument does he discuss even one form of cancer. He eschews statistics and mortality trends, and presents little evidence to support the introduction of complex and expensive technologies such as IMRT. Does Dr. Deye endorse the idea that "the marketplace will judge the cost/benefit ratio" for a new technology like IMRT? Certainly he knows that expenditures for radiation therapy are steadily increasing while reductions in cancer mortality over the past 20 years are at best modest and probably unrelated to improved radiation delivery systems.

Although not large, the number of patients who have received IMRT is sufficient to provide a reasonable assessment of its potential benefits. A recent Medline search using the search term "IMRT and prostate cancer" identified 30 citations, none of which showed IMRT to have any impact (positive or negative) on morbidity or mortality. As this "darling" of IMRT can be as effectively treated by conventional radiation, implants or surgery, one wonders why virtually every current and future owner of an IMRT system offers prostate treatment as the principal justification for its purchase.

Some of us recall earlier efforts to improve radiation therapy such as 70 MV x rays, hyperbaric oxygen tanks, neutron beams, and negative pi mesons. At the time, the rationale for each of these made as much sense as IMRT does today. However, whereas these earlier experiments were tried

on a limited scale and at relatively low cost, IMRT is market driven (as the commercial exhibits at AAPM and ASTRO meetings clearly demonstrate). It appears that competition between hospitals for patients plays a far larger role in purchase decisions than do expectations of improved clinical results.

AGAINST THE PROPOSITION: James Deye, Ph.D.

Opening Statement

This is not a new concern. It might have been voiced about physicists who looked for ways to use radioisotopes to quantify organ function or morphology, accelerators to replace Cobalt 60 units, and computerized treatment planning to expand point dose calculations, to name just a few. What all such events have in common is the "preoccupation" of scientists, especially medical physicists, with the utilization of recent scientific or engineering accomplishments for medical purposes. In each case scientists were pursuing new avenues of diagnosis or treatment as opposed to just performing functions in support of the status quo. And in each case it was not a given that there would be a clinical benefit relative to that status quo (e.g., 4 MV linacs over Cobalt 60 and electron beams over orthovoltage). One may wish to argue that some of the now-accepted technologies have not truly advanced the care of cancer patients. If so, then let's weigh these standard treatment and diagnostic methods on the basis of patient outcomes and eliminate or curtail those that don't *measure up*. However, *outcomes* data cannot be used to predict which new technologies will be beneficial, and we impede true advances if we decide on the basis of personal guesses or biases. As always there needs to be a balance between the new developments and the support of quality in standard practice. However, I am unaware of any data to suggest that this balance has been lost.

The proposition may be construed to mean that some of these new tools are moving too quickly into standard practice before their safety and efficacy have been adequately demonstrated. Yet, even if true, this argument would say that physicists are not spending enough time on these new developments rather than too much. In addition, if the proposition is extended to say that the implementation of some of these new technologies is so labor intensive as to detract from required clinical needs, this just underscores the need for clinical facilities to forego the use of these new methods until they have the appropriate staffing. To do otherwise jeopardizes patients and puts institutions at risk, but it should not be used as an indictment of the pursuit of the new technologies. It may be that some physicists have abrogated their role in advising clinicians and administrators on required staffing needs. And it may be that some clinical physicists are not trained to the level required by these new techniques. Yet neither of these possibilities should short-circuit promising developments.

There is ample reason to believe that many new technologies (from bio-imaging to IMRT) will in fact improve cancer care. Whether this can be demonstrated with a probability sufficient to *justify* the cost is a question that goes well beyond science, since it depends also on economics, politics and societal needs. But as was said in the opening sentence, "this is not a new concern" nor is it unique to medicine. It is the duty of the scientist to get the science right and to let those who deal with the *big* picture put things into perspective. The marketplace will judge the cost/benefit ratio, clinicians will judge the quality of patient care, and society will balance the agenda. It would be arrogant of the physicist to preempt any of these roles.

Rebuttal

My esteemed colleague is using the debate technique known as "begging the question." The question is not just IMRT or cancer mortality; it is technology in the whole cancer picture. In this setting one must consider morbidity and quality of life issues in addition to mortality. Many studies are proving that new image-guided therapies, of which IMRT is one, are allowing increased doses to tumors with smaller doses to normal tissues. Zelefsky *et al.* observed one-third the degree of rectal toxicity at 81 Gy to the prostate with IMRT compared with 3D CRT.[1] This is a major issue for patients who live a long time after treatment even if they are not "cured." Reduced morbidities and greater patient convenience can make radiation therapy the treatment of choice for tumors that historically may have had surgery as their primary treatment (e.g., breast cancer, prostate, brain). Thus, an argument based simply on mortality, underestimates the true value of IMRT as more sites become amenable to radiation therapy because of its increased precision and understanding of treatment bio-effectiveness extending beyond the physical dose. Similar considerations apply to other treatment technologies such as HDR, permanent seed implants, proton therapy, radio-immunotherapy and many variations of IMRT such as tomotherapy and robotic arms.

On the diagnostic side, fMRI, MRS and PET are delineating targets that require precision treatment delivery. They are also providing new information that is affecting treatment decisions and Quality of Life issues for incurable patients. These decisions are contributing to development of a more comprehensive picture of the disease process and offering appropriate treatment choices at different stages of disease.

Clearly there is a balance to be struck between the cost of new technologies and the probability of benefit. This question goes well beyond the expertise of the physicist who is asked to explore the true potential of many very exciting technologies. If physicists do their part with scientific rigor, others will be able to use these results to fill in the rest of the picture. In this manner physicists, along with many other interested parties, will be able to judge the art that rests on the science of medicine.

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10.8. Medical physicists would benefit by establishment of an Institute for Biomedical Imaging

Philip F. Judy and Stephen R. Thomas
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OVERVIEW

Both the U.S. House of Representatives and the U.S. Senate are considering bills to establish a National Institute of Biomedical Imaging (NIBI) within the National Institutes of Health. The House bill (HR-1715), introduced in May, 1997 by Rep. Burr (R-NC) has been referred to the House Committee on Commerce's Subcommittee on Health and Environment. The Senate proposal (S-990), introduced by Sen. Faircloth (R-NC) in July, 1997, has been referred to the Senate Committee on Labor and Human Resources. As stated in both bills, the purpose of the NIBI is to ''conduct and support research, training, the dissemination of health information, and other programs with respect to radiologic and other imaging modalities, imaging techniques, and imaging technologies with biomedical applications. As described by William Thompson MD, Chairman of Radiology at the University of Minnesota in a recent issue of *Medical Imaging*, ''It's critically important for us to try and get all the dollars centered in a biomedical imaging institute, and to distribute those dollars in a much more effective way than we ever have.'' The NIBI would be guided by an Advisory Committee consisting of 6 scientists, physicians, and health professionals knowledgeable about imaging, and 6 scientists, physicians, and health professionals from other disciplines.

Arguing for the Proposition is Philip Judy. Philip F. Judy is Director of the Division of Physics and Engineering and Associate Professor of Radiology at Brigham and Women's Hospital and Harvard Medical School. His early research, which developed methods to measure image quality of CT images, led to his present research that studies how variations in image quality affect radiographic-image perception. He is studying how variations in breast parenchymal patterns, genes, family, and race affect the perceptual and cognitive processes associated with the detection of breast cancer using mammography. The goal of this research is to produce earlier and more specific diagnoses from mammography. His past research has investigated lung and liver nodule detection using CT imaging. The long term goal of his research is to develop methods to reliably predict the clinical usefulness of novel imaging technologies for engineers who are developing and optimizing image technologies, and for health care policy makers, radiologists, and radiology administrators.

Arguing against the Proposition is Steve Thomas. Stephen R. Thomas is Professor and Director of Medical Physics within the Department of Radiology, University of Cincinnati College of Medicine. He has recently served as President of the American Association of Physicists in Medicine (1997). Dr. Thomas earned his Ph.D. degree from Purdue University in 1973 in solid state physics, and made the transition into medical physics through a postdoctoral fellowship at the University of Cincinnati in 1974. His research interests include F-19 MRI of perfluorocarbon compounds, and radiopharmaceutical dosimetry. He has served as a member of the NIH Diagnostic Radiology Study Section (1993–1996).

For the proposition: Philip F. Judy

Opening Statement

The introduction of bills in Congress to create the National Institute of Biomedical Imaging (NIBI) is the consequence of a 25-year effort by radiologists and medical imaging scientists. For the past few years I have been involved in that effort as the AAPM representative on the Board of Directors of the Academy of Radiology Research (ARR). The ARR is an organization of more than 20 medical imaging societies that is promoting the creation of the NIBI. The organizing principle of this effort is that the National Institutes of Health (NIH) are not structured to support the investigation of fundamental medical imaging questions.

Disease or organ questions determine the structure of the NIH. Consequently, the fundamental questions that emerge from NIH supported enterprises are addressed by molecular biology. Important medical imaging questions are neither disease-specific nor organ-specific. The answers to such questions emerge from physics, mathematics, computer science, and psychology. The creation of the NIBI, if achieved, will benefit the medical physicists who would receive increased grant support because their questions would emerge and their grants would be funded.

Two questions remain. What is the likelihood that the NIBI will be created and, if it is created, that it will deliver? The answers to the two questions are linked. Since the NIBI is promoted by ARR, which is dominated by radiologists, why did they not propose the creation of the National Institute of Radiology? To attract the necessary congressional support, the ARR leaders understand that the new institute must have a wider constituency than just radiologists. One constituency are the members of the 16 biomedical engineering organizations constituting the American Institute for Medical and Biological Engineering (AIMBE). The AAPM has representatives on the AIMBE Board and the current AIMBE president is a medical physicist (W. Hendee). I believe that the creation of NIBI requires an alliance of ARR and AIMBE. An effective alliance necessitates compromise, and that compromise naturally promotes the medical physics agenda. In any case, the creation of the NIBI seems to be on track and, its charter will increase the stature of medical physics within the NIH.

NIBI will have other roles that will provide opportunities for medical physicists to contribute to improved national health. NIBI will coordinate medical imaging research both within the NIH and in other federal agencies. One might argue that the chaos that exists in the funding of medical imaging research is a result of the lack of an effective medical imaging voice at the higher levels of decision making at NIH. NIBI would have authority to establish high level contacts with industry. Medical physics imaging research falls in the cracks between federal funding and industrial funding. A consensus regarding the appropriate roles of industry and government in funding medical imaging research will increase opportunities for medical physicists. NIBI will have a role as a third party with industry and regulators regarding the appropriate methods of evaluation of imaging systems. Methods of image evaluation are an important part of medical physics.

Rebuttal

Dr. Thomas argues that the NIH funding of biomedical imaging research is generous. Any argument that a large or appropriate amount of the NIH funds are spent on biomedical-imaging research is suspect until the biomedical-imaging expenditures are accurately classified.

Typically, the classification is done by officials at the NIH who are attempting to impress you with the magnitude of resources that they are devoting to your problem. We must distinguish between the cost of using mature imaging technologies and biomedical imaging research. One consequence of the effort to create the NIBI is an increasing sophistication at the NIH of what constitutes biomedical-imaging research.

Biomedical-imaging research is cut back disproportionately during funding downturns because its cost is included in the cost of the use of imaging technologies. It is reasonable to reduce purchases of expensive technology not critical to your mission when your budget is reduced or does not grow as expected. The reason that entrenchment leads a disproportionate decrease in funding of biomedical-imaging research is the perception at the NIH that biomedical-imaging research is not a specific national health care mission. The goal of creating the NIBI is to change that perception of decision-makers and avoid yo-yo funding of biomedical imaging research.

Dr. Thomas poses some specific and important questions that deserve more extensive debate than is possible in this forum. The following are brief responses to these questions.

Some of the cost of imaging at the NIH is better classified as purchases of mature imaging technologies rather than research. Monies would remain at the other institutes to purchase such mature imaging technologies.

The probable additional administrative cost of the NIBI is a point well taken, but this problem is not inherent to the proposal to create the NIBI, which has the potential to create savings by reducing redundancy. It is, however, inherent to our democratic government.

The NIBI with an appropriate charter would reduce biomedical imaging turf conflicts rather than increase them within the entire federal government not just the NIH.

Separation of medical imaging scientists and skilled image clinicians (radiologists) within the medical school and hospital is counterproductive. As medical physicists we have learned that close collaboration with physicians promotes technological innovativeness. Such close collaboration is the paradigm that medical physicists have perfected, and we bring that experience to these deliberations. I hope that increased funding of biomedical imaging would not encourage deans of medical schools and presidents of hospitals to physically and administratively separate basic imaging scientists from their clinical colleagues.

Just like other basic scientists, biomedical-imaging scientists will have to make a continuing effort to inform the public and Congress about their contributions to national health. The answers to the basic physics, computer science and psychology problems that emerge from biomedical imaging are as directly applicable to specific medical problems as the answers to the basic chemistry problems that emerge from the study of the human genome.

Against the proposition: Stephen R. Thomas

Opening Statement

As a medical physicist engaged in research and a former member of the Diagnostic Radiology Study Section, I am intrinsically in favor of any development which would enhance productive

biomedical research. However, a devil's advocate role is appropriate as we define issues related to the proposed NIBI and question whether major concerns have been addressed.

Let us examine the basic premise for establishing a new institute, namely, that under the current organization by disease and organ system, the NIH is ill-equipped to support a discipline such as imaging which extends across these boundaries. It is argued that there is no home for basic investigations that promote the science of imaging as a primary mission. But are we convinced that imaging has indeed been ill-served under the old roof? From 1995 to 1997, NIH funding to academic radiology departments increased by 14% to $105 million, primarily channeled through the NCI. A like amount from the NIH went into other imaging grants bringing the 1997 total to approximately $200 million. Current 1999 federal budget projections include a $250 million 5-year increase in NCI's $2.5 billion annual budget, and medical imaging as a specialty is expected to receive one-fourth of that increase. Congressional bills specify that existing administrative resources within the NIH will be utilized for NIBI and that appropriations for the new institute will equal the amount currently obligated by the NIH for biomedical imaging. Whether or not new funds would be identified is ambiguous at best. Under the scenario in which monies are withdrawn from existing institutes, it would be difficult for those institutes to justify supporting projects involving imaging. Ultimately, entrenchment may lead to an inability to fulfill specific national healthcare missions.

The benefit of this institute to medical physicists should be defined in terms of its ability to enrich the research environment. However, with a narrowed focus on imaging technology potentially separated from the clinical setting, the outcome might be to exclude medical physicists as the workload is assimilated by biomedical engineers and scientists/investigators from non-medical backgrounds. Before establishing this new institute, fundamental questions must be answered:

> Through what formula will monies be designated and transferred from other institutes to support the new institute?
>
> What fraction of the transferred monies would be siphoned off for administration of the new institute as opposed to productive research?
>
> Will the public (and Congress) enthusiastically continue to direct funds toward 'Radiology' rather than toward recognized and clearly tangible disease categories as national killers (e.g., cancer, cardiac disease, etc.)?
>
> Would the new institute be integrated effectively within the NIH to improve the health of the nation, or would developing antagonisms (turf rage) toward this new entity prove counterproductive to this mission?
>
> Would innovative technological advances be impaired as a result of effective separation between imaging science and clinical disciplines?

I am not convinced that answers to these questions have been formulated satisfactorily. Certainly, the impact on the research medical physicist has not been unambiguously forecast. The forte of the medical physicist is in the combined worlds of medical science and direct clinical applications. We must be assured that imaging will not be isolated as a technical discipline with disfranchisement of the practicing medical physicist.

Rebuttal

Phil Judy has indeed raised the critical issue—If created, will NIBI be able to deliver? There are a number of forces assembled that might conspire to deny this opportunity. Some of them have been alluded to in my opening statement. Consummation of an alliance between the ARR and AIMBE represents only a single piece of the puzzle. The leadership at NIH must truly want to accept NIBI into the fold—an attitude which at present is not evident. Also, if NIBI is to succeed there must be advance treaties with the organ/disease institutes.

The academic radiology community's enthusiasm for supporting and conducting strong basic research has been growing steadily over the past 20 years. Thus it is natural to think about having one's own institute. However, in reality, there may be more opportunities within well-funded existing programs than in a startup institute. The risk is in creating an institute in name alone without the prerequisite resources to enable an effective increase in biomedical imaging research. Perhaps the more logical approach would be to look harder for those opportunities. For example, NCI's relatively new Diagnostic Imaging Program presents untapped potential. The startup time for a new NIH entity will be prolonged. One might expend the same effort and achieve greater results within the existing structure.

I, for one, do not feel that the present funding of medical imaging research should be described as ''chaos'' induced by lack of an effective voice at the top. Efforts to better conduct the assembled chorus may serve to produce a harmony of results far in excess of those envisioned through NIBI. The NIH should represent science and clinical innovation and not be defined within narrow technologies. Medical physicists might well benefit most through reorchestrating communications within the NIH rather than through formation of a new institute.

10.9. Candidacy for Board certification in Radiological/Medical Physics should be restricted to graduates of accredited training programs

Timothy K. Johnson and Bhudatt R. Paliwal
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OVERVIEW

In medicine, physician candidates for certification by boards recognized by the American Board of Medical Specialties must be graduates of training programs accredited by the Accreditation Council for Graduate Medical Education. There are two certification boards for medical physicists, the American Board of Radiology and the American Board of Medical Physics. Neither board requires graduation from an accredited graduate or residency program for individuals admitted to candidacy for board certification. As a consequence, there is little incentive for program directors or their institutions to seek accreditation of graduate or residency programs from the Commission on Accreditation of Medical Physics Education Programs (CAMPEP). Also, the dissociation between accreditation and certification in medical physics ignores one of the major criteria for assuring the quality of practitioners in a healthcare discipline. However restricting certification eligibility to graduates of accredited programs would penalize individuals who continue to enter medical physics in unconventional ways that would never be considered appropriate for accreditation. How this dilemma should ultimately be resolved is the subject of this Point/Counterpoint.

Arguing for the Proposition is Timothy K. Johnson, Ph.D. Dr. Johnson is Associate Professor in the Department of Radiology, and Director of the Graduate Program in Medical Physics at the University of Colorado Health Sciences Center. He is the author of the MABDOSE internal radionuclide dosimetry software [see Med. Phys. **26**, 1389–1403 (1999)], and has high hopes for radioimmunotherapy as an alternative to external beam and chemotherapy in the treatment of cancer.

Arguing against the Proposition is Bhudatt R. Paliwal, Ph.D. Dr. Paliwal is a Professor of Human Oncology and Medical Physics at the University of Wisconsin, Madison. He joined the University of Wisconsin in 1973 and has served as the Director of Radiation Oncology Physics for more than 20 years. Dr. Paliwal has served on many AAPM committees, including AAPM committees, including the office of president in 1996. Currently, he is the chairman of the Commission on Accreditation of Medical Physics Education Programs (CAMPEP, Inc.) and the American College of Medical Physics. He is also a trustee of the American Board of Radiology. Dr. Paliwal is certified by the ABR and ABMP.

FOR THE PROPOSITION: Timothy K. Johnson, Ph.D.

Opening Statement

When a profession establishes itself as an entity, it does so with the assumption that its qualities, characteristics, goals, and aspirations are unique. According to Webster's definition of profession, assumption of these characteristics entails advanced education and training. The natural progression of a profession, as more and more individuals enter it, is for the founding members to create some method to ensure that new members really possess the traits that define the profession. The difficulty encountered by various AAPM committees, when trying to define what a ''trained medical physicist'' is, simply emphasizes the emotional nature of this issue.

In medicine, not just anyone can sit for the United States Medical Licensure Exam. You must have graduated from an accredited medical school. Similarly, you cannot practice law without passing a bar exam. With the exception of California, you cannot sit for the bar without having graduated from an accredited law school. California administers a pretest to assess competency of non-graduates to sit for the bar exam. While a pretest is conceivable for Medical Physics certification, it would require more time and effort from the testing bodies than they are probably willing to commit.

The primary reason for restricting board certification to graduates of accredited medical physics programs is efficiency. The time and effort required of volunteers who implement and proctor the examinations would be minimized. This is because graduation from an accredited program implies that a core body of knowledge has been received. Mastery of this knowledge can be tested in a cursory fashion through written and oral exams for certification. It cannot be exhaustively tested, because the body of knowledge is extensive. Additionally, the breadth and scope of problem-solving ability is not encapsulated in a written exam or thoroughly probed in an oral exam; again, the knowledge required to practice medical physics is too great. With certification linked to accreditation, the certification body effectively becomes a partner with the accrediting agency in promoting individuals to practice professionally as medical physicists.

It is certainly possible to have an open certification process so that graduates of unaccredited programs can become certified. Unfortunately, this opens a Pandora's Box for a curriculum to be called a ''Medical Physics'' education (e.g., a graduate physics program that includes a single image reconstruction course, or a terminal master's program for medical dosimetrists). To rigorously test graduates of such programs so that a minimum level of competence is guaranteed would require an inordinate amount of time. Most professions have addressed the certification problem by requiring graduation from an accredited program as a minimum standard for entering the profession. This requirement does not imply that an individual with a different educational background could not pass the exam. It simply provides a reasonable degree of assurance that with multiple checkpoints and reasonable time expenditures incompetent individuals are not promoted to jobs where they could injure people. This two-tier approach provides a level of redundancy in examining individuals and weeding out incompetents. In so doing, it protects patients and the integrity of the profession.

Rebuttal

Dr. Paliwal and I agree that the primary objective of certification is to assess minimum competence. Dr. Paliwal however, asserts that certification is an acknowledgment that the governing board has examined the candidate thoroughly in all knowledge appropriate to the profession. This is unlikely given the constraints in the exam format currently administered by the American Board of Radiology. Although the scope of the physics exams (written and oral) offered by the American Board of Radiology is broad, I recall at the conclusion of taking both exams the number of topics that were NOT covered (some with a sigh of relief).

The two issues that Dr. Paliwal presents are in fact hypothetical. Regarding the issue of candidates from foreign countries, the educational background of foreign applicants could be reviewed on a country-by-country basis for program similarities to accredited U.S. programs. Akin to physician licensure, individuals graduating from programs whose content is substantially similar to that embodied in AAPM Report No. 44[1] could be allowed to sit for board certification.

Regarding the issue of supply and demand of medical physicists, one doesn't address the problem by opening the floodgates to any and all comers. Rather than reducing standards, efforts should be expended in supporting and possibly expanding accredited programs to accommodate additional students. Instead of creating a candidate shortage, restricting candidacy would increase the census of students enrolled in accredited programs.

Relying on an accredited program as a requirement for licensure provides additional screening of a candidate's background. Since an ill-prepared individual could do irreparable harm to patients, extra caution should be used to guard against the unintentional promotion of incompetence. Requiring individuals who sit for board certification to come from an accredited program or its foreign equivalent is the most reasonable way to ensure this.

AGAINST THE PROPOSTION: Bhudatt R. Paliwal, Ph.D.

Opening Statement

The primary objective of certification is to assess the minimum competence of candidates involved in the practice of a profession. The issuance of certification by an examining Board is an acknowledgment by the Board that it has examined the candidate thoroughly in all aspects of basic and applied knowledge important to the profession. The Board must be fair in its practice and provide equal opportunity to all individuals who seek to establish their level of competence. The restriction of candidacy for board certification to graduates of accredited training programs would not provide a fair opportunity to individuals who did not graduate from an accredited program. Hence, limiting certification to candidates from accredited programs would be discriminatory to many highly competent and qualified physicists who are trained in nonacademic clinical environments.

This approach would also have an extremely adverse effect on our profession. There are only 11 accredited training programs, and one of these is in Canada. On the average, these programs produce about 120 medical physicists per year. This is about 2.5% of the current AAPM membership. Some of the new graduates are highly specialized in subspecialties of medical physics. Hence, limiting candidacy to accredited program graduates would create a shortage of certified candidates.

A large number of medical physicists, who over the years have made a significant contribution to the development of our profession, have come from many foreign countries and from nontraditional academic programs. The institutions where they were trained were not accredited and are not likely to be accredited in the future. They are unlikely to be able to participate in the accreditation process because of a lack of financial resources or other practical considerations. Consequently, limiting candidacy to accredited programs would be discriminatory to foreign, well-qualified individuals.

Above all, I believe a competence-based open certification process, allowing everyone to establish his or her credentials, is fair. It enhances competition, enriches the field, and contributes to high-quality patient care.

Rebuttal

It is true that Webster's definition of a profession and the creation of founding fathers are the guidelines we use to keep ourselves on a narrow and focused path. However, the changes and suggestions made by AAPM committees are usually not emotional in nature. They have relevance to the evolutionary nature of our profession and reflect the adjustments we need to make to keep our profession flourishing and our professional standards in synchrony with the changes taking place around us.

A candidate who has graduated from an accredited program does carry a seal of achievement of a minimum standard of education. In spite of the accreditation process, we find a significant diversity in the breadth and scope of education and training provided by accredited programs. Accreditation has not reached the level of standardization and specificity found in the legal and medical professions. The profession of medical physics is not bound by any geographic boundaries. We cannot even begin to compare ourselves to the legal and medical professions in terms of numbers. They deal with thousands of candidates each year, whereas we examine less than one or two hundred per year. If we were to plot a histogram of numbers of programs for each profession (medical, legal, and medical physics), medical physics would be at the same level as the *x* axis. We are not exactly being swamped by the number of candidates taking the board exams nor have we a surplus of medical physicists.

Our profession is undergoing substantial change in its scope and in many of its subspecialties, particularly in medical imaging, applications of lasers, and integration of computerized systems. AAPM has just formed an *ad hoc* committee to assist in the formation of a professional group for radiotherapy accelerator engineers, hopefully within the confines of AAPM. In order to attract new talent, we need to keep the pathways open.

An open certification allows the graduates from well-established programs in the physical sciences to prepare themselves for certification. It also provides candidates from North America and other developed countries an opportunity to establish their credentials. If they meet the specified standards they should be welcomed to the profession to share their expertise, help the profession provide the necessary resources to the community and contribute to the growth of the profession.

REFERENCE

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10.10. Graduation from a CAMPEP or equivalent accredited graduate or residency program should be a prerequisite for certification in radiological physics

Michael G. Herman and Howard Amols
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OVERVIEW

Virtually all American Board of Medical Specialties (ABMS)-associated certification boards require graduation from an accredited training program as an eligibility requirement for a certification examination. One exception is radiological physics, where eligibility is based principally on a graduate degree in physics or related science or engineering discipline, plus three years of clinical experience. Whether graduation from an accredited graduate or residency program in medical physics should be a prerequisite for certification in radiological physics is the topic of this Point/Counterpoint.

Arguing for the Proposition is Michael Herman, Ph.D. Dr. Herman earned a Ph.D. in experimental nuclear physics in 1986. In 1989 he joined the Radiation Oncology staff at Johns Hopkins. He served on the faculty and in the capacities of Acting Chief and Associate Director of Medical Physics. In 1998, Dr. Herman joined the Division of Radiation Oncology at Mayo Clinic Rochester. He is currently Head of Physics, Associate Professor and full member of the graduate faculty. He is ABMP certified with an ABR letter of equivalence. Dr. Herman serves actively in the AAPM, ACMP, CAMPEP and ABR. He is a fellow of the AAPM and ACMP.

Arguing against the Proposition is Howard Amols, Ph.D. After receiving a non-CAMPEP approved Ph.D. in Nuclear Physics from Brown University in 1974, Dr. Amols did a non-CAMPEP approved post-doc at Los Alamos National Laboratory. He has held medical physics positions at the University of New Mexico, Brown, and Columbia Universities where he also taught numerous non-CAMPEP approved courses in medical physics. He is currently Chief of Clinical Physics at Memorial Sloan Kettering Cancer Center which, perhaps not surprisingly, has a non-CAMPEP approved post doctoral training program. He is certified by the ABMP, and along with 265 other non-CAMPEP graduates is a Fellow of the AAPM. On January 1, 2005 he became the 46th consecutive non-CAMPEP approved President of the AAPM.

FOR THE PROPOSITION: Michael Herman, Ph.D.

Opening Statement

The Institute of Medicine publication "To Err is Human" substantially raised the profile of the costs of medical errors.[1] The profession of medical physics is not exempt from the necessary accountability this report and the public demand. Yet, due to many conditions, too many individuals are placed in (independent) medical physics services without the necessary training and experience to discharge clinical duties safely and competently. This practice results in

unacceptably low board scores, gives medical physics a bad name and worst of all, can greatly compromise patient care.

Quality patient care is paramount, and thorough clinical training is essential for individuals entering practice of clinical medical physics. The common premise among all 24 certification boards (including the American Board of Radiology (ABR)) of the American Board of Medical Specialties is "To achieve initial certification, each board requires between 3 and 6 years of training in an accredited training program and a passing score on a rigorous cognitive examination."[2] Former ABR president Casarella agrees that the certification exam alone cannot cover every area of practice and that all candidates sitting for the exam must have received proper training in the essentials of practice in an accredited program. "It is the successful completion of the residency itself that is the *sine qua non* (absolute prerequisite) of ABR certification."[3] Why should medical physics be different? The knowledge required to practice medical physics is too extensive to be completely evaluated in the certification process.[4] Structured training like a residency, followed by a certification exam represents the pathway by which a clinical medical physicist can be expected to develop the breadth and depth of knowledge to independently discharge clinical duties.

CAMPEP accredited medical physics residencies provide the absolute prerequisite training that, when followed by board certification, produce individuals properly prepared to practice medical physics. Unfortunately, there is a major shortage of qualified medical physicists and a dearth of accredited training programs to produce these individuals. These topics have been discussed fervently in recent AAPM newsletters. Raising the bar on the ABR exams could reduce the number of improperly trained individuals entering medical physics, but would exacerbate the physicist shortage.[5]

To maintain quality and increase supply, additional opportunities for structured training must be developed. These can take the form of a residency, a graduate or an on the job training program, as long as the essential prerequisites (as detailed in AAPM report #36)[6] are learned and CAMPEP provides accreditation. This broader model increases available programs (and graduates) and maintains the intellectual diversity that has historically been a strength of medical physics. AAPM and other organizations must support an increased focus on structured training and CAMPEP must facilitate accreditation of these programs. Certification bodies should accept only graduates of these programs (the ABR physics trustees suggest by 2012). The quality of patient care, our accountability to the public, and our stature among medical professionals are at stake.

Rebuttal

My Point/Counterpoint colleague and I agree that proper training for medical physicists is essential and that board certification combined with proper training instills confidence that individuals will enter the practice of clinical medical physics in a competent manner.

As noted, however, certification alone is not the answer, because it is impossible to test the breadth and depth of one's training in such an exam, and raising the bar serves only to reduce the number of qualified individuals but does little to improve the quality of candidates.

Dr. Amols requested statistics that suggest that CAMPEP-trained individuals fare better on the board exams. I am pleased to oblige. Nine CAMPEP-accredited residency programs have produced 54 graduates, of which 38 have taken the full certification exam. Of these, 36

candidates passed the full board exam on the first attempt. Thus the first time pass rate for graduates of CAMPEP-accredited residency programs is 95%.[7] The overall ABR physics pass rate in recent years is 53%, including first-through third-time takers.[8] I also examined for the ABMP for many years and the average pass rates for ABMP are similar to if not lower than the ABR values. I conclude from these data that a 95% pass rate for the subset of candidates trained in CAMPEP programs is significantly better and different than the average certification exam pass rates of ~50% for all applicants.

It is essential for AAPM and other organizations that represent clinical medical physicists to make it policy to support and facilitate CAMPEP-accredited structured training as THE requirement to sit for board exams. Completion of this pathway qualifies individuals to discharge duties in the clinical environment. Any program that meets the requirements for clinical training as outlined by CAMPEP and AAPM report number 36 should be accredited. Better and consistent training brings improved performance that is good for patient care and good for medical physics.

AGAINST THE PROPOSITION: Howard Amols, Ph.D.

Opening Statement

CAMPEP approved programs are good. We debate only whether it should become the only pathway into medical physics. For 100 years we've had multiple pathways; a degree in physical science or engineering, on the job training, fellowships, and more recently residencies. Whatever path taken, a peer-reviewed certification exam becomes the equalizer. This system has flaws but basically works and has brought intellectual diversity to our profession, which is one if its greatest strengths. "If it ain't broke don't fix it."

Yes, we have a manpower shortage, and many unqualified candidates pass the board exams. But restricting entry to the boards (and therefore the profession) only to CAMPEP graduates is not the best way to solve either problem. We can more fairly reduce the number of unqualified people passing the boards simply by failing everyone who deserves to fail. Make the questions harder and/or raise the passing score. It's that easy! CAMPEP can't fix the boards; training and certification are separate issues! In my 10 years experience as an ABMP examiner I've seen no evidence that a candidate's performance is correlated with CAMPEP training. I challenge my opponent to produce statistics to the contrary.

What about the manpower shortage? Restricting entry into medical physics only to CAMPEP graduates will only make this problem worse. There simply are not enough CAMPEP programs to meet manpower needs. I cannot accept the Cinderella fantasy we hear that by making CAMPEP mandatory the needed programs will magically materialize. There isn't enough money and there aren't enough teachers.[9,10] Even if there were, a CAMPEP only policy would divest our profession of intellectual diversity and creativity.

Another argument we hear in favor of CAMPEP is that other ABMS boards have similar requirements. So what? Other ABMS boards require students to dissect cadavers. Should we require that also? We are physicists, and no other scientific specialty has such a restrictive requirement. What about the argument that medical physics has become soooooo complicated that CAMPEP training is the ONLY way to master it? This argument is historically unjustifiable, self-serving, and insulting to thousands of competent medical physicists who've succeeded

without CAMPEP. Even if one believes this myth, what harm is done by letting non-CAMPEP people take the boards? If they're really incompetent they'll fail. Further, the CAMPEP only proposal makes no distinction between graduate programs and residencies. According to their own guidelines:[11] "CAMPEP accreditation of a program does not address the clinical competency of individual graduates. Certification that an individual medical physicist has demonstrated a prescribed level of professional competence is currently available from the American Board of Radiology."

In a recent survey of 2100 AAPM members[12] 91% supported board certification and 86% supported CAMPEP programs in principle, but only 21% supported barring non-CAMPEP graduates from the process, and only 14% supported CAMPEP residency as the only entryway. Support CAMPEP, yes. Only route possible, NO!

Rebuttal

Medical physics faces two major problems: a manpower shortage, and physicists with incomplete clinical training passing the boards. Neither problem has anything to do with CAMPEP. The former results from poor recruiting, and the latter from a board exam that is arguably not comprehensive enough in scope. Dr. Herman confuses these issues and tries to fix both by making CAMPEP mandatory. Historically, people have achieved competency and passed the boards without CAMPEP. Making CAMPEP mandatory exacerbates the manpower shortage, doesn't address the comprehensiveness or rigor of the boards, and without large infusions of money does not address the `dearth of accredited training programs' that he refers to either. Worse, it effectively bars entry into our field to a variety of bright people with broad ranging skills.

I agree with Dr. Herman that clinical training is essential and improper training compromises patient care, but the rigid framework of CAMPEP is not the right answer. Even CAMPEP's own guidelines state that "demonstrat[ion of] a prescribed level of professional competence is currently available from the American Board of Radiology (ABR)"[11] not CAMPEP.

Indeed, if this were not true there'd be no need for CAMPEP graduates to take the board exam! In his opening statement Dr. Herman said nothing about CAMPEP degree programs, I think because he and I agree that a CAMPEP degree guarantees little about clinical competency. He therefore limits his remarks to CAMPEP residency programs which do focus on clinical training. But he is again stymied by the "dearth of accredited training programs."

In summary, CAMPEP degrees offer little or no added value over other physics or engineering degrees with regard to clinical competency, and CAMPEP residencies cannot meet the manpower needs. For these reasons, as currently formulated, making CAMPEP mandatory for entry into medical physics is a recipe for disaster.

In his closing paragraph Dr. Herman states that "additional opportunities for structured training must be developed." I agree. I think a better solution is for AAPM, CAMPEP, and ABR to defocus on degree programs and instead recognize alternate pathways to formal residencies. For example, CAMPEP approved on the job training under the guidance of accredited mentors similar to the old guild system where one apprentices under a master, becomes a journeyman, and ultimately a master. If accreditation procedures can be agreed upon along these lines as alternatives to formal institutionalized CAMPEP programs I would be in favor.

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10.11. Deployment of a Maintenance of Certification program in medical physics serves the interest of the profession and the public

Stephen R. Thomas and Joseph S. Blinick

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OVERVIEW

Maintenance of Certification (MOC) is being implemented in most medical specialties as a follow-up to time-limited certifications. In the radiological disciplines, the MOC process is administered by the American Board of Radiology, and focuses on lifelong learning, continuous self-assessment, and periodic examination. Some medical physicists believe this process will upgrade the profession by encouraging physicists to remain current with their discipline. Others feel that staying up-to-date in the field is a professional and ethical obligation that practicing physicists are already pursuing, and that oversight by a professional organization is not required. This difference of opinion is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Stephen R. Thomas, Ph.D. Dr. Thomas is Professor of Radiology at the University of Cincinnati College of Medicine and Director of Medical Physics for University Radiology Associates. He serves as an ABR Trustee in Radiologic Physics (Medical Nuclear Physics) and is Chair of the ABR MOC Coordinating Committee. He is an elected member of the ABMS Committee on Oversight and Monitoring of MOC. Dr. Thomas has been active within the RSNA and currently is a trustee of the RSNA Research and Education Foundation. He is a Fellow of the AAPM and has participated at many levels within that organization, including President in 1997.

Arguing against the Proposition is Joseph S. Blinick. Dr. Blinick received his Ph.D. in Physics from Brown University in 1971 and began his career in medical physics at Boston City and University Hospitals in Boston. From 1974 until his retirement in 2001, he was Chief Radiation Physicist and RSO at the Maine Medical Center in Portland. Since that time he has continued to work as a consultant. He is a former Treasurer of the AAPM and also served as Placement Service Director. Dr. Blinick was certified by the ABR in Radiological Physics in 1976. He was also certified by the ABMP in Radiation Oncology Physics in 1991 and was recertified in 2001. He served for two years as an oral examiner for the ABMP in Medical Health Physics. He is a Fellow of the AAPM, the ACMP and the ACR.

FOR THE PROPOSITION: Stephen R. Thomas, Ph.D.

Opening Statement

In a major paradigm shift for medicine, the previously established mode of lifetime certification for healthcare professionals based upon a one-time successful passing of a cognitive examination has been replaced by time-limited certification incorporating a program of continuous professional development. This new approach has been embraced by all 24 member boards of The American Board of Medical Specialties (ABMS), with the boards being committed to

implementation of an appropriately designed Maintenance of Certification (MOC) program in their specialties and sub-specialties. Across the health care industry there has been a growing awareness that continuous professional enhancement is essential to ensuring high quality health care in this era of rapidly advancing technology.[1,2] The shift toward MOC is in response to the recognition that active programs and evidenced-based measures are required to demonstrate that practitioners are remaining current in their fields. In brief (details may be found in Ref. 3), the MOC program entails requirements related to the 4 components (Professional Standing; Life-long Learning and Self-Assessment; Cognitive Expertise; Assessment of Performance in Practice) linked to the 6 competencies (Medical Knowledge; Patient Care; Interpersonal and Communication Skills; Professionalism; Practice-Based Learning and Improvement; Systems-Based Practice) expected of healthcare professionals.

I am certain medical physicists would agree with the proposition that remaining up-to-date in one's discipline should be mandatory, both to satisfy the public trust and as a matter of professional responsibility. It is the means for accomplishing this goal that is the topic of discussion here. Public and professional confidence can be established and most efficiently maintained through unified programs that are sanctioned by the vested organizations. For radiology, that organization is the American Board of Radiology (ABR) which, as the certification Board for radiological physicists, has the vision to ensure that its diplomates possess the requisite knowledge, skills, and experience to provide high-quality patient care. Importantly, the MOC components and competencies were not formulated independently, but represent the consensus of all 24 medical boards as coordinated and approved by the ABMS. Thus all healthcare constituents can be assured that the MOC programs were carefully developed, unified as to concepts, and extend with consistency across all disciplines of medicine. This mechanism obviates any concerns that standards might not have been appropriately defined and executed for any specific individual. In a very real sense, coordination by the ABR assists the medical physicist through presentation of an unambiguous pathway for progression toward achieving the goal of documenting continuous professional enhancement. In the real world, characteristic vagrancies appear when a myriad of individually prescribed programs evolve independently. Without this integrating structure, the process runs the risk of being considered meaningless, and might ultimately come under the threat of external regulation.

As a positive logistical aspect promoting efficiency of the MOC process, the ABR will be expanding its website to provide personal, secure files for diplomates to assemble data and documents over the 10-year cycle. This will serve as a repository for CME credits, professional standing citations, cognitive exam results, etc. If desired by the diplomate, the ABR will assist in review of the diplomate's "MOC portfolio" at various stages in the cycle and offer helpful advice as progress is evaluated.

In summary, medical physicists will benefit through participation in a unified MOC program coordinated by the ABR that conforms to a national standard.

Rebuttal

In responding to my colleague, let me first address the IOM report on medical errors.[4] This report is focused exclusively on patient safety. The MOC process incorporates segments associated with this important topic. However, MOC has the broader mission to ensure progression toward higher-quality health care through documentation of diplomate participation in programs relevant to the evolution of technology in health care. Although the term "MOC" may not appear explicitly within the IOM report, many of the recommendations would be addressed through

implementation of MOC programs. For example, Recommendation 7.2 on performance standards for health professionals calls on licensing bodies to "Implement periodic re-examinations and re-licensing of doctors, . . . and other key providers." Clearly, MOC is positioned to play a crucial role in achieving the intent of this recommendation.

The issue of requiring MOC for diplomates holding lifetime certificates does deserve consideration. Because of legal constraints, the ABR cannot change the original terms of issuance. The ABR is actively encouraging all of its "older' diplomates to voluntarily enter MOC. All Trustees of the ABR have enrolled. Through a personal sense of professional responsibility and potential requirements of employers that medical physicists formally engage in MOC, it is the expectation that a majority of diplomates in active practice will sign up.

Dr. Blinick acknowledges the significance of assessing performance in practice (4th component of MOC). At the end of Dec. 2004, all Boards submitted Part 4 plans that currently are under evaluation by the ABMS. The challenge of measuring efficacy in these programs is recognized, but the expertise required is available. There are never absolute guarantees of outcome, but providing tools for assisting performance assessment represents a positive step forward.

The statistics quoted on the number of full AAPM members who do not hold certification require analysis. Medical physicists with an advanced degree working directly in a clinical environment undoubtedly are certified (or are planning to be). These are the individuals for whom MOC is intended. Other valued members of the AAPM include individuals with undergraduate degrees only, those waiting to qualify for certification, professionals not directly in patient care (basic scientists) and foreign nationals. There are valid reasons why certification may not be applicable under specific situations.

It is not claimed that an ABR-MOC certificate is a guarantee of competence. Rather, it documents that the diplomate has satisfied the requirements of the MOC program (including mastery of a body of knowledge and skills with accountability in their application to patient care), which can be considered an indication of the commitment to maintaining competency. This is a good thing!

AGAINST THE PROPOSITION: Joseph S. Blinick, Ph.D.

Opening Statement

A recent journal article[3] described the American Board of Radiology (ABR) Maintenance of Certification (MOC) program, which is designed to respond to public demand that the safety and quality of American medicine be improved.

The document states that Board certification has been accepted as a good, albeit imperfect, process. But now "questions have been raised as to whether professionals with lifetime certificates maintain the knowledge, skill and familiarity necessary to continue providing quality patient care." In fact, there is no evidence that certification provides any assurance of quality, much less that the MOC program is really necessary at this time. A report of the Institute of Medicine (IOM) estimated that between 44,000 and 98,000 people die each year in American hospitals due to medical errors.[4] Most of these errors are undoubtedly committed by licensed and/or certified practitioners. Furthermore, during the period in which the data were collected several member boards of the American Board of Medical Specialties (ABMS) had already

instituted recertification programs for their diplomats,[5] and evidence of continuing education had been required by most certification boards and state licensing boards for many years. The IOM had many suggestions for reducing medical errors including establishment of a Center for Patient Safety, a nationwide mandatory reporting system of medical errors with protection from lawsuits, and a commitment by professional societies to establish committees on patient safety. Nowhere is there a recommendation for maintenance of certification.

Even if we assume that MOC is desirable, the current program will not be effective. For one thing, it is voluntary for those certified before 2002. If the ABR really thinks older practitioners aren't keeping up, the MOC program should be required for all certificate holders regardless of when they were certified. In addition, MOC still relies heavily on amassing huge, but arbitrary numbers of continuing education units (CEU) and taking multiple cognitive examinations over a ten year period. Rockhill[6] states that "mandatory continuing education may actually limit learning." She advocates leaving control of continuing education with the individual. Miller[7] points out that knowledge of a field (which education provides and cognitive tests assess) is necessary but not sufficient. Professionals have to know how to apply this knowledge.

To its credit, the ABR has included a section on assessing performance in practice. Regrettably, it has left this entirely undefined for the present. Performing this type of assessment effectively will be both very difficult and very expensive. There have been many methods developed to measure performance in the past,[8] but none has proven to be universally reliable. Unfortunately, even if a professional can show that he/she knows how to apply knowledge, it doesn't guarantee that he/she will always do so properly in real situations.

Approximately 90% of radiologists are certified by the ABR,[9] but according to information provided by Michael Woodward of the AAPM, only 56% of AAPM full members are certified by the ABR or ABMP. Are the remaining 44% therefore incompetent? If one believes that certification is important to our profession, the priority ought to be to convince more physicists to become certified. In this regard, the complexity, cost and burdensome record-keeping of the MOC program are counter-productive.

The MOC program will not result in more competent physicists, nor will it promote professionalism among physicists.

It does, however, provide the perception that we are "doing something" about the problem of incompetent professionals.

Rebuttal

Since several medical boards have had time-limited certification for some time, the MOC program is not so much a paradigm shift as a burdensome and expensive addition to existing programs. Rather than actually addressing the question of professional incompetence, it seems primarily aimed at "achieving the goal of documenting continuous professional enhancement," and preventing "the threat of external regulation."

The program still relies heavily on accumulating mandatory CEUs and taking cognitive examinations, neither of which assures continued professional competence. Further, it is one thing for a board to require mastery of a well-defined body of knowledge for initial certification, but it's quite another for it to define what each practitioner currently needs to know after several years of post-certification career divergence have gone by.

The "Assessment of Performance in Practice" component is still completely undefined. It could be important if done right. But to do it right will be very difficult and expensive.

The remaining component, "Professional Standing" requires, among other things, documentation of "expertise-based appointments" to groups such as the NCRP, ICRP and NIH study sections or hospital medical staffs. This clearly favors academically based physicists who have both the time and the financial backing to participate. But it's hard to see how these activities actually assure clinical professional competence.

The MOC program fails to actually address the issue of continued professional competence and its cost and complexity make it an unnecessary burden for the relatively small number of medical physicists who are currently certified.

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10.12. The proposed MOC requirements for physicists are reasonable

Stephen R. Thomas and Jeffrey A. Garrett
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OVERVIEW

It is important for specialists in the medical professions to ensure that new technological developments are continually being incorporated into their practice and made available to patients. This is especially important for medical physicists because they are in the forefront of development and introduction of these new methodologies. Consequently the American Board of Radiology (ABR) has initiated a new Maintenance of Certification (MOC) process that is mandatory for all those medical physics diplomates holding time-limited certificates, and highly recommended for all others. The requirements of the MOC program include, over the 10-year MOC cycle, earning 500 continuing education credits, completion of 20 self-assessment modules (online multiple-choice "tests"), and successful completion of a closed-book, proctored multiple choice exam in the 8th, 9th, or 10th year of the MOC cycle.[1] The proposed annual fee for maintenance of certification is $170. These are extensive requirements that some believe are excessive and/or unfair. Others argue, however, that they are essential if we are to assure that all diplomates keep up-to-date in their knowledge so as to promote the best interests of patients. This disagreement is the topic of this month's Point/Counterpoint debate.

Arguing for the Proposition is Stephen R. Thomas, Ph.D. Dr. Thomas is Professor of Radiology at the University of Cincinnati College of Medicine and Director of Medical Physics for University Radiology Associates. Within the ABR, he has recently assumed the position of Associate Executive Director (Radiologic Physics). Through June 2006, he will continue to serve as an ABR Trustee in Radiologic Physics (Medical Nuclear Physics) and Chair of the ABR MOC Coordinating Committee. He is an elected member of the American Board of Medical Specialties (ABMS) Committee on Oversight and Monitoring of MOC. Dr. Thomas has been active within the RSNA and currently is a Trustee on the RSNA Research and Education Foundation. He is a Fellow of the AAPM and has participated at many levels within that organization including President in 1997.

Arguing against the Proposition is Jeffrey A. Garrett, M.S. Mr. Garrett is the Chief Medical Physicist and Radiation Safety Officer for Mississippi Baptist Medical Center in Jackson, MS. Mr. Garrett earned a B.S. degree in Physics at The Citadel and an M.S. in Medical Physics from East Carolina University in 1997. Upon graduating from East Carolina, Mr. Garrett worked as a Junior Physicist in Albuquerque, NM. From there he moved to Jackson, MS and was employed as a Staff Physicist until eventually assuming the role of Chief Physicist in 2001. Mr. Garrett was certified by the ABR in 2002 and currently serves on the AAPM MOC Task Group No. 127.

FOR THE PROPOSITION: Stephen Thomas, Ph.D.

Opening Statement

In March 2000, all 24-member boards of the American Board of Medical Specialties (ABMS) agreed to implement MOC. The mandate is that each board institute programs that include four components: professional standing; lifelong learning and self-assessment; cognitive expertise; and assessment of performance in practice.[2,3,4] Although individual boards have some flexibility in designing methods to comply, programs undergo rigorous scrutiny before receiving ABMS approval. The ABMS Committee on Oversight and Monitoring of MOC will hold boards accountable for adherence to their programs.

The ABR did not develop MOC requirements in a vacuum. Input and guidance were solicited from all sponsoring societies at a series of meetings hosted by the ABR (December 2001(Tucson, AZ): ABR Meeting on Maintenance of Certification; January 2004 (Tucson, AZ): Implementing MOC: Issues and Strategies; August 2005 (Chicago, IL): Self-Assessment Modules—Summit Meeting). It was recognized that the program elements must be constructed such that requirements could be satisfied in a reasonable fashion. Working groups including the AAPM Task Group on MOC and the RSNA MOC Coordinating Committee will play important roles in helping to shape programs as the process evolves.

Professional standing may be satisfied in a straightforward fashion through documentation of a valid, unrestricted license to practice medical physics (parity with the requirement for physicians). However, since few states require licensure for medical physics, an alternate pathway through letters of attestation has been established.

Lifelong learning and self-assessment require 500 continuing education credits over the 10-year MOC cycle consistent with the ACR guideline of 50 credits/year.[5] The ABR must be responsive to professional standards active in the industry. Extensive online continuing education (CE) programs are available through all of the professional societies to offset restrictions in time and travel budgets. However, to further assist, an optional method to acquire credits has been established through self-directed educational projects (SDEPs). SDEPs allow prospective integration of designated professional activities into educational self-improvement projects providing 15 credits each.

Self-assessment is accomplished through participation in 20 self-assessment modules (SAMs) over the 10-year cycle. The CME credits obtained for SAMs may be counted as part of the lifelong learning requirement. SAMs include questions (but no pass/fail) with feedback to the diplomate.

It is reasonable to expect diplomates to maintain the essentials of core knowledge fundamental to the practice of medical physics and to remain up-to-date on evolving technologies. Additional justifications for requiring the single cognitive exam taken toward the end of the 10-year cycle include: (1) the expectation of the public that such a process be in place for the medical profession;[6] and, (2) Recommendation 7.2 of the Institute of Medicine report on medical errors[7] to "implement periodic re-examinations." Every effort will be made to structure the exam as a productive self-improvement vehicle and not as simply a hurdle to surmount.

The need for MOC in medicine is self-evident and in concert with our sense of professional responsibility. Carefully considered programs have been instituted by the ABR to accomplish the task responsive both to our professional realities and to constraints applied by the ABMS. The requirements are reasonable and can be accomplished by conscientious medical physicists in the course of fulfilling their practice obligations.

AGAINST THE PROPOSITION: Jeffrey Garrett, M.S.

Opening Statement

The American Board of Medical Specialties has mandated that all member boards establish Maintenance of Certification programs that must follow a general set of guidelines. I contend that our ABR MOC Trustees should consider that many radiologic physicists, myself included, may not have the financial and/or staffing resources to fully comply with the current MOC program[1] and that the requirements must be appropriate for those being monitored. Additionally, there should be a logical reason for the requirements that are specified. Parts 1 and 3 are fairly reasonable and straightforward. Therefore, I will argue against the Proposition based on parts 2 and 4.

The required 500 continuing education credits, average 50 per year, and 20 self-assessment modules do not seem like a lot at face value. However, bear in mind that there are only 30–35 credits available per major meeting. If unable to attend at least one such meeting every year, satisfying this CE requirement will be difficult to say the least. Since 2000, I have only been able to attend 1 AAPM, 1 ASTRO, and 1 Summer School for reasons such as tight hospital budgets (travel budgets were frozen) and low staffing. Technically, I would be behind schedule at least 130 credits in just 5 years! Radiation oncologists need only 8 SAMs.[8] Anesthesiologists need only to accumulate 350 credits for the entire component.[9] Internal medicine physicians are only required to complete 100 credits[10]—which includes lifelong learning, self-assessment and assessment of performance in practice! Is it reasonable to place such high demands on physicists who have much lesser means than physicians?

I suggest reducing the number to something more manageable like 300 total credits. This would still require frequent attendance at annual meetings yet be flexible enough to allow for years when hospital budgets are tight or staffing is short. It also provides some incentive to perform additional research into relevant material rather than taking a quiz simply for the sake of accumulating credit—unless that is the intent of MOC.

Assessment of performance in practice is currently under review for practically all specialties. Some have suggested that for physicists this could be a peer review. I see a few problems with this idea. First, unless you have a friend who is a physicist in close proximity and is willing to do this for free, you will have to shell out several hundred dollars, maybe even thousands, to satisfy this requirement. Is that reasonable? Second, multiphysicist institutions present problems as to who is actually responsible for the program being audited. Finally, having no required standard review process will lead to widely varying peer reviews. My suggestion for therapy physicists is to allow Radiologic Physics Center (RPC) TLD results to be submitted. These would demonstrate that patient care has been administered properly according to established protocols. The demonstration of proper care could be traced to an individual, and the cost would not come out of the physicist's own pocket. Similar tests could be used for diagnostic physicists.

Rebuttal: Stephen Thomas, Ph.D.

I am gratified that my colleague finds parts 1 and 3 to be "fairly reasonable and straight forward." Certainly, I concur and, thus, will focus on addressing his concerns with the other components.

The requirement for CE credits is linked directly to the ACR guideline for medical physicists.[5] It would be incongruous if the MOC program did not support this standard. The issue is how to obtain those credits with a reasonable expenditure of effort. I understand the constraints on meeting attendance due to staffing considerations. I am less sympathetic with monetary arguments in light of salaries commanded by medical physicists today.[11] We should be prepared to expend some personal financial resources in fulfilling professional responsibilities. However, there are ample means to acquire credits at home through local CME programs and web-based opportunities. Also, SDEPs are functional and can be designed prospectively into professional activities and personal education plans. Note that the requirement for category 1 credits is 250 over the 10-year cycle (SDEPs would provide the others), well under the 300 deemed "manageable."

Practice Performance Evaluation (PPE) (part 4) remains in the process of development. The intent is to produce structured programs that could identify where improvement in practice might be incorporated. Currently, the three areas of radiologic physics being considered for PPE projects are: professional and regulatory guidelines; safety; and educational activities. Peer review would be included under the first with a working model for therapeutic radiologic physics published recently by AAPM TG 103 (Ref. 12). The AAPM MOC TG will play a critical role in shaping part 4 as it evolves and may well evaluate processes such as those suggested by my colleague.

In summary, the ABR MOC programs are reasonable and promote the integrity and professional interests of our medical physics discipline.

Rebuttal: Jeffrey Garrett, M.S.

Dr. Thomas states that MOC was not developed inside a vacuum. As proof of this he cites various conferences held to discuss particulars of the program. Absent, however is any attempt to collect opinions from physicists who are required to participate in ABR Radiological Physics MOC. A scan through one of the summaries of these conferences quickly reveals that the overwhelming emphasis is on physicians—not physicists. Is it reasonable to impose requirements on physicists that were originally developed for physicians? My hope is that the ABR Trustees will indeed listen to the recommendations offered by AAPM TG 127.

Dr. Thomas also presents a summary of ways to earn points toward lifelong learning and self-assessment. Most would agree that the majority of these credits would be earned by attending one of the professional meetings. As this is not possible every year, Dr. Thomas suggests that we should spend countless hours either at work or at home working on CE credits via SDEPs and SAMs. Why not simply make the requirements a little more reasonable? After all, isn't this *maintenance* of certification, not certification?

Also, note that SDEPs are prospective. Therefore, the countless hours we have spent commissioning and testing equipment in the last 3–5 years are not applicable. This is just plain wrong. Maybe my hospital will purchase a second CyberKnife so I can get SDEP credit. We do not have the time to sit around and think of projects to do for MOC, much less the time to write up the project and submit it to one of the MOC Trustees for review and approval.

MOC will have a significant and profound impact on the future of Medical Physics. Why not make it a positive impact and listen to those who are actually affected by MOC by developing a program that can be completed by all—not just a select few?

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10.13. Peer reviews of medical physics practices often yield little information because the AAPM has not been proactive in developing appropriate peer-review guidelines

Michael Gossman and Per Halvorsen
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OVERVIEW

In a recent Point/Counterpoint, Dr. Stephen Thomas stated that "…peer review would be included under the…professional and regulatory guidelines…" of the Practice Performance Evaluation program required for Maintenance of Certification for ABR diplomates.[1] In anticipation of this, or for other reasons, many medical physicists have begun to organize such peer reviews. Unfortunately, however, comprehensive guidelines for peer reviews have not been developed. Lacking such guidelines, some medical physicists have been known to conveniently "select" individuals who will provide "friendly" reviews of their practices. Such peer reviews are neither useful nor are they suitable for proper practice performance evaluation. It might be argued that leadership organizations such as the AAPM should have taken a more proactive role in development and dissemination of such guidelines for peer review, and this is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Michael S. Gossman, M.S., DABR. Beginning academically at Indiana University and the University of Louisville, he received B.S. and M.S. physics degrees, followed by medical physics education at Vanderbilt University, and certification in Therapeutic Radiologic Physics by the American Board of Radiology in 2003. He currently serves as a member of TG-152 and the Therapy Physics Radiation Safety Subcommittee of the AAPM, and has served as a reviewer for the *Medical Dosimetry* and *Applied Clinical Medical Physics* journals and as a Medical Consultant to the U.S. Nuclear Regulatory Commission. Mr. Gossman is the Chief Medical Physicist and RSO at the Tri-State Regional Cancer Center in Ashland, KY.

Arguing against the Proposition is Per Halvorsen, M.S., DABR. Mr. Halvorsen is a radiation oncology physicist at the Middlesex Hospital Cancer Center in Middletown, Connecticut. Since receiving his MS degree in Radiological Medical Physics from the University of Kentucky in 1990, he has worked in large academic medical centers and private community clinics. He has been active in the AAPM and the ACR on professional practice issues with particular focus on practice standards and peer review, serving on the ACR's Radiation Oncology accreditation committee and chairing or serving on many committees and Task Groups within the AAPM Professional Council. He is currently an At-Large member of the Board of Directors.

FOR THE PROPOSITION: Michael Gossman, M.S.

Opening Statement

Peer reviews are best accomplished by outsiders, yet medical physicists routinely self-review. Changes are needed to ensure the effectiveness of peer reviews. The purpose of the peer review

process is to provide the incentive and opportunity for medical physicists to improve their physics quality assurance programs.[2,3] The recommendations of an outside qualified medical physicist can be extremely valuable in establishing policies and procedures, including implementation of quality assurance guidelines developed by the AAPM and/or patterned throughout the field. This is also important in order to ensure operational conformance to regulations governing a medical physics practice.

To maintain high professional performance standards for medical physicists, the AAPM, ACR, and other organizations have recommended that peer reviews be conducted.[4,5,6,7] Many medical physicists are still not obtaining peer reviews. A solo medical physicist should obtain a peer review on an annual basis.[2] Where multiple physicists are involved, the chief medical physicist should obtain a peer review separate from the review for staff physicists. Staff physicists have no obligations other than those tasks assigned and directed by the chief physicist. Staff medical physicists should receive an annual performance review by their chief physicist, but the program as a whole is solely the responsibility of the chief physicist.

The routine of a physics program and the governing policies and procedures for the practice are strictly the obligation of the physicist in charge. In this sense, the solo physicist is the chief. Whether acting as consultants or not, the obligations of the physicists are to control and implement the quality management programs for all facilities in which they operate. For each facility, peer review analysis should be conducted on the whole program.

As it exists in our field currently, some chief medical physicists assign a staff physicist or part-time consulting physicist to review the very same program or group with which they work. Even if a subordinate physicist agrees to take on that responsibility, the peer review process suffers. This is absolutely not what is meant by "mutual agreement"[4] for two reasons. First, subordinate medical physicists provide some of the operational work and would, therefore, be attesting to the accuracy of their own work. Second, subordinate medical physicists would be commenting on the program their superior instituted, including opinions on the chief medical physicist's actual work. This creates significant conflicts of interest.

For any purpose, whether for satisfying site accreditation requirements or for application toward certification maintenance, this type of review is a "sham"! The effectiveness of the peer review process boils down to the fundamental understanding of its intended purpose: a peer review should evaluate the entire physics quality assurance program of the chief medical physicist. A review should be made by an outside qualified medical physicist who specializes in the same area. That individual should be unaffiliated with, and should not be providing physics work of any sort for, the facility so as to avoid bias or impropriety. Where appropriate guidance on the peer review process is lacking, the AAPM should take the initiative and recommend new peer review procedures that will improve the profession.

AGAINST THE PROPOSITION: Per Halvorsen, M.S.

Opening Statement

Our work as medical physicists can have a significant impact on the health and safety of our patients. The Institute of Medicine recognized that the continued professional competence of healthcare staff must be periodically assessed.[8] Our professional organizations have recognized

the importance of peer review in this context.[2,4,5,7] This shows broad agreement on the value of peer review in medical physics, and on this point I am sure that Mr. Gossman and I agree.

The debate centers instead on whether *"peer reviews of medical physics practices often yield little information because the AAPM has not been proactive in the development of appropriate guidelines."* Most medical physics peer reviews do not yield little information. In the rare cases that this occurs, the villain is not any failure by the AAPM to develop appropriate guidelines. Rather, the blame lies with the individual medical physicists participating in the review for failing to consult the many resources available to ensure that the peer review is appropriately comprehensive and yields a productive critique.

Though no peer-reviewed publication directly addresses the assertion at the center of this debate, I can relate my personal experience with more than 40 peer reviews. For more than a decade, I have been a surveyor for the ACR's Radiation Oncology accreditation program. During the same period, I have performed several privately arranged peer reviews, and have also been reviewed myself through both mechanisms several times. In all instances, the physicists involved worked conscientiously to ensure that the review was substantive in scope, appropriate in depth, and resulted in productive collegial critique.

The AAPM Task Group 103 published guidelines for peer review in clinical radiotherapy physics,[2] and TG 127 is currently working on a peer review model for all medical physics specialties, in accordance with the ABR's Maintenance of Certification requirement for Professional Quality Improvement. The ACR maintains an active accreditation program, and physicists serving as volunteer surveyors gain valuable experience in how to review and critique a medical physicist's practice. The American Board of Medical Specialties (ABMS) maintains links on its website to all 24 member boards; many contain useful information about their peer review programs.

The medical physicist, as an independent professional, should construct a peer review method that is appropriate for the practice environment by consulting the aforementioned resources and others as appropriate. I trust that most medical physicists have the intellect and integrity to exercise their professional judgment on what format would be most appropriate for their situation. Hopefully, most of us prefer to receive a tangible benefit from the effort in the form of a useful critique, rather than spending effort on an uninformative review.

In summary, the AAPM is active in developing guidelines and tools for its members to practice medical physics effectively, including providing guidelines for peer review. *We are not a society of technicians, but of professionals. Each individual professional should have the ability and integrity to invest the effort to assess the possible formats and appropriate scope of review in order to design a peer review process that will be productive for the reviewed physicist.*

Rebuttal: Michael Gossman, M.S.

The question that remains after these opening remarks is "how can the AAPM astutely direct the process of peer reviews?" I agree with Mr. Halvorsen that medical physicists should work conscientiously to ensure that their peer reviews are substantive in scope and appropriate in depth, resulting in productive collegial critiques. Such critiques cannot be productive when they are not independent. My colleague cannot dispute that some peer reviews *are* in fact shams or, at the very least, are not conducted with the level of independence needed to ensure that they are unbiased and, hence, constructive.

Nevertheless, the debate cannot end here. Neither the ABMS nor the ACR has published resources that specifically address peer review methods for medical physicists. Although the ACR suggests that procedures should be in accordance with AAPM guidelines, the current set of resources, including those made available in TG-11, TG-40, and TG-103, are insufficient and therefore inappropriate. More comprehensive guidelines that encourage independence will lead to more productive critiques and foster a higher level of support and quality assurance for medical physicists at all levels.

I challenge the currently active AAPM Task Group 127 to lead the medical physics community to a quality peer review process that is complete and broadly supportive of all medical physicists within our association. I believe the work from this group can produce a report which encompasses the method of peer review for all specialties of medical physics including solo practice, as well as for larger facilities where a chief medical physicist oversees work from subordinate physics staff.

It is my hope that this Point/Counterpoint will provide insight to those members who are considering participation in this professionally constructive quality assurance process and, equally, those who are currently involved, all of whom should consider the points mentioned here as a step toward improving the peer review process.

Rebuttal: Per Halvorsen, M.S.

Mr. Gossman appears to believe that staff medical physicists are merely well paid technicians; how else to explain the statement that *"Staff physicists have no obligations other than those tasks assigned and directed by the chief physicist.*" I strongly disagree. The AAPM-ACMP joint definition of a Qualified Medical Physicist (QMP)[9] states: "*For the purpose of providing clinical professional services, a Qualified Medical Physicist is an individual who is competent to practice* ***independently*** *one or more of the subfields of medical physics*" [emphasis added]. While medical physicists in training (e.g., residents or junior physicists not yet board certified) may not be subject to the type of peer review being debated here, all QMPs are capable of practicing independently and should therefore be expected to contribute their professional judgment and suggestions for practice improvement, even when serving as staff medical physicists.

Mr. Gossman states: "…*some chief medical physicists assign a staff physicist or part-time consulting physicist to review the same program or group with which they work…This is absolutely not what is meant by `mutual agreement'…"* On this point I agree with Mr. Gossman and, indeed, the TG-103 report that he references clearly states that "*The reviewer should, as much as practical, be independent from the reviewed physicist (for example, no business partnership or close personal relationship)."*

In summary, Mr. Gossman fails to substantiate the proposition that peer reviews of medical physics practices often yield little information and, furthermore, fails to recognize that our QMP colleagues are professionals expected to contribute their independent judgment to their practice environment regardless of their job title. I believe we can, indeed ***must***, meet that higher standard.

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10.14. Over the foreseeable future, the growth in technical complexity of radiation therapy will continue to drive the demand for more medical physicists

M. Saiful Huq and Jason W. Sohn

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OVERVIEW

The technology of radiation therapy, including 3D and conformal treatment planning, IMRT, gamma-knife and tomotherapy, and seed, intravascular and HDR brachytherapy, has created a nationwide demand for medical physicists. Whether this surge in technology, and the consequent need for physicists, will continue into the future is the subject of much speculation. This speculation is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is M. Saiful Huq, Ph.D. Dr. Huq received his Ph.D. in physics from the College of William and Mary in 1984. He is currently Director of Medical Physics at the Department of Radiation Oncology of the University of Pittsburgh Medical Center Cancer Centers. Dr. Huq has served on many AAPM Task Groups and Committees, including TG-51, and currently is chairing TG-100. He is Chair of the Calibration Laboratory Accreditation Subcommittee. Dr. Huq is a fellow of the AAPM, a fellow of the Institute of Physics, has been a co-recipient of the Farrington Daniels award, and has published more than 135 peer-reviewed journal articles, book chapters, proceedings papers and abstracts.

Arguing against the Proposition is Jason W. Sohn, Ph.D. Dr. Sohn is an Associate Professor of Radiation Oncology at Case Western Reserve University, and serves as Associate Director of Medical Physics and Dosimetry. He is a former AAPM chapter president, current member of several AAPM committees, and an ABR guest examiner. His editorial activities include serving as a reviewer for the International Journal of Radiation Oncology Biology Physics, Medical Physics, and AAPM reports. He teaches physics to medical and physics residents. His research interests are stereotactic radiosurgery, optical and radiological imaging, and intensity modulated radiation therapy.

FOR THE PROPOSITION: M. Saiful Huq, Ph.D.

Opening Statement

In the past two decades, rapid advances in technology have pushed the development of technology-intensive, image-guided modalities for cancer treatment that we recognize as modern radiotherapy. Biologic information from various physiologic imaging modalities is used increasingly to delineate target volumes accurately, and is becoming an integral part of the treatment design process. Some of the newer technologies and associated complex treatment procedures include, but are not limited to, image registration and fusion from various imaging modalities. Examples include high dose rate, prostate seed and coronary vascular brachytherapy, and stereotactic radiosurgery and radiotherapy. Image-guided radiotherapy and IMRT require

image guidance combined with immobilization devices such as breathing control or gating devices to minimize the impact of geometric uncertainties of organ motion and setup error. Accelerators are being marketed with integrated imaging devices to provide a means of seamless target identification, real time monitoring, delivery modification, delivery verification, dose reconstruction, and adaptive radiotherapy.[1,2] Patients and their family members are demanding better and higher quality care.

Clinical implementation of complex computer-augmented technology-intensive devices and procedures, including dose calculation and optimization algorithms, requires a clear understanding and critical evaluation of their limitations and performance characteristics. Because of their background in physical sciences, qualified medical physicists (QMPs) are in a unique position to evaluate and manage these devices and procedures on an ongoing basis; perform acceptance testing and commissioning of the software and hardware used for treatment planning and delivery; establish baseline QA parameters for ongoing safe use of the devices; develop procedures that satisfy regulatory mandates; design and perform appropriate patient-specific QA tests to verify correct and safe delivery of intended treatments; evaluate clinical outcomes of using the new technologies; and, most importantly, act as a technical resource to educate the radiotherapy community about the safe, efficient and intended use of the technologies. These procedures are very labor intensive and place a heavy demand on medical physicists.

The 1994 American College of Radiology survey[3] on radiation oncology in the U.S. shows that between 1983 and 1994 the number of FTE physicists increased by 60%. The 2003 Abt Study of Medical Physicist Work Values for Radiation Oncology Physics Services[4,5] found that between 1995 and 2003, practices offering remote afterloading brachytherapy increased from 46 to 66 percent, multileaf collimators increased from 19 to 79 percent, and electronic portal imaging rose from 20 to 53 percent. Technology-intensive procedures such as prostate seed brachytherapy rose to 89 percent, 3D conformal therapy (non-IMRT) to 92 percent, coronary vascular brachytherapy to 74 percent, and record and verify systems to 87 percent. The median relative work estimates for a QMP increased by a factor of 12 for IMRT treatment planning, 14 for special medical physics consultation and 16 for IMRT special physics consultation.[5]

These numbers indicate that the discipline of radiation oncology is continually changing in response to technology, practice, and state and federal regulations. They are a testament to the vital role that medical physicists play in radiation oncology and the delivery of patient care. As the growth in image-guided technology escalates, treatment procedures increase in complexity, and regulatory agencies place a premium on efforts to enhance safety, the demands for medical physicists will continue to grow. Under these circumstances, medical physicists will become even more important in the delivery of optimum patient care.

Rebuttal

Dr. Sohn supports his position with the assertion that once "technologies are in place" computerization and automation of physics duties and streamlining of new tasks for emerging systems "as experience is acquired" will likely reduce the demand for physicists. He also states that "improved clinical results from the use of advanced technology" is increasing clinical workloads. Most of these statements are consistent with my opening statement that clinical implementation of technology-intensive devices and procedures puts a heavy demand on medical physicists. I do not agree, however, with his contention that streamlining of physics activities will decrease the demand for physicists. Streamlining is necessary to ensure ongoing safe use of

various devices and procedures, and to keep pace with the ever-growing patient-specific multitude of procedures that are the product of emerging technology. Instead of reducing the workload, streamlining enables task accomplishment in a timely fashion. It is a myth that computerization and automation reduce workload.

Citing the helical tomotherapy machine as an example, Dr. Sohn argues that convergence of multiple devices will give rise to less complicated systems which will reduce the demand for physicists. To the contrary, the helical tomotherapy machine is a very complicated technology that not only performs most of the functions of the component devices that Dr. Sohn has identified, but also offers additional complex state-of-the-art treatment planning and verification procedures such as setup verification, delivery modification, delivery verification, and dose reconstruction. It also enables adaptive radiotherapy. This is a complicated technology that requires careful evaluation by medical physicists before safe implementation in the clinic. Clearly, convergence of multiple devices does not necessarily lead to a reduction of workload.

Dr. Sohn argues that the cost of physics support for new technologies should be balanced by keeping the number of physicists constant. Otherwise, as he states, "they will price themselves out of the market." He does not provide any rational basis for making such an argument. Image-guided radiation therapy will continue to grow and so will the demand for qualified medical physicists.

AGAINST THE PROPOSITION: Jason W. Sohn, Ph.D.

Opening Statement

Over the past two decades, few medical fields have been more technologically progressive than radiation therapy. Clinical workloads in radiation therapy have increased because of greater numbers of patients and increased complexity of treatment procedures. The upward trend in patients is not only a result of an aging population, but also a product of improved clinical results from the use of advanced technology. The workload expansion will certainly continue to increase, and investments to improve reliability and ease of use for clinical systems will be rewarded by the market.

The two trends of advancing technology and increasing demand for services ultimately are likely to reduce the demand for physicists, in order to make treatment costs affordable. The service cost/physics manpower issue has been studied by ACMP and AAPM.[4,6] Physicists' service-related charges have increased by 30%. When a strong demand for the delivery of services hits a personnel shortage, the impasse is generally eased by computerization and automation. I have witnessed the progression of medical physics from the simple mechanized delivery of a few select energies and fields for simple dose plans, to computerized systems directed by highly evolved control systems that deliver complex dose treatments. The entire clinical arena, from dosimetry to delivery, is trending toward self-contained computerized systems. No area of radiation therapy is untouched by significant advances in imaging technology, accurate patient positioning, improved computer modeling of radiation treatments, and precision-controlled delivery systems. All of this points to an important trend: the forced convergence and maturation of an industry to meet growing technology-focused demands.

Maturation of a process occurs when new tasks performed by a physicist for emerging systems eventually become simplified and streamlined as experience is acquired. Frequently a majority of

a physicist's duties for new technologies can be mechanized and automated once the technologies are in place. Clinics are beginning to desire entire systems that require little maintenance and fewer personnel, like the evolution of automobiles. A good example is the modern linear accelerator. We used to perform quality checks once a week. Today, greater reliability has reduced these quality checks to once per month.

As clinical systems mature, they become subject to convergence. Multiple devices, even entire diagnostic and treatment systems, are being folded into singular devices. Virtual simulation using CT scanners is steadily replacing x-ray simulators as clinics invest in a single diagnostic machine to replace two imaging systems. X-ray simulators may soon join cobalt teletherapy machines as functional curiosities from the past. The helical tomotherapy system is an excellent example of convergence. Should this technology prove itself in the clinic, one machine may replace the CT scanner, simulator, linac, and accompanying portal imaging system. Converging treatment systems will be less complicated, require less space, and will eventually reduce the demand on physicists.

We are now at the stage where we can determine whether new, advanced treatment systems/methods, including IMRT and IGRT, improve clinical outcomes. Furthermore, the improvement must be significant enough to justify the increased treatment cost. I believe that the demand for physicists will stay fairly constant as technology improves to extract greater efficiency from current and emerging clinical systems. Otherwise, the cost of physics support for new technologies will be so expensive that they will price themselves out of the market.

Rebuttal

As Dr. Huq points out, the demand for physicists has been increasing over the past several years. That is why I assert that market forces will move to automation to prevent crippling cost increases related to continued growth of physics personnel. Clinics will weigh the cost of hiring more physicists with that of buying increasingly closed, automated systems. Even now, most of the systems cited as "growing" in importance are automated replacements of older, labor intensive techniques: MLC replacing blocks, electronic portal imagers replacing film, HDR replacing LDR, Record and Verify replacing paper charts are examples. IMRT procedures have become routine. In the beginning, complex quality assurance measurements for each patient and plan required substantial time and effort from physicists. Now in many institutions, physics assistants are performing QA under a physicist's supervision. The AAPM recognizes the responsibilities of physics assistants and dosimetrists.[7] Complex dosimetry verifications are being simplified and reimbursement has been lowered as the IMRT process has become mature and streamlined.

Technology is a limitless enterprise, able to provide increasingly sophisticated techniques so long as they are affordable. We cannot continue to expand the clinical demand for physicists (and the corresponding rise in healthcare costs) without insurers stepping in to demand relief. The system is self-regulating. It is now time to shift away from personnel-intensive technologies to automated technologies in radiation oncology.

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10.15. The future will not need clinical therapy physicists

George Starkschall and George W. Sherouse
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OVERVIEW

Recently William Joy, founder of Sun Microsystems, published an article in *Wired* entitled "The Future Will Not Need Us." This provocative article caused the editor of the Point/Counterpoint series to think about whether there is a future role for medical physicists in radiation oncology (or in any discipline, for that matter). With the rapid evolution of nanotechnologies, microrobotics and intelligent machines, it does not require much imagination to foresee that many (if not all) of the functions presently provided by clinical therapy physicists will ultimately be attainable by machines, probably with greater uniformity, reproducibility and cost-effectiveness. Some would argue, however, that medical physics requires clinical adjustments and judgments that will always be beyond the reach of automated systems. This controversy is the subject of this issue of Point/Counterpoint.

Arguing for the Proposition is George Starkschall, Ph.D. Dr. Starkschall is Associate Professor of Radiation Physics at the University of Texas M. D. Anderson Cancer Center. He has served on many AAPM committees including Radiation Therapy, Program, Awards and Honors, and Development. He also served on the Board of Directors from 1992 to 1994. He was Scientific Director of the 1996 AAPM Annual Meeting and has organized several national and international symposia. He has authored or co-authored articles on radiation treatment planning, radiation oncology imaging, and electron-beam dose calculations, and edited several books on quality assurance and conformal therapy. He is certified in Therapeutic Radiological Physics by the ABR and in Radiation Oncology Physics by the ABMP.

Arguing against the Proposition is George W. Sherouse, Ph.D. Dr. Sherouse, a Florida native, received his M.S. in medical physics and clinical training at the University of Florida. After a brief stint as a product developer with a Canadian treatment planning company, he was recruited by the University of North Carolina to help reinvent radiotherapy computing. The result was a widely distributed 3D treatment design system called GRATIS™, which included the Ph.D. winning Virtual Simulator™.[1] Dr. Sherouse passed the 1990s on the faculties of Duke University and the Medical University of South Carolina, and is currently self-employed as a consulting medical physicist and mercenary product developer.

FOR THE PROPOSITION: George Starkschall, Ph.D.

Opening Statement

The need for clinical physicists is two-fold: (1) Radiation doses presently delivered in radiation therapy are high enough to cause unacceptable damage to uninvolved tissue, and (2) there is no direct indication of where the radiation dose is delivered. Consequently, validation is needed that the patient dose is correct and is delivered to the correct location. To validate dose delivery, medical physicists commission a treatment machine by acquiring data characterizing the

radiation output. The machine is subjected to quality assurance procedures to verify that the output does not change with time. Treatment planning systems are used to model radiation interactions in patients and to calculate where the radiation dose is delivered. Portal imaging is used to verify the accuracy of delivery. All of these tasks have significant medical physicist involvement. If radiation doses were significantly lower, or if dose delivery could be determined with greater confidence, the role of the clinical physicist in radiation oncology could be reduced.

In the future, cancer therapy is likely to remove one, or both, of the needs for clinical physicists. Future therapies will rely less on radiation than they do today. Future therapies will target cancer on a molecular level, and will likely be less toxic than present systemic therapies. One example is molecular chemotherapy that targets critical events in the carcinogenic process, such as growth factors, angiogenesis, and immune response. Another example is gene replacement therapy in which dysfunctional tumor suppressor genes are replaced. A third example is cytotoxic gene therapy in which tumor cells are targeted by toxic genes. Yet another example is the use of angiogenesis inhibitors, such as angiostatin and endostatin, to prevent proliferation of tumors by blocking generation of blood vessels. Finally, immunotherapies such as vaccine and antibody therapy may evolve to reactivate host anti-tumor activity. Common to all of these therapies is the use of targeted molecules or cells, with a reduction in systemic toxicity. Radiation, if used at all in the future, will be a supplemental technique for the newer molecular therapies. Radiation doses are likely to be significantly lower, and the planning and verification of radiation treatments will not be so critical.

One source of the uncertainty in dose delivery is the uncertainty in output of the radiation source. This uncertainty results in extensive commissioning measurements and an elaborate quality assurance program. Accelerators are being manufactured today, however, to deliver doses with much greater reliability. Consequently, commissioning these new machines may require little more than spot checks. In addition to a reliable source output, the dose delivered to the patient will also be more predictable. Electronic portal imaging devices are being developed that can acquire quantitative dose information in real time. This information can be compared with the dose distribution predicted from the treatment plan, and the difference fed back to the machine for real-time compensation. The use of such feedback mechanisms will allow us to "treat by wire" much as we now "fly by wire" in sophisticated aircraft.

This brave new world is not in the immediate future. Short-range job prospects for clinical physicists are excellent. In the longer-range future, however, as the use of radiation for cancer treatment declines and the sophistication of treatment machines increases, clinical physicists may go the route of chimney sweeps and blacksmiths.

Rebuttal

Dr. Sherouse justifies the future need for clinical radiation therapy physicists on the assertion that medical physicists provide the required expertise to ensure ongoing safety and quality in patient care. My argument is that the tasks performed by physicists to fulfill these needs may no longer be necessary. Commissioning and quality assurance procedures are presently performed on radiation equipment because we do not have the confidence that the output of a machine is predictable and unchanging. When we can predict the output of a radiation machine with a high degree of confidence, when we can demonstrate that the output of the machine remains constant with time, and when we can determine with confidence the true radiation dose received by the patient, our clinical justification will be severely curtailed.

Disasters such as the Therac 25 incident that Dr. Sherouse mentioned will, unfortunately, continue to occur. It is unlikely that the software failure that led to the incident would have been uncovered during any routine machine commissioning, quality assurance, treatment planning, or treatment verification procedure. It would be very difficult to justify supporting a full-time clinical physicist with little else to do than to wait for such an incident to happen. The actions of the on-site clinical medical physicist did not prevent the Therac 25 incident from happening; his role was to respond to the emergency and determine its cause. We learn from our experience, and, in particular, from our failures. It is highly unlikely that future linear accelerators will be designed with software that will fail in precisely the same manner as the Therac 25. The product has been improved by that tragic incident. Fortunately, such incidents are rare.

The role of the clinical medical physicist is likely to evolve from that of radiation consultant, playing an essential role in the planning and delivery of radiation treatment to that of radiation fireman, responding to critical emergency events. That is a very changed role for the medical physicist, and it is not the clinical role we know today.

How will clinical medical physics be supported in the future? Present reimbursement schemes recognize the clinical role of the medical physicist in supporting quality assurance directing, treatment planning, and providing consultation. It is not likely that health care payers would be willing to support one or more individuals at each radiation therapy facility whose sole purpose is to prevent the unforeseeable incident from occurring or to respond to critical events. Nor is it likely that creative, talented scientists would be attracted to a profession whose image would be similar to that of the Maytag repairman who sits around waiting for the emergency call that never comes.

AGAINST THE PROPOSITION: George W. Sherouse, Ph.D.

Opening Statement

Bill Joy's disturbing article contemplates the near-term potential for technological developments in self-replicating systems to render humanity as we know it obsolete. This could manifest as the creation of intentionally engineered "improved" physical forms for humans or, just as easily, the catastrophic proliferation of a lethal invention. In that light the current proposition becomes, "The future will not need *people* so neither will it need clinical therapy physicists." Even I can't argue with that. Dr. Starkschall wins a hollow victory.

But I accepted this assignment because I think there is a more immediate formulation of the proposition that does bear our attention, namely that "Technological developments in radiation oncology will, in the near term, render medical physicists unnecessary to effective clinical practice."

This is a timely conversation. Zealous advocates of the emerging generation of chattering teeth treatment units are already claiming that their devices will be self-contained, self-calibrating, self-monitoring and generally responsible for their own behavior. The caveat "except when they fail" is rarely spoken. Our history provides numerous cautions against such overconfidence in technology.[2] The well-documented story of the Therac-25 incidents[3] alone ought to maintain our sobriety. Three patients were killed by machine faults that the vendor insisted could not happen. It was left to a clinical medical physicist to prove otherwise.

It is the very nature of life-critical technology that increasing complexity requires more, not less, expert attention. That fact exists in tension with Arthur C. Clarke's famous observation that any sufficiently advanced technology is indistinguishable from magic. The risk exists that at the same time technology becomes more opaque, the dreamy spell cast by the new magic will enable the displacement of qualified magicians by sorcerers' apprentices. The difference will likely only be revealed in crisis.

The role of the clinical physicist is, simply, to ask questions and find answers that assure the ongoing safety and quality of patient care. The qualities that make us uniquely good at that work are a broad and deep base of interdisciplinary knowledge, formally-trained reasoning skills, strong curiosity, healthy skepticism and a relentless need to trace any mystery to its source. I have no fear of being forced into early retirement by a machine outperforming me on these counts.

In a more perfect world the need for qualified medical physicists would be codified in both the law and the fiscal structure. In *our* world, what little law there is requiring clinical physics services exists largely in reaction to serious accidents and, as evidenced by the latest HCFA rules, clinical physics has little standing among billable services. As a profession we have spectacularly failed to police our own training and credentialing in a credible way and we have refused to soil our hands with the actual hardball politics and *business* of health care, preferring to bicker among ourselves about points of ego while others cast our fate. What outcome did we expect?

I see a future that will need, but not *acknowledge* that it needs, *qualified* clinical medical physicists. That is a future in which we all lose, providers and patients alike. Advancing technology may briefly serve as a convenient smokescreen but the responsibility will rest squarely with a profession too self-absorbed to bother defining and justifying its own crucial existence.

Rebuttal

One can, without a doubt, hear the big Cure For Cancer clock ticking. I'm betting on the nanomachines myself. But for the indefinite meantime . . .

Dr. Starkschall's statement contains the very kernel of the problem which most concerns me. He describes the duties of a technician who monitors the performance of radiation machines and labels that person's job "clinical physicist." My mentors taught me that a clinical physicist is a health care professional of extraordinarily broad expertise who, first and foremost, takes care of *people*. The distinction is fundamental.

Yes, clinical radiation oncology physicists do take care of machines, but that increasingly demanding task is only one bullet in the job description. Our essential role is vigilance and strategic intervention in the customized high-tech care of individual people. There is just so much more to being an effective clinician than making radiation field measurements. It is our failure to clearly articulate and codify that distinction, among ourselves and in our interface to the world, which puts us at risk of obsolescence. Even in Dr. Starkschall's future where those dangerous radiation beams are no longer part of the Cure For Cancer, chances are good that there will still be an important role for physicist-clinicians capable of harnessing magic-seeming technology into the service of their patients.

And for the record, I have personally employed both a chimney sweep and a blacksmith within the last two years to provide services for which they were highly trained and uniquely qualified.

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10.16. Noncompete clauses in employment contracts violate a physicist's freedom to practice his/her profession

Shirish K. Jani and Prakash Shrivastava

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OVERVIEW

Increasingly, physicists are being asked by their current or potential employer to sign noncompete clauses promising to not work in the community for a specific period if they leave the employer. At times these clauses are accompanied by financial incentives to sign. Most physicists sign these clauses because they want the job or the incentive, or because they do not plan to leave the employer. But some believe that signing a noncompete clause violates their fundamental rights and freedoms as an American and as a professional. This controversy is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is Shirish K. Jani, Ph.D. Dr. Jani received his Ph.D. in molecular physics from North Texas State University in 1980. After completing a post-doctoral fellowship at the Medical College of Virginia, he joined the University of Iowa School of Medicine and later became the director of clinical physics. Since 1993, he has been at the Scripps Clinic in La Jolla, CA. He is certified by the ABR and the ABMP. Dr. Jani has served on many AAPM task groups and is an active member of the ACR Commission on Physics. He serves as an ABR Oral Examiner. Dr. Jani is a Fellow of the American College of Radiology and the AAPM.

Arguing against the Proposition is Prakash Shrivastava Ph.D., MPM(H). Dr. Shrivastava is a Professor of Radiation Oncology, Professor of Radiology and Professor of Biomedical Engineering at the University of Southern California, Los Angeles, CA. He serves as the Chief Medical Physicist and Radiation Safety Officer at the Los Angeles County Medical Center. He has a Master of Public Management (Health) degree from the Carnegie Mellon University in Pittsburgh, PA.

FOR THE PROPOSITION: Shirish Jani, Ph.D.

Opening Statement

A noncompete clause in an employment contract may require that the physicist, after leaving his/her current employment, does not work in the same geographic location for a specified interval of time. I have two major objections to such a clause.

First, some noncompete clauses are intended to protect trade secrets and the intellectual property of a company. For example, suppose an employee of a computer software company (such as google.com) joins the main competition (such as yahoo.com). He/she may possess and could transfer valuable proprietary information to the new company. In this instance, a noncompete clause may serve a useful purpose. However, a medical physicist rarely possesses trade secrets or intellectual property that is important to a new employer. Patients do not switch hospitals or healthcare providers in order to continue receiving the same medical physics services! Moreover,

the intellectual foundation of medical physics activities already exists in scientific journals and text books. Therefore, a noncompete clause is not needed to protect employers.

Second, a noncompete clause restrains medical physicists from engaging in lawful activities. For this reason, noncompete clauses are illegal in California. While there are narrow exceptions, the policy (California Business and Reference Code Section 16600) states: "Every contract by which anyone is restrained from engaging in lawful activity in a lawful profession, trade or business of any kind is to that extent void."[1]

Physicists typically sign contracts with noncompete clauses because (1) they want the job, (2) they can use financial incentives, and (3) they naively believe that they will never leave the hospital or institution. The most frequent reason to leave an employer is to seek a better work environment. Physicists who do not find their current work environment conducive to good practice often wish to find a new job without moving their residence. The noncompete clause prohibits them from accepting a nearby job. This is simply overly restrictive and unjust.

The noncompete clause is fundamentally wrong, should be illegal, and is not applicable to our profession.

Rebuttal

In his position against the proposition, Dr. Shrivastava tries to convince the reader that a noncompete clause "can be fair, legal and beneficial to both the employer and the employee." Let us first address the issue of fairness. Strictly enforced, a noncompete provision could mean that a former employee cannot make a living in the field without relocating. This is not fair. In addition, employees often leave due to workplace harassment and/or a power struggle. The severity of these conditions determines how fast an employer loses good employees. It would be far more beneficial for employers who are unable to retain good staff to identify the cause of losing their staff and to take corrective action, rather than to resort to a noncompete clause.

Another aspect of fairness deals with employers protecting intellectual property. This protection can be accomplished by a nondisclosure agreement instead of a noncompete agreement. Such nondisclosure agreements are valid most everywhere in the United States.

Let us now address the issue of legality. As mentioned earlier, the noncompete clause is illegal in California. In states where it is legal, the intent is to protect employers but also not to deprive employees of earning a living in their chosen field. This is a balancing act that hinges on fairness. An example is the case of Walia vs. Aetna, Inc., No. 992768, San Francisco Superior Court. In 1996, Aetna, Inc., merged with U.S. Healthcare. Aetna required U.S. Healthcare employees to sign an agreement that prohibited them from working for a competitor in the same state for two years, or for any competitor for six months, after employment with the company had ended. Those who refused to sign the agreement were terminated. One of the employees who refused to sign sued Aetna alleging wrongful termination. Aetna defended by arguing that public policy would be violated only if Aetna attempted to enforce the agreement. The jury sided with the employee and resolved that Aetna knew the agreement was illegal and nonetheless required employees to sign it.

Dr. Shrivastava ends his argument by stating that noncompete clauses "are as American as other types of negotiated contracts in our society." I completely disagree. In a free market such as ours, many of the glamorous start-ups are the products of free spirits. Imagine what the computer

industry of this country would look like today if IBM had elected to impose, and been allowed to enforce, noncompete clauses in every possible instance. Competition is American; prohibiting competition is not.

In summary, when a physicist signs a contract that includes a noncompete clause, typically he/she is agreeing not to engage in any business of a similar nature in that area after leaving the employer. It is wise to think twice before signing such a contract.

AGAINST THE PROPOSITION: Prakash Shrivastava, Ph.D.

Opening Statement

A noncompete covenant is a clause in an employment agreement or a separate contract standing by itself.[2,3,4] A number of questions arise when employees are asked to sign a noncompete covenant as a condition for employment. Is it fair? Is it legal? Is it enforceable? Should I sign it?

Is it fair? To employers who maintain their business or competitive edge by using proprietary, innovative ideas or technology it is critical that their intellectual property not be taken away by an employee and delivered to a competitor. It is the employer's right to protect intellectual property in order to survive in a free business environment. It is reasonable for an employer to protect itself by preventing the employee from taking knowledge acquired on-the-job to compete against the employer in a nearby enterprise.

Is it legal? It is in some states and not in others. In California, for example, noncompete covenants are not legal, but in Ohio they are. States base their laws on principles of fairness to businesses and also to individuals. An agreement cannot overly restrict employees' rights so as to violate their freedom to pursue their professions. Some specific limits on time (6 to 24 months) and distance are often allowed in noncompete covenants, so long as they are applicable to all employees and do not violate community interests.

Is it enforceable? Even if a covenant is legal and signed by an employee, it may or may not be enforceable, depending on the conditions of the agreement. Employers may have to prove in court that the covenant is necessary to protect their legitimate business interests. Not all employers would be able to convince a court that their business interests are important enough to prevent employees from working for someone else. If the competition is next door or in close proximity, however, and if it competes for the same clients, an employer may have a convincing argument.

Should I sign it? This is where the individual needs legal advice. The answer may depend on whether you are a new employee, or have been employed for some time without such an agreement. Mid-employment noncompete agreements may be less enforceable than agreements for new employees, unless the employee is given some additional advantage by signing them. In case of new employment, to sign or not to sign is your choice. Before you sign away your freedom to work for someone else in the same geographic area, make sure that the restriction is worth the benefits of employment. If you have options, consider working somewhere else. If you have plans to work in the area for yourself or with someone else, you should negotiate the noncompete contract before you sign it rather than when you are ready to end it.

In summary, noncompete covenants can be fair, legal and beneficial to both the employer and the employee. How can it be beneficial to the employee? Suppose two physicists work at a facility where the junior person learns the trade, and then leaves to help a competitor establish a new facility next door, which takes away all the business. The senior physicist is now out of a job. There is no single, simple answer to fairness, legality or validity of noncompete clauses. They are as American as other types of negotiated contracts in our society.

Rebuttal

Dr. Jani concludes that a noncompete clause is fundamentally wrong, should be illegal, and in any case should not be applicable to our profession as medical physicists.

Right or wrong is not the issue here. An individual's legal rights, and the protection of business investment or intellectual property are of concern. Legality is a community standard established to balance business interests and individual freedoms. In some communities with a high density of competing businesses, noncompete clauses are acceptable, useful, legal, negotiated contracts. As Dr. Jani correctly points out, these clauses mainly limit the time period within which the employee cannot compete or help the employer's competitors within a specified region. These limitations are restrictive but not prohibitive to the extent that the employees cannot earn a living.

Dr. Jani states that noncompete clauses should not apply to medical physicists, although they could apply to other professionals, because physicists, unlike others, do not have trade secrets or intellectual property. This surely is not a supportable fact. In addition, applying the clause to some professionals and not to others would be considered discriminatory in any community. In fact, in legal disputes courts often check to determine if employers apply the clause uniformly across the board.

When asked to sign a noncompete clause, a physicist has two options: (1) not take the job or (2) ask for specific names of regional competitors and agree not to take a new job with them for the specified period.

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10.17. Medical physicists should seek patent protection for new ideas before publishing articles about them

L. E. Antonuk and Perry Sprawls

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OVERVIEW

Knowledge about a subject grows as research results accumulate about the subject. Some scientists believe they should publish results quickly in order to stimulate the growth of new knowledge. In their view, rapid publication of results is an obligation, especially when the results are from research supported by public funds. Other scientists feel they should protect their results by patent applications, even though filing such applications delays publication of results. They claim that they deserve to share in profits from the fruits of their labors, and also that society benefits because companies will invest in results only when they are protected by patents. The controversy is becoming increasingly polarized as science becomes more secular and as scientists, including medical physicists, struggle to identify ways to support research. In this issue of Point/Counterpoint, two experienced medical physicists explore this polarization.

Arguing for the Proposition is Larry E. Antonuk, Ph.D. Dr. Antonuk, a Canadian citizen, received his B.Sc. (Physics, 1975) from the University of Calgary and his Ph.D. (Nuclear Physics, 1981) from the University of Alberta, having worked at TRIUMF in Vancouver. From 1981–1984 he was a Research Fellow for the University of South Carolina working at the Universite´ de Neuchatel, Switzerland and at the S.I.N. accelerator. From 1984–1987 he was a Research Associate for the University of Alberta working at the Laboratoire National Saturne accelerator in Saclay, France. He joined the Department of Radiation Oncology at the University of Michigan in 1987 where he is presently an Associate Professor of Radiation Physics and heads the active matrix flat-panel imaging group.

Arguing against the Proposition is Perry Sprawls, Ph.D. Dr. Sprawls received his Ph.D. degree from Clemson University in 1968 after joining the Emory University faculty in 1960. He is Professor of Radiology and Radiation Oncology at Emory and served as Director of the Division of Radiological Sciences. He is on the faculty of several other international universities and is a Director of the College of Medical Physics, International Center for Theoretical Physics, Trieste, Italy. He is certified by the American Board of Radiology in diagnostic physics, the American Board of Medical Physics in diagnostic imaging physics and magnetic resonance imaging and has served as an examiner for both boards. He is author of a series of textbooks on the physics of medical imaging.

FOR THE PROPOSITION: L. E. Antonuk, Ph.D

Opening Statement

The rapid and thorough dissemination of new knowledge is widely regarded as among the highest objectives of those involved in the pursuit of scientific discovery. It is also generally recognized that the successful translation of laboratory findings into practical application is of

critical importance to society at large, especially in light of the heavy dependence on federal funding of basic research in the U.S. Accomplishing this second goal often requires the involvement of commercial interests that are willing and able to invest the necessary resources to transform scientific discoveries or inventions into useful products. However, bringing a new technology to market is frequently a high-risk endeavor that is unlikely to bring substantial returns for many years. For this reason, the availability of patent protection through licensing can be of pivotal importance in the decision of a company to pursue the development of a new technology. This is especially true for small companies whose success may vitally depend on some degree of temporary relief from competitive pressures as afforded through licensing of patents. Moreover, small companies are often considerably more inclined to assume the higher risks and relatively lower short and medium-term rewards associated with bringing a new technology to market. Thus, seeking patent protection for new ideas prior to publishing may well be the determining factor in whether the results of research ultimately benefit society. At the very least, the existence of patents for a promising new technology often accelerates the process of making that technology available to benefit the public by providing the necessary economic incentives.

Recognition of the importance of the patent process in achieving successful application of new inventions is the fundamental principle of the patent system and is a central feature of the laws governing federally sponsored research in the U.S. For example, the Bayh-Dole act of the U.S. Congress, which became effective in 1981, gives universities and small businesses the right to claim ownership of patentable inventions that result from federally funded research. As a direct result of the incentives created by this progressive legislation, there has been an explosive growth in the patenting and licensing of university-based research results with several thousand administrative support staff assisting these efforts across the United States. In turn, this has led to the creation of numerous start-up companies, often involving university research staff. In an era when funding from government sources is increasingly uncertain, the revenues returned to universities through licensing of intellectual property contribute toward maintaining a strong and healthy climate for applied, as well as for pure, research. Moreover, royalty revenues used to support research generally allow greater discretion and flexibility compared to the more commonly available directed research funds. Finally, given that a patent application can be drafted and filed in the period between submission of a manuscript and the publication of the paper, delay in the reporting of results may entirely be avoided. In summary, the need to publish, and the need for patent protection (which will always remain a secondary objective in an academic environment), are both crucial to society's interests and need not entail compromise.

Rebuttal

I find myself in agreement with several points discussed so eloquently by Dr. Sprawls in his opening position. In particular, he concisely and accurately summarizes the importance, to individual researchers and to society at large, of prompt presentation and publication of scientific findings. Moreover, his statement, ''The U.S. patent application process does not deter timely publication of results if appropriate steps are taken for documenting research results'', directly supports a central theme of my position that delay in the publishing of results due to the drafting and filing of a patent application may be entirely avoided.

However, the ''conflict between publishing and concealing research findings,'' mentioned in Dr. Sprawls' opening position, is not something that normally enters into considerations of whether to seek patent protection for new ideas before publishing articles about them, which is the proposition to be addressed in this debate. The reason is that, in order to obtain protection for a

new idea through the filing of a patent, patent law requires the complete disclosure of the concept—that is, nothing withheld from a patent application can be protected by a patent. Therefore, ‘‘withholding valuable research findings from publication’’ would serve no purpose *vis-a`-vis* obtaining patent protection since those findings would necessarily need to be disclosed in the patent filing, which, if filed outside the United States or issued in the U.S. or elsewhere, would become a public document. Of course, a researcher or his institution could decide to protect an idea by choosing never to disclose it ~which would also necessitate never filing for patent coverage!, thereby potentially creating a trade secret. In an academic environment, however, obtaining trade secret protection would normally be inconsistent with the primary objective of publication.

AGAINST THE PROPOSITION: Perry Sprawls, Ph.D.

Opening Statement

Virtually all mankind benefits today from the many advances in medicine and healthcare that have occurred during the recent decades. This is especially true where physicists, other scientists, and engineers have contributed to the development of imaging methods that lead to more effective diagnosis and therapeutic procedures that reduce mortality and increase the quality of life.

This has not come from a few researchers working in relative seclusion but from many in the academic and industrial communities pursuing research and development projects.

Generally the objective of research is to extend the boundary of knowledge beyond what has been established by other investigators. Without a comprehensive knowledge of prior research results it is difficult to plan and execute effective research projects. Without this knowledge, extensive research efforts are wasted on repeating investigations that have already been conducted but not published by others. In many fields of research, scientists are quick to present and publish results not only to enhance the global academic process but also to establish priority and recognition for their research efforts. The additional value to the researcher who publishes includes participation in scientific meetings, academic promotion, and access to funding.

Today, with much research directed to technology and process development, another issue arises when the R and D results have financial value in the marketplace. This is the conflict between publishing and concealing research results. While individuals and their organizations have a right to financially benefit from their research efforts, this should not prevent timely publication. The purpose of the patent process in our country is to protect the intellectual property of an individual from unfair commercialization by others. It is not to be considered as a method of protecting knowledge and research findings. The U.S. patent application process does not deter timely publication of results if appropriate steps are taken for documenting research results.

There are many factors that should be considered by a researcher who is considering withholding valuable research findings from publication:

- How will this information best serve humankind?
- Will the benefits of publication to me outweigh a remote possibility of financial gain through the patent process?
- Is it even possible to get a patent on this?
- Does it really have a significant commercial value that should be protected by a patent?

- Am I or my organization willing to devote the resources (money, time, etc.) to the patent process?

The conclusion is that research results should be published in a timely manner and not delayed because of patent considerations.

Rebuttal

To publish or patent (and perish in the academic arena?), that is the question. Or is it the question that should be debated here?

Dr. Antonuk and I both recognize the value of the patent process and also the opportunity for academic recognition and the advancement of science and technology through the presentation and publication of research findings.

In his opening statement he has clearly shown how patent protection contributes to the total research and development process and can generate funding for on-going investigation. In many cases this can be consistent with academic publication.

The real question to be considered is not so much publish or patent but how to publish and patent so that neither is seriously compromised.

In response to Dr. Antonuk's thorough and compelling statement of support for the patent process I remind us of the need for prompt publication. This not only serves the academic aspirations of the individual scientist; it is one of the foundations of the total academic research process.

10.18. A hospital-employed physicist working in radiology should provide training to non-radiologists wishing to offer radiology services

James A. Patton and Guy Simmons

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OVERVIEW

Most hospital-based diagnostic medical physicists work principally within a radiology department. In this setting, professional loyalties and personal friendships evolve among the physicists, radiologists, and employees of the department. In most institutions, not all radiology services are provided by radiologists or by the radiology department. In these institutions, radiology services may be offered by cardiology, urology, obstetrics, cardiovascular surgery, and other departments, frequently in direct competition with radiology. These departments need and sometimes request the services of the medical physicist. The question for this issue of Point/Counterpoint is whether physicists are ethically obligated to meet this need (even when their services are not requested), or whether their professional relationships within radiology should take precedence over the provision of services to competing specialties.

Arguing for the Proposition is James Patton. Dr. James Patton obtained his Ph.D. in medical physics from Vanderbilt University in 1972 for work in single photon tomography and has been on the faculty at Vanderbilt since that time. He currently holds the rank of Professor of Radiology and Radiological Sciences and Professor of Physics. He is the chief nuclear medicine physicist, has taught nuclear medicine physics and instrumentation to radiology and nuclear medicine residents, nuclear medicine technologists, and cardiology fellows for 26 years, and has served as program director for nuclear medicine technology for 20 years. Dr. Patton's research interests include single photon tomography and applications of high energy imaging with dual head scintillation cameras. He has co-authored five textbooks in nuclear medicine. He is currently serving as President of the Southeastern Chapter of the Society of Nuclear Medicine.

Arguing against the Proposition is Guy Simmons. Guy Simmons, Ph.D., is a Professor at the Department of Diagnostic Radiology, University of Kentucky Medical Center. He is also President of Bluegrass Radiological Physics, Inc., a diagnostic and medical nuclear physics consulting firm. Dr. Simmons received the Ph.D. in nuclear engineering from the University of Cincinnati in 1972. He has served as Secretary and President of the American Association of Physicists in Medicine. He is currently a Physics Trustee of the American Board of Radiology and a member of the American College of Radiology Committee on Standards and Accreditation of the Commission on Medical Physics.

For the proposition: James A. Patton

Opening Statement

Many institutions have made the decision to place radiologic technology into the hands of nonradiologists for reasons that are often institution specific. Although these decisions are not the subject of this discussion, it is clear that nonradiologists will continue to perform radiology procedures.

Should radiological physicists train these specialists in basic radiation physics, instrumentation, radiation safety, and quality assurance? The answer to this question is ‘‘yes.’’ The alternative is for the specialists to train themselves or to attend concentrated courses outside of the institution. Neither of these alternatives is acceptable. Each results in inadequate training which, although it may meet the letter of credentialing requirements, certainly does not meet the spirit of the credentialing process. Radiological physicists within institutions are better equipped to provide the requisite training.

Every employee in a hospital, including the radiological physicist, has a responsibility to see that patients receive the best care possible. Radiological physicists have a moral and ethical obligation to see that procedures are optimized; equipment is monitored, maintained and utilized properly; and radiation exposures are minimized, regardless of the user. Regulatory organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), state bureaus of radiological health, and the Nuclear Regulatory Commission place stringent requirements on institutions regarding these topics. Radiological physicists have an institutional responsibility to see that the requirements are met, again regardless of the user. As hospital environments and patient care responsibilities continue to evolve, ongoing employment for physicists in an institution may be contingent upon their willingness to train across departmental lines.

This position is difficult for physicists who have worked side by side with radiologists for many years. However, radiologists are being forced to form partnerships with other physicians in orthopaedics, obstetrics and gynecology, nuclear cardiology, and interventional and vascular radiology, to name a few examples. In our institution nuclear medicine physicians and cardiologists share responsibilities in cardiac nuclear medicine (a hospital-based nuclear medicine service) and in the nuclear cardiology laboratory (a cardiology outpatient facility). Radiology-based physicists have responsibilities in both areas. Cardiology fellows attend radiological physics classes with nuclear medicine and radiology residents and sit for an examination at the completion of the course. They also rotate through the hospital-based cardiac nuclear medicine laboratory and radiopharmacy. Although these agreements to share responsibilities may not be ideal for radiologists, they appear to be necessary in order to survive. Radiological physicists can play a significant role in ensuring the success of such partnerships.

Rebuttal

I agree with many of Dr. Simmons’ statements. Radiologists are more qualified by training, knowledge, and experience to perform radiologic procedures, and turf/economic factors are driving the paradigm shift. I also agree that the allegiance of the radiological physicist is aligned with radiology. However, the environment is changing and radiologists and physicists have no control over the decisions that are being made. What is the future role of radiological physicists? We can take the high road, as Dr. Simmons suggests, and simply say that we will not be a part of a process in which we do not believe. On the other hand, we have an institutional responsibility that probably will not permit us to make this decision. But more importantly, we have a responsibility to patients to see that they receive the highest quality medical care involving diagnostic and therapeutic radiologic procedures, regardless of the provider. Therefore I think the

decision is clear. Although we may not agree with the process, we have no choice but to assist in the training of nonradiologists.

Against the proposition: Guy Simmons

Opening Statement

The pertinent questions surrounding the ethical dilemma of whether or not medical physicists should aid and abet nonradiologists in their quest to perform procedures for which radiologists are most qualified are the following. What is the driving force behind this encroachment? Is it based on a firm conviction, supported by objective data, that the accuracy of diagnoses and thus the quality of medical care will improve under this non-traditional approach? Or is the encroachment a result of turf battles and therefore driven by economic factors. Most astute observers would conclude the latter, which clarifies the dilemma considerably for physicists. If we are to be true to our ethical standards we must support policies that require all medical procedures to be performed by those who are best qualified and most competent in the respective field. In the area of medical imaging, there is no argument that the competence lies with radiologists, the only medical specialists that spend an entire five-year residency and devote their professional careers solely to the diagnosis of disease using imaging procedures. The notion that physicians in a different specialty can achieve a level of competence in clinical imaging equivalent to that of radiologists through a process that amounts to on-the-job-training is contrary to proven principles.

The time is long past in which one can become a competent medical physicist outside of a structured, formal graduate program. The same is true of technical fields. How can we therefore presume that diagnostic imaging procedures in the hands of physicians, whose formal training in this highly complex discipline is minimal or nonexistent, will not degrade the quality of health care? Most medical physicists are well aware of the scope and intensity of effort required to achieve a foundation in imaging science necessary for a physician to master the specialty of medical imaging. We know from experience that it cannot be accomplished in an anecdotal fashion.

It has taken many years and much effort by physicians and physicists to bring radiology to the state of prominence and respect it now occupies within the medical professions. For medical physicists to engage in practices that undermine and destroy the fruits of this labor is a disservice to our profession. Therefore the answer to the ethical dilemma is clear. As members of the radiology team, we should not lend our support to a process that we believe will degrade, not enhance, the quality of medical imaging services. The public we serve deserves better. Medical physicists should continue to devote their physician training efforts to time-honored participation in accredited residency programs for radiologists and continuing education for radiology practitioners.

Rebuttal

Dr. Patton makes several cogent points in his customarily elegant fashion. I will quote three passages from his discourse to support my counterpoint argument. Dr. Patton, whom I know to be a man of the highest ethical and moral standards, makes the following statement commensurate with his own principles; ‘‘Every employee in a hospital, including radiological physicists, has a responsibility to see that patients receive the best care possible. Radiological physicists have a moral and ethical obligation to see that procedures are optimized . . . .’’ What

better way to achieve this worthy goal than to insist that diagnostic imaging procedures be performed by the physicians best trained to do them; viz. radiologists? In his last paragraph Dr. Patton expresses a highly pertinent truism, ‘‘. . . radiologists are being forced to form partnerships with other physicians . . . .’’ The key word here is ‘‘forced,’’ implying that the migration of medical imaging to other specialities is driven by market conditions, not because it enhances the quality of medical care. Finally, he admits, ‘‘Although these agreements to share responsibilities may not be ideal for radiologists, they appear to be necessary in order to survive.’’ I agree that the survival of radiology as a medical specialty is essential to the delivery of quality medical care. But capitulating to the forces that threaten radiology is not the way to ensure survival. As radiological physicists we are better advised to oppose those who seek to fragment medical imaging and support efforts to keep it where it belongs—in the hands of radiologists.

10.19. The Joint Commission for the Accreditation of Healthcare Organizations should require that all physicians who perform fluoroscopy be credentialed in radiation management by their healthcare facility

Benjamin R. Archer and David S. Gooden

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OVERVIEW

Patient exposures in fluoroscopy for specific examinations vary widely among physicians. Some physicians cause high exposures because they have a ‘‘heavy foot’’ or because they take an inordinate time to perform fluoroscopic examinations or fluoroscopy-guided procedures. Exposures are lower with other physicians, perhaps because they are more conscious of the exposure of patients to radiation, and also because they may be better trained in the efficient use of radiation. There is some suspicion, not well documented, that nonradiologists tend to produce higher patient exposures than radiologists. An initiative proposed from time to time to remedy the cause of high fluoroscopic exposures is to require on-the-job training of physicians before they are credentialed to perform fluoroscopy in the hospital. Some physicists support this initiative, while others believe it will not be productive and require too much time and effort from medical physicists. This is the subject for this issue of Point/Counterpoint.

Arguing for the Proposition is Benjamin R. Archer, Ph.D. Dr. Archer is currently an Associate Professor of Radiological Sciences at Baylor College of Medicine where he has been employed since 1984. He received his doctorate from the University of Texas Graduate School of Biomedical Sciences/M. D. Anderson. He has served on numerous AAPM committees and task groups. Currently he co-chairs the NCRP 49 Rewrite Committee and serves as Treasurer of the American Board of Medical Physics. He is also active in the American College of Medical Physics and the American College of Radiology.

Arguing against the Proposition is David S. Gooden, Ph.D., J.D. David S. Gooden is the Director of Biomedical Physics at Saint Francis Hospital in Tulsa. For almost 30 years he has served as radiation safety officer and radiological physicist for diagnostic x-ray, radiation therapy and nuclear medicine. Dr. Gooden has provided radiation safety consultation in many areas, including health care, veterinary medicine, nuclear reactors, electric utilities, universities, industrial radiography, waste management, scrap metal salvage, foundries, and oil and gas production. Dr. Gooden is certified by ABHP (health physics), ABR (radiological physics), and ABMP (radiation oncology physics).

FOR THE PROPOSITION: Benjamin R. Archer, Ph.D.

Opening Statement

Massage therapists, beauticians and realtors must be licensed in order to practice in most states. However, little or no training is required for most physicians who daily expose their patients, staff and themselves to ionizing radiation! Fluoroscopic radiation is known to have caused

cancer and severe injuries in a small but growing population of physicians and patients. More than fifty radiation burns, including a very recent one that produced a deep necrotic ulcer and ultimately rendered the humerus of a patient visible (Fig. 1), have been reported in the United States. A 1994 advisory notice issued by the U.S. Food and Drug Administration warned facilities of the potential dangers of invasive fluoroscopic procedures. The notice recommends that facilities ''assure appropriate credentials and training of physicians performing fluoroscopy.''

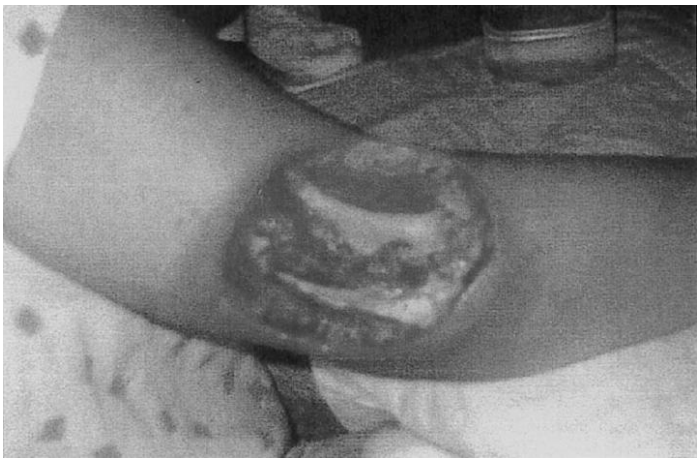

FIG. 1. Radiation burn resulting from debridement following radiofrequency cardiac catheter ablation procedure. Injuries of this magnitude are very rare. This case will be discussed fully in an article in the first edition of the Journal of the American College of Medical Physics in 2000. (Photo courtesy of L. K. Wagner)

Medical staff credentialing is the verification and assessment of practitioner qualifications and the granting and delineation of clinical privileges. The credentialing process was instituted to protect patients from unethical or untrained practitioners by recognizing the competence of a professional.

Recognition of competence may be through certification, licensure, registration or a combination of the three. It nearly always involves the completion of an accredited or approved educational program. The credentialing of a medical staff member implies verification of competence. There is a wide distinction, however, between the credentialing of a cardiologist, radiologist, pain interventionalist, or other fluoroscopist as technically competent to perform a procedure versus the credentialing of the same physician as competent to safely use fluoroscopic radiation. Credentialing these physicians as technically competent gives no assurances that they have received training in the safe uses of fluoroscopy. I submit that the current ''rubber stamp'' granting of privileges to untrained practitioners is both illogical and unethical. The fact is that these individuals can and are injuring patients and even one preventable radiation injury caused by ignorance and indifference is absolutely unacceptable!

Furthermore, as the pre-MQSA experience has shown us, unless credentialing is adequately enforced, the results will be less than satisfactory. Enforcement should logically come from the JCAHO. Dr. J. B. Spies clearly elucidated the rationale at the 1992 ACR/FDA Workshop on Fluoroscopy: ''Since all health facilities require accreditation by the JCAHO in order to receive Medicare and Medicaid funds, adding a requirement for fluoroscopy certification would in essence be self-enforcing by the individual facilities.'' Thus, if the JCAHO were to require

appropriate credentials for fluoroscopists in radiation management, then each healthcare facility would have to see that its staff complied or else be faced with the unseemly prospect of forfeiting revenue. Concern about malpractice litigation should also provide convincing motivation for facilities to proactively seek credentialing and to welcome the JCAHO influence and audit. But the major motivation should result from plain common sense and the innate ethical realization that we should always do the ‘‘right thing’’ for our patients.

Rebuttal

Physicists can write prescriptions for patients! Surgeons can interpret mammograms! Red Goose shoes will rule the world (I wore them too)! David, these statements are as nonsequitur as your contention that it is wasteful to spend money on credentialing fluoroscopists. Radiation injuries caused by physicians are not a Chicken Little story. The cost of education pales against the human suffering and expense of malpractice lawsuits. We are presently aware of at least five such trials that are in progress. There have been and will be more.

Fluoroscopic equipment has become more powerful and complex. Longer and more difficult procedures have become commonplace. To illustrate just how essential it is to credential fluoroscopists in radiation management, Dr. Lou Wagner and I just completed a study of radiation doses from two modern special procedure fluoroscopic units (JVIR, in press). We found that a prolonged procedure on a large patient performed with less than ideal radiation management techniques resulted in a dose of 8.8 Gy more than the same exam performed with ideal techniques! In other words, physicians who are ignorant of practical physics concepts and instrumentation can unwittingly produce erythema and dermal atrophy in their patients. The boogey man here is apathy.

Let’s be clear on what we mean by credentialing because I believe we are not that far apart. As you suggest, ‘‘better training in medical schools, residencies and good institutional radiation safety programs can reduce fluoroscopic injury to near zero.’’ Completion of an approved educational program (with appropriate testing) provides the evidence needed by the facility to approve the practitioner’s qualifications. A physician can be credentialed simply by completing an appropriate course(s) in radiation management. The JCAHO audit would insure that program goals are being achieved.

Again, even one radiation injury caused by lack of education is unacceptable. An attitude change is required. It should become our quest as radiation experts to assure that the words reportedly spoken by a cardiologist in a recent trial regarding a radiation burn on his patient are never again heard: ‘‘I only wish I had known that I could have done that to my patient; I thought a burn like that could only happen in radiation therapy.’’

AGAINST THE PROPOSITION: David S. Gooden, Ph.D., J.D.

Opening Statement

The earth is flat! The sun and stars rotate around the earth! Lead can be changed into gold! Radiation is so dangerous that it requires extraordinary controls and regulations! These beliefs are based on scientific truths that existed at the time of the belief. Three beliefs are abandoned and now seem foolish. The fear of radiation, however, remains deeply ingrained in us. This fear is traceable to a foundationless

linear-no-threshold model of radiation injury promoted by activists who in the 1950s sought to stop testing of nuclear weapons. Requiring more extraordinary controls such as special credentials for physicians using fluoroscopy propagates this unreasonable fear of radiation.

My position on special credentials comes from a lifetime association with radiation and the study of radiation injury. As a small boy (late ’40s and early ’50s), our family doctor would invite my mother and sister to observe my body with an upright fluoroscopy device (estimated 25–50 R/min). I remember my mother leaving me at the Red Goose Shoe Store in Atlanta while she shopped. My sister and I played with the x-ray shoe-fitting machine for hours (estimated 3000 R/hr). While at Emory University, I worked with an early prototype Co-60 device and performed dosimetry on a kilocurie Cs137 irradiation facility. At the University of Missouri Research Reactor, I had safety responsibilities for kilogram quantities of 98% enriched U-235 and megacuries of spent fuel. For 35 years, I have helped both medical and nonmedical industries use radiation in a safe, productive manner. My study and experience taught me that large acute doses of radiation could cause severe injury and death. Also, there is evidence that radiation is a weak carcinogen for moderate exposures (10s to 100s cGy) at high dose rates.

Radiation is dangerous and I do not want to return to the lax practices of the 40s and 50s. However, radiation is not extraordinarily dangerous. Rather, it is dangerous like gasoline, fire, explosives, electricity, hammers and saws, syringe needles, and all other tools. It is dangerous like water, oxygen, vitamins, drugs, chemicals, food, sunshine, sleep, and all other things that cause harm if exposures are too great.

Radiation, like all things that serve humankind, must be used with caution. Although new life saving interventions requiring long fluoroscopy times have caused a few dozen acute injuries during the past few years, I believe that radiation medicine remains the safest of the major branches of health care. Other branches of medicine kill and maim thousands each year.

Reasonable control and regulation of radiation is appropriate, but extraordinary controls are not required. Better training in medical schools and residencies, and good institutional radiation safety programs, can reduce fluoroscopy injury to near zero. To spend money on special credentials for fluoroscopists is wasteful and sends the erroneous message that radiation is extraordinarily DANGEROUS. We can serve our patients best by using our limited resources where the greatest benefit can be realized rather than by throwing more money at the radiation boogey man.

Rebuttal

My colleague, Ben Archer, makes a good argument in favor of certification of all physicians who perform fluoroscopy. Dr. Archer and I agree that acute fluoroscopy injury can be, and should be, reduced to (or near to) zero. Our beliefs in the root causes of injuries (and, thus, the cure), however, differ. Ben appears to believe that the injuries are caused by untrained and/or unethical physicians. I believe otherwise. The injuries that I know of in Oklahoma have not occurred at the hands of untrained, unethical physicians. In fact, they were caused by radiologists and cardiologists well-trained in interventions requiring fluoroscopy. Far from being the result of unethical practice, they resulted from interventions without which the patients would likely have died. I believe most of the recent fluoroscopy injuries have resulted from the ethical practice of trained physicians.

The root causes of the recent fluoroscopy injuries are 1) inadequate early supervision of residents in training programs, 2) the learning curve associated with new life saving interventions that require long fluoroscopy times, and 3) the intense concentration on the procedure to the exclusion of noting important fluoroscopy parameters. Important parameters include: 1) the distance between the patient and the x ray tube, 2) the x ray output mode (normal or supercharged), 3) time (use freeze frames and/or light foot), and 4) the movement of the x-ray entry point to different locations on the patient. The entire team assisting in the intervention must be encouraged to stay cognizant of fluoroscopy parameters to maximize benefit and reduce risk.

Since untrained and unethical physicians are not the root cause of fluoroscopy injuries, safety will not be improved with requiring more credentials. Requiring extra credentials will, however, promote the unreasonable belief that radiation is extraordinarily dangerous and, thus, distract from the medical use of this wonderful tool. Root causes of fluoroscopy injuries should be addressed in training programs and institutional safety programs. The curriculums of medical schools and residencies should teach that radiation is like a surgeon's scalpel. It is itself neither good nor evil, but instead a tool that can be used to great benefit if used with reasonable (not extraordinary) caution. Curricula should include early training in reasonable caution. Directors of institutional radiation safety programs should promote a partnership with physicians in the safe and beneficial use of medical radiation for diagnoses and interventions.

10.20. The Ph.D. degree is a handicap in the job market for clinical medical physicists

J. Daniel Bourland and David S. Marsden
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OVERVIEW

The Ph.D. degree signifies that the individual has the ability to pursue an original investigation designed to generate new knowledge in a particular field. It is the appropriate degree for the person interested in an academic career in the discipline. For skilled application of existing knowledge in a clinical arena, however, some may view the Ph.D. as undesirable because the degree connotes greater interest (and possibly knowledge) in research than in application. However, an individual with the Ph.D. degree has met higher academic standards, and may be viewed more as an equal with other professional in a clinical setting. The relative merits of the Ph.D. degree compared with a less research-oriented degree (e.g., the MS degree) in seeking a nonacademic position in medical physics is the subject of this Point/Counterpoint.

Arguing for the Proposition is J. Daniel Bourland, Ph.D. Dr. Bourland is Assistant Professor and Head, Physics Section, in the Department of Radiation Oncology, Wake Forest University, Winston-Salem, NC. He is Chair of the AAPM's Electronic Media Coordinating Committee and the African Affairs Sub-Committee. He performs clinical service, research, and education in the areas of 3D treatment planning, radiosurgery, and the uses of images in treatment planning.

Arguing against the Proposition is David S. Marsden, Ph.D. After thirty years as the Radiation Safety Officer and Director of both Medical Physics and the Radioimmunoassay Laboratory at St. Luke's Roosevelt Hospital in New York City, Dr. Marsden recently retired to form a family operated consulting firm, Marsden Medical Physics Associates LLC. Dr. Marsden has been a physics advisor and oral and written board examination committee member for the ABR. He was the Chairman of the AAPM Training of Radiologists Committee. He helped create the Clinical Ligand Assay Society and served this organization in every elected position. He was recently awarded fellowship in the ACR.

FOR THE PROPOSITION: J. Daniel Bourland, Ph.D.

Opening Statement

The Ph.D. degree is a handicap in the job market for clinical medical physicists because it reflects the character of the individual who has taken the time to earn the degree. This character, in general, makes some Ph.D.s ill-suited for clinical medical physics work, and this trend is known by administrators and other physicists. Thus, a certain stigma is associated with the Ph.D. degree that is a handicap for recruitment to clinical medical physics positions. The Ph.D. medical physicist is an individual who has interrogated a research topic at great depth. By nature, the Ph.D. shows that one is curious about his environment and interested in investigation through theoretical and experimental methods. Thus, Ph.D. medical physicists may not be satisfied with the completion of routine quality assurance work—a daily supply of work is not the ticket to

contentment. This inherent discontentment makes the Ph.D. one who is difficult to please because challenge and variety are either not present, or possibly not accommodated in a clinical position. While critical thinking is an attribute for medical physicists in the clinic, the tendency for the Ph.D. to ponder a situation can result in over analysis and little solution. Also, many Ph.D.s have concentrated on their research during their educational years, and have little clinical or practical experience. Such individuals do not belong in the clinic for reasons of efficiency and safety for themselves, co-workers, and most importantly, patients. Another difficulty with the Ph.D. is the salary expectation, which runs 10 to 20% higher than for MS-level positions. So the Ph.D. will cost more than the MS in the same clinical position.

Some Ph.D. medical physicists serve whole-heartedly in clinical positions. In general, however, administrators and co-workers know that the Ph.D. medical physicist will (1) eventually get bored with routine clinical work, (2) be interested in detailed research projects with doubtful clinical application, (3) ask to do some other kind of work when clinical service is required (redefine the position), (4) ask for higher compensation, and (5) be difficult to please in other facets of employment. These common characteristics are a handicap to the Ph.D. seeking a clinical medical physics position, and provide a clear distinction between Ph.D. and MS level positions.

Rebuttal

Dr. Marsden's response to the Ph.D. being a handicap lists advantages of the Ph.D. degree. These advantages may be valuable for the Ph.D. medical physicist, but they do not apply to the routine clinical environment. Higher earning potential, credibility, and a balanced working environment (''Doctor'') may make one's job professionally more satisfying, but distract from the duty at hand, which is clinical medical physics. While academic institutions need medical physicists at the Ph.D. level, community settings need people who will do a variety of routine tasks. Note that ''routine'' does not mean mundane, though this is sometimes the case. Even academic institutions hire MS-level medical physicists in their clinics to provide most of the clinical service and to free up Ph.D. time for teaching and research. As discussed by Dr. Marsden, clinics hiring MS medical physicists may pay less than a Ph.D. However, given today's competitive job market, this differential is becoming less and less the case. Certainly, board certification is a primary salary differential and reflects an important point—the MS degree for medical physics is a perfectly valid level of education. The AAPM offers educational fellowships to encourage clinical medical physics training at the MS level, and the MS is acceptable for gaining entrance to board certification exams. MS medical physicists can enhance their careers by serving in administrative positions, directing allied health training programs, or serving as the sole institutional physicist. Thus, a pathway of service is an alternate to the academic track.

For these reasons and those stated earlier, clinical medical physics positions are well covered by MS medical physicists, and the Ph.D. medical physicist is best matched to the academic environment. I propose that the best clinical medical physicist is one who has either the MS or Ph.D. degree, has strong analytical skills, is dedicated to clinical service, shows his expertise by board certification, and has strong computer skills since our field is becoming heavily computerized. Credibility will be earned based on one's skills and wisdom in responding to clinical situations, not on the level of degree.

AGAINST THE PROPOSITION: David S. Marsden, Ph.D.

Opening Statement

Although a Clinical Medical Physicist can work independently and become board certified with only a master's degree, a doctoral degree is an advantage in the job market. Even though individuals with a master's degree may be hired more readily in some environments, their ability to attain higher levels of achievement are compromised. To be on the medical staff at a hospital, a Ph.D. is required. To achieve Full Professor or Department Chair status in an academic setting, a Ph.D. is often a prerequisite. The doctoral degree enables physicists to choose from a broader range of employment opportunities. Maybe that's why in 1999, masters level Medical Physicists were 11/2 X more likely to change jobs when compared with doctoral level Medical Physicists.[1]

The salaries of Clinical Medical Physicists with a doctoral degree are higher than the salaries of Clinical Medical Physicists with a master's degree. In 1999, physicists with a doctoral degree and board certification had an average income of $116,500, whereas, physicists with a masters' degree and board certification had an average income of $100,900. Physicists with a doctoral degree and no board certification had an average income of $93,800; whereas, physicists with a masters' degree and no board certification had an average income of $81,300 (AAPM Survey, 1999). Fifty-six percent of AAPM members have a Ph.D. degree and thus, benefit from the possibility of higher earning potential.

In addition, many Clinical Medical Physicists work in the medical community, which highly regards the title ''Doctor.'' Being able to use the title ''Doctor'' in a medical setting creates a situation in which Physicists are seen as credible competent professionals (which may or may not be true). The title affords physicists the opportunity to work on an even playing field. Most people do not understand the title Medical Physicist and when we talk in terms of working with radiographic or mammographic units they confuse us with service technicians. Most patients don't realize that Physicists are part of their radiation treatment team. Like it or not, the use of the title ''Doctor'' connotes importance and causes people to take our profession and us more seriously.

To complete a doctoral program, an individual must engage in several years of research. The application of the scientific method to a research problem teaches students to think critically and logically. Thus, students gain more than just rote on-the-job training. They are taught to analyze the methods they are using and evaluate all possible options, which makes them more marketable. An employer can expect an individual with a doctoral degree to possess versatile problem solving skills as well as specific technical information.

The additional education required to obtain a doctorate affords several benefits for later employment. The ability for enhanced career attainment, higher earning potential, and professional credibility, creates a more balanced working environment.

Rebuttal

Research done while completing a doctoral degree is an exercise in the use of the scientific method and analytical skills. Just because an individual possesses the skills to complete a research project does not necessarily indicate he or she has a similar ''character'' or even a desire to work as a researcher. Students have a myriad of reasons for attending graduate school and developing different proficiencies in research and clinical work depending on their interests, program attended, and completion of clinical internships, etc. Indeed, there may be some medical physicists who become ''bored with routine clinical work,'' or attempt to ''redefine the

position.'' However, these tendencies are probably based more on an individual's need for challenges or on the nature of the work environment, rather than on the individual's educational background.

Obviously, physicists without practical experience should not be working in clinical positions. Whether or not an individual is competent to function in an applied physics position is based more on professional experience than on academic degree. Master's degree programs are not set up to offer more clinical experience than doctoral programs.

My colleague asserts that ''the character of the individual who has taken the time to earn the degree (Ph.D.)...makes some Ph.D.s ill suited for clinical medical physics work, and this trend is known by administrators and other physicists. ... .'' I am unaware of any data (statistics, AAPM publications) that support this assertion. It seems to be a generalization based on opinion rather than fact. If it were true, then very few Ph.D.s would be employed, which is obviously not the case.

REFERENCE

1. American Association of Physicists in Medicine, ''Professional Information Survey Report, Calendar Year 1999,'' 2000.

10.21. Medical physicists need professional malpractice insurance

Michael Davis and Jeffrey Masten
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OVERVIEW

Many medical physicists work full-time as independent contractors, sometimes as a member of a physics consulting firm. Other physicists work full-time as an institutional employee, but provide consultative physics services part-time as a source of supplemental income. For all of these individuals, the cost and breadth of coverage of malpractice insurance is a key concern. Some physicists believe that coverage is essential regardless of cost. Others choose to go without coverage because of the cost and the rationale that malpractice insurance enhances the risk of lawsuit. The controversy over malpractice coverage is explored in this point/counterpoint.

Arguing for the proposition is Michael Davis, M.S., J.D. Mr. Davis received his Masters degree in Radiological Medical Physics from the University of Kentucky. He recently left his position as Director of Radiation Oncology for the Greenville Hospital System in South Carolina to join Varian Medical Systems. He also worked at the M.D. Anderson Cancer Center in Houston for eight years. During that time he obtained a Doctor of Jurisprudence degree from the South Texas College of Law. Mr. Davis is certified in Therapeutic Radiological Physics by the ABR. He currently chairs the Legal Affairs and Risk Management subcommittee of the AAPM.

Arguing against the Proposition is Jeffrey Masten, M.A., J.D. Mr. Masten is a Staff Physicist at the Medical X-Ray Center, P.C. in Sioux Falls, South Dakota. He earned his M.A. in Physics at Columbia University, NYC, in 1972, his J.D. at the University of South Dakota in 1976, and is an M.S. candidate in Medical Physics at the University of Colorado, Denver. He has been a trial lawyer for 25 years with a particular interest in the use of scientific evidence in litigation.

FOR THE PROPOSITION: Michael Davis, M.S., J.D.

Opening Statement

We are potentially victims of our own success. The technologies used in radiology and radiation oncology clinics have advanced dramatically during the last few years. This rate has increased the need for physics services. This is one cause of the recent spiral in salaries of medical physicists. Utilizing new technologies and making more money can be exciting and rewarding. Unfortunately these very happenings make us tempting targets.

All of us take pride when our work positively touches the lives of people. Countless patients owe at least part of the detection or treatment of their illnesses to our professional efforts. But occasionally a failure occurs. In some of these failures, a patient or family member may decide that the efforts of the healthcare team fell short. And he or she may seek monetary compensation.

In a perfect world there would never be a treatment error. Unfortunately, this is not the world in which we work. Sometimes an error that affects a treatment outcome gets past us. And

sometimes someone sues because of the outcome. When this happens our fate is left in the hands of an attorney and a judge or jury of peers.

Anyone who has ever been involved in a lawsuit knows that it generates enormous stress. This stress is greatest when one is on the wrong end of the suit. A lawsuit may drag on for years. An adverse decision in a malpractice case can destroy much of what has taken years to build. Even if one is ultimately victorious, the legal costs can be staggering.

Obtaining malpractice insurance is one cost of doing business today. Our dependence on computer software, elaborate technology, and other professionals on the team put us at risk. Participation in increasingly complex treatment methods, such as IMRT, has compounded this risk.

Because we are not the people taking direct responsibility for patient care—i.e., we are not physicians—the malpractice insurance costs for physicists tend to be relatively reasonable. In fact, as a percentage of what one stands to lose without coverage, it is trivial. Even if the cost of professional malpractice insurance was much higher, cost trimming or "going bare" would not be wise.

When we reach a point where the legal system, every one of our colleagues, and we ourselves as physicists are perfect, then we can dispense with professional malpractice insurance. That time has not yet arrived.

Rebuttal

Mr. Masten believes that liability is the employer's problem. Ideally this is true. But there are several factors that make relying upon the good graces of employers a mistake. We are in a dynamic healthcare environment. Who has responsibility for our malpractice defense if our employer closes its doors or merges with another organization? Often a lawsuit is not initiated until years after the initial causal event, because the plaintiff may not experience symptoms for some time. What if we have changed employers during that period? And how many of us even know if the group policy provided by our employer is adequate?

As Mr. Masten states, moonlighting or solo practices are clearly exceptions to relying upon an employer-sponsored master policy. But what about the gray areas that arise even if we are not involved in these activities? We remain qualified medical physicists even outside of work. What happens if we offer advice to friends or strangers at a social event? Would our employer have any responsibility for defending us if those to whom we gave information decide that we have caused damage through poor professional advice?

Mr. Masten worries about finger pointing and hard feelings on the part of the employer if we have a separate malpractice insurance carrier and decide to give notice to that carrier. But that is a small price to pay for having our own attorney who has our interests at heart, rather than simply relying on an attorney assigned to us by the employer. Counsel for the employer will try to protect the overall interests of the employer, and may have to balance those interests against the individual needs of the employee. By contrast, the physicist's own attorney would be focused solely on what is in his or her best interest.

Physicists are familiar with the concept of weighing risk versus benefit. I believe that the potential threats created by not having professional malpractice insurance far outweigh the financial costs of obtaining it. As Mr. Masten said, better safe than sorry is an admirable attitude.

AGAINST THE PROPOSITION: Jeffrey Masten, M.A., J.D.

Opening Statement

My comments are directed toward physicists employed by an entity (e.g., a hospital, clinic or group practice) that maintains a master policy providing malpractice coverage for its employees. Moonlighting and solo practice are excluded. Should a physicist spend the money to have an independent policy separate and apart from the employer's?

One frequently heard argument against malpractice insurance is that the coverage makes the insured a "target" for lawsuits. As we shall see, that is a poor justification for not purchasing malpractice coverage because anyone participating in the treatment of a patient that results in a malpractice claim is likely to be named in the lawsuit. Plaintiff's counsel will not pick and choose defendants based on insurance coverage, especially when failure to identify an indispensable party to the suit may result in dismissal of the claim altogether.

The dominant factor in a decision to secure individual coverage must be consideration of the likelihood that the employee, but not the employer, will be sued. The employee must further assess his or her ability to pass the defense onto the employer should a lawsuit occur. This is the point at which the current drive toward certification and recognition of the physicist as a professional who exercises independent judgment becomes important.

If the employer can tell an employee how to do his job, liability is the employer's problem. That is the gist of the master-servant relationship. If, however, the employee exercises independent judgment, the employee may be considered an independent contractor. In this case the liability may reside exclusively with the employee. So long as employment falls within the master-servant doctrine, additional malpractice coverage is superfluous. There is no reported case in which an employer has argued successfully that it could not control a physicist's actions, and therefore that the master-servant relationship did not exist.

There may be additional fallout from securing a separate policy. A professional malpractice policy requires that the insured give notice of any event that may result in a claim. If you decide to be especially conservative and give notice to your carrier, but your employer has a different view, there may be some hard feelings even if the court decides (as it most likely would) that the employer's carrier cannot decline coverage for failure to give notice. With multiple carriers involved, settlement negotiations can easily degenerate into finger pointing and recrimination, especially if the right personalities and large potential damages are involved.

Better safe than sorry is an admirable attitude. But before a physicist buys a separate policy, it may be best to talk it through with an experienced attorney.

Rebuttal

The most attractive argument in favor of obtaining professional liability coverage is based on a risk/benefit analysis, i.e., the amount you could lose in court pales in comparison to the cost of

the insurance. While I agree with Mr. Davis that every physicist should be covered by some form of liability insurance, I do not agree that this necessarily requires an individual policy in all situations.

Physicists in solo practice, working in a group that does not have a master policy, or moonlighting as an employee of some other organization, definitely need individual coverage. For the rest of us, the decision depends in part on an analysis of our employment contract, the laws of the jurisdiction where employment takes place, and a realization that double coverage doesn't always mean double protection. An office visit with a competent local attorney is the place to start.

The bottom line is "Who should pay for the peace of mind which might be afforded by a separate professional liability policy?" I don't see why I should dig into my bank account for protection from my employer. Mr. Davis is correct that professional liability coverage is part of the cost of doing business today. However, if 100% of my effort is devoted to my employer's business, then it's not unreasonable to expect the employer to pay 100% of the cost of my liability coverage.

10.22. Medical physicists should not publicly endorse commercial products

Michael G. Davis and D. Jay Freedman
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OVERVIEW

From time to time, a medical physicist may have an opportunity to evaluate a technology early in its development or deployment. If the evaluation is positive, the company responsible for the technology may ask the physicist to endorse it, or at least be identified as an evaluator. The reward may be a financial contribution to the physicist or the institution, or may simply be enhanced personal or institutional recognition. Some physicists see nothing wrong in an endorsement, whereas others believe it undermines the physicist's integrity and credibility. These points of view are discussed in this Point/Counterpoint.

Arguing for the proposition is Michael Davis, M.S., J.D. Mr. Davis received his Masters degree in Radiological Medical Physics from the University of Kentucky. Currently he is the Director of Radiation Oncology for the Greenville Hospital System in Greenville, South Carolina. He worked at the M.D. Anderson Cancer Center in Houston for eight years prior to moving to Greenville. During his time in Houston he obtained a Doctor of Jurisprudence degree from the South Texas College of Law. Mr. Davis is certified in Therapeutic Radiological Physics by the ABR. He currently chairs the Legal Affairs and Risk Management subcommittee of the AAPM and is also a member of the ethics committee.

Arguing against the proposition is D. Jay Freedman, M.S. Mr. Freedman received his M.S. in Physics from the University of Alabama in Birmingham in 1979. In 1987, he spent a year as guest physicist at Rambam Medical Center in Haifa, Israel. The following year he enrolled at Hebrew Union College in Jerusalem while continuing to lecture in Medical Physics at Haddassah Medical Center. He received Rabbinic Ordination in 1994 at the Hebrew Union College in Cincinnati. Since then he has performed various pastoral duties as well as working in Medical Physics. Freedman was appointed chairman of the AAPM Ethics Committee in January 2001. He has been a senior physicist at Hartford Hospital since March 1999.

FOR THE PROPOSITION: Michael G. Davis, M.S., J.D.

Opening Statement

No one really believes that Tiger Woods is a champion just because he uses a particular brand of golf ball. We know he endorses the manufacturer of that golf ball at least partially because of lucrative offers of money to do so. Tiger Woods is an entertainer and endorsements are part of what an entertainer does for a living. Medical physicists are not entertainers. Our professional goals and obligations are very different. We claim that our evaluations of equipment and vendors are based upon objective scientific reasoning. But can these opinions be truly objective, or

viewed as truly objective, when companies are offering us perks in exchange for public endorsements?

When we publicly endorse a product or company, we cross a line. We are no longer supplying information to colleagues who seek us out for an opinion through a phone call or professional publications. Instead, we are voicing an opinion that most of our colleagues will hear. Often behind this endorsement is free or bargain-priced equipment, money for research, lucrative consulting contracts, expensive dinners, or invitations to speak at vendor functions. Nothing may be wrong with receiving any of these things *per se*. But when these benefits are perceived as payments for product endorsement, our individual integrity, and our credibility as a profession suffer.

The chief victims of paid endorsements may be the less experienced medical physicists among us. They may not have gained all of the background and tools needed to make objective choices regarding vendors. It is one thing to inform them by using peer-reviewed equipment or software comparisons within the pages of *Medical Physics*. It is quite another thing to expose them to quotes of a well-respected senior physicist emblazoned upon a vendor's booth at an AAPM meeting.

Medical physicists have a responsibility to keep vendors honest. We must make sure that a vendor provides the product and support promised at the time of purchase. We must also make sure that we are honest with our colleagues regarding vendor choices before them. This is how we improve products and service, which lead to improved patient care. Credibility is the key to all of this. Our job is made more difficult when our credibility as physicists is compromised by product endorsements from our colleagues.

Most of us would be flattered to see our photo on an advertisement. Most of us would love to have our opinions widely quoted for our friends and colleagues to read. However, we chose a different path when we decided to become medical physicists. I believe that this choice requires that we not allow ourselves to become marketing tools. After all, we are not entertainers.

Rebuttal

I agree with Mr. Freedman that medical physicists should receive fair remuneration for their work, but he and I philosophically part company after that. Professionals must never forget for whom they work. The attorney-client privilege exists in law because the client is paying for the exclusive use of the professional services of the attorney in a particular matter. A lawyer who forgets this and shares confidential information with opposing council, or anyone else for that matter, has breached an ethical duty because doing so may weaken the client's case.

However Mr. Freedman indicates that we can serve two potentially opposing interests simultaneously if we are careful so as not to create a true conflict of interest. These two opposing interests are the employers of our medical physics services and the commercial vendors selling products to those employers. I contend that the act of trying to serve two opposing masters is by its very nature a true conflict of interest. There is no fine line to be walked. There is however a clearly marked boundary to be avoided.

Mr. Freedman also says that we as medical physicists have no Consumer's Union to turn to for advice in product evaluation. I would contend that collectively we are in fact a Consumer's Union for medical physics and radiation therapy products. We test and evaluate equipment constantly

and most of us are very willing to express our opinions about the strengths and weakness of a product to whomever asks.

Finally, I disagree with the premise that there is an obligation to provide public endorsements of products. By its very nature an endorsement avoids mentioning flaws in a product or service while it enhances the good. Part of the reputation we build professionally with colleagues is in our willingness to mention these flaws in our exchanges of information with them. To leave out the bad information damages this reputation. And as Joseph Hall said "A reputation once broken may possibly be repaired, but the world will always keep their eyes on the spot where the crack was."

AGAINST THE PROPOSITION: D. Jay Freedman, M.S.

Opening Statement

In the 1970s there was a television program called *Mary Hartman, Mary Hartman*. During one of the first episodes, the title character said in earnest, "Everything I know I learned from commercials."

I hope and expect that we Medical Physicists are more discerning than Mary Hartman. However, there is much to be said for the educational value of advertisements we receive in a professional context. We depend upon vendors to provide us with supporting documentation for their claims, and we rely on our colleagues to help us select the best equipment and devices. Because we do not have an independent testing laboratory such as the Consumer's Union to help us out, we must rely—at least to some extent—on endorsements from respected colleagues. For this reason we might even say that from an ethical point of view we are obligated to provide and use product endorsements.

Obligated is a strong word and deserves further comment. For that, I turn to the literature of my faith community. I am sure others have similar sources.

Mishnah Samuel tells a story about two sages who lived 2100 years ago. They were walking in the countryside when they were confronted by a local resident. The resident questioned the right of the healer to heal if, as they all agreed, it was God who brought the illness. The sages responded that just as we are commanded by God to tend trees and crops, so must we tend the human body. Further, because saving a life is one of the strongest commandments in the Hebrew Bible, and because curing the ill is linked to this commandment, healing is considered a major obligation.

It is a short step from the obligation to heal to the obligation to share our knowledge of helpful healing tools and devices. As physicists we are not empowered to treat patients directly. However, we do possess knowledge needed by those who are so empowered. We can provide our best advice only if we are using the best equipment available. We can only know what that equipment is if we are well informed. Thus, it is essential that those who know be encouraged to share their knowledge with those who need to know. Further, the sages taught that *a physician who heals for nothing is worth nothing*. The meaning, of course, is that fair remuneration is expected.

Physicists have a moral responsibility to lend their reputations to commercial products they believe in. We need to be sure, however, that we do not abuse that responsibility. That is a truly fine line to walk, and we should take great care in doing so.

Rebuttal

The truth is, having argued against the proposition, I am actually somewhat hesitant to oppose it wholeheartedly. The reason is that it is quite difficult, at worst, to remove crass selfinterest from the picture, or, at best, to eliminate the appearance of a conflict of interest. Yet we still need the help that endorsements potentially can provide when making purchasing decisions.

This paradox may be characterized by the often-conflicting need for individual freedom, as opposed to the constant demand for group responsibility to the group. Pursuing the latter need not exclude the former. However, a paradigm shift in individual members of the group, and in the group as a whole, may be required for this effort to succeed. Moses Pava[1] refers to this shift as the "logic of appropriateness" rather than the "logic of consequence." In practice, such a shift involves asking oneself, "how does this decision help the group?" instead of, "what's in it for me?" The two are not necessarily mutually exclusive.

Organizational guidance in this area is helpful. Studies have shown that most people want to do the right thing when they are able.[2] Pava argues that in order to promote ethical behavior in its employees, an organization must model that behavior in word and deed. This includes clear statements of what the expectations of the organization are, and adherence to published ethical guidelines by the organization's leadership.

Individual members must also participate in organizational efforts to enable ethical behavior. As Bowen McCoy put it, "What is the nature of our responsibility if we consider ourselves to be ethical persons? Perhaps it is to change the values of the group so that it can, with all its resources, take the other road."[3] The AAPM Ethics Committee is currently wrestling with this issue. Participation in discussions at meetings and written input are always welcome.

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2. A. Etzioni, *The Moral Dimension: Toward a New Economics* (Free, New York, 1988).
3. B. McCoy, "The parable of the Sadhu," Harvard Business Rev. **61** (1983).

10.23. Medical physicists should not encourage or participate in off-label, non-FDA-approved uses of intravascular brachytherapy devices

Shirish K. Jani and Howard Ira Amols

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OVERVIEW

FDA-approved medical devices such as intravascular brachytherapy sources may be used for an off-label (nonapproved) application if, in the judgment of the physician, such use is warranted for an individual patient. Often an off label use is being evaluated in a sponsored clinical trial, with the aim of accumulating enough data to determine whether FDA approval should be sought for the off label use of the device. Physicians frequently are tempted to use a device off-label, because they believe the device may benefit a particular patient even though the accumulated data are insufficient to verify the belief. Participation in such use presents an ethical dilemma for the physicist. This dilemma is explored in this Point/Counterpoint.

Arguing for the Proposition is Shirish K. Jani, Ph.D. Dr. Jani received his Ph.D. in Molecular Physics from North Texas State University in 1980. After completing a post-doctoral fellowship at the Medical College of Virginia, he became Chief of Clinical Physics at the University of Iowa. Since 1993, he has been at the Scripps Clinic in La Jolla, CA. He is certified by the ABR and the ABMP. Dr. Jani has served on many AAPM task groups and is an active member of the ACR Commission on Physics. He has served as an ABR Oral Examiner. Dr. Jani is a Fellow of the American College of Radiology and the AAPM.

Arguing against the Proposition is Howard Ira Amols, Ph.D. Dr. Amols received his Ph.D. in Nuclear Physics from Brown University in 1974, followed by post doctoral training at Los Alamos National Laboratory. He has held medical physics positions at the University of New Mexico, Brown, and Columbia Universities. He is currently Chief of the Clinical Physics Service at Memorial Sloan Kettering Cancer Center in New York City. He is certified by the ABMP, and is a Fellow of the AAPM. During his tenure at Columbia University he was intimately involved in the early development of IVB. For better or worse, he is probably best known for penning numerous infuriating columns in the AAPM Newsletter.

FOR THE PROPOSITION: Shirish K. Jani, Ph.D.

Opening Statement

An intravascular brachytherapy device approved by the food and drug administration (FDA) for marketing has clear and well-defined labeling for its use. The device label includes indications for use, precautions, and radiation dosage. The FDA grants its approval on the basis of safety and efficacy as established by well-designed clinical trials. For example, a 30 mm long Sr-90 source train is approved by the FDA for the treatment of restenosis in a native artery where the lesion is $\leq$ 2 cm. If such a device is used to treat a saphenous vein graft (SVG) lesion or a 6 cm arterial lesion, the application is considered an off-label use. Physicists should neither encourage nor

participate in off-label uses of an intravascular brachytherapy device. This opinion is based on the following three reasons.

First, in an off-label use, the device has not been proven to benefit the patient. The FDA requires that studies be conducted under carefully-controlled conditions to document such a benefit. It is unethical to use a device off-label when such use is under investigation at other centers. As an example, the role of intravascular brachytherapy to treat SVG lesions and long arterial lesions is currently being investigated in multi-institutional trials.

Second, patient safety is not established for an off-label use. A good example of such concern is the treatment of a long lesion by multiple stepping of a short FDA-approved source. A recent publication highlights a case of a late acute thrombosis 15 months after such a stepping treatment.[1] The accompanying editorial points to double-dosing or even triple-dosing the arterial segments where a deliberate source overlap of 5 mm was used with a Sr-90 device.[2] The high dose may have prevented re-endothelialization, leading to a thrombotic event. The patient pays the price of such misuse, either in late thrombosis or in terms of years of antiplatelet therapy. By one estimate, one in four late thrombotic events are fatal.[2]

Finally, why should physicists be involved with the issues mentioned above? Although we do not prescribe radiotherapy treatments and doses, we are (and should be) full members of the team caring for the patient. Physicists are not merely technical staff; they are an integral part of the professional group involved in the decision-making process. Physicists have an obligation to institutions and patients to assure safe and effective radiotherapy. This obligation includes not participating in off-label applications of intravascular brachytherapy devices.

Rebuttal

Dr. Amols correctly points out that off-label use of an IVBT device is not illegal. However, *in the absence of sufficient data*, an off-label use is still an experiment on the patient. It should be done under a protocol and within the framework of the Institutional Review Board (IRB). The main issue is the patient's right to know whether he/she is being subjected to an unproven procedure.

I disagree with Dr. Amols' assertion that patients may be in imminent danger if IVBT is not performed. Even when other options are limited, an investigational protocol can easily be established. This is precisely what is done at our institution, and certain patients are treated under a "compassionate use" protocol.

A central question is how physicists can discourage off-label use. First, there needs to be discussion up-front with the radiation oncologist and the cardiologist on possible off-label use. As pointed out by Dr. Amols, the physicist needs to evaluate the dosimetric implications of, for example, sequential stepping of a line source. Second, the physicist may get the IRB involved. Finally, when physicists are pressured to become unwilling participants, the issue of liability may be raised. Use of an unproven device can compromise the defense of a medical negligence case. Overlapping of external fields, resulting in twice the dose to a region of the spinal cord, is considered negligence. Similarly, over/under dosing of an arterial segment without full knowledge of its implication is negligence. Physicists cannot hide behind some technicality that off-label use is not illegal according to the FDA; or that the NRC does not object to such procedures.

I made my argument on scientific/medical merits. Dr. Amols rightfully argued from an administrative perspective. It is a fact that physicists are professionals who take an active role in medical care and engage in intellectual discussions about right and wrong choices. But the choice of off-label use is not simply a choice of right or wrong. Often it is a choice of financial gain over the medical needs of the patient.

The subject of off-label use is relatively new to the radiotherapy community. As the field moves to more interdisciplinary applications of radiation, the issue of off-label use will undoubtedly continue to arise. The stand we take today will set an example for the issues of tomorrow.

AGAINST THE PROPOSITION: Howard Amols, Ph.D.

Opening Statement

First, let us point out that off-label use of an FDA approved device is *not* illegal. FDA regulates the manufacture and sale of medical devices, but does not regulate the practice of clinical medicine, at least not to the extent of dictating its practice by individual physicians. Off-label use of a medical device is neither illegal nor uncommon. It is perfectly legal for a licensed physician to treat any part of the human body with radiation. At the risk of hyperbole, we point out that radiation therapy of acne, athletes foot, baldness, and halitosis are all on-label uses of radiation. Only intravascular brachytherapy (IVB) of an artery is off label. Treating the fore-mentioned conditions with radiation may be deemed unwise, or even stupid, but it is not off label, and certainly not illegal. Neither stupid nor off label are necessarily illegal. One may ask why IVB has been singled out by the FDA as a "significant risk device," and has precisely defined criteria for "on-" and "off-" label use, while radiation treatment of conditions such as acne and halitosis is acceptable. This, however, is a topic for another Point/Counterpoint column.

A principal responsibility of the medical physicist in IVB, as in any radiation procedure, is to advise the physician on physics, dosimetry, safety, and quality assurance aspects. If a physician, using the best clinical judgment, decides that the medical needs of a particular patient will be best served by an off-label use of an IVB device, then the physicist has an obligation to remind the physician that what is being proposed is off label, and to advise the physician about the possible dosimetric and safety consequences and uncertainties of the proposed procedure. If, for example, an off-label use might cause a 100% overdose to a segment of artery, the physicist must inform the physician of this possibility. But if, knowing these facts, the physician still believes that the off-label application is in the best interests of the patient (a patient, by the way, who might die of a heart attack if nothing is done), then the physicist has a professional obligation to assist the physician in performing the procedure.

If a physician consistently engages in clinical activities that a physicist believes are unwise or reckless, and consistently ignores the recommendations of the physicist, then a sensible physicist should start looking for another job—even if nothing illegal has transpired. Only when a physician's consistently bad judgment and off label use of IVB devices crosses the line from ill-advised to illegal does the physicist have an obligation to refuse to participate. The physicist then also has an obligation to report such activities to the proper authorities.

But let's not pretend that we have the medical training to determine when off-label use of a perfectly legal medical device is or isn't in the best interests of a particular patient. Especially not

when we are working side by side with radiation oncologists and interventional cardiologists who do have that expertise.

Rebuttal

Dr. Jani correctly states that IVB devices are approved for marketing with well defined labeling for their use. He suggests that physicists should not participate in off-label use. We must, however, differentiate between *approved for marketing*, and *approved for use*. FDA regulates the marketing of medical devices by manufacturers, but not the use of such devices by licensed physicians. I also see a distinction between physicists not encouraging off-label use, as opposed to not participating in off-label use. Sometimes, an experienced physician will conclude that off-label use of an IVB device is in the best interests of a particular patient suffering from life threatening cardiovascular disease, especially if the patient has few alternative medical options remaining.

Many IVB patients have failed (i.e., recurred after) multiple previous interventional procedures, and the physician may have little choice but to offer them either off-label IVB treatments, or slow death! Imagining myself as a patient, I would rather have that choice made by my personal physician rather than by a well meaning regulator in Washington who has never seen my EKG or angiogram.

Like Dr. Jani, I would never encourage a physician to routinely engage in off-label medical procedures. But refusing to participate may result in even more harm to some patients. Dr. Jani suggests that some patients may already have suffered late thrombosis as a result of being overdosed during off-label IVB procedures. This may be true, but it can only be determined from controlled clinical trials, which we both support. But even if true, there is still a balance between risks and benefits for some patients. Physicists have the expertise to assess dosimetry and safety issues associated with off-label use, and the obligation to counsel physicians on such matters, but it is the physician who is trained to make the final decision.

Physicians guilty of consistently bad judgment should be barred from practicing medicine. But let's not limit the treatment options good physicians can offer their patients by having physicists walking out of the treatment facility. It is not our duty to veto the informed decisions of physicians to treat particular patients.

Life is full of hard choices, particularly for patients with life threatening cardiovascular disease. *Sometimes* off-label use of a medical device is in the patient's best interests. Let's leave such decisions in the hands of competent physicians who have the benefit of our expert physics council.

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10.24. Medical Physicists should actively discourage institutions from advertising technologies such as IMRT and HDR Brachytherapy in order to recruit patients

Marc Edwards and William Bice

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OVERVIEW

The acquisition of sophisticated technologies is frequently used as a marketing ploy to attract patients to healthcare institutions. This strategy can be interpreted as simply an example of capitalism and free enterprise. However, one can also argue that the approach is exploitive because most patients have little idea of what the technologies are and whether they might benefit from them. This controversy is explored in this month's Point/Counterpoint.

Arguing for the Proposition is Marc Edwards, Ph.D. Dr. Edwards is the chief physicist for Radiation Oncology Associates of Kansas City. During the "academic phase" of his career, Dr. Edwards participated in training medical physicists, residents and therapists at the University of Missouri's Columbia and Kansas City campuses. He is a fellow of the AAPM, has served on committees of the AAPM and ACR and is a former council member of the National Council on Radiation Protection and Measurements. He is certified in therapeutic and diagnostic radiological physics by the ABR and also occasionally serves as an oral examiner for the American Board of Radiology.

Arguing against the proposition is William S. Bice, Jr., Ph.D. Dr. Bice received his doctoral degree in medical physics from the University of Florida in 1985. Soon after, he was assigned to the Radiation Oncology Service at Brooke Army Medical Center in San Antonio. After leaving the military in 1989, Dr. Bice began providing consulting physics services, founding his current firm, International Medical Physics Services, in 2000. He is certified in therapeutic and diagnostic radiological physics by the ABR. Dr. Bice holds an adjunct faculty position in the CAMPEP-accredited medical physics program at the University of Texas Health Science Center at San Antonio.

FOR THE PROPOSITION: Marc Edwards, Ph.D.

Opening Statement

Medical physicists can be justifiably proud of their role in the development and clinical delivery of intensity modulated radiation therapy (IMRT) and high dose rate (HDR) brachytherapy. These advances offer the hope, and accumulating evidence suggests the reality, of improved outcomes in cancer treatment. The technologies are expensive, and it is important to seek adequate reimbursement for their use. One response to the economic pressure of high cost is to increase utilization. However, economic pressure should not subvert the professional and ethical responsibilities of the healthcare community.

Early objections to Direct-to-Consumer (DTC) advertising focused on unsubstantiated clinical claims for IMRT, together with possible, but as yet unknown, long-term complications.[1] Additional discussion introduced issues of "protected personal speech," "restricted commercial speech" and the role of the Food and Drug Administration (FDA) in advertising regulation.[2] This discussion assumes that the efficacy of IMRT and HDR brachytherapy is no longer in doubt, and that advertisements are not in violation of the law.

DTC advertising is moderately successful, at least for prescription drugs. A Government Accounting Office (GAO) study found that in 2001, drug companies spent about $2.7 billion on DTC advertising, and that 5% of patients requested and received a prescription for a particular drug in response to DTC advertising.[3] The greatest amount of prescription drug advertisement money is spent on proprietary (i.e., nongeneric) drugs for chronic conditions, which yield a high return on investment for drug companies. If the reimbursement for IMRT was not many times more than conventional treatment, one probably would see less advertising.[4]

Much DTC advertising is justified as promoting patient awareness and public education about a particular disease and its possible treatments. Thus the patient is "assisted" in making a choice by being made aware of available options. However, decision-making can be overwhelming in the context of illness.[5] Conflicting and sometimes confusing information is available from healthcare providers (some in the form of advertising), support groups, books, journals and the Internet. This overload of information can prevent the patient from making good decisions. The proper role of the healthcare provider is to facilitate the transformation of information into knowledge for each individual patient.[5] If DTC advertising is represented as altruistic education and awareness, then the advertising funds should be donated to independent groups, such as the American Cancer Society, whose mission is in part to provide unbiased information.

The traditional role of the healthcare community, arising from ancient times, was fiduciary, with protection of the patient's interest the primary concern. Respect for others, empathy, compassion, honesty, integrity and professional excellence are the roots of medical professionalism. Among the key values of medical professionalism are service, advocacy and altruism. Business values such as cost, profit and competition contrast sharply with medical values. The fundamental problem with DTC advertising is that it corrupts the relationship between the healthcare professional and the patient by making it captive to both medical and business values. The patient becomes a "consumer," to be pursued in a marketplace by providers competing to capture "market share." Health care becomes a commodity to be bought and sold at the market price, and the patient-consumer must disentangle the economic self-interest of the supplier from the value of the product. Healthcare providers and patients have protested loudly when managed-care companies have attempted to impose market dynamics on the patient-provider relationship. Yet, healthcare providers are, by their actions in directly pursuing patients, self-imposing similar market dynamics.

The ethical implications of the commodification of health care have been explored by E.D. Pellegrino, from the Center for Clinical Bioethics.[6] In a commodity transaction, the ethics of business replaces professional ethics. Business ethics legitimate self-interest, competitive edge and a level of treatment based on the purchaser's ability to pay. When health care is viewed as a commodity, providers seek to "sell it" like any other commodity, including using advertising to create demand among those who can pay. In rejecting this model, Pellegrino argues that health care is not a commodity and that treating it as such is deleterious to the ethics of patient care. He avers that health is a "human good," and that an ethical society has an obligation to protect it from a market ethos.[6]

The most important thing to a patient is not the availability of some high technology device, rather it is the ability of a team of physicians, physicists, dosimetrists and therapists to use a technology with skill for the benefit of the patient. Such a commitment can be communicated only within the framework of a professional fiduciary relationship between the healthcare provider and the patient. Pursuit of patients through DTC advertising detracts from this relationship. The moral and ethical responsibility of healthcare providers, including medical physicists, is to discourage marketing activities such as DTC advertising.

Rebuttal

Physicists should not support DTC advertising because it is "here to stay," or because the other guy does it. Competition, when it is for academic insight or technological advancement, does ultimately benefit the patient. It is much less evident that advertising to induce a patient to seek treatment with a particular technology or at a particular center results in better patient care or societal benefit. DTC advertising does put pressure on the healthcare system, but this pressure is to respond to a synthesized demand, rather than to advances demonstrated by clinical research and affirmed by professional standards. Let's affirm our traditional fiduciary responsibility to patients by rejecting DTC healthcare advertising.

AGAINST THE PROPOSITION: William Bice, Ph.D.

Opening Statement

Advertising in medicine is legal. The Sherman Anti-Trust Act of 1890, with its primary focus on discouraging monopolistic practices, laid the foundation for advertising by professionals. Since then United States courts have repeatedly upheld the right of physicians to advertise, largely on the basis of free speech. In 1975 the American Medical Association was successfully sued by the Federal Trade Commission for restricting advertising through its code of ethics. It became unlawful for physicians to restrict medical advertising in 1977.[7]

Legal, of course, is not the same as ethical.

The concept of what is ethical in medical advertising has changed dramatically in the last 100 years. Called reprehensible at the turn of the last century, largely ignored except for the direct solicitation of patients by the 1960s, accepted and overwhelmingly practiced in today's medical marketplace, the ethical nature of medical advertising has evolved. The AMA now states that "there are no restrictions on advertising by physicians except those that can be specifically justified to protect the public from deceptive practices." The entire thrust of the guideline is that physicians and patients must not be misled.[8]

As an example, consider the promulgation in 1997 of guidelines by the Food and Drug Administration for electronic advertising of prescription drugs.[9] These guidelines were published to clarify what keeps an advertisement from being misleading. With these guidelines, drug companies were provided firm legal ground upon which to base their direct-to-consumer advertising efforts. Many feared the consequences of opening the advertising floodgates, primarily citing increased prescription drug costs. Rosenthal , found that, while spending for advertising prescription drugs has increased dramatically from 1996 to 2000, as a percentage of overall sales the advertising cost has remained relatively constant (at about 14%). Additionally, the cost for direct-to-consumer advertising, while increasing, has remained at about 1–2% of the

sales budget while promotion to healthcare professionals has accounted for the other 12–13%.[10] What this means is that advertising probably sells prescription medicines but does not, by itself, increase the cost.

It is important to remember that the physician is still the gatekeeper. Whether for diagnosis or therapy, patients are never treated without a prescription. Returning again to the example of prescription drugs, Rosenthal noted that, although 25% of patients seen by a physician mentioned a drug that they saw advertised, only 6% actually received a prescription for the drug.[10] Doctors do pay a price for this gate keeping. They cite increased time spent in consultation as the primary drawback to an increasingly informed patient. Dealing with misinformation and its correlate, unrealistic expectations, burdens the doctor-patient relationship. Nevertheless, responsibility for inappropriate prescribing with subsequent increased costs rests upon the physician's shoulders.

An argument can be made for medical advertising based simply upon its prevalence. Television, radio and newspaper ads promoting healthcare products and services have become ubiquitous. These ads are no longer restricted to elective services such as plastic surgery or cosmetic dentistry. Everyone does it. From the sole practitioner promoting his practice on a thinly-disguised National Public Radio "announcement," to recurring advertisements for prostate cancer treatment appearing daily in the sports section of the local newspaper, the promotion of medical services to patients has become firmly entrenched. However seedy these marketing practices may seem, they are here to stay. And, in a competitive medical marketplace filled with cronyism, managed care, and physician ownership of treatment facilities, healthcare promotion often is a matter of survival.

This competition has been good for medicine. Heightened public awareness, more involvement by the patient (how and where can I get the best treatment?), better patient compliance and a pressure on providers to offer improved care are all the result of advertising.

Rebuttal

Dr. Edwards, in his eloquent and impassioned opening statement, presents arguments based upon premises that do not bear up under scrutiny. His assertions fall into three areas: a distinction between medical and business ethics, the biased nature of direct-to-consumer (DTC) advertising, and the innate evil in commodification of medical services.

In distinguishing between medical and business values, Dr. Edwards listed some noble notions indeed! Falling on the side of the medical profession are "respect for others, empathy, compassion, honesty, integrity and professional excellence," as well as "service, advocacy, and altruism." These are in contrast with those dastardly business values, "cost, profit, and competition." It does not follow that making a profit precludes having any or all of the attributes above. In fact, the case is more likely the opposite. Successfully competitive businesses—the ones that demonstrate long-term profitability—are those that engender those very same values that Dr. Edwards ascribes to the medical profession. With regard to the appropriateness of using advertising as a tool to promote awareness, the crime is not in the promotion of the product or the procedure, but in using advertising to mislead.

There is an inherent bias in DTC advertising. Dr. Edwards would contend that this bias makes advertising promotional rather than educational. While the goal of promotion may be different than that of education, the two are inseparably entwined. There is no such thing as pure education; it is always presented with a bias. Consider the too frequent example of the patient

that has been "educated" by a urologist with regard to the treatment options for early stage prostate cancer but has never heard the words "brachytherapy" or "radioactive seed implant" or "IMRT." Education, or at least awareness, accompanies promotion. And, as illustrated in the case above, the awareness driven by promotion can provide a check on biases from other, more traditional, sources of patient information. And what if the patient is uneducable? What if the stresses accompanying serious illness result in "bad" decisions? The physician is still the gatekeeper; without a prescription, the treatment does not occur.

The practice of medicine has clearly become a business. Medical services are a commodity to be bought and sold. The rise of HMOs, physician ownership of treatment facilities and negotiated pricing with insurance carriers attest to this. Today's medical practitioner is faced with market decisions as confounding as medical decisions. Even in a system with set base-pricing—Medicare rates—there are competitive pressures to acquire patients. More patients mean more income, or better equipment, or newer facilities.

Forgotten in all of this commodification is the true consumer, the patient. And like buyers everywhere, they must beware. Gone are the days, thankfully, when the only input that the patient had in purchasing medical care was "Well, whatever you think, doc." The patient should have as much access to as much information from as many sources as he desires. Only then can he make the grave decisions that are his to make. Across the street from where I live is a billboard advertising one of the local healthcare systems. A smiling face beams down from this lofty perch, just above a caption proclaiming "My doctor gave me a choice." Our patients deserve nothing less.

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10.25. Medical physicists in developed countries should actively help medical physicists in developing countries

Gary D. Fullerton and Joseph Ting
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OVERVIEW

Every medical physicist has benefited from the guidance and counseling of more senior members of the profession. As a result, the profession of medical physics has evolved to a level where it makes substantial contributions not only to patient care, but also to the ongoing development of new tools and techniques to improve medical diagnosis and treatment. Each of us in the field has an obligation to partially repay the debt we owe our mentors by helping others who need guidance and counseling. Nowhere is the need for help greater than in developing countries in which medical physics and high-tech medicine are just getting started. However, each of us has responsibilities to the institution that pays our salary and expects its patients and clinicians to benefit from our knowledge and expertise. Providing assistance outside the institution takes time and energy away from those inside the institution who need our attention. Two different viewpoints on these conflicting demands on our time and effort are presented in this issue of Point/Counterpoint.

Arguing for the Proposition is Gary Fullerton, Ph.D. Dr. Fullerton is the Malcolm Jones distinguished Professor of Radiology and Director of the Graduate Program in Radiological Sciences at the University of Texas Health Science Center at San Antonio. Dr. Fullerton has served the AAPM on many committees, as Secretary from 1982–1984 and President in 1991. Currently he is Editor of the *Journal of Magnetic Resonance Imaging*, Secretary General of the International Organization for Medical Physics and Secretary General of the International Union for Physical and Engineering Sciences in Medicine. He is certified in radiological physics by the ABR and is a strong supporter of the development of the medical physics profession in the international arena.

Arguing against the Proposition is Joseph Ting, Ph.D. Dr. Ting is Associate Professor in the Department of Radiation Oncology at the Emory University School of Medicine. He is certified by, and a frequent oral examiner for the American Board of Radiology. He has authored or co-authored several articles on the technical aspects of external beam therapy, and has three patents pending. He teaches both residents in radiation oncology and graduate students in medical physics, and has been a guest speaker at several institutions and conferences, including Sun-Yat-Sen Hospital in Taipei and the International Conference on Medical Imaging, Medical Physics and Precision Radiation Therapy in Guangzhou.

FOR THE PROPOSITION: Gary Fullerton, Ph.D.

Opening Statement

The fundamental but oblique question embedded in this issue is, ‘‘Are medical physicists professionals charged with the development and maintenance of knowledge related to their practice or are they laborers with duties related solely to the hourly work and wage they receive?’’ Professionals from all walks of life weigh the ethical questions concerning the allocation and application of time to achieve the greatest good for clients. Laborers, on the other hand, need only apply their efforts to the allotted task in the contracted time. Medical physics is, in my view, a profession for which the participants have responsibilities far beyond those of the given workday task.

Presently there are 4500 medical physicists in the USA and more than 16 500 worldwide that are members of the International Organization for Medical Physics. For every medical physicist in a developed country there are two or three practicing in developing countries under less technically advantaged circumstances. There are many reasons that physicists from developed countries should focus on assisting these colleagues. These reasons range from enlightened self-interest to a global concern for humanity.

The ability of medical physicists to practice and provide the diagnosis and treatment of patients depends on two factors: (1) a specialized knowledge of the field that allows safe and efficacious patient care, and (2) a set of well designed and maintained technical tools that make their work possible. These tools range from accelerators to imaging devices and measurement instruments. If the education and training of medical physicists in developing countries are not over time brought to the level of those in the developed countries, then medical physics stands to lose. First, the larger numbers of medical physicists practicing in reduced circumstances are in the majority. The reduced circumstance could become recognized as the worldwide standard for the level of medical physics practice to the loss of medical physicists everywhere. Second, the inadequate application of advanced technologies in developing countries and resultant failures could undermine public confidence in medical physics techniques. Such losses could make high technology medicine politically unpopular and treatments less accessible to patients. This places the future viability of our profession in jeopardy. Medical physicists should defend the integrity of their profession, if they wish to be respected by the patients they serve as well as by other medical professionals.

Evolution and progress are key elements in the practice of medical physics and other components of high technology medicine. The standard of practice today will not be the standard of practice five years from now. Medical physicists must continue to provide new and better ways to diagnose and treat disease or be prepared to turn over their profession to less demanding roles filled by technology specialists. The cost of research and development of new devices remains a major component in the cost of medical physics and the medical specialties that use the physics devices. Growing demands for cost effectiveness require that medical physicists spread the cost of future improvements over a greater fraction of the world population. Medical physics needs to seek the advantages of globalization just as do other purveyors of high technology solutions to human problems.

The application of physics to health care is our profession. The medical physicist should make the fruits of his or her labor available to humanity. Extending commitments to the developing world preserves the future of medical physics from the rush to improve day-to-day clinical productivity. The difficulty of the decision typifies the ethical dilemma of all professionals.

Rebuttal

Dr. Ting and I agree, ‘‘It is inappropriate for physicists to toot around the globe.’’ We differ in my belief that there are many legitimate reasons for American medical physicists to participate in international conferences, cooperative research projects and cooperative educational programs. The professional medical physicist needs to assess benefits and costs to reach an ethical decision concerning international participation. The example of the meetings in China discussed by Dr. Ting is a good one. When I visited China in 1990 there were only 20 MR units in the country; now there are thousands. Chinese patients profit from both the technology and the clinical interpretation skills gathered from the international literature. The idea that IMRT and EPID can be implemented in China, together with the interpersonal interchanges (friendships) that are being developed with the inventors of these techniques, are motivators for change in China. In 1990 China did not have a society of medical physics; today China is a member of the IOMP with more than 400 individual members. In addition, Taiwan and Hong Kong medical physics societies report 150 and 50 members, respectively. My graduate program in San Antonio now receives applications for medical physics graduate study from China that include masters degree training in medical physics at Chinese universities. The meetings that Dr. Ting dismisses for low productivity have been potent harbingers of change in China.

AGAINST THE PROPOSITION: Joseph Ting, Ph.D.

Opening Statement

In recent years, health dollars allocated to patient care in the U.S. have been drastically curtailed. Often, costs of radiation treatments or diagnostic procedures far exceed the dollars recovered from third party payments. Most hospitals and clinical departments are operating under stressed budgetary constraints with no end in sight. With these constraints in mind, it is inappropriate for medical physicists to toot around the globe and support medical physics activities in foreign lands.

A medical physicist who attends a foreign meeting in support of medical physics activities costs his or her employer approximately $1,000 per day in salary and benefits. Lodging, transportation, and other incidental costs should also be added. Medical physicists who wish to provide aid to foreign countries should obtain separate and dedicated funding from other, government or private, sources.

The total direct and indirect labor costs plus expenses exceeded one million dollars for the U.S. physicists who attended the two most recent medical physics meetings in China (October 1999 and May 2000). Most of these physicists were not reimbursed by the conference hosts for their expenses or time and effort. Instead, U.S. institutions generously donated one million dollars to those conferences in the form of labor and direct expenses.

I am not suggesting that U.S. medical physicists should not contribute to training foreign medical physicists who will function in important roles in their countries. I have personally trained many foreign medical physicists who have later become important contributors either in America or in their home countries.

I do object, however, to supporting and hosting conferences in foreign lands. Meetings and lectures offer high visibility but low productivity and they are the wrong forum for training and teaching purposes. For example, how many Chinese hospitals and patients will benefit from the IMRT and EPID presentations and discussions that occurred during the two China meetings mentioned earlier?

There are many aphorisms cautioning us to spend money wisely; for example: ‘‘A penny saved is a penny earned’’ and ‘‘there is no free lunch.’’ Most of us draw our salaries from our hospital or clinic employers that, in turn, are supported by third party carriers, and indirectly, patients. There is no provision in this support to underwrite medical physics activities in foreign lands. Medical physicists in the U.S. should spend their time attending to challenges on our home front and not compromising their efforts by focusing on medical physics activities in foreign countries.

There are more cost-effective ways than meetings to aid foreign medical physicists and strengthen medical physics programs abroad. They include, for example: Sponsoring foreign medical physicists to spend time at U.S. hospitals; establishing ongoing working relationships with foreign hospitals; formulating joint training sessions; teleconferencing; and providing grants for foreign medical physicists to attend special purpose workshops (not general meetings).

Rebuttal

I have known Dr. Fullerton for over twenty years and I have a great respect for his professional and scientific endeavors. However, assumptions and statements made in his ‘‘Opening Statement’’ are false. Here are a few examples:
(1) ‘‘Professionals’’ are not the only persons who need to consider the allocation of time and effort to achieve the greatest good for clients. ‘‘Laborers’’ who receive hourly wages need to do the same. I do not understand Dr. Fullerton’s differentiation of ‘‘professionals’’ and ‘‘laborers.’’ We all are workers to achieve the greatest good for our clients. In this case, our ultimate clients are patients.
(2) I do not believe that there are 16 500 medical physicists who are practicing medical physics in a manner directly impacting the well-being of patients and their diagnostic and treatment outcomes. I do not argue against physicists sharing knowledge with others. But, spending money hosting conferences abroad is not an efficient method to provide aid. Dollars could be better spent by sponsoring foreign medical physicists to study at institutions of excellence in this country.
(3) The danger of lowering the standard of practice is far fetched. I often tell my children to ‘‘look up and never down.’’ Standards of practices will continuously improve and cannot be ‘‘reduced’’ as Dr. Fullerton imagines. It is human nature. Otherwise, we would still be living in caves and cooking with twigs.
(4) I do not challenge the desirability of a mutual exchange of ideas and inventions with persons from abroad. But sponsoring and attending conferences are not effective forums for such exchange.

Finally, we should stop wasting precious dollars sponsoring and attending meetings abroad. We should not use the excuse of ‘‘educating medical physicists’’ to get a paid trip abroad. We should take ‘‘educating foreign medical physicists’’ more personally and carefully. It is a very serious commitment.

10.26. The World Wide Web is a net disservice to medical physicists in developing countries

Kwan-Hoong Ng and Azam Niroomand-Rad
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OVERVIEW

Many people, physicists among them, believe that the World Wide Web (WWW) is a great service to developing countries because it provides access to information about sophisticated healthcare technologies and methods. Some believe, however, that the WWW is a disservice because it raises hopes and expectations, and encourages deployment of sophisticated equipment and procedures that require resources that would be better used to support fundamental public health and education efforts. These opposing viewpoints are the topic of this issue of Point/Counterpoint.

Arguing for the Proposition is Kwan-Hoong Ng, Ph.D. Dr. Ng is Professor and director of the medical physics program at the Department of Radiology, University of Malaya Medical Centre, Kuala Lumpur, Malaysia. He obtained his master's degree in medical physics and biomedical engineering from the University of Aberdeen United Kingdom and Ph.D. in medical physics from the University of Malaya. He is one of those rare physicists outside the US who is board certified by the American Board of Medical Physics. Dr. Ng is the editor and co-founder of the *Electronic Medical Physics World* (EMPW). He serves on several committees in the International Organization for Medical Physics (IOMP) and a council member for the International Union of Physical and Engineering Sciences in Medicine (IUPESM). He is the founding president of the South East Asian Federation of Medical Physics. Dr. Ng has published over 60 papers in peer-reviewed journals.

Arguing against the Proposition is Azam Niroomand-Rad, Ph.D., an Iranian by birth. Dr. Niroomand-Rad received her Ph.D. in Physics from Michigan State University in 1978. She completed her Medical Physics postdoctoral training at the University of Wisconsin —Madison in 1983. She has received an Honorary Doctor of Science from Cazenovia College, N.Y., in 2001. She is now a Professor and Clinical Physics Director in the Department of Radiation Medicine at Georgetown University Hospital in Washington D.C. She is board certified by the ABR in Therapeutic Radiological Physics and by the ABMP in Radiation Oncology Physics. She is a Fellow of AAPM and has served on many AAPM committees, task groups, Board of Directors (twice), as well as President of the AAPM Mid-Atlantic Chapter. She has served IOMP as Chief Editor for *Medical Physics World,* and has been active on many IOMP/IUPESM committees. She is now serving AAPM as Associate Editor for Medical Physics, Chair of International Affairs, and Chair of International Scientific Exchange Programs where she has organized radiation therapy courses/workshops for many developing countries. She is presently the Vice-President of the IOMP.

FOR THE PROPOSITION: Kwan-Hoong Ng, Ph.D.

Opening Statement

The advent of the WWW makes it easy to locate and retrieve information. Important medical developments and discoveries can be disseminated expeditiously throughout the world, and most medical professionals have rushed to embrace this technology, hoping to reap the benefits. But could the World Wide Web actually be a disservice to medical physicists in developing countries?

The gulf between the *plugged-in* and the *not plugged-in* world is widening. Developing countries struggle with the high cost of a basic electronic infrastructure, which is a precondition for enjoying the benefits of any high technology, including the WWW. It was reported recently that wealthy industrial nations, comprising less than 20% of the world's population, account for 80% of Internet users.[1] This disparity exists because the cost of being connected is prohibitively high in most developing countries. In the United States, for example, the monthly internet access charge represents a mere 1% of the average monthly income. In Sri Lanka, Bangladesh and Nepal it is 60%, 190%, and 280%, respectively. Accessing and downloading data-intense information requires high bandwidth and a stable communications network. The total bandwidth for all of Latin America is roughly equal to that of Seoul, Korea. All of these issues greatly handicap medical physicists in developing countries who would like to take advantage of the WWW.

The challenges facing medical physicists from developing countries differ greatly from those encountered by their counterparts in advanced countries, because the access to technology, socioeconomic landscape and other factors vary. In developing countries, basic sanitation, safe drinking water, and basic health services are major needs. Scarce public funding, if available at all, is and should be channeled to solving these fundamental problems, rather than on providing access to high-tech medical know-how and medical physics services that would benefit only a small portion of the people.

Medical physicists in developing countries, especially younger physicists, have the misconception that instant answers to their queries can be obtained from the WWW. They do not realize that basic knowledge can be mastered best by studying standard textbooks, reading journals, and performing hands-on experiments. They become disillusioned when the hospitals they work in are unable to purchase equipment necessary for the performance of tasks gleaned from the web. This disillusionment contributes to the brain drain of medical physicists from developing countries, adding to the many setbacks faced by these countries.

Although medical physics list-servers have opened up opportunities for global communication, the selection and discussion of topics are dominated by physicists in developed countries, and their relevancy to the needs of developing countries is questionable. Considerable time is needed to sift through these postings, and one can become confused and disorientated at the end of the day, particularly because scientific facts are not distinguished from personal opinions. Medical physicists from developing countries often feel intimidated about posing questions, because their questions have attracted sarcastic remarks in the past. This adds to their frustration.

In conclusion, we cannot deny that the web is a net disservice to medical physicists in developing countries.

Rebuttal

Admittedly many journals offer free online access and content alert services. However, these services tend only to tantalize the appetite of the readers because they are unable to access full articles from the two leading journals, *Medical Physics* and *Physics in Medicine and Biology*. There is no reduced subscription cost to these journals for online access only. My colleague claims that the global medical physics listserver allows physicists in developing counties to communicate with others in advanced countries. However, only a mere 4% of subscribers to the listserver are from developing countries. Most physicists in developing countries cannot afford access to the WWW. How can the listserver be described as a total service when it does not reach a large number of physicists?

Free distance learning and other *free* stuff are not free, because one has to pay for access and, often, for enrolling. And virtual applications have major limitations that do not measure up to hands-on experience for basic skill acquisition. Competency is acquired from working with experienced and knowledgeable medical physicists, not through self-learning from the WWW. The investment necessary to implement new clinical protocols and establish the efficacy of new techniques is expensive. Most developing countries still lack basic equipment and test tools.

If the WWW has such a positive impact on teaching and educating medical physicists in developing countries, then why are organizations such as the American Association of Physicists in Medicine (AAPM), International Atomic Energy Agency (IAEA), and International Organization for Medical Physics (IOMP) sponsoring and funding workshops and courses for developing countries?

My colleague questions how the WWW could have a negative influence in any developing country. The focus is not on *negative influence,* but rather on whether the WWW is a *total service* or a *disservice*. It is my opinion that the WWW is a net disservice.

AGAINST THE PROPOSITION: Azam Niroomand-Rad, Ph.D.

Opening Statement

In my opinion, the WWW has already had a very positive impact and will continue to serve medical physicists worldwide, particularly in developing countries. The development and impact of this technology in the teaching and education of medical physicists, and in the dissemination of information to medical physics communities, will be substantially different in the coming years. The amount of scientific information on the web is large and will continue to grow. One of the major developmental needs is to organize the information so that it can be located easier and faster. I believe that the net benefit from this technology will be even greater for medical physicists in developing countries than for medical physicists in developed countries.

Like all new technologies, developed countries accommodated to WWW technology earlier than developing countries. But developing countries have benefited more from the WWW, by combining an old technology—the telephone— with the computer. The WWW permits worldwide dissemination of scientific knowledge and rapid communication among individuals and groups. It has facilitated regional and international interactions, and thus participation of medical physicists from developing countries in virtual committee and council meetings without enduring (often unaffordable) travel expenses. As an example, medical physicists in developing countries can communicate with other medical physicists by joining the global medical physics list server (medphys@LISTS.WAYNE.EDU) and they can use the "Ask your Medical Physicist"

(www.medphysics.wis.edu) site to direct any medical physics question to experts. These excellent services, which have been produced by a few medical physicists, are free of charge.

In addition, WWW technology has allowed free dissemination of scientific and professional information, free distance learning, and free access to abstracts and published papers to medical physicists worldwide. For example, the IOMP has taken a lead in posting medical physics information and activities on the www.iomp.org website. One of the IOMP long-term goals is to post information about all the medical physics graduate programs world wide (including the core curriculum), minimum required standards for medical physicists, and codes of practice in various aspects of medical physics. AAPM refresher courses are available on the web (www.aapm.org), again free of charge. There are some electronic journals such as the *Red Journal* (*International Journal of Radiation Oncology, Biology, Physics*) and *Green Journal* (*Radiotherapy and Oncology*) that are available electronically to all medical physicists free of charge.

It is hard to understand how the WWW could have a negative influence in any developing country, when all this information is made available to everyone without enduring much economical hardship. A difficulty in some developing countries, of course, is the lack of English fluency, which cannot easily be overcome because the availability of scientific materials in most other languages is so limited.

Rebuttal

Dr. Ng argues that the gap between the *plugged-in* and the *not plugged-in* world is widening because the cost of being connected is prohibitively high in most developing countries. He defends his position by computing the average monthly internet access charge, as a percentage of average monthly income for individuals living in the USA, and comparing it to similar calculations for physicists in Sri Lanka, Bangladesh, and Nepal. In my opinion, this comparison is not valid because it is not necessary to own a personal computer with personalized internet access in order to utilize www technology in developing countries. Considering the many challenges facing developing countries, as described in Dr. Ng's statement, it is more beneficial to make proper allocation of public funds to meet the basic health needs of the public. Widespread utilization of WWW technology should be financed mostly by the private sector for the benefit of the general public in both developed and developing countries. Electronic infrastructures should be set up in universities, schools, hospitals, and public libraries to narrow the seemingly widening gap between *plugged-in* and *not-plugged-in* nations. I believe the existence of WWW technology in developing countries has made governments realize that they need to provide PCs and on-line access to many organizations if they want their countries to be connected to the modern world.

I agree with Dr. Ng that textbooks, journals, and hands-on experiments are the best methods to acquire the basic knowledge and skills needed by a medical physicist in any country. However, I disagree with his conclusion that utilization of WWW technology by medical physicists has led to a major *brain drain* from developing countries. There are many contributing factors to the *brain drain* for such countries, including lack of social, religious, and political freedom and economic hardship. The disillusionment of medical physicists enhanced by the WWW is hardly the source of the "*brain-drain*" problem.

I also agree with Dr. Ng that it is not easy to sort facts from personal opinions on the Internet. Hopefully, this problem will be resolved eventually by development of more efficient search engines for the WWW. Finally, it is understandable that some medical physicists from

developing countries feel intimidated about participating in public discussions posted on the medical physics list server. In my opinion, those who privately contact medical physics experts for advice and clarification of scientific and professional issues, greatly outnumber medical physicists from developing countries who are intimidated by the medical physics list server.

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10.27. Results of publicly-funded scientific research should be immediately available without cost to the public

Colin Orton and Christopher Marshall
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OVERVIEW

The Public Library of Science offers to publish (for a fee) scientific articles electronically for immediate access upon acceptance. Recently, the U.S. House of Representatives Appropriation Committee called for immediate electronic access to accepted scientific manuscripts describing research funded by the NIH, possibly through a government electronic repository or PubMedCentral. There are legitimate societal issues associated with providing immediate access to results of NIH-funded research. But there are pragmatic issues related to immediate access, including the potential impact on society memberships, advertising revenues, and participation in scientific meetings. These issues are debated in this month's Point/Counterpoint.

Arguing for the Proposition is Colin Orton, Ph.D. Dr. Orton obtained his Ph.D. in radiation physics from the University of London in 1965 and subsequently worked as chief physicist at NYU Medical Center, Rhode Island Hospital, and Detroit Medical Center, with academic appointments at NYU, Brown University, and Wayne State University. He is currently Professor Emeritus at Wayne State and President of the International Union for Physical and Engineering Sciences in Medicine. Dr. Orton is a Past-President of the AAPM and served as Editor of *Medical Physics* from 1997–2004.

Arguing against the Proposition is Christopher Marshall, Ph.D. Dr. Marshall received his Ph.D. from the University of London, England. He joined the NYU School of Medicine faculty in 1969 where he is now a Professor of Radiology. In 1970 he founded and continues to direct the Department of Radiation Safety at NYU, which provides radiation safety and diagnostic medical physics services to NYU, its Medical School and three affiliated hospitals. Dr. Marshall has been closely associated with the business affairs of *Medical Physics* for two decades, as Chair of the AAPM Publications Committee, Chair of the Presidential Committee that established the current business model and currently as the Chair of the Journal Business Management Committee.

FOR THE PROPOSITION: Colin Orton, Ph.D.

Opening Statement

Scientific journals play a vital role in the dissemination of the results of scientific research, especially those journals with high standards and peer review of manuscripts. I would never support any action that might compromise the ability of peer-reviewed journals to continue publishing with such high standards.

The real question to be addressed in this Point/Counterpoint debate is: "can publicly-funded research be published with "free access" without causing financial stress to journals that disrupts

their ability to provide proper peer review?" I believe the answer to this question is "YES," and I will support my answer by using *Medical Physics* as an example.

Medical Physics relies on three major sources of income: the dues allocation from AAPM members, non-member (mainly library) subscriptions, and advertising, both in the hard copy (the majority) and the online journal. If we were to allow free online access to all articles immediately after publication, most of these sources of income would dry up: there would be no reason to subscribe and no market for hard copies of the journal where most of the advertising revenue derives. Clearly this is untenable. But what if only a fraction (about one-third, which is the current proportion of articles in *Medical Physics* that are publicly funded) of manuscripts were to be provided "free"? Most of the papers would still be available only to subscribers and, in my opinion very few subscriptions would be "lost." Indeed, if readers could be induced to visit our online journal in order to read these "free" papers, I can envisage an actual increase in online ads due to the increased traffic.

The NIH will now put the author's final version of each manuscript in PubMedCentral subject to a delay of as long as 12 months after publication. This will not be the same as the published version of the paper since, for example, it will not include the journal page numbers needed for referencing the article. However, the NIH is willing to publish a link to the online version of the manuscript on the publisher's website. The way I see this program working to our best advantage would be for the AAPM to provide the NIH with "free" links to the full text of all government-funded research papers in the online journal immediately upon publication. Thus any individuals who are not subscribers to the hard copy journal but want to read these papers will have to visit the online journal, where they will not only be subjected to our online ads but will also be offered access to the Abstracts of all of the other manuscripts, including those for which the full text is not accessible "free." I suspect that many of these readers will want to view the full text of some of these papers and will decide to pay to view them. This will provide increased revenue for the journal. Organized properly, the NIH program could benefit not only the NIH and the public, but also the AAPM.

Rebuttal

Thanks to the excellent leadership of the AAPM Journal Business Management Committee by my colleague Dr. Marshall over the past half-dozen-or-so years, our journal is in outstanding financial shape. Dr. Marshall clearly understands the business of running a scientific journal and, if the Proposition of this Point/Counterpoint debate related to free access for all publications of scientific research, then I would agree 100% with all the arguments presented against it in Dr. Marshall's Opening Statement. Such open access would, indeed, devastate the peer-review process and force us to institute page charges for authors, which I would agree is not a good business model. However, this is not the Proposition under debate. Here we are discussing open access to only publicly-funded research papers which, for *Medical Physics*, relates to only about one-third of all articles published. The remaining two-thirds of papers would still be available only to subscribers. What we have to guard against, of course, is any expansion of open access to more than just publicly-funded research papers. However, I believe that copyright laws will protect us from this so we should not oppose the current NIH initiative because of fear that this might lead to expansion. Instead, we should embrace the initiative as a means to enhance the readership of our journal.

As I demonstrated in my Opening Statement, because the NIH platform (PubMed) will include a direct link to each manuscript on the website of the journal,[1] the NIH-proposed program should,

if handled carefully, lead to an increase in readership, subscriptions, and advertising. This hence could be a "boon" for the journal and the AAPM, which we should all support. More profit for the journal means more educational and other programs that the AAPM can provide to members. We might even see a reduction in our membership dues!

AGAINST THE PROPOSITION: Christopher Marshall, Ph.D.

Opening Statement

The proposition that the results of scientific research might be made available without cost to the public is a chimera. There is a cost to prepare and disseminate such information, which ultimately must be born by the public indirectly through taxes or the added cost of goods and services. Publication on web-based platforms makes content generally accessible through the Internet, thus creating a demand for "open access"—without a subscription or specific payment. However, open access potentially undermines the system that gives credibility to scientific research. While authors may provide free access to their results by posting them on the web at any time, publication in a peer-reviewed journal provides validation commensurate with the stature of that journal.

The rigors of peer review, revision and resubmission coupled with publishing standards and copy editing creates a distinctly new product with added value that is traditionally protected by copyright. There is significant associated cost and publishers bear other costs for online publications: to develop and deploy new technologies; to connect content through active links to references in other publications; to actively manage an archive of published articles essentially in perpetuity. These costs are quoted to range from $800 to $3750 per manuscript[2]—and are larger for the most prestigious publications because of the extra cost of reviewing and rejecting the material never published. Libraries and individuals traditionally pay for these services by purchasing subscriptions. For international journals published in the USA, like *Medical Physics*, many subscriptions are from outside the USA, thus spreading the cost.

Since open access eliminates the need for paid subscriptions, how will it be funded? The proponents complain that commercial journals make profits and the professional society journals return income to their societies. While this is true, the elimination of profit would eliminate the incentive to publish and weaken the professional societies and their programs,[3] but the editorial costs would remain. Most scientific publications are not supported by advertising income, and for online publications this has limited potential because of their format.

The conclusion is that the authors must therefore pay to publish,[4] which assumes that all are able to pay or be prepared to subsidize those unable to pay, and that the ability to pay will not bias the rejection rate. While there are good examples of journals that use the author-pay model,[5] these do not represent a general business model for most publications.[6] Unfortunately, the issue has become politicized[7] and there is pressure for open access regardless of the consequences.[8] For NIH-funded research, resulting peer reviewed manuscripts are to be made freely available on an NIH platform at the public expense,[9] notwithstanding the fact that the peer review process was conducted at the expense of another publisher. The situation is evolving and the only certainty is that the public will ultimately bear the cost.

Rebuttal

I agree that *Medical Physics* has multiple sources of income, but for this reason it is not a general example—many scientific publications depend entirely on subscription income. The premise that the only threat is from the NIH must also be questioned. Other agencies in the USA and elsewhere will potentially follow this example and claim the right to redistribute content without payment or charge. However, the NIH example illustrates other dangers. U.S. law prohibits the NIH from funding politically incorrect research on stem-cells,[10] so the NIH will not provide automatic open access to associated papers. Is work that has not been funded by public sources less relevant to the public interest? Seminal work by Darwin and by Einstein does not pass this test, but is of the highest level of public significance.

The open access movement advocates for open access to all the important research that is published. The former Director of the NIH, Harold Varmus has urged "young scientists to consider publishing their best work in open access journals."[11] But since some open access sites, such as those of the Public Library of Science, depend on author fees drawn from research funds (in addition to grants and donations)[12] while others depend on direct public subsidies as in the NIH model, will politics intrude further into science and publishing through control of funding? Can we also have confidence that the NIH and others will adequately maintain their open access sites as politics and the economy influence budget priorities?

Consider the following: All references that I have cited are links to open access websites. They will only remain accessible if these sites are maintained—long term archival access requires motivation and economic stability, which has been traditionally built around the subscription model of publishing. Can we risk literally giving this away?

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10.28. Scientific citation indices are useful in evaluating medical physicists for promotion and tenure

David W. O. Rogers and William R. Hendee
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OVERVIEW

Citation indices (CIs), which can be obtained online from the Institute for Scientific Information (ISN) Web of Knowledge by subscription or through your hospital or college library, are measures of how frequently scientific publications are cited in subsequent articles by other authors. They can be viewed as an impact factor for an author's publications. In some institutions, CIs are evaluated by Rank and Tenure Committees that are considering individuals for promotion. Some well-recognized medical physicists support this practice, while others believe it puts individuals in highly-specialized disciplines (such as medical physics) at a career disadvantage. This controversy is the subject of this month's Point/Counterpoint.

Arguing for the Proposition is David W. O. Rogers, Ph.D. Dr. Rogers holds a Canada Research Chair in Medical Physics in the Physics Department of Carleton University in Ottawa. Previously he worked at the National Research Council of Canada where he headed the Ionizing Radiation Standards group from 1985. He obtained his Ph.D. in experimental nuclear structure physics under A.E. Litherland at the University of Toronto in 1972. His research centers around radiation dosimetry including clinical dosimetry protocols and the development and application of Monte Carlo techniques to medical physics problems. He currently serves as Deputy Editor of Medical Physics.

Arguing against the Proposition is William R. Hendee, Ph.D. Dr. Hendee received the Ph.D. degree in physics from the University of Texas. He joined the University of Colorado, ultimately serving as Professor and Chair of Radiology for several years. In 1985 he moved to Chicago as Vice President of Science and Technology for the American Medical Association. In 1991 he joined the Medical College of Wisconsin, where he serves as Dean of the Graduate School of Biomedical Sciences and President of the MCW Research Foundation. His faculty appointments are Professor and Vice Chair of Radiology, and Professor of Bioethics, Biophysics, and Radiation Oncology. He also is Professor of Biomedical Engineering at Marquette University and Adjunct Professor of Electrical Engineering at the University of Wisconsin-Milwaukee.

FOR THE PROPOSITION: David Rogers, Ph.D.

Opening Statement

If properly used, citation analysis can be a useful tool for a committee which is assessing a medical physicist since it gives one type of indication of the impact of the physicist's research, which we will assume is part of the physicist's job description.

Citation analysis is useful because it provides an assessment of the impact of a researcher by a broad range of his/or her international and mostly impartial peers, rather than by committee members who most likely do not understand the research. It is a better indicator of the value of the research than a publication count since a persistent author can almost always get even a poor paper published.

Citation analysis can be used well or it can be used badly. One must be vigilant to avoid using the tool badly. So what are the ground rules for effective use of citation analysis? 1) Citation analysis must not be the only indicator used. The impact of a piece of work may not be reflected by citations, such as if a new technique is recommended in a Task Group report which subsequently receives the majority of the citations. 2) The citation counts must be appropriately compared to similar counts for a body of peers. Some perspective can be gained looking at the citation counts for the most cited papers in Medical Physics and PMB which were recently reported by Patterson.[1,2] These are a baseline on the upper limits on citation counts in the field. Even these most cited papers have relatively low citation counts compared to some other fields. 3) Self-citations must be removed from the counts. 4) The researcher being evaluated should be asked to provide a list of sources to be considered, since papers or reports outside ISI's journal database are only associated with the first author. For example, under my name you will not find any citations to the EGS4 manual which I co-authored since they are only listed under the name of my co-author WR Nelson. 5) One must account for the fact that medical physics research often has a long time constant, unlike some areas of biology where researchers can sometimes react to another paper's results in a matter of months. One of my papers was cited nearly twice as often 6 to 10 years after publication as in years 1–5. 6) In common with all evaluations of co-authored publications, the role of a given author in a published work needs to be assessed—was it a small part or the driving force for the whole project?

But how useful is citation analysis as an indicator? By going to http://scholar.google.com/ and typing in a name you can get a very quick indication of the impact of someone's research, as long as you compare the results to those of peers. However, this free site is not as comprehensive as the more rigorous results found at the subscription ISI Web of Knowledge.

One myth that must be dispensed with is the argument that an incorrect result will generate more citations than a correct paper. Only errors by highly regarded authors ever get broadly cited for the errors they contain, while most errors are just ignored.

In summary, citation analysis can provide a useful insight into the impact of an individual's research output. This must not be the only criterion used by a promotion committee, but it is a useful indicator when trying to judge the impact of work which is likely to be outside the committee's immediate fields of expertise.

Rebuttal

While I agree with many points that Dr. Hendee has made, I believe that the constraints I gave on what is the appropriate use of citation analysis covers many of his objections. So, for example, when selecting a proper peer group, account must be taken of the popularity of a given area of research. So it would not be appropriate to compare someone doing research in IMRT to someone investigating fundamentals of primary standards of air kerma in x-ray beams. On the other hand, within a hot mainstream field like IMRT there are researchers whose work has more impact and this is almost universally signaled by a high citation count. At the same time, there are many IMRT papers with few citations, despite this being an area with many publications. A

promotion committee would have some useful information about a candidate if they knew which group the candidate's papers belonged to.

While I agree that truly major breakthroughs often do not come from the mainstream of research, I feel that when these major breakthroughs do occur, they will get widely cited. Einstein did not work in the mainstream in 1905, but even in his day his work was widely cited as evidenced by the many people we hear about who disagreed with his work. My opponent's quotation from Smolin, who makes many valid points, is nonetheless just Smolin's opinion and I would suggest it is not correct in general. Innovative papers are cited widely if the innovation is of any use, either to our understanding or in practice. We have all seen papers which were very innovative but of no value since no-one ever used them. We work in applied physics and if something isn't used, then what is the value? One characteristic of a strong researcher is to work on problems where the solution will have some impact. Should we reward someone for an innovative solution to an unimportant problem? An innovative breakthrough, even in a field outside the mainstream, will be cited frequently. I agree that there is the rare case of something only being found to be important much later, but the exception proves the rule.

In short, citation analysis, when done properly, allows a committee to evaluate the impact of an individual's work in a reasonably unbiased way. Citation analysis must never be the sole means of evaluation, but it can be a useful tool and a valuable component of the assessment.

AGAINST THE PROPOSITION: William Hendee, Ph.D.

Opening Statement

A citation index is a measure of the frequency with which a particular scientific publication is referenced by other scientists in their own publications in peer-reviewed journals. Publications that have a high citation index are widely interpreted as having greater impact on the scientific progress in a field than those that are referenced less frequently. Within a particular discipline, publication citations suggest that one's scientific work is contributing to a major pathway of research in the discipline, and that other scientists consider it to be credible and substantive.

Within limits, citation indices are a measure of the importance of one's scientific effort as viewed by peers, and often they are interpreted in this manner. However, a high citation index may reveal primarily that one is working in the mainstream of research in a discipline, and that there are many other scientists working in the mainstream and citing each other's publications. An individual conducting research in an area where many others are working will have a higher citation index for publications than will a person in a discipline where fewer scientists are publishing. This difference in citation index is more a reflection of the number of researchers in the field than a measure of the relative importance of the publications. Further, a high citation index may indicate simply that one is in the mainstream of research rather than at the margin or on an independent pathway that few researchers are following. That is, the citation index is as much a measure of conformity as it is a measure of importance of one's work—and in many cases conformity overrides importance.

Major breakthroughs in science typically do not come from scientists working in the mainstream of research. Usually, they come from individuals of extraordinary creativity and independence who ask new questions, recognize unexamined assumptions, or extrapolate ideas from one field to another. As Smolin has described,[3] "Many of Einstein's contemporaries testified that he was

not unusually talented mathematically. Instead, what enabled him to make such tremendous advances was a driving need to understand the logic of nature, tied to a breathtaking creativity and a fierce intellectual independence. But Einstein does not stand alone. One can cite many examples showing that big advances in physics come when unusually creative and intellectually independent individuals ask new questions and forge new directions." Smolin goes on to say:[3] "People who develop their own ideas have to work harder for each result, because they are simultaneously developing new ideas and the techniques to explore them. Hence they often publish fewer papers and their papers are cited less frequently than those that contribute to something hundreds of people are doing."

The risk in giving substantial weight to citation indices in evaluating scientists for promotion and tenure is that decisions may favor those working in the mainstream of well-populated fields of research, and reflect conformity of the research effort rather than original and independent thinking. The unusually creative and free-thinking scientist would frequently be penalized by the citation-index criterion, whereas the mediocre scientist pursuing inquiry along a common pathway with many others would be rewarded. This distinction is in exactly the wrong direction if truly creative scientists are to be nurtured, and fields such as medical physics are to thrive in the academic setting.

Rebuttal

In research institutions, several criteria are used to determine an individual's suitability for promotion and tenure. They include the level of peer-reviewed research support, the individual's publication record (number of publications and prestige of the journals in which they appear), and the stature of the individual as a researcher as attested to by highly-regarded peers. In some institutions, citation indices also are used.

Medical physicists often do not fare well in these analyses of productivity. Unlike other basic scientists, many medical physicists have heavy clinical workloads that interfere with their research efforts. Often they are engaged in teaching graduate students, residents and technologists, which also takes time from research. Medical physics research is frequently technology-focused rather than disease-focused, which presents challenges when seeking research support from the National Institutes of Health. And, finally, medical physics is a niche specialty within biomedicine, so that citation indices are smaller than those for scientists working in more-populated disciplines without the constraints facing medical physicists.

Even with these handicaps, many medical physicists are highly-productive researchers, educators and clinical physicists who deserve to be recognized and honored by the promotion and tenure process. This recognition requires insight by the rank and tenure committee into the profession of medical physics, and a willingness to judge physicists as individuals and not as cases to be evaluated against pre-established measures such as citation indices. Further, the committee must understand that scientific advances usually are made by individuals working at the margins of a discipline rather than in the mainstream, where the citation indices are invariably greater.

Intelligent decisions about rank and tenure require extraordinary knowledge and judgment about the worthiness of individuals. They should not be prejudiced by dependence on criteria that more often reflect conformity within a discipline rather than a presence at the frontiers of knowledge.

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10.29. Offering the physics exam to residents early in their residency is helpful to the residents and the radiology department

Krishnadas Banerjee and Gary T. Barnes
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OVERVIEW

A few years ago the rules of the American Board of Radiology were changed to permit residents to take the physics certification examination as early as the second year of their residency. Some physicists believe this change encourages early learning of the physics of radiology, which is helpful in understanding clinical radiology. Others believe that residents should be dissuaded from taking the examination early, because physics is best learned through repetitive courses. This controversy is the topic of this month's Point/Counterpoint.

Arguing for the proposition is Krishnadas Banerjee, Ph.D. Dr. Banerjee received his M.Sc in Physics from Calcutta University. He came to the University of Pittsburgh as a Fulbright Scholar and completed his Ph.D. in Biophysics in 1966. He did two years of postdoctoral fellowship at Saha Institute of Nuclear Physics in Calcutta. In 1970 he joined St. Francis Medical Center in Pittsburgh, Pennsylvania as the Director of Medical Physics. He started a master's degree program in Medical Physics in collaboration with Carnegie Mellon University. Dr. Banerjee has been teaching radiology, nuclear medicine physics, and radiation biology to residents since 1970. He has been a written and oral board examiner for the American Board of Radiology for a number of years.

Arguing against the Proposition is Gary T. Barnes, Ph.D. Dr. Barnes is currently Professor Emeritus, Physics and Engineering Division, Department of Radiology, University of Alabama at Birmingham (UAB) and President of X-Ray Imaging Innovations. He received his Ph.D. in physics from Wayne State University, Detroit, Michigan and medical physics postdoctoral training at the University of Wisconsin, Madison. He joined the UAB in 1972, and in 1998 started X-ray Imaging Innovations, a company whose mission is to improve medical x-ray imaging. From 1976 to 1987 he was chief of the Physics Section and from 1987 to 2002 Director of the Physics and Engineering Division of the Department of Radiology. He continues to be involved part-time at UAB Chairing the Radioisotope and Radiation Safety Committee and teaching radiology residents. Dr. Barnes is a past president of the AAPM and its Southeastern chapter. He is a Fellow of the American College of Radiology and the American Association of Physicists in Medicine and is a Diplomate of the ABR (Radiological Physics).

FOR THE PROPOSITION: Krishnadas Banerjee, Ph.D.

Opening Statement

Let me preface my discussion with a little history. Until a few years ago a physician candidate took the ABR clinical and physics written examinations simultaneously at the beginning of the last year of residency. If the candidate passed both examinations (s)he was allowed to take the

oral clinical examination in the next Spring. If (s)he failed the written physics examination and passed the clinical written exam, (s)he was also examined in physics at the oral board examination.

In speaking with my colleagues, I have come to realize that although the teaching of clinical radiology is well prescribed, the teaching of physics is not so organized. In many institutions, the same physics course is repeated during each year of residency. The ACGME requires 80 hours of didactic education in physics and radiation biology for radiologists. Usually, these classes are held once or twice a week either early in the morning or late in the afternoon after the residents have finished their clinical duties. In one prestigious university, physics teaching is outsourced to a consultant physicist over a period of three months before the written physics examination.

Although a solid background in physics is essential to understanding the modern technologies of CT, MRI, fMRI, PET, and SPECT, most residents are not interested in really understanding physics. Rather, they are interested in passing the physics portion of the written examination. Residents often try to learn physics by "cramming" just before the examination. Others attend review courses or purchase board-review textbooks with the hope of finding answers to questions asked in the examination.

Many students find it difficult to master the huge volume of knowledge covered in the physics and clinical portions of the written board examination. So when the opportunity was provided in 1999 to take the physics portion of the written examination separately in the second year of residency, most residents chose to do so, in an attempt to "divide and conquer" the large amount of subject matter. By passing the physics portion first, they are then able to concentrate on the clinical exam in the third and fourth years of residency.

From my perspective there are two clear advantages of dividing the written board examination into two parts. (1) By concentrating on learning physics concepts in the first year of residency, a solid physics underpinning is achieved that improves the resident's ability to understand and use sophisticated technologies such as CT and MRI. This underpinning leads to a greater appreciation for the applications of physics in clinical radiology. After passing the physics examination in the second year, physicians can turn their attention to topics of clinical radiology for the remainder of their residency training. (2) Division of the examination is only part of the solution to improving the quality of graduate medical education in radiology. Program directors should consider recruiting candidates with solid physics backgrounds, and training programs should improve the quality of physics courses taught to residents. The latter involves increasing the time allotted for physics in resident curricula, ensuring that experienced and knowledgeable faculty are providing the education, and rewarding these faculty for their teaching contributions. It also means teaching the applied physics of imaging systems later in the residency as physicians are scheduled through various clinical rotations.

Rebuttal

I have known my "opponent" in this Point/Counterpoint for more than 20 years, and we have worked together on written and oral examinations for the American Board of Radiology. He is a stellar teacher, as evidenced by the teaching chair awarded in his name at the University of Alabama.

My opponent and I agree that having residents take the physics exam early in their period of training is helpful to the department and to the teaching of clinical radiology. We differ, however,

on the issue of whether this is a constructive way to learn physics. Dr. Barnes believes that taking the exam early is counter-productive, and even suggests that it would be better to drop physics entirely from residency training than to offer the exam in the second year of training. He believes that it is preferable to administer the exam in the fourth year of residency.

I personally believe that residents who take their exam in the fourth year of training do not learn any more physics than those who take the exam in the second year. This is because the residents want to learn just enough physics to pass the exam, no matter when it is given. They do their learning just ahead of the exam, so having residents repeat a physics course for 2 or 3 years doesn't accomplish very much. In addition, the major challenge in teaching physics is to make the subject interesting and relevant to the practice of radiology, no matter when the teaching occurs.

Learning physics early in the residency helps residents understand imaging technology and radiation safety when they encounter such challenges during clinical rotations. They will be conscious of the need for dose reduction in fluoroscopy, limited exposures in computed tomography, restriction of the number of films taken during angiography, and application of the optimum procedures for data acquisition in ultrasound and magnetic resonance imaging.

In addition, the American Board of Radiology does not require residents to take the physics exam in the second year of residency. They can take it in the third or even the fourth year if they choose to do so. Further, a residency program can decide when its residents should take the physics exam. The policy of the Board is permissive, but not specific; residents can take the physics exam any time after the first year of residency.

If residency program directors make time available for residents to study physics during their first year of training, and if physicists who teach residents make an effort to portray physics as interesting and relevant to the clinical practice of radiology, then I am comfortable that offering the exam in the second year of residency will not handicap the physics learning process in radiology.

AGAINST THE PROPOSITION: Gary T. Barnes, Ph.D.

Opening Statement

There is no question that offering the physics exam to residents early in their residency is helpful to the radiology department. It is also helpful to residents in their moving through the ABR exam process. It is my position that it is not helpful in their learning a useful level of physics. As a result it compromises radiology and patient care.

Prior to 1999 residents were eligible to take the written physics and clinical exams early in their fourth year of residency. If the resident successfully passed both, (s)he was then eligible to take their oral exams at the end of their fourth year. A problem with scheduling the written exams in the beginning of the fourth year of residency is that residents were spending significant time in the latter part of their third year and beginning of their fourth year of residency studying for the written exams. This, coupled with the fact that they spent time studying for their oral boards in the latter part of the fourth year, resulted in their taking considerable time away from their clinical support of the department at the time in their residency when they were most useful to the

department. This was a major consideration in allowing residents to take their written exams earlier in their residency.

A secondary consideration is the role of the written exams. They are a high-pass filter for the oral exams. That is, residents that are unable to pass the written exams would have little or no chance of passing their oral exams. Furthermore, giving an oral exam to a candidate who fails is tough on the candidate and tough on the examiner. For these reasons the written exams were instituted more than thirty years ago. Previously there was only the oral exam which all residents were eligible for at the end of their residency, and physics was one of the categories in which they were examined.

Starting in 1999 the current ABR policy went into effect and residents were eligible to take their written physics exam in the beginning of their second year of residency and their written clinical exam in the beginning of their third year. They could elect to take either written exam later, but in order to be eligible to take their oral exam they have to pass both the written physics and clinical exams.

Prior to 1999, physics education of residents typically involved one or more courses in the first two years of residency, followed by a board review course prior to their taking the written physics exam in the beginning of their last year. In their fourth year of training residents have a mature understanding of radiology. This maturity was evident in the questions they would ask and was helpful in their understanding of the role physics plays. Also, a cardinal principle of education is repetition. The process prior to 1999 allowed for repetition. The current process does not.

Subsequent to the changes that went into effect in 1999, most residents have elected to take their physics written exam at the beginning of their second year of residency and early in their training. There are a number of problems with this that limits their education, negatively impacts radiology, and negatively impacts patient care. First, after one year during which residents are struggling to master a vast field, their knowledge of radiology is superficial and their ability to appreciate the role and importance of physics is even more limited. They have not rotated through a number of areas such as nuclear medicine or angiography, where a knowledge of patient and personnel radiation levels, and the interplay of radiation levels and image quality, are important considerations.

Second, their focus at the end of their first and beginning of their second year is on passing the written physics exam. They do not want to learn anything that is not related to their doing well on the exam. Unfortunately, the ABR written physics exam is superficial at best. Residents who have little understanding of imaging physics and its utility in the practice of radiology still pass the exam. Memorization and little or no understanding of imaging physics principles is all that are required. The idea of such an individual acting as a radiation safety officer or being licensed to practice nuclear medicine is absurd. Residents passing the written physics exam at the present time often have little knowledge of imaging physics principles, patient dosimetry and radiation safety. Residents who have a very good understanding of physics often do not do as well on the exam as residents with a more superficial understanding. They do well but often not as well. In view of these experiences I advise residents not to think too much. This advice has proved useful.

Third, the cardinal principle of education, "repetition", is not utilized. Residents are exposed to one meaningful physics course—the board review course. On passing the exam they naturally

focus on other more immediate aspects of their residency training. Little or no attention is subsequently paid by most residents to physics.

At one time a knowledge of radiation and imaging physics principles was one factor that differentiated radiologists from other physicians doing imaging. This is no longer the case. A non-radiologist can easily take a two or three day short course in an area of imaging and have a fund of physics knowledge that exceeds that required to be a diplomat of the ABR. In the late 1980s and early 1990s there were a number of patients who suffered severe burns when undergoing fluoroscopic procedures.[1] The majority, if not all, of these cases involved non-radiologists. If radiologists practicing at the time had the limited physics training of current residents, they might have contributed to this problem. It is my experience that the level of physics in the cardiologists' fluoroscopic clinical competence statement[2] is far more detailed and extensive that the material currently taught to radiology residents.

I have been teaching physics to radiology residents for more than thirty years. In the UAB Department of Radiology a Distinguished Faculty Teaching Award was initiated by residents in my name. Until recently I had been teaching concepts and ideas to residents that will be useful in their future practice. Now I prepare them to take an exam. It is no longer teaching. It is more akin to training dogs to jump through hoops. The level of radiological physics they learn to pass the exam is insufficient to be useful in their future practice. I question whether I am making productive use of my time. Allowing residents to take the physics exam after one year of training, and when they pass (as almost all of them do) claim that they have an acceptable level of understanding of radiological physics is not consistent with reality. It would be more honest to drop physics and the physics exam from residency training altogether, than to continue the current hypocrisy.

Through their exams and their policies, the ABR dictates residency training, whether the Board admits it or not. It is my opinion that the ABR made a mistake in allowing residents to take the written physics exam after only one year of training. Residents do not learn a level of physics that will be helpful to them in their future practice. The physics written exam needs to be scheduled later. A practical compromise would be to allow residents to take both the physics and clinical written exams in the beginning of their third year of training.

Rebuttal

I agree with many of the points that my esteemed colleague makes: 1) the teaching of physics to radiology residents is not well prescribed; 2) a solid background in physics is essential to understanding modern imaging technologies; 3) residents often try to learn physics by "cramming" just before the board examination; 4) a good physics underpinning leads to a greater appreciation for the applications of physics in clinical radiology; and 5) after passing the physics exam (early) in the second year residents can turn their attention to clinical radiology for the remainder of their training.

Points that I dispute are: 1) most residents are not interested in really understanding physics and only want to pass the exam; and 2) by concentrating on learning physics concepts in the first year of residency, a solid physics underpinning is achieved that improves the resident's ability to understand and use sophisticated technologies such as CT and MRI.

Obviously, all residents want to pass the written physics exam. It has been my experience, however, that most residents also want to understand physics as it relates to obtaining good

images, patient dosimetry and radiation safety. It is the physicists' job to communicate and demonstrate how physics is useful in these regards.

I contend that residents do not achieve a solid physics underpinning with the exam being offered early in their residency. Offering the exam early is conducive to "cramming" and not to understanding. The radiological physics learning experience, as with most learning experiences, benefits by repetition. One course focusing on passing the exam achieves minimal long-term retention and understanding. Further, once most residents pass the physics exam, the other aspects of radiology are so demanding that they have little or no time to learn physics. The physics that radiology residents learn occurs prior to and not after their passing the physics written exam.

As a result of the ABR physics written exam being offered early in the residency, residents now learn less physics than radiologists that completed their residency five or more years ago. To reverse this trend, the physics exam should be offered later. A practical compromise would be to allow residents to take both the physics and clinical written exams in the beginning of their third year of training. Residents would have rotated at least once through all clinical rotations and be in a better position to understand the role that physics plays. It would allow time for both an introductory physics course and a board review course, and therefore repetition. If a resident fails either the written physics or the clinical exam, s(he) could retake the exam in the beginning of the fourth year and, presuming a pass, could to take the oral exam in June of the fourth year. Prior to 1999 and for more than 25 years, residents took the physics and clinical exams at the same time. It was not considered to be a problem because everybody was in the same boat.

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10.30. Medical physicists should seek employment elsewhere when resources are insufficient for quality patient care

Wlad T. Sobol and Ivan A. Brezovich
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OVERVIEW

Quality assurance is one of the major responsibilities assumed by medical physicists (MPs) in hospital radiology and radiation oncology departments. The work done by MPs to assure quality of care is usually performed in the "background" in that it is often done outside normal clinical hours, and is not directly a source of revenue to the hospital. Consequently, hospital administrators are often unaware of this vital role played by MPs and hence, when faced with the need to trim budgets, they sometimes see MPs as "expendable." This is exacerbated by the fact that few hospital administrators understand what MPs do. Many MPs are thus faced with a situation where they do not have sufficient staff to maintain a level of quality assurance they consider necessary to protect patients. Their choices are to work ridiculously long hours, to provide "substandard care," or to "quit." Whether or not it is best for physicists facing this situation to seek employment elsewhere is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Dr. Wlad Sobol. Dr. Sobol received his Ph.D. degree from the Jagiellonian University in Cracow *Magna Cum Laude* in 1978. In 1986 he emigrated to the United States and joined the Department of Radiology at Bowman Gray School of Medicine in Winston-Salem, NC as an Assistant Professor and, in 1991, he moved to the Department of Radiology at University of Alabama in Birmingham, where he is Professor of Radiology. At UAB he has been very actively involved in education, and is Director of the Clinical Medical Physics (Imaging) Residency Program. In 1999 he served as a President of the Southeastern Chapter of the AAPM. He was a member of the Board of Editors of *Medical Physics* for several years, served on or chaired several AAPM committees, and was Co-Director of the 2001 Summer School. He chaired the MRI Examination Panel of the ABMP that developed the MRI examination for the Board. Dr. Sobol is board certified by the American Board of Radiology in Diagnostic Radiological Physics and by the American Board of Medical Physics in Magnetic Resonance Imaging Physics and is a Fellow of the AAPM.

Arguing against the Proposition is Ivan Brezovich, Ph.D. Dr. Brezovich received his Ph.D. in Physics from the University of Alabama in 1977 and has since spent his entire career as a medical physicist at the UAB, initially in the Department of Diagnostic Radiology and, since 1977, in the Department of Radiation Oncology, where he has been a Full Professor since 1988. He is also a Professor in the Department of Biomedical Engineering. Dr. Brezovich is Chairman of the ACMP Reimbursements Committee and has served on many AAPM professional committees since 1991 and is currently a member of the Professional Economics and Government and Regulatory Affairs Committees, the Emerging Technology Work Group, and the European Affairs Subcommittee. In 1994 he served as a President of the Southeastern Chapter of AAPM. Dr. Brezovich is a Fellow of the AAPM, the ACMP, and ACRO, and a Diplomate of the ABR in both Therapeutic and Diagnostic Radiological Physics.

FOR THE PROPOSITION: Wlad T. Sobol, Ph.D.

Opening Statement

For the sake of keeping the arguments in focus, let me state that I am not concerned with extreme situations caused by economic, socio-political, or environmental factors as well as acts of war or effects of natural disasters. I will also exclude conditions where remuneration for services rendered is not the primary motivation for work. Finally, I will exclude global ventures and focus on domestic (i.e., U.S.) operations.

This leaves us with a typical healthcare business environment where a medical physicist is a hired employee tasked with performing specific duties for a set remuneration (specified in an employment contract as salary and benefits package). In this setting, highly skilled professional employees are constantly facing negotiations covering a broad spectrum of job-related issues. This phenomenon is very well known and widely referred to as office politics,[1] games,[2] power plays,[3] or even war.[4] While negotiating skills are extremely valuable to any working professional, they can be difficult to master,[5,6,7] which explains why an entire field of study, known as negotiation science, has emerged in recent years. For the sake of the current argument, we shall enumerate the key elements in negotiations, as identified by negotiation science:[8]

- target (or target value) refers to the best possible outcome the negotiating side hopes to achieve;

- reservation point (or reservation price) is the minimum the negotiating party will accept before abandoning the negotiations;

- best alternative to a negotiated agreement (BATNA) represents the best fallback position available to the negotiator, should the negotiations fail;

- power in negotiation is the degree of leverage that a particular party has during negotiation;

- interests are the ultimate goals of the negotiating parties;

- positions are the particular stances negotiation parties take to arrive at their ultimate goals;

- anchoring refers to the first offer put forth during negotiations.

It is quite obvious that the negotiating process can be extremely complicated and require a great deal of preparation, skill, and experience.

Thus, it is very difficult to predict an outcome of any negotiation, especially if the interests of the parties are undefined (we do not know what "resources" mentioned in the proposition represent, much less what makes them "insufficient," especially for "patient care"). Furthermore, the reservation points for different individuals facing the same negotiating targets can be vastly different, making attempts at detailed discussion moot. Facing such a broad range of possible negotiating scenarios, one can only conclude that the power of quitting is too big to be relinquished lightly. Having this option available as a possible BATNA greatly increases the medical physicist's power in any job-related negotiation. That empowerment allows us to select a BATNA that truly enhances our negotiating positions by allowing us to think and analyze situations at strategic, rather then tactical, levels. This view is further supported by reports of real

world experiences[9] which indicate that many successful professionals have the ability to recognize hopeless situations and simply quit before further struggle makes things worse.

AGAINST THE PROPOSITION: Ivan A. Brezovich, Ph.D.

Opening Statement

The simplistic suggestion "just leave" flies into the face of every sense of human decency and responsibility, the very bonds that keep our society together. Apart from the typical disruption following resignations of key personnel, sudden departures of therapy physicists can be deadly.[10,11] Market forces are too slow to safely bring back a stable equilibrium.

Unlike physicians, medical physicists have many skills that are specific to a facility and are not readily interchangeable. To safely "orchestrate the entire treatment process," as an ASTRO Board Chairman summarized our role in radiotherapy, medical physicists must thoroughly understand every machine and procedure, as well as the workings of the entire system, including human dynamics. High-tech equipment like accelerators and treatment planning systems has its specific flaws, and physicists are expected to detect and safely defuse the ensuing death traps. Manufacturers limit their product warranties to repairing or replacing defective equipment. The responsibility for clinical applicability and consequences of malfunctions lies squarely on the shoulders of the physicist. The margin of safety remains very narrow for a long time when an experienced physicist leaves, even if the replacement is highly qualified.

Furthermore, while physician training is universal, there are no uniform educational standards for medical physicists. In many states, cancer clinics can hire any self-proclaimed "experts" with no demonstrable qualifications and put them in charge of their patients. Other states require a graduate degree and on-the-job training, but no examination. Even a board-certified Qualified Medical Physicist (QMP) may not have all the knowledge on which a clinic has learned to depend. Physicists are expected to check dose prescriptions,[12] yet the required knowledge is neither taught in graduate school nor tested during ABR exams. Physicists who possess such precious expertise are hard to replace.

If physicists cannot provide quality patient care because their facilities lack adequate equipment and support staff, or expect an unreasonable workload—42% of medical physicists at cancer centers work more than 50 h/week[13]—they may be tempted to seek employment elsewhere. However, before taking such a drastic step, they need to consider potential consequences. An experienced physicist will flatly refuse to accept such a position. With no qualified takers, the clinic may hire one of the abundant recent graduates, who has little more than online training and is desperate for a first job. Lower salary expenditures and additional revenue from salvage treatments necessitated by ineffective initial treatments may even give the false impression that the personnel change was beneficial.

Because of the unique features of medical physics, its practitioners have obligations in addition to those of other medical specialists. If unable to provide quality patient care, they must make every conceivable effort to resolve the problems and remain on the job. If resignation becomes inevitable, these physicists must explicitly inform the physicians and top administrators about the true reasons for their departure, even if such action adversely affects future employment. Simply walking out on their patients is not an acceptable option for medical physicists.

Rebuttal: Wlad T. Sobol, Ph.D.

I have no quarrel with my fellow debater's first argument pointing out that abrupt departures are likely to be disruptive and thus are to be avoided. Medical physicists are expected to follow professional etiquette—these professional rules of conduct demand that the exit be managed in orderly fashion. But, I thought, our arguments were about "whether" (to quit), while this point is about "how" (to resign).

The second point implies that experienced medical physicists are so special that, without them, the entire process would collapse and therefore it is their duty to keep on going no matter what. This assertion flies in the face of experience that is best summarized by the proverb "graveyards are full of irreplaceable people." Every one of us will be replaced; the question is when and how.

The third argument states that if an experienced physicist quits, a lesser-caliber replacement is likely to follow. This scenario is further amplified by pointing out that no "good" professional would want a "bad" job. I am dumbfounded; as far as I know, this is how the American society works—"good" jobs are offered to top-level candidates; "bad" jobs will attract mediocre applicants, if any. If the question is whether a competent, experienced professional would want to stay in a bad job at a facility whose management consistently ignores pleas for improvement, then this is an issue of motivation for work, not about the ability to resign. In other words, this argument is about setting a reservation point, not for establishing a BATNA.

In closing, I prefer professional freedom over restrictions. I choose to view my fellow medical physicists as highly trained, responsible, and ethical professionals. I want them to have a freedom of choice that includes walking away from a hopeless cause. I trust their judgment and their ability to make wise decisions.

Rebuttal: Ivan A. Brezovich, Ph.D.

I never said that quitting should not be an option for therapeutic medical physicists. With proper precautions, departures may even benefit patients, at least in the long run. However, using my distinguished colleague's terminology, quitting by itself does not confer upon physicists sufficient "power in negotiations" to achieve this "reservation point," *viz*. the minimum amount of resources for patient care that they can accept.

For diagnostic physicists, whose responsibilities for patients are primarily indirect through assuring image quality, departures should be less problematic. If you get replaced by a "cheap" physicist, radiologists can recognize the deteriorating performance of equipment before patients get hurt. Disruptions of patient flow and higher equipment maintenance cost will pressure administrators to rectify the inadequacies that led to departure.

Therapeutic physicists, on the other hand, are directly responsible for human lives. Except for extreme cases of overdosing,[10,11] a "cheap" replacement may even be a financial asset to the facility. The fact that one-third of sophisticated radiation treatments may not be delivered as prescribed[14] demonstrates the difficulty to even recognize poor quality in radiotherapy. High-quality physicists, therefore, have special ethical obligations.

Medical specialists are aware that any dissatisfied, overly fatigued person—about 15% of physicists spend more than 55 h/week on the job[13]—is prone to make mistakes. They also know how faulty, outdated hardware and software impair treatment quality, and that a new physicist

will have even greater difficulties dealing with the inadequacies. Quality physicists should consider quitting only when it is the "best alternative to a negotiated agreement (BATNA)," after their negotiations to obtain the resources required for quality patient care have failed. To benefit patients, departures must be accompanied by a detailed explanation for their reasons. Simply walking off the job is highly irresponsible for a therapeutic physicist.

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