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Volume 2

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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 continue to be among the most popular articles read in *Medical Physics* as demonstrated by consistently high online readership statistics. Indeed, they are usually the most downloaded of all articles in the monthly statistics. To commemorate the first 10 years of Point/Counterpoint debates (1998-2007) 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*. This was published in 2008 and is available on the *Medical Physics* website. This Volume 2 of *Controversies in Medical Physics* includes all the Point/Counterpoint debates published from 2008-2012. Although the Point/Counterpoints here 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 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. All the Point/Counterpoints in this volume were moderated by Colin Orton and edited by Bill Hendee. The Moderator devised all of the Propositions, selected appropriate authors and edited their contributions, and wrote the Outlines. We would like to acknowledge the administrative assistance of Penny Slattery, Journal Manager and Mary Beth Drapp, Editorial Assistant, who helped bring these Point/Counterpoints to press, and Farhana Khan, AAPM Webmistress, for her technical support in preparing the book for online publication. Persons participating in Point/Counterpoint debates 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 volume, and look forward to suggestions you may have for future Propositions in the series which should be addressed to Colin Orton, Moderator, at ortonc@comcast.net.

Colin G. Orton & William R. Hendee Editors

December, 2012

CHAPTER 1

General Radiation Therapy

1.1. Tumor hypoxia is an important mechanism of radioresistance in hypofractionated radiotherapy and must be considered in the treatment planning process

David J. Carlson and Kamil M. Yenice
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OVERVIEW

With the increased use of normal tissue sparing highly conformal therapy it has become possible to treat patients with fewer treatments at high dose/fraction. Fewer fractions, however, mean fewer opportunities for radioresistant hypoxic cells to reoxygenate during the course of treatment and this might reduce tumor control. It has been suggested that tumor hypoxia is an important consideration for such hypofractionated regimes, and, as such, it should be considered in treatment planning. This is the concern debated in this month's Point/Counterpoint debate.

Arguing for the Proposition is David J. Carlson, Ph.D. Dr. Carlson obtained his Ph.D. in Medical Physics from Purdue University and then completed a Radiation Oncology Physics Residency at Stanford University. He then moved to his current appointment as Assistant Professor at the Yale University Department of Therapeutic Radiology. He is certified by the American Board of Radiology in Therapeutic Radiologic Physics. Dr. Carlson served as President of the AAPM San Francisco Bay Area Chapter and is currently President-Elect of the Connecticut Area Medical Physics Society Chapter of the AAPM. One of his major research interests is radiobiological modeling for radiotherapy.

Arguing against the Proposition is Kamil M. Yenice, Ph.D. Dr. Yenice obtained his Ph.D. in Physics from the University of Toledo, Ohio and, subsequently, completed an M.S. in Radiological Physics at Wayne State University, Detroit. He worked as a faculty physicist at Memorial Sloan Kettering Cancer Center from 1999 to 2005. In 2005 he moved to University of Chicago, where he became the Chief of Clinical Physics in 2007. He is certified by the American Board of Medical Physics in Radiation Oncology Physics. He has served on several AAPM committees including the AAPM Task Group 101 (SBRT).

FOR THE PROPOSITION: David J. Carlson, Ph.D.

Opening Statement

Tumor hypoxia is a well-established and accepted mechanism of radioresistance and correlates with treatment failure in radiation therapy.[1] While normal tissues typically have median oxygen concentrations from 40–60 mmHg, 90% of solid tumors have median values below normal, half have median values <10 mmHg, and a third contain subvolumes with concentrations <2.5 mmHg.[2,3] Treatment failure in radiotherapy for tumors with high levels of hypoxia has been primarily attributed to the decreased radiosensitivity of hypoxic tumor cells.[4]

With fractionated radiotherapy, the problem of hypoxic radioresistance is reduced by reoxygenation between fractions.[3] Hence, while hypofractionated techniques offer valuable physical and logistical advantages over conventional radiotherapy, the potential for reoxygenation is reduced because the total dose is delivered in fewer fractions. Recent studies have shown that tumor hypoxia must be included in cell survival models to obtain predictions consistent with clinical data[5] and that hypofractionation may result in decreased biological effectiveness for hypoxic tumors.[6] These results highlight the potential for the introduction of errors into calculated alternate dose prescriptions when using models that do not explicitly consider tumor hypoxia.

Accurate methods to quantify the spatial and temporal distributions of hypoxia are needed to establish which patients will benefit most from treatment strategies aimed at overcoming the radioprotective effect of tumor hypoxia. A commonly proposed strategy involves identifying hypoxic tumor subvolumes that should be given additional radiation dose.[7] The major challenge with this approach is that the spatial distribution of hypoxia can change over a period of several days.[8] Practical dose boosting strategies require noninvasive techniques to image hypoxia distributions periodically combined with adaptive planning. While this may be impractical for conventional fractionations, it is feasible for extreme hypofractionation where large doses are delivered in a few fractions. Alternate strategies that do not rely on frequent imaging include the co-administration of hypoxic cell radiosensitizers,[5,6] cytotoxins that directly target hypoxic cells,[3] and gene therapies that rely on the selective induction of HIF-1.[3] Hypoxic cell radiosensitizers are most effective and clinically tolerable when delivered with a few large radiation doses.[5,6] Carefully conducted modeling studies can also be used to determine biologically optimal fractionations.[6] Radiobiological modeling tools that account for cellular oxygenation should be incorporated into treatment planning systems.

Recent clinical results using hypofractionation are promising, but does this mean that tumor hypoxia is not a problem? Even a small fraction of patients with treatment failure is of concern, and it is likely that hypoxic radioresistance is a contributing factor to observed local failures. Concurrent therapies targeted directly at hypoxic cells would also allow for a reduction in the large radiation doses employed in extreme hypofractionation and associated normal tissue toxicities. The greatest benefits are expected in patients with the most hypoxic tumors. Future clinical trials of treatment strategies aimed at overcoming hypoxic radioresistance should therefore select the hypoxic patients prior to randomization. Patient-specific radiotherapy and treatment individualization will only truly be achieved with full consideration of tumor hypoxia in the treatment planning process.

AGAINST THE PROPOSITION: Kamil M. Yenice, Ph.D.

Opening Statement

Stereotactic body radiation therapy (SBRT) has nearly transformed the field of radiotherapy by its unprecedented clinical efficacy for the treatment of primary and metastatic disease.[9] A recent study of linear-quadratic modeling incorporating tumor hypoxia suggested that generally shortened treatment regimens of SBRT-like fractionation would significantly restrict the potential for tumor re-oxygenation between fractions thereby decrease tumor cell killing compared to standard fractionation.[6] These concerns seem to be not validated by the recent outcomes of SBRT trials for both primary and metastatic diseases which compare favorably to surgery and conventional radiotherapy with minimal adverse effects.[10,11] Furthermore, another modeling study by Ruggieri et al.[12] suggested that inherently inhomogeneous dose distributions from SBRT could deliver significant simultaneous boost doses to about 50% of the tumor volume and counterbalance the potential loss of reoxygenation within a few fractions. This study conceivably offers an explanation of otherwise unexpected clinical outcomes with SBRT under presumed hypoxic conditions.

A more explicit consideration of hypoxia in the treatment planning process requires biological imaging to assess oxygenation levels of tumors.[13] The knowledge of spatial distribution of hypoxia is especially critical if dose intensification is to be used to overcome hypoxic radioresistance, although this may not be relevant in the context of SBRT-like fractionations and their characteristic inhomogeneous dose distributions, as illustrated by Ruggieri et al.[12] Such a strategy relies on the reproducibility of tumor hypoxia as detected by hypoxia imaging. However, a recent study by Nehmeh et al.[14] showed that significant variability in spatial uptake could occur between ^{18}F-fluoromisonidazole (^{18}F-MISO) PET scans in patients with head and neck cancer, limiting its clinical use as a hypoxia imaging agent for tumor therapy. In fact, most currently used hypoxia imaging modalities[13] have inherent limitations with respect to their sensitivity to appropriate tissue oxygen levels relevant to tumor therapy, specificity for acute versus chronic hypoxia, reproducibility, clinical efficiency, and lack of quantitative assessment protocols, in addition to the fact that they are not easily accessible to the vast majority of centers which use hypofractionation. Finally, in order to preferentially boost regions of hypoxia in the paradigm of Ling et al.,[15] one needs to establish accurate conversion of the intensities in the hypoxia images into radiosensitivity maps for dose escalation. Currently, the lack of information on the uptake characteristics of hypoxia tracers significantly affects the conversion process from imaged oxygenation levels to appropriate dose intensification maps.[16]

In summary, extreme hypofractionation schedules (1–5 fractions of 8–30 Gy) used in SBRT necessitate highly inhomogeneous conformal dose distributions for small targets, which in turn circumvent the issue of hypoxia-induced radioresistance due to reduced number of fractions. Imaging modalities for hypoxia are not clinically ready for primetime and are not easily accessible for routine clinical use in many centers. Finally, considerable dose intensification in the hypoxic region as well as the use of hypoxic-cell sensitizers along with hypofractionation schedules (especially for “non-traditional” target sizes and sites) might lead to unintended dose burden in the surrounding normal tissue.

Rebuttal: David J. Carlson, Ph.D.

Dr. Yenice raises several important issues which are summarized below with my responses.
Recent clinical outcomes of SBRT trials are promising. Favorable clinical results do not mean that tumor hypoxia is not a problem. The current extreme ablative doses in SBRT required to overcome hypoxic radioresistance restrict what types of tumors can be treated. Concurrent strategies targeted directly at hypoxic cells, particularly the co-administration of a hypoxic cell radiosensitizer,[5,6] will improve the therapeutic ratio of SBRT and allow the clinician to treat a larger fraction of the patient population.
Inherently heterogeneous dose distributions counterbalance the loss of reoxygenation in SBRT. Ruggieri et al.[12] concluded that the “blind” dose boosting intrinsic to SBRT may counterbalance the loss of reoxygenation. Their results, however, still showed a sharp decline in therapeutic ratio for treatments with less than ten fractions for hypoxic tumors, which is consistent with the conclusion of Carlson et al.[6] Their study also implied that boosting is essential for successful SBRT. Individualized treatments designed to target patient-specific hypoxic subvolumes will always be more biologically optimal and efficient than “blind” dose boosting.

Hypoxia imaging is not sufficiently mature to provide accurate maps of tumor oxygenation for hypoxia dose boosting. Better imaging techniques will improve treatment individualization in the future. Practical dose boosting strategies are more feasible for SBRT as hypoxia distributions could be imaged prior to each fraction to capture temporal changes.[14,17] Accurate and reproducible hypoxia imaging is not necessary for systemic therapy with hypoxic cell radiosensitizers and cytotoxins as these drugs have no problems diffusing to hypoxic cells.

Hypoxia dose boosting and hypoxic cell sensitizers might lead to unintended dose burden in normal tissue. It is possible to employ a hypoxia dose painting strategy without significantly increasing normal tissue dose.[18] In particular, co-administration of a hypoxic cell radiosensitizer would allow for a reduction of the radiation dose prescribed, thereby decreasing normal tissue dose. It has been shown in many studies that hypoxic cell radiosensitizers do not increase the radiosensitivity of normal tissues.

Rebuttal: Kamil M. Yenice, Ph.D.

My opponent bases his argument largely on findings of the two recent studies: Brown et al.[5] and Carlson et al.[6] Neither of these studies provides unequivocal scientific evidence for reduced potency of hypofractionated treatments in the case of hypoxia. Both studies exclusively use linear quadratic (LQ) modeling[19] for the prediction of hypofractionated treatment outcome. The validity of LQ modeling for extremely hypofractionated treatment regimens such as SBRT has been questioned in the literature.[20] Moreover, Brown et al.[5] inaccurately reported a relapse rate of 31% for radiosurgery patients treated to 20 Gy to the periphery from the EORTC 22952-26001 trial[21] as the base of their argument for antihypoxia augmented SBRT treatments. However, the 31% relapse rate observed in this trial included both the surgery and radiosurgery arms to multiple brain metastases without the whole brain radiotherapy (WBRT). A more interesting finding of the EORTC trial was that both the cumulative incidence of intracranial progression and relapses after 24 months at sites treated with either surgery or radiosurgery improved by nearly a factor of two when WBRT was added to both surgery and radiosurgery. This clearly showed the importance of microscopic disease or other factors that were prevalent besides the presumed hypoxic tumor conditions.

Finally, a meta-analysis by Overgaard and Horsman[22] showed that there was a statistically significant benefit to combining radiation therapy with antihypoxia modification compared to radiation alone. However, the observed benefit with antihypoxia-augmented radiation therapy over radiation alone was modest at best (<8%), certainly not in the range of the substantial improvements that LQ modeling predicts[2] with hypofractionated treatments. The clinical benefit of extreme hypofractionation demonstrated in several trials over standard fractionation already far exceeds such modest improvements. With all the difficulties associated with hypoxia imaging and challenges for inclusion of tumor hypoxia in the treatment process, including tumor hypoxia in the treatment planning process is equivocal at best.

In conclusion, to paraphrase Johnnie Cochran, if the data don't fit you must quit.

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1.2. Pulsed reduced dose rate radiation therapy is likely to become the treatment modality of choice for recurrent cancers

C.-M. Charlie Ma and Gary Luxton
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OVERVIEW

Cell-survival studies have demonstrated that some cancer cells exhibit hyper-radiosensitivity (HRS) at very low doses and attempts are being made to use this phenomenon to advantage for the re-treatment of recurrent cancers. Patients are being treated with external beam therapy at doses/fraction of the order 0.2 Gy, with just minutes between fractions, up to very high total doses, much higher than could be delivered with conventional fractionation. This has been called either pulsed low dose rate (PLDR) or pulsed reduced dose rate (PRDR) radiotherapy, but we will use the latter terminology here so as to avoid confusion with PLDR brachytherapy. It has been suggested that PRDR is likely to become the treatment of choice for recurrent cancers, and this is the proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is C.-M. Charlie Ma, Ph.D. Dr. Ma received his Ph.D. in medical physics from the University of London (UK) and is now Professor, Vice Chair and Director of Radiation Physics in the Department of Radiation Oncology, Fox Chase Cancer Center, Philadelphia. Dr. Ma is active in research, education and clinical implementation of Monte Carlo simulation techniques for radiotherapy dosimetry, and image-guidance, quality assurance, and treatment assessment for intensity-modulated photon therapy, electron therapy, and particle therapy. His research interests also include radiobiological modeling and MR-guided high-intensity focused ultrasound surgery and non-thermal therapy.

Arguing against the Proposition is Gary Luxton, Ph.D. Dr. Luxton received his Ph.D. in Physics in 1970 from the California Institute of Technology, where he had the privilege of serving a year as teaching assistant to Dr. Richard Feynman. He is currently Director and Professor of the Physics Residency program in the Department of Radiation Oncology at Stanford University. He was formerly Head of Physics and Vice-Chairman, Department of Radiation Oncology at the University of Southern California. One of his current interests is radiobiological modeling applied to new treatment protocols such as hypofractionated radiotherapy, and, among other topics, he has done research in ophthalmic plaque brachytherapy, negative pi-meson and heavy-ion therapy beams, radiosurgery, and IMRT.

FOR THE PROPOSITION: C.-M. Charlie Ma, Ph.D.

Opening statement

There has been no consensus standard of care for the treatment of recurrent cancer patients who have been previously irradiated. The prescription dose depends not only on the treatment intent, either curative or palliative, and the time interval from their initial radiation treatments, but also on the potential high radiation risks resulting from the significant doses received by nearby critical organs and structures.

Recently, a PRDR external beam radiation therapy technique has been investigated for treating recurrent cancers through pilot clinical studies[1,2,3] and *in-vitro*/*in-vivo* radiobiological experiments.[4,5] The idea behind the PRDR technique is to take advantages of both the hyper-radiosensitivity of tumor cells below

their transition doses, which are generally greater than those of normal tissues, and the increased normal tissue repair at low dose rates.[6,7] The way to achieve this is to divide a daily radiotherapy treatment into a number of subfractions (pulses) with each subfractional dose less than the tumor transition dose but greater than the normal tissue transition dose so that radiation repair is triggered in normal tissues but not in tumor cells. The radiation pulses are delivered at certain intervals to achieve an effective low dose rate to maximize normal tissue repair. In one study, conventional photon and electron PRDR treatments have been employed at the University of Wisconsin, Madison,[1,2,3] to treat various recurrent cancers, including breast carcinoma and glioblastoma multiforme, with forward planning techniques. A daily dose of 2 Gy is delivered in ten pulses with 3 min intervals, resulting in an effective dose rate of 0.067 Gy/min. The monitor units for each pulse are calculated to deliver an average dose of 0.2 Gy to the target volume. At the Fox Chase Cancer Center, Philadelphia, image-guided radiation therapy has been investigated for the treatment of recurrent cancers such as non-small cell lung carcinoma, pancreatic carcinoma, and rectal carcinoma, utilizing advanced delivery techniques such as intensity-modulated radiation therapy (IMRT) and volumetric-modulated arc therapy (VMAT).[8] Every daily treatment consists of ten gantry angles for step-and-shoot IMRT or ten intensity-modulated arcs for VMAT, each delivering approximately 0.2 Gy to the treatment target, with a 3 min interval between treatments.

With advanced treatment techniques to provide superior target coverage and additional normal tissue sparing, PRDR may become the treatment modality of choice for recurrent cancers and even possibly for some radiation-resistant cancers. Limited clinical outcome data suggest that the PRDR treatment is well tolerated with minimal acute and late toxicities with accumulative doses up to 236 Gy, and with local control comparable to other irradiation techniques.[3]

AGAINST THE PROPOSITION: Gary Luxton, Ph.D.

Opening statement

Patients with recurrent cancers form an important broad category, perhaps 15%–20% of radiotherapy patients. Treatments are complex and difficult. Difficulties arise from the hazard of adding to normal tissue injury from previous radiotherapy, heightened possibility of complication from over-treatment of the tumor bed and surrounding tissue, and higher preponderance of poor patient health. Failure of initial irradiation might signify a recurrent or persistent tumor intrinsically more aggressive or more resistant to therapy.

The Proposition asserts that an experimental treatment, referred to as PRDR external beam radiotherapy is *likely* to become the treatment method of choice. The method is mainly based on experimental studies of cell survival *in-vitro*, typically in the 85%–99% range. In several cultured cell lines, these experiments have found HRS, an increase in biological response per unit dose compared to the corresponding response to conventional higher dose fractions. The transition in response, typically in the range 0.3–1 Gy, has been called increased radio-resistance (IRR).[6] The PRDR method seeks to exploit the HRS-IRR phenomenon to clinical benefit. A proliferation of experiments and theoretical considerations reflecting the influence of molecular biology was referred to in a recent review article as "a resurgence that was coincident with improved funding,"[9] suggesting that the true state of the art may be in flux. The usefulness of the effect invites skepticism, however, as there is no established evidence that the increase in radiation sensitivity is less for normal tissue than for tumors. HRS is seen in cells derived from normal tissues as well as in normal tissue *in-vivo*.[10,11] With lower dose per fraction to normal tissue, HRS might enhance cell kill more in normal tissue than in tumor. In fact, the entire effect might not exist at all with a particular tumor *in vivo.* For example, an international collaboration found that, despite substantial HRS observed in a human malignant glioma cell culture, a negative effect occurred when the same cell line was studied *in vivo* in mice.[12] Response to the same low dose per

fraction (0.4 Gy) that had exhibited HRS in culture was markedly smaller than response to the same total dose (50.4 Gy) delivered by conventional fractionation (1.68 Gy/fraction) in the same overall time (6 weeks).[12]

Sophisticated experiments have explored and suggested possible underlying mechanisms of HRS-IRR.[13] These stimulate theoretical interest but do not establish a mechanism across different tissues with an increased therapeutic ratio compared to conventional fractionation. The method could have the opposite effect. As with many areas of research, preliminary reports of quasi-positive clinical findings with limited numbers of patients[2,14] may generate optimism. The statement, however, that the current state of the art suggests it is likely that pulsed low dose rate radiotherapy will become the treatment modality of choice for recurrent cancer leaps to a conclusion unsupported by the data. After carefully designed controlled clinical trials, it may turn out to be true for selected cases. There may be a real hazard, however, that due to the great difficulty of treating the underlying clinical problem, an inferior treatment might be adopted *a priori* through inertia without any hard evidence of efficacy.

Rebuttal: C.-M. Charlie Ma, Ph.D.

Dr. Luxton has raised several important concerns about the potential clinical application of the PRDR technique for recurrent cancers. Indeed, caution must be exercised with the initial introduction of this technique to each body site since HRS is exhibited by some normal tissue cells but not all tumor cells.[6,10] However, it is the improvement in the therapeutic ratio, not just HRS, that will make the PRDR technique the treatment modality of choice for many recurrent cancers. The rich i*n-vitro* and *in-vivo* experimental results have laid a strong radiobiological foundation for the PRDR technique and these have been used to guide pilot studies to find optimal doses, dose rates, and fractionation schemes for particular body sites.[2,3,8,14,15] A clear advantage of the PRDR technique over conventional radiotherapy is the reduced normal tissue damage at lower dose rates, which has offered hope for some recurrent patients with severe and/or life threatening symptoms, who have been otherwise considered unsuitable for re-irradiation with conventional radiotherapy. The fact that many radioresistant tumor cells exhibit higher RHS/IRR ratios at lower doses and dose rates[6] also suggests that the PRDR technique may be a better choice than conventional radiotherapy for some recurrent cancers because of the possible existence of such radioresistant tumor cells. Radiation therapy has changed significantly in the past several decades because of technological advancements. The improvement in radiobiological understanding has for a long time lagged behind this technological development, but it is expected to play a more significant role in the further advancement of radiotherapy for both curative and palliative care. The favorable outcomes of some pilot studies on radioresistant malignant tumors (8 patients), recurrent breast carcinoma (17 patients), and glioblastoma multiforme (103 patients)[2,3,14] not only demonstrated the clinical effectiveness of the PRDR technique for these body sites but also provided convincing evidence to support future large scale and/or randomized clinical trials to determine the efficacy of the PRDR technique for other recurrent and potentially radioresistant cancers.

Rebuttal: Gary Luxton, Ph.D.

I offer the following comments on the clinical evidence introduced by Dr. Ma. Preliminary data in studies with limited follow-up indicate that PRDR can be reasonably well tolerated. The remarkable potential gains in modeled tumor control probability in cell lines derived from human glioma in his first reference[1] were *not*, however, translated into improved survival in PRDR treatment for recurrent glioma in his second reference.[2] In that study, median survival from initiation of PRDR was 5.1 months for Grade 4, 5.6 months for Grade 3, and 11.4 months for tumors initially classified as low-grade. These dismal survival rates are essentially the same as those for other experimental treatments, such as the eight recurrent glioma Phase II drug trials reviewed in Ref. 14 of the proponent's second reference.[2] For

PRDR re-treatment of locally recurrent breast cancer described in his third reference,[3] a trend toward higher local control was indeed found compared to re-treatment with electron beams in a 1978 study with a similar follow-up period, 92% versus 69%. The 17 patients of the study, however, was a number too small for meaningful statistical significance, and, furthermore, the acute toxicity rate was 23%, which is higher than the 8% reported for the electron- beam re-treatments.

The studies quoted by the proponent of the Proposition show that there is a *possibility* that PRDR might provide an improvement over competing treatments in some cases, and do indicate that PRDR methodology can be clinically implemented. What is missing, however, is acceptable evidence that there is, or will be, even with employment of IGRT + IMRT, any real improvement due to PRDR.

Radiobiological studies have not informed us that there will be a better therapeutic ratio. With today's evidence, PRDR can be implemented but it is more costly and is, at best, experimental.

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1.3. Hypofractionation is a proven safe and effective modality for postoperative whole-breast radiotherapy for early breast cancer patients

Stephen L. Brown and Alan Rodger
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OVERVIEW

Whole breast irradiation for early breast cancer patients has traditionally been delivered at 1.8–2.0 Gy/fraction in 25–35 total treatments. There has been recent interest, however, in reducing the number of fractions by increasing the dose/fraction so as to contain costs and make the treatments more convenient for both patients and staff. Conventional wisdom would suggest that this might result in decreased effectiveness and/or increased risk of complications, but a few recent clinical trials seem to show that these fears might not be realized in practice and that hypofractionation is both safe and effective for these treatments. This is the Proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is Dr. Stephen L. Brown. Dr. Brown received his Ph.D. in Medical Biophysics in 1991 from The University of Toronto in the Medical Physics stream at The Ontario Cancer Institute incorporating Princess Margaret Hospital. He has since been in Detroit at Henry Ford Hospital where he holds the position of Staff Scientist and Associate Professor of Radiation Oncology at Wayne State University. Dr. Brown's research interests bridge the area between medical physics and radiation biology, with the central theme of exploiting tumor and normal tissue physiology to improve the therapeutic index of response to treatment. The wave of his current funding involves imaging adenoviral-delivered radiation sensitizers and imaging mitigation of normal tissue radiation injury. He has coauthored over 60 research publications and book chapters.

Arguing against the Proposition is Alan Rodger, MB, ChB. Dr. Rodger held the post of Professor and Medical Director of the Beatson West of Scotland Cancer Centre in Glasgow from 2003 until he retired in 2009. An Edinburgh graduate, he trained in surgery and clinical oncology, completing training at the M. D. Anderson Cancer Center. He specialized in breast cancer in the Edinburgh Breast Unit and then, in 1992, he took up the foundation posts of Director of Radiation Oncology at the Alfred Hospital and Professor of Radiation Oncology at Monash University, Melbourne, Australia, returning to Scotland in 2003. He is a member of the Cochrane Breast Cancer Editorial Group, Radiotherapy Specialty Editor for *The Breast*, and an International Advisor to the National Breast and Ovary Cancer Centre of Australia. His writing focuses on evidence-based clinical oncology.

FOR THE PROPOSITION: Stephen Brown, Ph.D.

Opening Statement

Hypofractionation applied to the whole breast in the modern era is safe and effective because of advances in technology that build on clinical experiences.[1] Recent randomized radiotherapy trials in Canada and the UK with a decade or longer follow-up demonstrate that hypofractionation, higher than standard radiation doses delivered over fewer than standard number of fractions, postoperatively to whole breast gives at least comparable tumor control and late irradiation morbidity as does conventional

fractionation for patients with early breast cancer.[2,3] The supposed benefits of a classical multiple 1.8 or 2 Gy fractionation schedule are predicated on (1) the possibility of "reoxygenating" hypoxic tumor regions, and/or (2) exploiting differences in radiation repair capacities of adjacent late responding normal tissues and tumor, typically characterized as having α/β ratios of 3 and 10 Gy, respectively; apparently neither factor limits the efficacy of hypofractionation radiotherapy. Regarding reoxygenation, radiotherapy-induced changes in the oxygen distribution resulting from the particular hypofractionation schedules employed are either similar to the conventional schedule or, alternatively, hypoxia may not be a limiting issue as has been argued to explain the unexpectedly high responses of tumors of the brain and lung following single fraction radiation.[4] The recent breast cancer hypofractionation studies provide measures of tissue fractionation sensitivities, α/β ratios, for soft tissue and breast cancer that were found to be similar and small, in the range of 3–4 Gy, suggesting that the radiation response of both breast cancer and normal breast are characterized by a relatively large proportion of repairable radiation lesions (small α/β ratio).[5]

The benefit of a reduced number of fractions in addition to patient convenience is improved efficiency of delivery and less cost. From a radiobiological perspective, the intensification of treatment has benefits beyond the reduced time available for tumor growth during treatment. First and foremost, tumors respond better than theoretically expected with hypofractionation as evidenced for a variety of tumors including breast cancer. It has been hypothesized that a "new biology" governs tumor response to high dose radiation, especially focal radiation.[4,6] Experimental evidence indicates that tumor response is affected by adjacent irradiated tumor through autocrine and paracrine factors via a bystander effect and/or by the response of nontumor cells, especially normal tissue stroma.[4] It has been hypothesized that tumor response is influenced by the volume of normal tissue exposed, heterogeneity of radiation dose,[4] and the unexpected radiation sensitivities of vasculature and/or cancer stem cells.[6] Of particular current interest are the benefits of hypofractionation schedules combined with strategies to sensitize tumor and/or mitigate normal tissue injury. New preclinical evidence suggests that the effectiveness of both radiosensitization and radiation mitigation strategies improve under hypofractionation conditions; early clinical results show both approaches are safe.[7,8] Consequently, although hypofractionation is a proven safe and effective modality for postoperative whole-breast radiotherapy for early breast cancer patients, the therapeutic advantage of this strategy is expected to improve even further.

In conclusion, hypofractionation radiotherapy is safe and efficacious in contrast to what is expected from radiobiology theory and what is predicted from the results of historical clinical experience.

AGAINST THE PROPOSITION: Alan Rodger, MB, ChB

Opening Statement

This Proposition fails on two grounds: "Hypofractionation" is neither defined nor specific enough to permit its general recommendation; and the data on clinical effect are immature.
The START Trialists' Group[9] defined hypofractionation as an "alternative schedule (of radiotherapy) based on a lower total dose delivered in fewer, larger fractions." They allude to the use of such schedules over decades. Yet many of the earlier schedules did not reduce total dose.[10] Hypofractionation embraces a plethora of schedules, doses, and fractionations: Daily and less than daily, shortened or "standard" overall treatment time, and fraction doses from just over 2 Gy to several times that, with doses selected empirically,[11] clinically,[10] or radiobiologically.[3,13] The standard is 50 Gy in 25 daily fractions over 5 weeks, yet there is no randomized trial evidence justifying its elevated position.

Hypofractionation is, therefore, *any* schedule of dose, fractionation, and duration delivered in less than 25 daily fractions. It cannot then be that *hypofractionation* is proven safe and effective.
Second, "proven" demands proof. The minimal level of proof is evidence from a well-conducted randomized controlled trial (RCT) of superiority, or no inferiority, for all acute and late toxicity and for clinical effect. For whole-breast radiotherapy, the normal tissues are skin and subcutaneous fat, muscle, ribs, neural tissue, upper limb, and vascular tissue such as coronary arteries and great vessels. Clinical effectiveness is measured against the end points of overall survival, cause-specific survival, and local (and/or regional) recurrence. Only three RCTs qualify for consideration: The START A and B[9,12] and Canadian[13] trials. Between them they compared four different dose/fractionations against the standard in 5685 women. Median follow-ups were 61,[12] 69,[13] and 72[9] months. Overall survival and cause-specific survival were not reported in detail in the START trials[9,12] but overall survival was documented in the Canadian trial.[13] While there is, as yet, no significant survival difference, the follow-up is too short to be categorical. Local recurrence was the same, but again at relatively short follow-up.

My concerns with these trials are short follow-up and lack of prospective assessment of late toxicity. While the trials assiduously measured cosmesis, late toxicity is affected by both surgical and radiotherapy factors. Only the latter was assessed in these trials. Acute and late skin and subcutaneous effects were expertly assessed. For lung and rib damage, the trials recorded only symptomatic patients: No prospective radiological assessment was employed. Yet it was shown that radiological assessment detected a higher incidence of radiation-induced osteonecrosis than expected.[11] Of more significance is late cardiotoxicity, the lag period for which is 10 years.[14]

Lastly, the Canadian study[13] excluded nearly 2500 patients before randomization some because their breasts were considered too large. Many advocate hypofractionation use only when volume is taken into account and dose-compensating schemes are implemented.[15]

This Proposition fails because hypofractionation is too nonspecific a term and because the proof of effectiveness is immature and inadequate regarding prospectively measured late toxicity.

Rebuttal: Stephen Brown, Ph.D.

Benefits of hypofractionation for postoperative whole-breast radiotherapy for early breast cancer patients that are not in dispute are improved patient convenience, less treatment costs, potentially less acute toxicity and, when assessed at five years, its effectiveness compared to standard schedules. At odds are the definition of hypofractionation and its long-term safety. Unfortunately on both counts, my esteemed colleague's arguments are flawed because he confuses proof of concept with optimization. Contrary to Dr. Rodger's view, hypofractionation is unambiguous. It is defined as "radiation therapy that gives larger doses (fractions) of radiation in fewer treatment sessions and over a shorter period of time than standard radiation therapy."[16] My assertion is that many hypofractionation schedules may be efficacious and safe; only one long-term study is needed for the proof of concept.

The results of the Canadian study that my colleague uses to support his case compares 42.5 Gy, 16 fractions, 22 days to the standard, 50 Gy, 25 fractions, 35 days.[2] The median follow-up at 144 months presented late last year demonstrates that hypofractionated whole-breast irradiation provides excellent long-term local control and limited late morbidity, similar to that seen with conventional fractionation for whole-breast irradiation.[17]

Future optimization will likely demonstrate further safety and improved efficacy as alternate fractionation schedules are tested that maximize tumor and minimize normal tissue responses. In addition, tumor radiosensitizers, such as the gene therapy approach developed at Henry Ford Hospital in

Detroit,[18] and normal tissue radioprotectors that function on intrinsic cellular radiation sensitivities (i.e., not the cell's repair capacity), examples of which are being developed under the NIH-sponsored Centers for Medical Counter Measures Against Radiation Injury,[19] appear to be more effective under hypofractionated than standard schedules.

In summary, the current studies employing hypofractionation for the treatment of breast cancer are of sufficient duration to declare that hypofractionation is both safe and effective; future optimizations are possible building on clinical experiences and radiobiological advances.

Rebuttal: Alan Rodger, MB, ChB

My eminent opponent fails to persuade me. His claims that recent randomized trials have decades of follow-up are wrong, as I showed in my initial statement. Long-term toxicity data are not yet available. His radiobiological arguments are dubious and confused. While hypoxia may be an issue in inoperable breast cancer, it is unlikely to be relevant in a breast from which an early cancer has been fully excised. I accept that the UK START Trials provide radiobiological evidence that the α/β ratio for breast soft tissue and breast cancer cells may be similar, but my opponent makes the mistake of then extrapolating data from fractionated schedules to single fraction treatments.

There is, as yet, no randomized trial evidence to justify recommending single fraction radiotherapy to the breast. The randomized trials of intraoperative radiotherapy and of brachytherapy techniques are incomplete. That they may be common practice in some centers is no justification.
While preclinical evidence of the possible effectiveness of radiosensitizers or radiation mitigation strategies in conjunction with hypofractionated schedules is undoubtedly interesting and, while early clinical results suggest safety, for these there are no long-term data on effectiveness and safety from randomized trials. This is an argument for further research, not a wholesale change in practice.

The last supporting argument for the motion is based on convenience and reduced cost. It would be ground breaking indeed if those reimbursed on a fee-for-service basis were to embrace hypofractionation. Perhaps this explains why the trials of fractionated hypofractionation were pursued in Britain and Canada.

Less treatment over fewer days is always worthwhile—provided it is safe and it works. Those objectives can only be proven by well-conducted randomized trials with sufficient follow-up. We have excellent trials and some continue, but we need more time. It is too early to say that "hypofractionation is a proven safe and effective modality…for early breast cancer."

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1.4. The linear-quadratic model is inappropriate to model high dose per fraction effects in radiosurgery

John P. Kirkpatrick and David J. Brenner
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OVERVIEW

The linear-quadratic (LQ) model is frequently used for modeling the effects of radiotherapy at low and medium doses per fraction for which it appears to fit clinical data reasonably well. It has also been used at the very high doses per fraction encountered in stereotactic radiosurgery, but some have questioned such use because there are little clinical data to demonstrate that the model is accurate at such high doses. This is the proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is John P. Kirkpatrick, M.D., Ph.D. Dr. Kirkpatrick is an Associate Professor at the Department of Radiation Oncology, Duke University Medical Center. He has a Ph.D. in Chemical Engineering from Rice University, Houston, and an M.D. degree from the University of Texas Health Science Center, San Antonio, TX. His major research interests include treatment of tumors of the central nervous system, base of skull and spine, stereotactic brain and body radiosurgery, IMRT and other highly conformal techniques employing spatiotemporal optimization, tumor hypoxia, and quantitative modeling of the response of malignant and normal tissue to ionizing radiation.

Arguing against the Proposition is David J. Brenner, Ph.D., D.Sc. Dr. Brenner is a 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 the Liverpool Football Club.

FOR THE PROPOSITION: John P. Kirkpatrick, M.D., Ph.D.

Opening Statement

The LQ equation is widely used to describe the effects of ionizing radiation on normal and neoplastic tissue.[1] In radiotherapy, we seek death of malignant cells and, more importantly, control/cure of disease while avoiding damage to the surrounding normal tissue. In conventionally fractionated radiotherapy, the LQ model is a useful tool to help predict isoeffects as a function of the total dose, dose/fraction, and treatment time.

In stereotactic radiosurgery, damage to the tumor is maximized and injury to normal tissues is minimized by administering high dose radiation—typically >12 Gy—to the tumor in a single fraction while limiting irradiation of adjacent tissue. At high doses per fraction, it is inappropriate to utilize the LQ equation because the model does not accurately explain clinical outcomes, is derived largely from *in vitro* observations, and does not consider the impact of radioresistant clonogen subpopulations.

Clinical outcomes from radiosurgery suggest that a single, high radiation dose is more efficacious than the "biologically equivalent" total dose calculated from the LQ model for conventionally fractionated radiotherapy.[2,3,4] For example, about 10% of patients with arteriovenous malformations (AVMs) treated to 42 Gy in 12 fractions (biologically equivalent to one 15 Gy fraction based on the LQ model with α/β =3 Gy) exhibited obliteration, and the rate of bleeding is not different than that in untreated patients.[4] In contrast, single fraction radiosurgery at 15 Gy yields an obliteration rate of about 50%.[5]

The discrepancy between clinical outcomes and predictions based primarily on *in vitro* cell survival curves may be related to radiation-induced changes in supporting tissue. Much of the data used to generate survival curves and estimate LQ model coefficients comes from *in vitro* cell culture experiments, typically at doses/fraction well below those used in radiosurgery. Preclinically, vascular endothelial damage appears to be triggered *in vivo* above 10 Gy/fraction.[6] Pathological studies of malignant and benign human brain lesions treated with radiosurgery show profound changes in the vasculature.[7,8] For example, for the treatment of AVMs, obliteration of abnormal vasculature and normal tissue damage are rare below 12 Gy but climb steeply above this dose threshold. Histopathological studies of AVMs show that the dominant damage following radiosurgery is loss of vascular endothelial cells, followed by obliteration of lumens.[7]

While the LQ model assumes an essentially homogeneous cell population, the tissue microenvironment is, in fact, quite heterogeneous. Local hypoxia is present in many tumors, significantly reducing radioresponsiveness of the overall tumor.[9] Moreover, tumors contain a subpopulation of cancer "stem cells" exhibiting enhanced repair of radiation damage, which may severely limit curability.[10] Neither heterogeneity of mechanism nor target population is reflected in the LQ model.

It is certainly possible to modify the LQ equation such that the model fits the dose-response curve and then rationalize that the addition of a new parameter reveals some fundamental mechanism.[1] However, one should not extend an empirical model outside the data set from which it has been derived. By truly understanding the underlying mechanism, we can create a robust model that both informs us clinically and aids us in formulating new therapeutic strategies.

AGAINST THE PROPOSITION: David J. Brenner, Ph.D., D.Sc.

Opening Statement

First, the standard LQ model is an approximation to more exact (but more complex) models. LQ generally works fine at doses per fraction below about 15–20 Gy. At higher doses per fraction, more exact versions of the LQ are available and can be used. Second, in order to use the standard LQ model to predict isoeffect tumor-control doses between high dose single fractions and multiple-fraction regimens, it is important to consider that reoxygenation will generally be different between the two cases. This can be taken into account with simple extensions to the LQ model.

1. High doses

It has long been known that the linear-quadratic model is an approximation to a wide range of damage-kinetic models, which describe the kinetics of DNA double-strand breaks (DSBs) and other basic lesions.[11] In such models, DSBs are resolved either through restitution or binary misrepair. At typical radiotherapeutic doses, most DSBs are removed by restitution, which results in the classic linear-quadratic dose dependence. At very high doses per fraction, binary misrepair can dominate, which results in a linear relation between effect and dose.[11] Overall, these mechanisms produce a linear-quadratic-linear dose-response relationship, as has been pointed out by many authors.[11,12,13,14,15]

In fact there have been detailed analyses, both experimental and theoretical, as to the doses below which the standard LQ approximation is reasonable to use. Experimentally, *in vivo* studies have suggested that the LQ works well up to about 20–24 Gy for a variety of murine end points,[1] and Garcia *et al.*[16] recently showed that *in vitro* cell survival followed the standard LQ up to about 15 Gy. Theoretically, Sachs *et al.*[11] estimated that the LQ approximation would be reasonable at doses below about 17 Gy and suggested practical corrections to the LQ model at somewhat higher doses. In practice, doses per fraction much above ~20 Gy are relatively unusual in radiosurgery, and so corrections to the LQ model in the relevant dose range are not major and are not hard to do.[11]

Of course one cannot rule out the possibility of other mechanisms, such as vascular endothelial damage contributing to radiation-induced tumor control. It is not yet clear how significant such mechanisms are in the clinic, but it is now clear that such effects are present at both low and high doses per fraction[17] and are not uniquely high-dose phenomena.

2. Reoxygenation

Almost all tumors have a hypoxic component, and one of the main motivations for fractionated radiotherapy is to permit reoxygenation between fractions. Clearly, this cannot happen with a single fraction, so if the goal is to produce isoeffect doses for tumor control between a single and a fractionated dose, one needs to model for reoxygenation. A simple modification to the LQ model that takes reoxygenation into account is available for such calculations,[18] although the rationale for treating malignancies with a single fraction, and thus losing the benefits of reoxygenation, remains unclear.

Rebuttal: John P. Kirkpatrick, M.D., Ph.D.

The most important goal of modeling dose/response data is to predict clinical outcome. In conventionally fractionated radiotherapy, there is often a wealth of clinical data at the dose/fraction of interest and the clinician is justified in using the linear-quadratic model—or a modified form of this model—to *interpolate* response over a limited range. The prudent clinician, however, will exercise caution when radically altering a fraction scheme[19] no matter how compelling the radiobiological rationale.[20] In radiosurgery, clinical data are much more limited. Thus, "radiosurgeons" are faced with the task of *extrapolating* their clinical experience at low doses per fraction to the high-dose/fraction region utilizing a model with parameters largely derived from *in vitro* cell survival curves and small animal experiments.

Dr. Brenner argues that the *modified* linear-quadratic model provides a reasonable fit of isoeffect data up to about 20 Gy/fraction but, in most intracranial radiosurgeries, the maximum tumor dose is above 20 Gy. I will not argue with the complex mathematical formalisms and biophysics underlying these models, though one would be surprised if the modified models could not fit these data given the large number of adjustable parameters. However, as these data are typically based on cell-suspension experiments, they do not reflect changes at the tissue level which become more important as the dose/fraction increases.[21] Dr. Brenner alludes to "a simple modification to the LQ model" to account for reoxygenation but spatial/temporal variations in pO_2 in the tumor microenvironment are far more complex. And what about the effects of heterogeneous inherent radiosensitivity/repair, repopulation, and vascular endothelial damage (which is qualitatively different from the low dose response) at radiosurgical doses?[21,22,23]

Our present understanding of these mechanisms and their impact on tumor control and normal tissue complications at high doses/fraction is inadequate to model clinical isoeffects. Fortunately, our knowledge on these mechanisms is growing and it is incumbent on radiobiologists to incorporate this knowledge into models that not only predict clinical outcomes at elevated dose/fraction but also lead physicists and physicians to enhance treatment planning and biochemotherapies.

Rebuttal: David J. Brenner, Ph.D., D.Sc.

The heart of this debate can be summed up in Dr. Kirkpatrick's suggestion that LQ is merely an empirical, descriptive model. If this were so, one would indeed be very hesitant about using LQ as a guide for designing new protocols—the calamitous failure of the empirical NSD model comes to mind here.[24] But it was not so. In fact almost all mechanistically based radiobiological reaction-rate models reduce to the linear-quadratic model if the dose is not too high.[11] The LQ approximation to these radiobiological models is not merely some empirical power series expansion in dose; rather, it includes[11] the generalized Lea–Catcheside factor for protraction-based sparing,

$$G = (2/D^2)\int_{-\infty}^{\infty} R(t)dt \int_{-\infty}^{t} e^{-\lambda(t-t')} R(t')dt', \quad (1)$$

where $R(t)$ is the temporal dose distribution of the radiotherapy. Equation (1) provides a mechanistic description of the interaction of a DSB (or other primary lesion) made at time t', subject to first-order repair with rate constant λ, with another DSB made at a later time t—hardly the nonmechanistic empirical model that Dr. Kirkpatrick characterizes LQ to be.

As described above, LQ is indeed a lower dose ($\leq$ 15–20 Gy) approximation of more detailed mechanistic models, and these more detailed models can certainly be used if one is interested in effects at, say, 25–30 Gy/fraction.[11] But this procedure is certainly not the "extension of an empirical model" that Dr. Kirkpatrick suggests.

Dr. Kirkpatrick spends some time discussing AVM data. In fact a recent comprehensive analysis[25] of essentially all reported dose-response data for AVM obliteration, with doses per fraction ranging from 4 to 28 Gy, indicated that the data over the entire dose range were consistent with a standard sigmoidal LQ-based dose response, with an α/β value of about 2 Gy. No evidence here of different mechanisms at high versus low doses. Likewise the preponderance of evidence suggests that radiation-induced vascular endothelial damage to malignancies, while its clinical significance remains unclear, also occurs both at low and high doses.[17]

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1.5. PDT is better than alternative therapies such as brachytherapy, electron beams, or low-energy x rays for the treatment of skin cancers

Timothy C. Zhu and E. Ishmael Parsai
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OVERVIEW

With photodynamic therapy (PDT), light is used to activate a photosensitizer drug to induce an oxidative reaction that causes cells to be destroyed. It has now been about 15 years since the FDA authorized PDT for the treatment of cancer, yet it is rarely used in clinical practice. It has been suggested that we are now ready to apply PDT for the treatment of skin cancers and this is the Proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is Timothy C. Zhu, Ph.D. Dr. Zhu received his Ph.D. in Physics from Brown University, RI in 1992 and then spent two years in postdoctoral training in Radiation Oncology Physics at Roger Williams Medical Center, RI. From 1994 to 1998 he was an Assistant Professor in the Department of Radiation Oncology, University of Florida, Gainesville and then moved to the University of Pennsylvania where he is Associate Professor of Radiation Oncology. His research interests include photodynamic therapy (PDT) dosimetry, *in vivo* dosimetry, external beam treatment planning, monitor unit calculations, and image-guided interventions and he has published over 110 papers. He has been very active in the AAPM as member or Chairman of many committees and Task Groups. He chairs Task Group No. 140 (Absolute Calibration of Light Power and Fluence Rate for PDT) and is the current president of the Delaware Valley Chapter. Dr. Zhu is certified in radiation therapy physics by both the ABR and the ABMP.

Arguing against the Proposition is E. Ishmael Parsai, Ph.D. Dr. Parsai was awarded his M.S. and Ph.D. degrees in Medical Physics by the University of Missouri, Columbia in 1988 and the University of Toledo, Ohio in 1995, respectively. Since 1993 he has worked in the Department of Radiation Oncology, University of Toledo, where he is currently Chief of the Medical Physics Division and Professor and Director of Medical Physics Programs in the College of Medicine. His research interests include mathematical modeling using Monte Carlo simulation, optimization of external beam therapy and brachytherapy, 3-D dosimetry, and radiation detectors and he has published 40 peer-reviewed articles and 6 book chapters. Dr. Parsai is certified in radiation therapy physics by both the ABR and the ABMP.

FOR THE PROPOSITION: Timothy C. Zhu, Ph.D.

Opening statement

PDT is an emerging cancer treatment modality based on the interaction of light, a photosensitizer, and oxygen.[1] The mechanism of action involves the production of reactive oxygen species (e.g., singlet oxygen from the oxygen molecule) when a photosensitizer is activated by nonionizing light. The clinical effect caused by the reactive oxygen species can be direct target (tumor) cell kill by necrosis or apoptosis, vascular damage leading to tissue ischemia, immune modulation, or a combination of the three.[2] Clinically, PDT has shown some efficacy in the treatment of a variety of malignant and premalignant conditions including head and neck cancer, lung cancer, mesothelioma, Barrett's esophagus, prostate, brain tumors, and skin cancers.[3]

From a physics point of view, PDT is well suited for skin cancer treatment because of the easy access of disease sites, simple geometry for light delivery, and limited light penetration (<1 cm) in tissue. PDT has shown high efficacy for skin cancers, especially for basal cell carcinoma, which is the most common skin cancer in humans.[2] Compared to radiation therapy, the major advantages of PDT are threefold. First, nonionizing light is used for tumor killing, thus avoiding targeting DNA and allows PDT to be performed repetitively. Second, photosensitizers may be administered in ways that target tumor and avoid healthy tissues. One common example is ALA which can be applied topically on the region of treatment. Unlike traditional photosensitizers, ALA is a prodrug that can produce a photosensitizer (PpIX) *in situ* once absorbed by tissue and it has exhibited preferential uptake in tumor cells.[4] The third advantage is that the PDT dose response, unlike radiation therapy, usually has a threshold behavior, with a sharp boundary between necrotic and undamaged tissue.[2] This can be used to achieve dramatic clinical responses with minimal side effects to adjacent critical organs.

PDT has its limitations, mostly due to the complex interactions of light, photosensitizer, and oxygen. Unlike radiation therapy, where the radiation dose is well understood and can be calculated with great accuracy based on CT data, comprehensive *in vivo* PDT dosimetry, whether implicit or explicit as proposed by Wilson et al.,[5] is still emerging and is not used routinely in many clinical trials.[2] Accurate PDT dosimetry is essential in order to utilize the full potential of PDT. For some skin cancers such as melanoma, for which PDT treatments are often avoided in the clinic due to perceived limitation of light penetration in melanin,[3] comprehensive PDT dosimetry should help optimize new PDT treatment protocols with suitable photosensitizer and light fractionation combinations.

In conclusion, despite its many limitations, PDT is much less expensive to use than radiation therapy and has been shown to be highly efficient and noninvasive, with excellent cosmetic results and quicker recovery time after treatment.[4] It can often be applied concurrently with radiation therapy and is thus a worthwhile treatment modality to explore further.

AGAINST THE PROPOSITION: E. Ishmael Parsai, Ph.D.

Opening statement

Radiation therapy (RT) is often indicated as a definitive or adjuvant treatment for skin cancers in patients where the cosmetic and/or functional outcome of a surgical procedure is expected to be unsatisfactory. The main RT modalities for these cases are 50–250 kV superficial x-ray beams, megavoltage electrons and, in more recent years, high dose-rate brachytherapy. The choice of a specific modality is typically made based on the treatment site, the size and location of the lesion, the stage of a disease, and the overall health of the patient. For adjuvant RT, the objective is to reduce the risk of loco-regional recurrence by irradiating the tumor bed after surgery.

Brachytherapy offers the advantage of the source of radiation being placed in the immediate proximity to the targeted tumor tissue using surface plaques/molds or intracavitary, interstitial, or intraluminal catheters.[6,7] The development of artificial radionuclides and remote afterloading devices has made this procedure safe for both the patient and the delivering personnel. In external beam therapies, megavoltage electrons are gradually replacing superficial x rays in treatment of skin cancers. Use of electron beams is deemed advantageous due to their exceptional dose uniformity within the targeted tissue and a sharp fall-off beyond the distal boundary of tumor. By design, all these procedures allow for the delivery of conformal high total dose to the tumor and minimal dose to the normal surrounding tissues. Radiation dosimetry formalism has been extensively developed and refined into AAPM Task Group reports,[8,9] guiding the administration and quality assurance procedures for each modality. Consequently, accurate quantification of prescribed doses to tissues and their safe delivery, as well as the availability of computerized treatment planning systems, have made radiotherapy treatments effective and reliable.

Application of photodynamic therapy as an alternative to radiation for skin tumors is still at its infancy. From the patient's side, it is typically a painful procedure[10] leading to prolonged phototoxicity.[11] From the treatment delivery standpoint, the need to have a combination of conditions (drug, oxygen, and light) to be present for a sufficient biological effect makes this therapy failure-prone and highly patient-dependent. Presently, the practical objective for treatment delivery is to achieve some threshold values[12] based on best-known parameters, which are often measured at the time of treatment. The importance of proper dosimetry for the drug uptake, delivered light, and the level of oxygen present in a tissue during the treatment cannot be overemphasized. All three parameters generally have to be evaluated on a patient-by-patient basis, with adjustments made for heterogeneity of the physical and chemical environment. Determination of availability of the O_2 level in tissue is sketchy at best[13] and the depth of penetration limits for light may not give adequate coverage for thicker lesions.

At present, PDT dosimetry is far from being as quantitative as it is for any of the radiotherapy treatments. The possibility of salvage therapy of cancer recurrence cases is definitely the main attraction of PDT. However, the high cost of a new treatment center setup may not be justified until treatment regiments are quantified, optimized, and standardized, which may take many years of research and randomized clinical trials.

Rebuttal: Timothy C. Zhu, Ph.D.

Management of pain/discomfort is a challenge in a minority of patients. The possible intolerable pains for patients undergoing ALA-mediated skin cancer PDT can be significantly reduced by a two-segmented procedure with the first part of the light treatment performed using low light fluence rate ($\leq$ 40 mW/cm^2), with the normal fluence rate used for the remainder of the treatment.[14] This method is routinely used in many centers and can be well tolerated. For ALA and most of the second generation photosensitizers (such as BPD), phototoxicity usually dissipates within a week.[15] Skin toxicity in particular is also significantly reduced compared to the first generation photosensitizer, Photofrin®, by shifting the wavelength further to the red, away from the peak wavelength of the sun.

We agree that adequate PDT dosimetry (light, photosensitizers, and oxygen) is a key to successful clinical application of PDT. In the past decade, significant development has been made in understanding the models that describe the interaction among light, photosensitizer, and oxygen.[2,5,15] Currently, the most commonly used quantity in clinical PDT is PDT dose, defined as the energy absorbed by the photosensitizer (or a product of photosensitizer and light fluence rate). PDT dose can be routinely determined in the clinical setting using *in vivo* dosimetry.[15] Quantitative models that describe the production of singlet oxygen are emerging.[16] Alternatively, implicit dosimetry[5] (e.g., fluorescent photobleaching) can be used for PDT dosimetry.[2] The fact that these methods of dosimetry are not currently in widespread use in PDT should be a cause for more physics involvement rather than a cause for discouragement of its clinical use.[15]

For nonmelanoma superficial skin cancers, PDT presents the same physical advantage of conformal dose coverage as inherent with electron therapy and brachytherapy treatments, but has the added advantage of using a nonionizing radiation. For deep seated skin cancers such as melanoma, megavoltage photon and electron beams are currently used. However, in principle, PDT can be used interstitially for thicker skin lesions, probably as a salvage treatment initially.

Rebuttal: E. Ishmael Parsai, Ph.D.

Tumor targeting and treatment in radiotherapy of all types is achieved through imaging, precise treatment planning, and advanced delivery techniques. For PDT, different imaging approaches are needed since the chemical environment is of much greater importance to the success of treatment. While preferential photosensitizer uptake by the tumor tissue has been demonstrated, this is not always the case for systemically administered drugs.[17] More recent topical photosensitizers resolve localization issues by

being applied directly to the skin site, but the proper level of the drug uptake remains problematic. To ensure that the limited physical penetration depth of both light and topical photosensitizer do not compromise adequate coverage of the tumor volume, PDT can only be used for superficial lesions that are not heavily pigmented. Even though subsequent local retreatments are not contraindicated, for those skin cancers that do not achieve local control the first time, there may be distant metastasis beyond the local PDT capabilities.

Having a sharp boundary between treated and untreated tissues is extremely advantageous if the precise extent of the region being treated is known. PDT presents a situation where the treatment outcome is determined by several interdependent parameters characterizing a highly heterogeneous environment. Thus, drug uptake and the dose of light are highly influenced by the tissue type; the oxygen level depends on the initial tissue oxygenation and the rate of oxygen depletion, which changes with the light fluence and as a result of PDT-induced hypoxia through vascular collapse.[13] The common approach to clinical dosimetry of measuring the amount of administered photosensitizer and the incident light exposure is clearly inadequate. Therefore, the issues of imaging and dosimetry will remain fundamental limitations in the foreseeable future.

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1.6. High intensity focused ultrasound may be superior to radiation therapy for the treatment of early stage prostate cancer

Stanley H. Benedict and Gert De Meerleer
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OVERVIEW

The use of high intensity focused ultrasound (HIFU) for the treatment of cancer as an alternative to radiotherapy is increasing dramatically. Some would argue, however, that its use is premature because it has not yet been proven as effective as conventional therapies such as intensity-modulated radiotherapy (IMRT), and brachytherapy, especially for the treatment of early stage prostate cancer. This is debated in this month's Point/Counterpoint.

Arguing for the Proposition is Stanley Benedict, Ph.D. Dr. Benedict received his Ph.D. in Biomedical Physics from UCLA and his M.S. in Radiological Health Physics from San Diego State University. He is an Associate Professor and Director of Radiological Physics at the University of Virginia, Department of Radiation Oncology, which recently installed the first dedicated MR imaging-guided focused ultrasound surgery center in the United States. Dr. Benedict has served on several AAPM task groups and committees and is the current Co-Chair of AAPM TG 193 on Image Guided Focused Ultrasound. He has published over 40 journal articles and several book chapters.

Arguing against the Proposition is Gert De Meerleer, M.D., Ph.D. Dr. Meerleer obtained his M.D. degree in 1994 and his Ph.D. in Radiation Oncology in 2000, both from Ghent University, Belgium. He currently practices as radiation oncologist and Professor at Ghent University Hospital where he is responsible for the treatment of urological and gynecological malignancies. He has published extensively in radiotherapy, especially the use of IMRT for the treatment of prostate cancer. He is an active participant in ESTRO and is currently Director of the ESTRO multidisciplinary teaching course on prostate cancer.

FOR THE PROPOSITION: Stanley H. Benedict, Ph.D.

Opening statement

There are many options for the treatment of localized prostate cancer, and each has its own unique risks and benefits. For early stage prostate cancer, HIFU may be superior to radiation therapy—either external beam radiation therapy (EBRT) or brachytherapy (LDR or HDR). HIFU is a minimally invasive treatment option for prostate cancer that uses either a transrectal or transurethral applicator coupled with image guidance to focus high intensity ultrasound energy in the prostate.[1] At a very precise and targeted location identified using ultrasound or MRI guidance, the temperature is rapidly elevated to 55–70 °C; a lethal thermal dose which causes irreversible tissue destruction.[2] MRI coupled with HIFU provides precise image guidance for these procedures as well as near real-time temperature feedback via MR-thermometry,[3] making accurate destruction of prostate target tissue practical. Although HIFU remains investigational in the United States for prostate cancer, several thousand patients have been treated in trials outside of the United States.[4,5,6] Clinical HIFU protocols typically involve ablation of the entire prostate gland and are indicated especially for nonsurgical candidates such as elderly men who are unwilling or unable to undergo radical prostatectomy or receive radiation therapy for locally advanced or recurrent disease.[7]

HIFU has several practical benefits as compared to RT. While both are minimally invasive procedures, HIFU can deliver a treatment in a single session. The effects of HIFU are immediate; the targeted tissue is ablated with this technique. HIFU uses nonionizing ultrasound energy, which does not suffer from the same risk of late radiation effects as with ionizing beams; thus HIFU can be repeated if needed and can be combined with EBRT.[8] MR-guided HIFU provides the unique capability to perform temperature feedback and "dosimetry" *in situ* and imaging immediately postprocedure to verify treatment, thus providing confirmation of complete destruction of a defined target region.

The superior benefits of HIFU are demonstrated by the very promising reported outcomes in the studies performed outside the United States. These report excellent biochemical control and, while side-effects (urinary stricture, retention, incontinence, impotence) are reported, they are at a rate lower than for RT.[9,10,11,12,13,14] These early results, for mainly low- and intermediate-risk cancers (T1-T2 N0M0 disease, Gleason score of < 7, PSA level <15 ng/mL, and a prostate volume <40 mL),[12] and for outcomes without the long, widespread clinical adoption as compared to radiation therapy, have been acceptable, but would benefit from further confirmation in prospective multicenter trials, several of which are now underway.

HIFU also holds promise for focal ablation of defined regions of prostate cancer.[15] Focal use of HIFU should reduce the adverse sexual, urinary, and bowel effects of whole gland ablation. New techniques under development for MRI-guided HIFU treatment enable the integration of diagnosis, planning, and treatment of localized prostate cancer using MRI and could transform the management of this disease into a minimally invasive outpatient procedure with high precision and a low-level of side effects.

AGAINST THE PROPOSITION: Gert De Meerleer, M.D., Ph.D.

Opening statement

High-dose external beam radiotherapy has resulted in excellent biochemical control rates (BCRs) of >90% in low risk prostate cancer patients. A dose response relationship has been demonstrated in randomized phase III trials with a gain of 10%–20% when the dose was increased from 66 to 70 Gy to 74 to 78 Gy[16,17] or even higher.[18] When the supporters of HIFU state that it is as effective as EBRT, at least they should mention with which EBRT dose they are comparing their HIFU results. Moreover, there are no data to support such a statement and, any data there are, comes from a few research groups, making publication bias likely. Data on modern high-dose EBRT have been published by hundreds of research groups all over the world making the data concerning this treatment much more solid.

A recent publication in European Urology defined the evidence to use either Ablatherm or Sonablate HIFU as primary therapy for low risk disease as "very poor."[18] BCRs at 5 years ranged between 66%–77% (Ablatherm) and 45%–84% (Sonablate). Up to 66% of the patients received neoadjuvant androgen suppression and more than 2/3 of the patients underwent transurethral resection of the prostate (TURP),[19] two features that significantly influence post-treatment PSA values. Surprisingly, the need for recurrent HIFU treatment (up to four times!) was not considered as HIFU failure. Regardless, the BCR results obtained by HIFU are quite far from the 93%–98% achieved with modern high-dose EBRT and should be considered as inferior.[16,17,18]

Also, the HIFU toxicity profile does not make up for the difference in control rates. Bladder neck and urethral stricture and urinary incontinence have been reported in 2%–30% and 2%–34% respectively. Rectourethral fistulae have been reported in up to 3% of the cases. Rates for erectile dysfunction range from 20% to 50%.[19] Modern EBRT technology such as IMRT performs at least as well.[20,21] New generation HIFU devices have, however, been hypothesized to induce a more favorable toxicity profile.[12]

Only a randomized trial can compare HIFU with modern EBRT. Unfortunately, this is not likely to happen in the near future. Until then, HIFU should not be considered as a standard treatment for localized prostate cancer and can only be advocated within the framework of a well-conducted prospective study with a transparent description of the methodology (e.g., toxicity scale) and, most importantly, without violation of international standards. For example, androgen suppression has no place in the treatment of low risk disease and should be avoided.[22]

Rebuttal: Stanley H. Benedict, Ph.D.

Dr. De Meerleer correctly states that there have been too few clinical trials to provide "high quality" evidence to fully support the use of HIFU to treat prostate cancer—so we need them. Getting this evidence has been challenging for this emerging technology, particularly in an era where institutions have invested substantial resources and technology into IMRT, brachytherapy, and robotic surgery. Dr. De Meerleer correctly identified problems with the current literature such as the lack of proper trials which compare HIFU with "modern IMRT techniques," but there are also issues with determining if the latest image guidance and ultrasound devices have been used, which can reduce complications and ensure a thorough and complete treatment. In much of the literature cited by Dr. De Meerleer, ultrasound imaging was used to guide treatments, which has poor resolution of the prostate gland, and limited feedback of temperature rise and ablated tissue volume. Newer, MR-guided HIFU systems have emerged that provide superior imaging of soft tissue, are more reliable, and provide near real-time feedback of thermal effects and estimates of ablated tissue volume.

Another "problem" reported in the literature involves the delivery of multiple treatments with HIFU. However, while a single treatment is the ideal, the option to be able to provide multiple treatments could also be a beneficial feature of HIFU relative to RT.

In conclusion, I agree with Dr. De Meerleer that prospective randomized trials are the most effective way to answer questions about competing technologies for treating early stage prostate cancer. However, I also support our physician colleagues in their efforts to evaluate the rapidly evolving new technologies for image guided HIFU. Ultimately, with this preliminary work followed by well designed clinical trials, we will be able to determine the most appropriate use of HIFU in prostate cancer, as well as for other oncologic and pathologic conditions.

Rebuttal: Gert De Meerleer, M.D., Ph.D. top

I have read Dr. Benedict's opening statement with interest but certainly with a growing feeling of confidence in my position. The introduction focussing on technological aspects is interesting and I have nothing on which to comment. But the good part for me starts at the "results" section. He states that "The superior benefits of HIFU are demonstrated by the very promising reported outcomes…." In fact, the referred publications suggest the opposite. None of the published HIFU series can compete with the results achieved with modern external beam radiotherapy such as IMRT or modern brachytherapy. For example, for low-risk disease, the actuarial 5-year biochemical relapse-free survival (bRFS) in the cited references was 77% (Ref. 4) and 85%.[9] This contrasts sharply with the >90% obtained with IMRT[20] and brachytherapy.[23] For intermediate-risk disease, these data were 71% (Ref. 4) and 72%.[9] Again, these results do not rival the >90% bRFS obtained with IMRT[20] and brachytherapy.[23,24] With longer follow-up, IMRT still results in better bRFS.[25]

Dr. Benedict also states that urinary side-effects are less frequent than those reported with radiotherapy. One of his references,[4] however, shows that over 20% of the patients required TURP during follow-up, a number that is much higher than for IMRT and brachytherapy.[20,23,24,25] Moreover, he does not mention rectal toxicity, although up to 15% of patients might develop severe rectal toxicity after HIFU.[19]

It was probably not the aim of Dr. Benedict, but the references he cites provide a perfect "Counterpoint." The data provided clearly show that the Proposition for this debate is not supported by data at all. One should rather conclude the opposite. I do, however, agree with two points made by Dr. Benedict:

(a) Inclusion of patients in randomized controlled trials is the most valuable scientific way to go.

(b) Technological progress might improve the results.

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1.7. QA procedures in radiation therapy are outdated and negatively impact the reduction of errors

Howard Ira Amols and Eric E. Klein
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OVERVIEW

The design and maintenance of a comprehensive quality assurance program in radiation therapy is one of the most important roles played by radiation oncology physicists. It is claimed, however, that such programs are often outdated and may increase rather than decrease the risk of errors. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Howard I. Amols, Ph.D. Dr. Amols was awarded his Ph.D. in Physics by Brown University in 1974. He then became an NCI postdoctoral fellow at Los Alamos Laboratory and subsequently has held professional positions in therapy physics at the University of New Mexico, Brown and Columbia Universities. Since 1998, he has been Chief of the Clinical Physics Service at Memorial Sloan Kettering Cancer Center, where he directs the activities of about 50 other physicists. He is certified in Radiation Oncology Physics by the ABMP and is a Past President of the AAPM. He currently serves as a member of the AAPM Task Group No. 188 (Strengthening Medical Physics in Radiation Medicine).

Arguing against the Proposition is Eric E. Klein, Ph.D. Dr. Klein is Professor of Radiation Oncology at Washington University, where has been for 21 years. He has published over 80 papers, half as first author and many on quality assurance issues. He is certified by the ABR in Therapeutic Radiologic Physics. Dr. Klein is very active in the AAPM and ASTRO, previously serving as chair of AAPM's Quality Assurance and Outcome Improvement Subcommittee and TG-142 (Linear Accelerator Quality Assurance). He was called as an expert witness to a Congressional hearing on the use of radiation in medicine in 2010. Dr. Klein has been involved with CAMPEP's Residency Review Committee since 1995 and directs the longest standing accredited residency program.

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

Opening statement

Imagine if automobile maintenance was still performed as it was 25 years ago. Changing tires, spark plugs, and distributor points every 10 000 miles, repainting rusty chassis, and adding water to the battery weekly. Starting your car on a cold morning means "adjusting the choke," pumping the gas before turning on the ignition, and idling for 10 min before shifting into gear. We'd be pumping the brakes and spinning steering wheels whenever we went into a skid. But nobody does this anymore because it isn't necessary. Cars are built better and have different maintenance problems. Taking your car into the shop now usually means replacing a computer chip or sensor that didn't exist 25 years ago.

Linacs also are built better than they were 25 years ago, but we haven't changed our QA procedures accordingly. We still routinely check "cGy/mu," isocenter accuracy, laser drift, etc. Sure, we've added new QA procedures for modern accessories (EPIDs, MLCs, CBCT, etc.), but we never subtract. We never redesign the process to reflect the characteristics of modern equipment. We just increase the workload. How many patients have been mistreated recently because a laser drifted or a linac dose rate changed between Monday and Tuesday? None!

Big mistakes today usually result from:

1. Mistakes made during commissioning: Wrong dosimeter to calibrate a stereotactic radiosurgery (SRS) beam; corrupted computer file or software bug; not understanding a "hidden equation" underlying an Excel spread sheet, or the data format required for a computer program.

2. Being rushed or complacent and not following existing procedures.

Outdated QA procedures are fixated on 1–2% or mm drifts in things that rarely drift anymore. Why not spend less time testing "outdated" things and more time testing things that have been injuring patients recently?

The "name of the game" for new technology is acceptance testing, accuracy, commissioning, interconnectivity, and training; yet outdated QA procedures focus on labor-intensive measurements of precision. Case in point: the SRS beam that was miscalibrated because an inappropriate dosimeter was used to calibrate the small fields. I suspect that daily, monthly, etc., checks of linac output, etc. were precise and in compliance with recommended QA procedures, but the equipment was miscalibrated from day one, and no one checked accuracy (e.g., did an external audit).

At my own institution, like most others, we used to check laser alignment for every SRS patient. Recently, however, we changed our procedures and patient setup is now adjusted and confirmed using CBCT. Further, our new linac has isocentric accuracy ("star shots" geometric/mechanical measurements, etc.) of <0.5 mm. So why care if the lasers are properly aligned? Why waste time checking this when mistreatment of SRS patients is now more likely to result from computer errors?

Space does not permit a detailed listing of QA report recommendations that should no longer top the list of everyday checks, but, hopefully, I have made my point. Let us eliminate some "historical" QA tests to reflect the quantum changes in equipment design and focus more on QA tests that are more likely to prevent "modern" treatment errors.

AGAINST THE PROPOSITION: Eric E. Klein, Ph.D.

Opening statement

Three Mile Island, Chernobyl, Fukushima. Names synonymous with nuclear power plant catastrophes. Riverside OH, Tyler TX, Indiana PA, Cleveland (Plain Dealer), Epinol, Panama, Glasgow, Zarragosa, New York (Times),[1] etc. Names synonymous with radiotherapy events for which patients were either injured or killed. Events for which QA procedures were not followed. Perhaps QA procedures are outdated, but they are not negatively impacting error reduction. In fact, they are still preventing catastrophic errors.

Somehow, with limited resources, physicists must maintain current procedures while embracing a paradigm shift prioritizing error reduction.[2] The AAPM TG-142 report[3] accomplishes this by suggesting tests with more frequency and scrutiny for greater risk procedures (IMRT, SBRT), and less frequency for mundane tests that are benign with regard to error impact. Simultaneously, the long awaited AAPM TG-100 report[4] will guide the physicist on how to develop QA programs using failure mode and effects analysis (FMEA). This is not an easy task. TG-100 was constituted in 2004 and has yet to produce a final report. Ford et al. published an FMEA based manuscript[5] describing analysis of the 269 steps of taking a patient from consult to treatment. This was an expansive undertaking involving consultants. There is an effort to analyze the impact of human factors and culture on errors and error reduction, with training available through workshops and annual meetings. But no matter what strides are made, vendors will continue to sell complex equipment to facilities with understaffed and/or undertrained physics personnel. Engineers will continue to adjust machinery without involving physicists for proper review. And software will still be written that is not robust enough to prevent unforeseen user misappropriation. It is no wonder that of the top ten worst software bugs ever reported, two involved radiotherapy.[6]

An example for which a procedural upheaval is immediately needed is IMRT QA. Every evening around the country, thousands of physicists (or QA technicians, residents, fellows, students) perform time-consuming measurements to validate that the correct dose is being delivered to a "box," a poor surrogate for the actual patient. In terms of prioritization, physicists should be spending time performing on-screen plan reviews to unmask potential problems that would go undetected with simplistic phantom QA. This includes incorrect image fusion, erroneous hot spots, improper beamlet segmentation, etc. These problems could still go undetected with alternative QA techniques such as independent Monte Carlo calculations or leaf position-timing analysis.

Which brings up a final point vital to existing and future quality assurance procedures training. Physics residency programs, which are growing rapidly in number, must include teaching of human engineering and process analysis, beam modeling and critical review of treatment plans and, despite how outdated they may seem, routine quality assurance of imaging, planning, and delivery systems.

Rebuttal: Howard Ira Amols, Ph.D.

Dr. Klein agrees that "QA procedures are outdated" but asserts "they are not negatively impacting error reduction." Wrong! If they are outdated then doing them wastes time. Every minute wasted means something more important either doesn't get done on time, or is rushed by the now overworked physicist, increasing the chances of a serious mistake.

Dr. Klein and I do agree that QA tests need to be prioritized such that "mundane tests" (his words) with low error impact should be done less frequently, while high error impact tests should be done more frequently.

We also agree that medical physics training programs must do a better job teaching QA. I would include courses on the history of medical physics disasters. Dr. Klein, for example, refers to "Riverside, Tyler, Glasgow, etc." How many new medical physicists even know what he is referring to (i.e., sites where horrific medical physics errors occurred)? Physicists must truly understand the consequences of their mistakes.

I am also concerned that QA has become a cookbook kind of exercise. Do whatever it says in TG-51: put a lead sheet in the beam, get k_Q from Table I, etc. Don't think about it, just follow the directions! Cookbooks tell you how to make a soufflé or calibrate a linac, but they don't tell you how to not mess up. And that is what physicists are supposed to know. We are teaching people how, but not why, and there is an old expression: "the person who knows how will always be working for the person who knows why."

A physicist who knows *why* QA tests are done and *how* equipment really functions, will also know when those tests are no longer necessary and, more importantly, what can go wrong and how to prevent it.

Finally, antiquated QA manuals "advising" us to make unnecessary tests are misinterpreted by regulatory agencies that then turn them into laws. Let's get these counterproductive anachronisms off the books!

Rebuttal: Eric E. Klein, Ph.D.

I agree with Dr. Amols that mundane non-beneficial quality assurance procedures must be reduced. TG142 promotes that concept and TG100 will soon enable physicists to accomplish this.

Regarding the fact that linear accelerators are built better than they were 25 years ago, this is obvious. However, not all facilities possess new machinery. Some accelerators are old and/or not maintained well. Some hospitals are buying new machines for purposes of competition, without having proper maintenance in place or, more importantly, trained physicists with sufficient time to do the necessary quality assurance or implement new available procedures. As new ancillary devices are being added to

accelerators, I concur that the workload has increased. But if there are not enough physics FTEs allocated for this new complex machinery, isn't the increased workload a battle to be negotiated with administration. We have to remember that staffing levels and tools available at a large academic center are much more comprehensive in number and versatility compared to a small practice with a solo physicist.

If we can't win the battle to have the appropriate number of physics FTEs in place, then how can we maintain safety? I agree that QA of improperly commissioned planning and delivery systems is worthless. Perhaps manufacturers should be required to supply an expert to work with the local physicist to perform end-to-end tests as part of final commissioning. This is especially important for the imaging aspects of localization devices which tend to be technologically more volatile.

As mentioned in my opening statement, routine quality assurance procedures would have stopped most of the horrific events that have happened in radiation therapy. Allocation of time to simply check output and flatness (sensitive indicator of energy) and a sliding window DMLC or SMLC output check is time well invested each day.

Finally, as I own a hybrid car made by a Toyota based company, I somehow can't help routinely checking the brakes and floor mat placement.

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1.8. Vendor provided machine data should never be used as a substitute for fully commissioning a linear accelerator

Indra J. Das and Christopher F. Njeh
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OVERVIEW

Measurement of beam distributions on a new linear accelerator during the commissioning process is one of the most time-consuming and error-prone activities in radiation oncology physics. Linear accelerator vendors do provide beam distribution data to their customers but most physicists use these as guidelines and prefer to do their own extensive measurements. It has been suggested that the vendor provided data are not accurate enough for clinical use and should not be considered a viable alternative to collection of a complete set of measurements during the commissioning of the linear accelerator. This is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Indra J. Das, Ph.D. Dr. Das obtained his Ph.D. in Biophysical Science from the University of Minnesota, Minneapolis in 1987. He subsequently held academic appointments in the University of Massachusetts Medical Center, Worcester, and Fox Chase Cancer Center and the University of Pennsylvania Medical School, both in Philadelphia. He currently is Vice-Chair, Professor and Director of Medical Physics in the Department of Radiation Oncology, Indiana University School of Medicine, Indianapolis. He is Board certified by the ABR and the ABMP and is a Fellow of several societies, including the AAPM, the ACR, ASTRO, and the ACMP. He has actively served on numerous committees of several organizations including, in the AAPM, Chair of TG-106 (beam data commissioning), and TG-155 (small field and nonequilibrium photon beam dosimetry). He has served on the Editorial Board of *Medical Physics* and the AAPM Board of Directors, and has published over 150 scientific papers and book chapters.

Arguing against the Proposition is Christopher F. Njeh, Ph.D. Dr. Njeh obtained his Ph.D. degree in Medical Physics from Sheffield Hallam University, UK and, after graduation, he worked at the Addenbrooke's Hospital in Cambridge and Queen Elizabeth's Hospital, Birmingham, UK. He then came to the USA as a Visiting Postdoctoral Fellow at the University of California, San Francisco where he was subsequently appointed an Assistant Professor of Radiology. He later completed a Medical Physics residency at Johns Hopkins University, Baltimore and is currently Chief Medical Physicist at Texas Oncology in Tyler, TX. Dr. Njeh is certified in Therapeutic Radiologic Physics by the ABR. His major research interests include image-guided radiation therapy and accelerated partial breast irradiation. He is author or co-author of over 50 papers and 10 book chapters, and is co-editor of two books.

FOR THE PROPOSITION: Indra J. Das, Ph.D.

Opening Statement

Linear accelerator technology has improved significantly over the past sixty years providing reliable, reproducible and accurate beams for clinical use. Vendors have attempted to standardize machines of the same vintage with similar characteristics. However, accelerators may not have identical beam parameters due to inherent problems in manufacturing design and complexity of wave guide, bending magnet, focusing magnet, target design, flattening filter or scattering foil, ion chamber, collimator, and multileaf collimator or cone used in photon and electron beams.

The beam characteristics of an accelerator are dependent on the energy spectrum that can be modeled through Monte Carlo simulation[1] or measurement[2] but could be significantly different between machines due to even the slightest variations in design or assembly. Additionally, they can be altered during installation and beam tuning in order to match existing beams, and this might make the vendor provided beam data no longer appropriate.

Radiation dose distributions depend on beam energy and associated radiological parameters.[3] Clinically, beam characteristics are measured in terms of central axis depth dose, and diagonal and off-axis profiles at various depths which, together, make a 3D data set for treatment. Das et al.[4] provided rationale and processes for beam data commissioning. Hrbacek et al.[5] provided a tool using the gamma index for beam matching and showed that even if one matches the central axis beam data, the off-axis data might still be significantly different. A slight change in the composition of the target material, the position of the flattening filter, or the electron beam direction, can change beam characteristics significantly. Such changes will only be detected if the beam data is commissioned properly.[4]

Beam characteristics of small photon fields ($<4 \times 4$ cm^2) that are used in IMRT and SRS have large variations in depth dose, profiles, and output factors. These factors are dependent on machine, electron source size and detector.[6] The source size of an accelerator has significant impact on the dosimetry, and this varies between machines. Small changes in collimator or multileaf design also alter the dosimetric parameters.[7,8] Changes as small as 0.3 mm in leaf gap are shown to significantly impact IMRT plans.[7] In addition, any changes in jaw position and speed during installation could affect the beam characteristics of a virtual or dynamic wedge.

Electron beam characteristics are sensitive to even the slightest variation in bending magnet, scattering foil, and cone design. Two machines of the same model/configuration may not be identical in terms of beam profiles, depth dose, and the virtual source position. These parameters get magnified for small and/or irregular electron fields that are used frequently.

The basic question one can ask is what is an acceptable limit of tolerance, ±0.5, ±1.0, ±2.0, or ±5%? It is a common conviction that precision in treatment requires the beam data to be within ±1% and this cannot be met with vendor provided machine data. Depending on the extent of differences between vendor and commissioned data catastrophic radiation incidents may not be far-fetched. Hence, vendor provided machine data should never be used as a substitute for fully commissioned beam data.

AGAINST THE PROPOSITION: Christopher F. Njeh, Ph.D.

Opening Statement

High tumor control rates can only be achieved if the dose can be delivered to the patient within a narrow tolerance range.[9] For example, a 5% difference in the delivered dose may result in changes in the order of 10%–20% in tumor control probability and 20%–30% in normal tissue complication probability.[10] ICRU Report 24 (Ref. 11) recommends an accuracy level of 95% and this imposes narrow tolerance limits on every step in the radiation treatment chain from beam data collection to dose delivery. Radiation therapy is a complex process with numerous potential sources of error[12] and efforts must therefore be made to reduce the uncertainties. Machine data collection and commissioning potentially present significant sources of error. More importantly, such errors are systematic and impact all patients and I believe this task should be left to the vendor for several reasons.

First, the process of commissioning a linear accelerator requires, among other tasks, the acquisition and processing of a significantly large amount of machine beam data.[4] The number of measurements involved is so large that the entire process is considered to be one of the most complex and error-prone in radiation oncology today.[13] The need for high accuracy in data collection can never be overstated. In most cases, beam data collected during commissioning a linear accelerator are treated as reference and

performed only once in the lifetime of the machine. A credentialing study conducted by the Radiological Physics Center (RPC) found an alarming number of institutions (30%) failing to pass clinically acceptable tolerance limits of 7% dose or 4 mm distance to agreement in their phantom irradiations. Incorrect output factors and percentage depth doses were identified as some of the causes of failure.[14] Several recent reports of radiation incidents have been associated with commissioning errors.

Secondly, studies have demonstrated the equivalence of either locally collected data to vendor provided beam data, or data for machines of the same models.[15,16,17,18] Cho et al.[16] from the RPC, for example, measured data on over 50 Varian Clinac 2100 units and found that all dosimetric data were within the clinically acceptable range of less than 1%. They also found acceptable agreement with the vendor machine data. Sjostrom et al.[19] studied the characteristics of eight Varian iX accelerators with 6 and 15 MV photon beams and 6–18 MeV electrons and concluded that all photon and electron beams, except the 15 MV photon beam from two accelerators, could be represented by one set of data.

Beam data collection plays a critical role in accurate radiation dose delivery and tumor control. I therefore submit that, in order to minimize errors in the process, such responsibility should be left to the vendor.

Rebuttal: Indra J. Das, Ph.D.

Dr. Njeh and I agree completely in terms of accuracy needed for patient care but differ significantly in terms of implementation. The responsibilities of a physicist are to provide expertise in every aspect of the clinical practice i.e. commissioning, calibration, quality assurance (QA), treatment planning, and advice for accurate and safe radiation dose delivery to patients.

WHO (Ref. 19) reported 3125 radiation incidences collected during 1976–2007 where 56, 24, 11, and 9% of the errors were found to be in the treatment planning, beam data commissioning, treatment delivery, and data transfer, respectively. Commissioning amounts to 24% of the incidences and that is why TG-106 (Ref. 4) was created to provide guidelines to clinical physicists. Very similar to the Finnish data,[17] the Radiological Physics Center (RPC) (Ref. 20) also showed that nearly half of the centers did not meet the absolute machine calibration (error up to 8%). In view of such findings, should we outsource our machine calibrations to the RPC or a national laboratory, machine mechanical QA to our engineers, and treatment planning and beam data commissioning to specific vendors? How do we know that the outsourced data are accurate?

It should be pointed out that incident No. 25 reported by the IAEA (Ref. 21) showed that the manufacturer-provided depth dose data for an institution had an 8% error when compared to the in-house physicist's measured data that was verified independently by an outside physicist. We cannot allow our job and responsibilities to be outsourced to a vendor. As pointed out by Rogers et al.,[22] we do not want to turn ourselves into technologists lest we lose our existence. We must use our intelligence and derive pride in being a critical health care partner to perform every task needed for safe and accurate dose delivery. We should never compromise quality by outsourcing our critical work.

Rebuttal: Christopher F. Njeh, Ph.D.

Professor Das has presented reasons why each machine should be independently commissioned. However, I put forward the following counter arguments.

- As Professor Das stated, linear accelerators have improved significantly over the years. It is reasonable to assume, therefore, that each of these modern machines could be reliably characterized by a set of beam data.[16,17,18]
- Variability of beam data due to changes in machine characteristics such as target design, flattening filters, etc., is about the same as the precision that can be expected of data measurements. For example, Watts[18] found the variation in relative output factors and depth doses between six machines to be less than 0.2 and 0.4%, respectively, which is similar to beam data measurement precision of 0.2%.

- Variations in reported measured output data for small fields are mostly attributed to measurement errors such as using a Farmer chamber instead of a pinpoint chamber or diode, rather than variations in true machine characteristics.
- In-house physicists will still need to check the golden data against measurements for installed machines, especially for those situations with the highest potential for variation between machines such as small fields and off-axis dose profiles.
- Machine data is only clinically useful when used to model the beam in treatment planning software; hence, the physicist's time could be better spent validating the modeling of the machine data. For example, Keall et al.[23] showed that golden data was sufficiently accurate for the determination of incident electron fluence for Monte Carlo treatment planning.
- Misadministrations, sentinel events or catastrophic radiation events are more likely to occur when machine data are collected by the in-house physicist than using the vendor provided data, because the true variation between machines is less than 1%, whereas inaccurately measured output factors, for example, could be more than 10% in error.[24]
- In conclusion, it is accepted that two linear accelerators cannot be truly identical. However, within the limits of experimental error of less than 1%, vendor-provided (golden) machine data should be acceptable as a substitute for in-house physicist collected data.

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1.9. The traditional L-shaped gantry for radiotherapy linear accelerators will soon become obsolete

Joseph Stancanello and Fang-Fang Yin
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OVERVIEW

With the advent of new technologies such as TomoTherapy, the GammaKnife, and the CyberKnife, radiotherapy treatment machines are beginning to look a lot different from the traditional L-shaped design of linear accelerators that we have used for the past 40 years or so. This has led some to suggest that the L-shaped gantry for linear accelerators will soon become obsolete, and this is the Proposition debated in this month's Point/Counterpoint

Arguing for the Proposition is Joseph Stancanello, Ph.D. Dr. Stancanello graduated with Ph.D. and Executive MBA degrees from Politecnico di Milano-School of Management, Italy, in the field of radiation oncology. He is currently specializing in driving strategic innovation at International Institute for Management Development in Lausanne, Switzerland. He has taught mathematical analysis at Padova University, Italy, and worked in the Medical Physics Department at Vicenza Hospital, and at Bracco Imaging. His scientific interests cover diagnostic and therapy areas and his managerial interests are in competitive advantage and strategic innovation. He is currently managing Europe, the Middle East, and Africa strategy and collaborative research for Siemens Healthcare Oncology.

Arguing against the Proposition is Fang-Fang Yin, Ph.D. Dr. Yin obtained his Ph.D. in Medical Physics from the University of Chicago and is currently Director of Radiation Physics and Professor of Radiation Oncology at Duke University Medical Center. He is certified in Therapeutic Radiological Physics by the American Board of Radiology and his major research interests are imaging in radiation therapy, intensity-modulated radiation therapy, image-guided radiation therapy, treatment planning optimization, management of organ motion, and stereotactic brain and body radiosurgery/radiotherapy.

FOR THE PROPOSITION: Joseph Stancanello, Ph.D.

Opening Statement

The linear accelerator (linac) had become firmly established as a radiotherapy tool by the late 1970s (Ref. 1) and, since then, the L-shape geometry of treatment machines has become the most prevalent design. Since the mid-1980s, linacs have made up over 90% of all new machine installations in the U.S.[2] Hence, the L-shape design has been the dominant linac geometry for the past three decades, with little in the way of radical change occurring during this time.[1] In the modern era of radiotherapy, improvements in treatment quality, safety, and efficiency, calling for stronger integration of treatment delivery and imaging systems into high-degrees-of-freedom platforms, have threatened to bring this dominant L-shape geometry of linac design into question.[3]

Let us look at the long-standing dominance of the current linac design. Reasons why we might soon see the emergence of a new dominant design include the long intergeneration time (three decades) and the presence of alternative (disruptive) technologies. As to the first, our situation is comparable to the platform lifetimes observed in a commodity sector like the steelmaking industry,[4] where inertia to innovation is expected to be even greater than in healthcare. This intergeneration time is one of the longest historically reported.[4] Also, one important and pertinent principle is: The longer the intergeneration time, the smoother the transition to the next dominant design.[5] As to the second, the

presence of disruptive technologies could support a platform change:[6] Co-60 source based designs, for example, would have appeared outdated a few years ago, but are being re-evaluated with the ViewRay Renaissance machine (ViewRay Inc., Oakwood Village, OH) due to the advantages offered when used in conjunction with real-time MR imaging, proposing a geometry concept different from the current dominant design.

In recent years, we have seen many innovative radiotherapy treatment solutions come to the market, such as the CyberKnife, TomoTherapy, and the Mitsubishi MHI-TM2000 design (Mitsubishi Heavy Industries Ltd., Nagoya, Japan), while others such as the MR-linac[7] and the Renaissance are nearing commercial release. Each novel design brings unique advantages and disadvantages, but what is more interesting for this discussion is how these solutions may represent the frontier of a new dominant linac geometry. Let us assume that, like other technologies, the progress of linac development follows an S-curve.[8] It demonstrates a slow initial growth phase as the technological difficulties are addressed, followed by a steep growth period, culminating in a saturation point as existing design factors constrain further development. It could be argued that after 30 years, linac design is nearing the saturation point, and is under threat from designs new and old. In the current era of ferment the aforementioned examples suggest that we critically review the current design.

In conclusion, we are ready for a "paradigm shift" such that we will soon see the evolutionary or revolutionary establishment of a new geometry in radiotherapy.

AGAINST THE PROPOSITION: Fang-Fang Yin, Ph.D.

Opening Statement

The goal of radiation therapy is to deliver a prescribed radiation dose conformal to the treatment target while minimizing dose to the surrounding normal tissues and critical organs. The radiation delivery method plays a critical role in achieving this goal. Currently, external beam radiation is primarily administered through the use of delivery technologies with L-shaped gantries. However, a growing number of patients are being treated with technologies using (1) ring-shaped gantry (i.e., TomoTherapy); (2) a robotic head or gantry (i.e., the CyberKnife); or (3) multiple Co-60 sources (i.e., the GammaKnife). In addition to clinical judgment, many technical factors play important roles in selecting the most suitable technique for each patient, including flexibility of patient immobilization, options for target localization and monitoring, strategy and sophistication of planning, and options for treatment delivery and verification.

Regarding immobilization, both the robotic and L-shaped gantries offer a larger range of options compared to the ring-shaped gantry, largely due to their open geometry design. The L-shaped gantry offers a variety of target localization and monitoring options. Current imaging capabilities include 2D, 3D, fluoroscopy, and 4D, as well as real-time monitoring with imaging and tracking techniques.[9,10] In terms of delivery options, the L-shaped gantry allows multiple high energy photon and electron beams, and a wide variety of treatment techniques such as 2D, 3DCRT, volumetric static or rotational IMRT, TBI, TSI, gated delivery, delivery with coplanar and noncoplanar beams, fixed gantry angle, conic arcs, and dynamic conformal arcs with MLC.[9,10,11,12] Many studies have shown that the noncoplanar beam approach has advantages over a coplanar approach in treatment planning of complex targets.[13,14,15,16,17] The flexibility of an L-shaped gantry allows more versatile treatment delivery than with other technologies. In terms of treatment verification, both kV and MV in-room imaging systems have been integrated into L-shaped gantry systems for target localization. Any technique used by other approaches could also be used in L-shaped gantry machines. There is no evidence that any disease which is treated with other technologies could not be treated with L-shaped gantry machines. The delivery efficiency of the L-shaped machine is achieved by its cone beam and a dose rate currently up to 1000 MU/min. Furthermore, the L-shaped gantry is the most efficient method for delivery of simple treatments, such as

two opposed fields. Complex treatments can be delivered efficiently by simultaneously varying gantry speed, dose rate, and leaf speed with stable dose output for a long delivery time.

Delivery systems with the ring-shaped gantry, the robotic head or gantry and multiple Co-60 sources have many unique features for treatment of some specific disease sites. However, the L-shaped gantry machines are more favorable compared to other delivery systems considering multiple factors such as treatment flexibility and versatility, integration of imaging and delivery, treatment accuracy, dose conformity, delivery efficiency, safety, operational costs, and purchase expense. For these reasons, the well-established delivery technology with L-shaped gantries will not soon become obsolete.

Rebuttal: Joseph Stancanello, Ph.D.

Each innovative solution has advantages and disadvantages. However, the point is whether these solutions represent a presage of a new dominant geometry. Dr. Yin is correct in his evaluation from a static perspective of clinical practice, but applying a dynamic view, i.e., looking at current trends in radiotherapy, many advantages of the L-shape will be dramatically reduced. Following are a few examples. Immobilization will play a lesser role in the future due to the current trend toward frameless applications. All the current imaging capabilities highlighted by Dr. Yin have already been implemented in the innovative non-L-shaped solutions. Although the use of multiple energies is beneficial for deeply seated tumors, the possibility of focusing beams from many angles has demonstrated the feasibility of using just 6 MV instead. Regarding the noncoplanar beam approach, current innovative designs already allow for this possibility. Also, the articles cited by Dr. Yin illustrate the advantages of noncoplanar arrangements with respect to the current dominating design while the comparison should be drawn against new innovative solutions. MV and kV imaging are already easy to integrate into new innovative geometries. Some new solutions are already equipped with dose rates of 800 MU/min, and technology is likely to enable them to be used at dose rates even higher in the near future, as envisioned by Dr. Yin for the L-shaped design.

The innovative treatment solutions make claims of significant improvements in key areas such as conformality and motion management. In response, the current linac design has been extended to introduce technologies such as VMAT and MLC-based tracking. The overall result will be to stretch the performance of the dominant design so that the “physiological” leap to a new one will be accelerated. Instead of linac development following a single S-curve,[18] one may witness an evolutionary division yielding multiple S-curves, one for innovative designs based on the L-shaped linac geometry, and others representing the emerging solutions, where the shift in paradigm may bring a faster pace of innovation culminating in a platform change.

Rebuttal: Fang-Fang Yin, Ph.D.

Dr. Stancanello lists two reasons for the possible replacement of the L-shaped gantry design: Long intergeneration time (three decades) and the presence of alternative (disruptive) technologies. While long intergeneration time may not be typical for healthcare technologies, there is no evidence to suggest that intergeneration time is necessarily indicative of outdated system configurations. For example, CT configuration has been ring-shaped for four decades, but that is not under question. Furthermore, the L-shaped gantry design has not prevented the development of new technologies to improve cancer treatment. The developments of MLC-based static gantry intensity-modulated radiation therapy, rotational and volumetric modulated radiation therapy, cone beam CT-based image-guided radiation therapy, and 4D gated radiation therapy, were all based on the L-shaped gantry design. MR and PET imaging technologies could also be integrated with L-shaped linac gantries similar to CT-on-rails technology. As I mentioned in my opening statement, emerging treatment machines other than L-shaped gantries often have some unique features for the treatment of specific disease sites. However, there are no indications that one or more of the emerging system designs will establish dominance over the L-shaped gantry design considering its flexibility, versatility, accuracy, conformity, efficiency, safety, cost,

and the ease with which imaging and other accessory systems can be integrated. Nevertheless, with continuing technological advancements, the differences among various technologies may be narrowed as one system may adopt advanced features from others. It is, however, premature to hypothesize that the L-shaped gantry design will soon become obsolete.

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CHAPTER 2

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

2.1. Helical tomotherapy will ultimately replace linear accelerator based IMRT as the best way to deliver conformal radiotherapy

Tewfik Bichay and Daliang Cao
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OVERVIEW

It is rare for a concept conceived, developed, and brought to the clinic by medical physicists, to cause the excitement that has been created by the tomotherapy machine. Many physicists and radiation oncologists are convinced that helical tomotherapy is the be-all and end-all of intensity modulated radiation therapy (IMRT) delivery systems. However, manufacturers of conventional linear accelerators have not stood still and many of them are developing cone-beam CT and intensity modulated arc therapy capabilities for their linear accelerators which, they claim, will provide the ability to deliver IMRT treatments with versatility and verifiability comparable to those achieved with tomotherapy. The premise that helical tomotherapy will ultimately prove to be the best way to deliver IMRT is the claim debated in this month's Point/Counterpoint.

Arguing for the proposition is Tewfik Bichay, Ph.D. Dr. Bichay obtained his B.Sc. degree in Human Physiology from McGill University, Montreal, his M.Sc. in Radiation Biology from Concordia University, Montreal, and his Ph.D. in Medical Biophysics from the University of Western Ontario, London, Canada. He is currently Director of Medical Physics, Radiation Oncology, The Lacks Cancer Center at St. Mary's Health Care, Grand Rapids, MI. He started his career as a radiation biologist before transitioning into medical physics with a residency at the Ottawa Regional Cancer Center. He is certified in Radiation Oncology Physics by the ABMP and his present research interests center around applications of the tomotherapy system and improvement in treatment accuracy with image guided radiation therapy (IGRT).

Arguing against the proposition is Daliang Cao, Ph.D. Dr. Cao received his B.S. degree in Physics in 1997 from the University of Science and Technology of China, and his Ph.D. degree in Physics in 2002 from the University of California, Santa Cruz. He started his training in medical physics at the University of Maryland, Baltimore after a 2-year postdoctoral fellowship at Los Alamos National Laboratory. He is currently working as a medical physicist at the Swedish Cancer Institute in Seattle. His research interests include optimization, intensity modulated arc therapy, image-guided radiotherapy, 4D planning, and adaptive radiotherapy.

FOR THE PROPOSITION: Tewfik Bichay, Ph.D.

Opening Statement

The introduction of IMRT in the clinic has significantly improved the ability to deliver a highly conformal radiation dose distribution to a complex target while minimizing collateral damage to neighboring tissues. IGRT moves this process ahead by precisely locating a highly conformal dose distribution with daily verification and with the potential for daily correction.

There are four key elements of highly accurate IGRT and IMRT: stability of the imaging system, number of available beam directions, dynamic range of intensities, and position verification. The more stable the system, the sharper the images and the more accurate beam placement can be. To enhance physical stability many imaging systems have taken on a ring gantry doughnut shape, for example CT units, PET, MRI, gamma cameras, etc. The ring gantry of a tomotherapy unit exploits this structural stability resulting in an isocentric imprecision of 0.2 mm, five- to tenfold better than typical arm-gantry systems.

It is well recognized that increasing the number of fields can improve the overall dose conformality.[1] In typical arm gantry-based IMRT, selection of the most effective gantry angles may not be obvious. This can result in the loss of useful directions prior to the initiation of optimization. In tomotherapy IMRT, the optimizer has full access to 360 deg of rotation.

One of the weaknesses of multileaf collimators (MLCs) is that most of them are motorized, which makes them prone to motor breakdown, positional inaccuracies, and velocity fluctuations. This can lead to significant dose errors.[2,3] However, binary MLCs, such as the 40-leaf MIMiC system of North American Scientific and the 64-leaf system of tomotherapy, are inherently much more reliable since the sensors need to read only in open or closed positions.[4] In addition, the MLC motion is extremely rapid, opening and closing within 20 ms, and the dwell time at each position can be automatically varied from 1 to 400 ms.[5] The combination of number of ports, gantry directions, and dwell times yields substantial flexibility in generating an optimized field map. This allows an almost infinite dynamic range of intensities, not only for every angle, but also for every point in the target volume from that angle. IMRT without a wide dynamic range of intensities will always be inferior.

The maximum field size for typical accelerators without the need for junctions is less than 40×40 cm^2. Larger fields for IMRT require complex junctioning and/or extended SSD whereas, with tomotherapy, fields of up to 160 cm in length can be treated without the need for junctions. In fact, several centers are using tomotherapy for total marrow irradiation.[6]

The imaging chain of tomotherapy allows a full 38 cm diameter imaging ring. The detector serves a dual purpose in that, besides imaging and patient positioning, the 511 xenon ion chambers can also be used to obtain quantitative dose values, allowing the delivery to be validated. Reconstruction of the actual dose can then be calculated on the acquired 3D CT data set.

Given the superior design of the imaging/delivery hardware, the construction of the MLC, and the integrated design, it is clear that the tomotherapy approach to IMRT will lead the way to the future.

AGAINST THE PROPOSITION: Daliang Cao, Ph.D.

Opening Statement

Helical tomotherapy[7,8] is an excellent modality for both IMRT and IGRT. It is unlikely, however, that tomotherapy will ultimately replace conventional linear accelerator based IMRT as the best way to deliver conformal radiotherapy. Using cone-beam CT and arc-based IMRT, conventional linear accelerators can match tomotherapy in terms of both IGRT and IMRT capabilities. Additionally, linear accelerators provide more flexibility than is available with tomotherapy.

A key feature of the helical tomotherapy system is its ability to deliver highly conformal treatments. For many treatment sites such as the prostate, however, it is unlikely that further clinical benefits will be realized by increasing the number of beam angles beyond a traditional static-field IMRT plan. Additionally, rotational IMRT will soon be offered as an option on conventional linear accelerators. In fact, at least two manufacturers of linear accelerators have announced plans to offer the control systems capable of delivering intensity modulated arc therapy (IMAT). IMAT is a delivery technique whereby the leaves of the conventional multileaf collimator are in motion and the dose rate is varied while the beam rotates around the patient.[9]

New inverse planning algorithms have also been developed that make it possible to take full advantage of the IMAT delivery technique.[10] A recently published study reported on a comparison of tomotherapy and IMAT treatment plans for ten patients.[11] The results demonstrated that IMAT can typically provide treatment plans comparable to those for tomotherapy. In addition, IMAT has the advantage of delivering noncoplanar arcs (an option not available with tomotherapy). For some intracranial and head-and-neck tumors, the use of noncoplanar arcs can provide significant dosimetric benefits due to preferential sparing of adjacent sensitive structures.[11] Noncoplanar delivery is of particular importance in stereotactic radiosurgery/radiotherapy.

IGRT solutions are available for both tomotherapy and conventional linear accelerators. Tomotherapy provides megavoltage fan-beam CT scanning while conventional linear accelerators can provide kilovoltage cone-beam CT. The fan-beam approach used by tomotherapy has improved scatter rejection that reduces image noise. The use of kilovoltage imaging in most linacs, however, is advantageous because the lower beam energy results in improved soft tissue contrast. Studies have shown that both imaging techniques provide images that are sufficient for verification of patient setup.[12,13]

Finally, tomotherapy systems are dedicated specifically to IMRT and IGRT and cannot match the versatility of a linear accelerator. For some patients, the delivery of three-dimensional conformal treatments on a linear accelerator provides a more efficient solution than is available with tomotherapy. Linear accelerators also provide the ability to deliver electron fields. For many superficial targets, the use of electrons from a linear accelerator is clearly a better choice for its simplicity of dose delivery as well as its higher skin dose and sharper dose fall-off beyond the target.

For the ability to deliver a wide range of treatments ranging from palliation to the most complex IMRT plans, linear accelerators will continue to provide the most efficient and flexible solution.

Rebuttal: Tewfik Bichay, Ph.D.

Many studies have shown that adding beam angles greatly improves dose distributions in IMRT.[1] In fact, as Dr. Cao points out, manufacturers of conventional accelerators are increasing the number of beam angles by developing IMAT. However, IMAT is limited by the number of monitor units used, typically 500–700 MU, resulting in very poor modulation.[10] Some simple mathematics demonstrates the limitations of a motorized leaf in IMAT delivery. In a typical 7° arc of 1.17 s, the leaves can move no more than 2.3 cm; at best a modulation factor of 2, or about 50-fold less than the comparable modulation factor in tomotherapy. This challenges the recent results of Cao *et al.*[11] claiming dose distributions equivalent to those with tomotherapy.

My colleague is correct in that noncoplanar arcs are not possible in tomotherapy. However, the availability of hundreds of thousands of beamlets can overcome much of this limitation even in very complex targets adjacent to sensitive structures.[14] There is also the considerable potential for radiobiological gain. In tomotherapy every cell receives its full complement of dose in less than a minute. In conventional accelerators the time from first to last photon may be 20 min or more allowing significant tumor cell recovery.

Dr. Cao claims that conventional accelerators are more versatile in that they can treat noncomplex sites such as those normally treated with electrons. Superficial treatments for skin lesions have been carried out with tomotherapy with excellent results, in certain cases superior to conventional electrons.[15] In any event, the ability to treat simple lesions efficiently should not distract from the theme of this debate which is that IMRT is best performed by a tomotherapy system. Other companies continue to make advances to mimic the tomotherapy model, proving that they have come to terms with the fact that helical tomotherapy is the better modality for IMRT.

Rebuttal: Daliang Cao, Ph.D.

As noted by Dr. Bichay, a stable imaging system is critical to the accurate delivery of IMRT. With helical tomotherapy, this stability is achieved by minimizing the isocenter shifts while the gantry is rotating. With CBCT, the shifts in the imaging isocenter as a function of gantry angle are characterized for each linac and corresponding corrections are applied for image reconstruction. Such shifts of the kV isocenter are highly reproducible,[13] so excellent system stability can also be achieved with CBCT. In fact, CBCT imaging provides a powerful tool for patient setup verification. Additionally, recent studies have shown that the accuracy of kV CBCT-based dose calculations is sufficient for daily dose verification purposes when motion artifacts are absent.[16]

Dr. Bichay states that conventional MLCs are "*prone to motor breakdown*" and that "*positional inaccuracies and velocity fluctuations … can lead to significant dose errors*." Conventional linacs and MLCs, however, have excellent reliability records with typical up-times of greater than 98%. Additionally, conventional MLCs have proven to be accurate and reliable in the delivery of IMRT.

Dr. Bichay states, "*IMRT without a wide dynamic range of intensities will always be inferior*." First of all, there are no inherent limitations to delivering a wide dynamic range of intensities with a conventional MLC. Second, when a rotational approach is used for delivering IMRT (such as with tomotherapy or IMAT), the requirement for a high degree of intensity modulation is reduced due to the large number of available beam segments or beamlets. As demonstrated in a recent IMAT study, highly conformal dose distributions can be obtained that are comparable to those achieved with helical tomotherapy using a limited number of arcs for most cases.[11] Furthermore, access to full 360° delivery is no longer solely available with helical tomotherapy due to the recent development of linac-based rotational IMRT systems.

The design of helical tomotherapy does make it possible to treat large volumes without abutting fields. However, only a very small percentage of radiation therapy patients require field sizes in excess of 40×40 cm^2.

In conclusion, while helical tomotherapy serves as an excellent clinical tool, the availability of CBCT and IMAT ensure that conventional linear accelerators will not be replaced by tomotherapy as the best way to deliver conformal radiotherapy.

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2.2. It is STILL necessary to validate each individual IMRT treatment plan with dosimetric measurements before delivery

J. Charles Smith and Sonja Dieterich
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OVERVIEW

Almost a decade ago, we published a Point/Counterpoint debate on the need for validation measurements for each individual IMRT patient [Med. Phys. 30, 2271–2273 (2003)]. Now, after many more years of experience with this modality, the necessity for such patient-specific measurements has been questioned, and this is the topic discussed in the month's Point/Counterpoint debate.

Arguing for the Proposition is J. Charles Smith, M.S. Mr. Smith graduated from St. Joseph's University in Philadelphia in 1987 with a B.S. in Physics and a minor in Mathematics, and received his M.S. in Physics from the University of Maryland, College Park, in 1990. He entered the field of Medical Physics in 1991 with a consulting group in the Washington DC region, and took his current position at St. Joseph Mercy in Port Huron, MI, in 1993. There, he is the Radiation Therapy Physicist and RSO, and helps in Nuclear Medicine and Diagnostic Radiology as needed. He is certified in Radiation Therapy Physics by the American Board of Medical Physics.

Arguing against the Proposition is Sonja Dieterich, Ph.D. After completing her Ph.D. in Nuclear Physics at Rutgers University in 2002, Dr. Dieterich received training in Medical Physics at Georgetown University Hospital, Washington DC, from 2002 to 2003. In 2003, she accepted a faculty position at Georgetown, where she became Chief of the Cyberknife program in 2006. In 2007, she moved to Stanford University Hospital, Stanford, CA, as Clinical Associate Professor and Chief of Radiosurgery Physics. Dr. Dieterich is certified in Therapeutic Radiologic Physics by the ABR and is Chair of the AAPM Task Group 135 (QA for Robotic Radiosurgery). Her current interests are the development of QA/QM programs for new technologies, motion management, and SRS dosimetry.

FOR THE PROPOSITION: J. Charles Smith, M.S.

Opening Statement

Ultimately, all the Quality Control/Quality Assurance (QC/QA) we do is supposed to assure that we are delivering dose to the patient in the manner and amount planned.[1] With regard to IMRT, there has been debate over whether or not we have the proper tools to test this in a meaningful way.[2,3] Hopefully, systems-analysis tools will be developed to address this, and we will train ourselves to think in terms of statistical process analysis. In that light, should we do patient-specific tests now? I would say yes, even if better tools need to be developed for the future. It may well be that the leaf motions and subsequent fluence and dose maps generated by treatment planning system (TPS) algorithms have predictable patterns, but I am aware of no one who has successfully discovered or characterized them. Nor are there any TPS systems that can model all the parts of a linac and how their behavior changes with use. Until these and related questions are addressed, I can see no *a priori* means to determine by a standard test suite whether or not a particular dose map can be successfully delivered by a particular linac with a particular confidence level. Is such a failure likely? Actually, it seems that with today's delivery systems, the answer may be no, but failures do happen. The crux of the biscuit is what could happen if failures do occur. Given that we often have high dose gradients around critical structures, there is a very real risk of underdosing the cancer and/or overdosing the organs at risk. One may claim that such errors wash out with daily setup variations, organ motion, and such. Perhaps, but new tools for immobilization,

gating, etc., are reducing these variations,[4] which means that a systematic error, such as a bad dose delivery, could be significant. The hope is that such dose delivery errors will be detected and corrected at plan QA. However, even if our current tests are insensitive to small but significant errors,[2,3] basic failures that can be devastating (such as missing data, mechanical breakdown, and software failure) or even of lesser consequence (such as beam intersecting patient support assembly parts), can be found at this stage, before the patient is placed on the treatment couch. Remember, an error with 200 MU delivered to a planned mostly open region (as in 3DCRT) is one thing; such an error with 1250 MU to a planned mostly blocked region is potentially fatal.

I do hope that a better program based on process and failure mode analysis will be developed, but I believe per patient QA is necessary for the foreseeable future if only as a means to catch gross error. It is not the most desirable system but, for now, it is all we have.

AGAINST THE PROPOSITION: Sonja Dieterich, Ph.D.

Opening Statement

"IMRT treatment" today can mean a widely varying combination of delivery systems (TomoTherapy, CyberKnife, Gamma Knife, and MLC-based linac IMRT by several vendors), treatment planning systems, and record and verify systems for data transfer. Factoring in the installed software versions of these systems results in thousands of technology combinations with different probabilities for major failure. Choosing a single patient-specific measurement performed before the course of several weeks of treatment may be a good decision to spend QA time and resources, but it may also create a false sense of safety with other, more severe failure modes being overlooked.

The first failure mode we have to think about is the treatment planning and delivery software. If the software fails to save the plan correctly, what is the default fallback? For some software, it is an open field with full MU per field, while other software would not allow plan delivery at all. Second, which files are used to execute the IMRT QA measurements? If it is a copy of the treatment delivery file, we have to ask ourselves what, exactly, are we testing? A more thorough MLC QA may be more appropriate in such instances.[1] If our validation measurements are based on the delivery files, how, if at all, do we ensure that these files do not get corrupted sometime between the measurement and the end of treatment six weeks later? Lastly, for patients where we deliver dose to very inhomogeneous areas such as lung,[5] using advanced respiratory motion compensation (e.g., gating, Calypso, or Synchrony tracking),[4] what, exactly, are we verifying in a homogeneous, static phantom, with sometimes all fields delivered from the AP direction?[6]

As in 3D-conformal treatments, which can also fail to be delivered correctly with lethal consequences (e.g., by omission of physical wedges or malfunctions of the enhanced dynamic wedges), and where there are no current recommendations for patient-specific measurements, there may be equally or even more effective methods for patient-specific QA than a measurement.

Even doing a patient-specific measurement for IMRT did not prevent a large fraction of institutions failing the RTOG credentialing process using the RPC phantoms in their first attempt.[7] The lesson learned here is that it is not only doing a measurement *per se*, but also application of the correct experimental setup, execution, and analysis of the measurement, that will ensure that it is indeed a safeguard and not just an exercise to satisfy "compliance."

In conclusion, we should consider a dosimetric measurement to validate an IMRT plan as one among many QA tools available to verify a safe delivery. Depending on the combination of equipment, software, and other QC measurements, it should not be the only method considered to assure safety, unless otherwise proven to us by a thorough failure modes and effects (FMEA) analysis.[8] For the future,

we should strive to implement systems that can measure the daily delivered dose distribution to patients.[9]

Rebuttal: J. Charles Smith, M.S.

Dr. Dieterich makes many valid points, similar to some of my own. What she does not say is why we no longer need to perform patient-specific QA in the current state of affairs. In fact, she states that it is "*one of many tools*," implying that it is still a valid test, at least in some situations.

As both of us state, directly or indirectly, the whole QA mentality needs to change to a systems/failure mode based framework. We are not the first to have made this argument, as some of my references show. It is also true, as we both note, that the patient-specific tests we do today have serious limitations and omissions that can lead to a false sense of security. Yet this is not an argument to cease testing, but rather an argument to know our tests and their weaknesses, hopefully while pursuing better methods.

She notes that there are almost limitless combinations of technology, making meaningful test design seem almost impossible. Again, this is not an argument to cease testing, but rather an argument to design one's tests around the local conditions, preferably based on a more general template.

3D treatment errors can be devastating, but the delivery is static, and the dose maps are at least known to be deliverable if commissioning is done properly. *In vivo* verification is encouraged, if not required. Each IMRT delivery is dynamic and, at least in principle, unique. Dr. Dieterich also implies that the patient-specific IMRT tests are meaningless if the TPS, test devices, and methods are not properly commissioned and used. This is true, but I believe that this is a separate issue outside the scope of this debate.

All in all, it would seem we agree that the current state of affairs is at best undesirable. However, I still believe that current patient-specific QA measurements are better than nothing until such time as different methods and tools become available. Thus, we should still do them.

Rebuttal: Sonja Dieterich, Ph.D.

My opponent states that we should do patient-specific tests. I agree. However, his subsequent arguments fail to justify a measurement as the ONLY patient-specific test that can ensure patient safety. On the contrary, the literature he provides, specifically Refs. 2,3, argue that a measurement will only provide QA for one of many branches of the fault tree. Even more significantly, many of the concerns that are cited, such as the behavior of the linac or missing data, cannot be addressed by a patient-specific measurement alone.

IMRT is not just about measuring fluence maps. Indeed, as Dr. Sherouse pointed out in the reference Mr. Smith cites,[2] what these fluence maps mean and how they should be measured and interpreted in a meaningful way is anything but clear. Yes, we do have to verify the fluence maps in order to satisfy the requirements of the Current Procedural Terminology (CPT) code, but this code does not specify how to do it: By measurement or independent calculation?

So, let us focus beyond CPT codes on the question of what keeps us safe. A measurement that is not well thought through, which does not cover all branches of the fault tree, which does not verify by means of the measurement setup the actual delivery conditions, and which does not verify the high dose gradient areas of IMRT plans very accurately, does not keep us safe. Image guidance and respiratory motion compensation may, at first glance, imply a higher delivery accuracy, but they also carry the potential to introduce a much larger inaccuracy than a minor error in the fluence map if they, and the QA of these techniques, are not correctly implemented.

We do not have to wait for an FMEA analysis to be done to critically think about all components of an IMRT plan delivered on a specific device/software combination in order to make an informed decision if

a patient-specific measurement, an alternative approach, or a combination of both, is the most prudent way to ensure safe treatment delivery.

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2.3. EPID dosimetry must soon become an essential component of IMRT quality assurance

Wouter van Elmpt and Gary A. Ezzell
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OVERVIEW

Electronic portal imaging devices (EPIDSs) are rapidly replacing conventional film for portal imaging, but they can also be used to measure exit dose distributions. This could become an important tool for the verification of IMRT dose delivery and some have even suggested that it will soon become an essential component of IMRT quality assurance (QA). This is the Proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is Wouter van Elmpt, Ph.D. Dr. van Elmpt received his M.Sc. from the Eindhoven University of Technology, with a specialization in Medical Physics, in 2004. His thesis was on the development of a portal dose prediction model for dose delivery verification during treatment and quality assurance in radiotherapy. He received his Ph.D. degree from Maastricht University in 2009 where his thesis research was on 3D dose verification using EPID dosimetry combined with 3D in-room cone-beam imaging. He is now a research fellow on adaptive radiotherapy in lung cancer at the Maastricht Radiation Oncology (MAASTRO) and the Maastricht University Medical Centre, Maastricht, The Netherlands.

Arguing against the Proposition is Gary A. Ezzell, Ph.D. Dr. Ezzell obtained his MS in Applied Nuclear Science from the Georgia Institute of Technology in 1977 and his Ph.D. in Medical Physics from Wayne State University in 1994. He is currently Associate Professor of Radiation Oncology, College of Medicine, Mayo Clinic and Consultant in the Department of Radiation Oncology, Mayo Clinic, Scottsdale, AZ. Dr. Ezzell has served the AAPM in numerous capacities including Secretary, member of the Board of Directors as Chapter Representative and Board Member-at-Large, and Chair of the Scientific Program and Treatment Delivery Subcommittees. He is Board certified by the American Board of Radiology in Therapeutic Radiological Physics

FOR THE PROPOSITION: Wouter van Elmpt, Ph.D.

Opening Statement

Advances in radiotherapy over the past ten years have put a high demand on technical capabilities of the treatment machine and on the design of the treatment plan. With IMRT applied for more and more treatment sites, adequate quality control procedures of planning and delivery are mandatory to achieve high-quality treatments. Image-guided radiotherapy (IGRT) takes control of the geometric (i.e., patient setup) accuracy necessary for these advanced treatments, but a routinely used dosimetric counterpart of IGRT is still lacking. Pretreatment QA is frequently applied using film and ionization chamber measurements in phantoms or using specially designed 2D detectors. *In vivo* verification is currently limited to conventional and 3D conformal radiation therapy techniques using point detectors (e.g., diodes, TLDs), which are not very useful for IMRT verification. EPID dosimetry fills this gap allowing dosimetric verification of conventional and advanced techniques, both pretreatment and during treatment.

In a recent review paper on portal dosimetry,[1] various approaches and techniques for using EPIDs for dosimetry purposes are described. The accuracy achieved depends on the specific method used:[2,3] Using proper calibration methods an uncertainty in the dose determination of about 2% (one SD) can be

achieved. A typical pretreatment IMRT QA procedure using EPID dosimetry requires only a single dummy run before the start of the radiotherapy course and therefore allows its use in high patient-throughput radiotherapy departments. Analysis can be automated[4] to reduce workload, and standard evaluation tools that exist for film or conventional dosimetry can be used. EPID dosimetry can detect errors related to the delivery of beams, e.g., MLC positioning errors, incorrect data transfer to the linear accelerator, and limitations or inaccuracies of the treatment planning system, e.g., nonoptimal tongue-and-groove parameters or penumbra modeling.

Another option that favors the use of EPID dosimetry is verification during treatment: With EPIDs it is possible to perform *in vivo* dosimetry. In most situations, the EPID is able to measure the transit (i.e., exit) dose behind a patient for the actual delivered beams. Various methods have been described that use this measured dose to verify patient treatment, either by comparing directly the predicted and measured doses at the position of the EPID (Refs. 5,6) or by reconstructing (e.g., backprojecting) the dose actually delivered to the patient.[7,8] This is a powerful method to ensure that treatment beams are delivered correctly during patient treatment. In this way, EPID dosimetry is also able to assess the impact of possible deviations on the patient treatment. This is an important advantage compared to phantom measurements.

In conclusion, the above-mentioned features (i.e., simple, accurate, and fast procedure and the possibility to be applied *in vivo*) make EPID dosimetry a very attractive alternative to other types of dosimetry for IMRT verification. The next step will be to use EPID dosimetry routinely for *in vivo* dose verification to assure that the planned dose is actually delivered to the patient during the entire course of treatment. Both of these features make EPID dosimetry an essential component of IMRT QA.

AGAINST THE PROPOSITION: Gary A. Ezzell, Ph.D.

Opening Statement

"Must" is a strong word. That EPID-based dosimetry can be a useful tool is well proven. The imperative must would be justified only if that tool provided critical quality assurance information that alternative methods cannot. Of that, I am skeptical.

Let us consider what the quality assurance process is to accomplish and what QA issues are specific to IMRT. The concern is that IMRT can push dose calculation algorithms and delivery systems to the point that they may be insufficiently accurate. In addition, IMRT is often used to shape dose distributions tightly around sensitive structures. So, the three general questions for which we seek assurance are as follows:

(1) Is the dose calculation sufficiently accurate for this patient?

(2) Is the delivery system behaving as intended, such that the accuracy of the delivered dose is not degraded?

(3) Is the dose being delivered to the right location in the patient, such that the clinical outcome is not compromised?

These questions apply throughout the course of treatment but primarily need to be assessed before the first fraction. I argue that EPID dosimetry is not uniquely beneficial for pretreatment QA. Granted, EPID dosimetry offers the possibility of measuring transit dose during treatment and then backcalculating the dose to the patient. While that appeals as an interesting physics problem, its value in improving patient care is questionable.

In the list of QA concerns above, (3) is best resolved using imaging. Typical pretreatment QA tests items (1) and (2) (i.e., calculation and delivery) in a combined, total system fashion: For each field we calculate the dose expected to a phantom irradiated *en face* using the same dose calculation algorithm used for the patient. We then measure the dose at a given depth using a well-understood dosimeter (film

or array of ion chambers or diodes), compare measurement and calculation, and decide if the agreement is good enough. If not, then we start looking for reasons: dose calculation algorithm, behavior of the delivery system, or (do not forget!) problems with the measurement.

If we use EPID dosimetry, what changes? We no longer calculate dose to phantom but instead calculate *response of the imager*, a distinctly non-tissue equivalent device.[1] Further, flood-field calibration of the imager removes the off-axis variation in dose, so the "measurement image" needs to be corrected by putting the (presumed) variation back in. So the expected image is the output of a calculation that is different from the algorithm used for the patient and dependent on vendor-provided routines that need to be validated themselves.

EPIDs are complicated systems that need to be configured specially for dosimetry, are not independent of the linac control system that is being tested, and require significant QA themselves.[9,10] Each month we check each imager's performance and frequently adjust the positional or electronic calibration. One basic rule of QA is to "use a tool that is simpler to understand and maintain than the system it will be used to test." EPID dosimetry is a good tool in the right hands, but it is neither ideal nor obligatory for everyone.

Rebuttal: Wouter van Elmpt, Ph.D.

I am glad Dr. Ezzell shares the opinion that EPID dosimetry can be a suitable tool for performing IMRT QA. However, he raises several interesting points.

To perform dosimetry one needs to have a measure of dose. Calibration and QA of a measurement device are something that holds for all equipment, whether it is film, ion chamber, specially constructed array detector, or EPID. An EPID is, in this respect, no different from other measurement devices.[2] The calibration and QA procedures for imaging with the EPID can easily be extended for the dosimetry part.[1]

The interesting physics problem, as my opponent describes, is the use of the EPID also during treatment to verify the dose delivery, and this has been solved and described in several papers.[1] Centers in the world that have clinical EPID dosimetry procedures in place show that various types of errors have been detected using EPID dosimetry and that these can be corrected, hence indisputably improving patient care.[1,4]

In response to Dr. Ezzell's points (1) and (2), EPID dosimetry is at least as suitable as measurements with film or an ion chamber/diode array because EPID dosimetry combines the high spatial resolution of film with the absolute dosimetry of an ion chamber. Another big advantage is that, at present, it is the only system with which it is possible to verify the 3D dose distribution inside the real patient instead of in a simplified phantom geometry.[7] Interpretation and quantification of possible problems in dose calculation and dose delivery are assessed in the complex geometry where it really matters: The patient.

The last comment of Dr. Ezzell that EPID dosimetry needs to be in the right hands goes together with commercial availability of the procedure. Manufacturers are, and must be, encouraged to provide comprehensive, user-friendly tools to the medical physicist for QA of IMRT.

Rebuttal: Gary A. Ezzell, Ph.D.

My colleague has based his support of EPID dosimetry on two arguments: (1) It can be very efficient for pretreatment QA and (2) it can be used for *in vivo* verification of dose to the patient. (1) Maybe. (2) Is that important?

Whether or not EPID dosimetry is actually more efficient than other methods depends more on the details of the information flow than the measurement device. Taking an EPID image pretreatment is not inherently quicker than irradiating a detector array. If the planning, delivery, imaging, and analysis are well integrated, then the process can be fast. If not, then less so. It is more a matter of programming than physics. Wait for the next version.

Further, there is a trade-off between integration and independence. If you use a fully integrated system from a single vendor, calibrated following a vendor-recommended procedure, then there may be potential for hidden assumptions to permeate the process. Is the output of the planning system used to calibrate the EPID dose? Are you the master of your tools? Do you understand how they work? As with any QA system, make sure yours can find the errors you think might happen. Can you be confident that you will find the error you never considered?

As to the potential for *in vivo* dosimetry, I am mildly skeptical that more people will be cured because of it. *In vivo* dosimetry would not replace pretreatment tests, so the question is: how might doing it influence outcome? Imaging to hit the target adds value. Using multimodality imaging to define the target adds value. Imaging to follow individual response adds value. If the fluence and aim are as designed, will imaging for *in vivo* dosimetry add value? What might change that you could not detect in simpler ways?

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2.4. Radiochromic film is superior to ion chamber arrays for IMRT quality assurance

Slobodan Devic and Malcolm R. McEwen
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OVERVIEW

Because of the complexity of fields used for IMRT, it is important to verify that all delivered fields are the same as those that were planned. A number of methods to make the required beam intensity distribution measurements to assure such congruence are in use, including radiochromic film and ionization chamber arrays. The claim that radiochromic film is superior to ionization chamber arrays for IMRT quality assurance is the Proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is Slobodan Devic, Ph.D. Dr. Devic obtained his Ph.D. degree in Physics in 1997 at the University of Belgrade. He moved to the USA in 1998 and worked as a Research Associate in Radiation Oncology Physics at the Mallinckrodt Institute of Radiology, St. Louis, before moving in 2000 to Montreal General Hospital and McGill University and, in 2008, to his current position at the SMBD Jewish General Hospital in Montreal. He is a Fellow of the Canadian College of Physicists in Medicine and his major research interest is radiochromic film dosimetry and its applications.

Arguing against the Proposition is Malcolm R. McEwen, Ph.D. Dr. McEwen obtained his Ph.D. in Radiation Physics from the University of Surrey, England in 2002. He then moved to Canada to his current position as Senior Research Scientist at the Institute for National Measurement Standards, National Research Council of Canada, Ottawa. Dr. McEwen's research interests are the development of calorimetric absorbed-dose standards for electron and photon beam dosimetry at industrial and radiotherapy levels, calibration of secondary dosimeters in photon and electron beams, and development of protocols for therapy-level absolute dosimetry.

FOR THE PROPOSITION: Slobodan Devic, Ph.D.

Opening Statement

The end of the past and the beginning of the new millennium brought a change in the design of radiation fields used to treat malignant diseases. Radiation oncologists embraced intensity modulated radiation therapy (IMRT) as an alternative to conformal radiation delivery.[1] The earlier radiation therapy approach was based on uniform radiation fields, whereas the new one has employed fluence maps built with beamlets.[2] As our knowledge of cancer functional substructures using functional imaging expands, the old dogma of delivering uniform dose to the target as a prerequisite of tumor control is slowly vanishing. Instead, the dose painting radiation delivery approach based on biological target volumes is paving the way toward the future.[3] As a result of this paradigm shift in radiotherapy, beam design and delivery quality assurance (QA) programs have become more complex.

Fluence maps used to build IMRT plans feature high dose gradients, usually extending over fairly small spatial regions. Consequently, questions have arisen as to whether clinical linear accelerators can actually deliver the IMRT dose distributions shown on screens of the treatment planning systems. The natural tool to answer this question at a time of increasing use of IMRT has been radiographic film, which has had a long history of use in radiotherapy QA programs. A particular version of Kodak ready-pack EDR-2 film was developed for this purpose.[4] Although radiographic film based dosimetry had disadvantages (temperature of developer, nontissue equivalence of silver halide based sensitive

component, etc.), various protocols were developed for the use of radiographic film for IMRT QA. The current trend toward filmless radiology and radiotherapy departments, however, will lead to essentially no access to traditional radiographic film and wet developer systems.

Recently, radiochromic film,[5,6] which has all the advantages of conventional silver halide film (two-dimensional dosimetry, thinness, ruggedness, and permanent record) but without its numerous disadvantages (need for development and its impact on the readout signal, temperature and chemical composition of developer, nontissue equivalence, sensitivity to visible light, strong energy dependence at low photon energies, etc.), has become an important dosimetric tool. Its high spatial resolution combined with low spectral sensitivity make it ideal for the measurement of dose distributions in regions of high dose gradients. Relatively poor spatial resolution and energy dependent response of alternative dosimeters (including ionization chambers) may introduce uncontrolled uncertainties in dose measurements for dose distributions composed of a large number of beamlets and their accompanying overlapping penumbral regions.

The latest development in radiochromic film is external beam therapy (EBT) GAFCHROMIC™ film,[7] designed to replace silver halide radiographic film for IMRT QA procedures. In addition to higher sensitivity than its predecessors (MD-55 and HS), this model is available in larger sizes and at much lower cost than previous GAFCHROMIC™ film models.

AGAINST THE PROPOSITION: Malcolm R. McEwen, Ph.D.

Opening Statement

Quality assurance covers a wide range of tasks, but fundamental to any radiotherapy treatment verification is the measurement of absolute dose. Isodose curves, leaf operation, and plan verification are secondary to the need to be able to say accurately what dose was delivered. For that, the ionization chamber is the undisputed gold standard. Ion chambers are stable, reliable, easy to calibrate, and have a well-understood simple physical process underlying the measurement. An ion chamber array, whether it be 1D or 2D, is a straightforward extension of the single ion chamber used for reference dosimetry or beam scanning. One-dimensional arrays have been used for more than a decade,[8] and 2D arrays are now available from several manufacturers.[9,10]

Ion chamber arrays are attractive for IMRT quality assurance for many reasons. From an absolute dose point of view, it is a huge advantage that the array technology is based on that used for reference dosimetry, and therefore the properties of ion chambers apply—accuracy, long-term stability,[9] linearity with dose,[10] infinite repeatability, and the measurement of both integrated dose and instantaneous dose rate simultaneously. The last two points are essential if one wishes to investigate beam startup, leaf movement, or other linac-related issues.

Ion chamber arrays are easy to set up, require little user training, and can be moved easily from one machine to another. All the commercial systems currently available come as integrated array/electrometer/software packages and, therefore, there is little user input into the result and the measurement reflects the dose delivered, not the measurement technique used. That results should be user-independent is a fundamental (but generally ignored) aspect of a QA program. Multiple vendors and models mean users can choose what best suits their needs and that there is competition, which results in continued development.

One obvious criticism is that the resolution of all arrays is relatively coarse. Anything less than 3 mm is not practical at present. Several authors[8,10] have shown, however, that for the majority of measurements, this apparent coarseness does not have a significant effect on the measurement of dose distributions. If higher resolution is required, it has been shown that simple mechanical systems can be used to make small shifts to the whole array to easily give 1 mm resolution.[11,12] Arrays have been extensively

validated using both point detector scans[8,9] and film techniques,[13] and the conclusion of those authors is that ion chamber arrays measure dose distributions correctly. From the data presented, it would seem that an array can also be used for daily output checks with the central ion chamber of the array replacing a separate measurement of ion chamber in phantom. Thus, absolute, 2D beam data can be obtained on a daily basis.[14]

Equipment is rarely used for only one measurement and arrays have a range of uses beyond IMRT QA including MLC calibration[15] and even Monte Carlo beam modeling.[16] Considering all these points it is difficult to imagine any dosimeter system that could be superior to the ion chamber array for quality assurance of IMRT.

Rebuttal: Slobodan Devic, Ph.D.

I agree that the ionization chamber is one of the most convenient and well known dosimeters used so far in radiotherapy physics. However, its relatively poor spatial resolution could be a key detriment if used for IMRT QA. As an example, one of the most commonly observed IMRT failures is the hot junction (usually 1–2 mm wide) in the split IMRT field for H&N patients. It might not be prudent to generalize performance characteristics of a certain detector (ion chamber) based on the fact that a particular (even IMRT) delivered plan has given an expected result.[10]

While the ionization chamber has been the dosimeter of choice for reference and relative dose measurements in the past when large radiation fields have been used for patient treatments, the question here is whether ion chambers provide accurate and reliable dose data for the fields used for IMRT. Conversion of the chamber signal (charge created within the cavity filled with air) into dose in the medium when the chamber is not present, relies on the existence of charged particle equilibrium and requirements imposed by cavity theory. Bragg–Gray cavity theory requires that, for example, the size of the cavity is small compared to the range of the charged particles, and that the energy deposited within the cavity originates only from the charged particles crossing it. All these conditions are readily achieved in large radiation fields and with the presence of one ionization chamber in large homogeneous waterlike phantoms. One should be more careful, however, when conditions are present where a large number of beamlets with overlapping penumbral regions are traversing a detector that consists of a large number of air-filled cavities.

To summarize, the poor spatial resolution of ion chambers as well as requirements for charged particle equilibrium and cavity theory signal-to-dose conversion are major concerns that support my contention that radiochromic film is superior to ion chamber arrays for IMRT quality assurance.

Rebuttal: Malcolm R. McEwen, Ph.D.

It is not a recent phenomenon that radiotherapy requires new dosimeters to meet an emerging treatment modality—from the discovery of x rays, treatment technology and practice have run ahead of dosimetry. For techniques such as IMRT, SRS, VMAT, etc., measurement technology and, even more so, dosimetry protocols, are several years behind the routine treatment of patients, and such a gulf spurs development in dosimeters leading to the wide range of options available today.

So which is best? The case for radiochromic film is weak. It is true that it has the highest spatial resolution of any dosimeter system currently available and clearly has niche applications (one can cut it to a particular shape, wrap it around structures, etc.), but it has a number of significant problems that need to be stated:
1. Timeliness of the result—current film protocols require a delay of 24 h between irradiation and read-out of the film. Although this may be acceptable for research and specialized purposes, it is unacceptable for routine QA. By contrast, linac-mounted ion chamber arrays can provide immediate information on the dose delivered to the patient for each irradiation.

2. Noise and accuracy—these are still an issue for radiochromic film. Batch film calibration is required (using a calibrated ion chamber) and high levels of noise in the scanned images means that multiple films are required to yield uncertainties less than 1%.
3. Stability of the system—it was clearly demonstrated in 2009 that this field is far from mature since EBT film was replaced by a new version, EBT-2, requiring a different calibration process.
Radiochromic film undeniably has its uses but it is a field in development and the report card states "could do better." For IMRT QA *today*, ion chamber arrays offer the best combination of accuracy, spatial resolution, and ease of use.

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2.5. Co-60 tomotherapy is the treatment modality of choice for developing countries in transition toward IMRT

Patrick F. Cadman and Bhudatt R. Paliwal
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OVERVIEW

Radiation oncologists in developing countries want to do the best for their patients, so they are attracted to the use of the latest high-tech developments such as IMRT and tomotherapy. They do face significant fiscal constraints, however, so provision of these new technologies as inexpensively as possible is essential. It has been suggested that Co-60 tomotherapy might be the most appropriate way to provide IMRT in developing countries, and this is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Patrick F. Cadman, M.Sc. Mr. Cadman obtained his M.Sc. in Medical Radiation Physics from McGill University, Montreal, in 1993 and has since worked as clinical medical physicist at the Tom Baker Cancer Centre in Calgary, Alberta and senior medical physicist with the Saskatoon Cancer Centre. He is Associate Professor in the Physics and Engineering Department at the University of Saskatchewan in Saskatoon and Fellow of the Canadian College of Physicists in Medicine. He currently serves as a section editor for the *JACMP*. His clinical and research interests include all aspects of IMRT, treatment planning validation, and Co-60 tomotherapy.

Arguing against the Proposition is Bhudatt R. Paliwal, Ph.D. Dr. Paliwal received his Ph.D. from the University of Texas in Houston at the Graduate School of Biomedical Sciences, M. D. Anderson Hospital in 1973. He then joined the University of Wisconsin School of Medicine and Public Health as Assistant Professor of Radiology. Currently, he is Director of Radiation Oncology Physics and Professor of Human Oncology and Medical Physics. He has more than 200 publications related to radiation oncology. Dr. Paliwal has received numerous awards including the William D. Coolidge Award for distinguished contributions to Medical Physics from the American Association of Physicists in Medicine in 2002. He has served the AAPM in many ways including Chairman of numerous committees and Task Groups, as President and as a member of the *Medical Physics* Editorial Board.

FOR THE PROPOSITION: Patrick F. Cadman, M.Sc.

Opening Statement

Since the early 1950s the dissemination of robust, low-cost Co-60 teletherapy units has enabled many of the world's cancer patients to receive treatment. In the late 1990s, Van Dyk and Battista[1] revisited Co-60 with a fresh perspective and concluded that with improved technology, patients in both developed and developing countries might benefit from Co-60 teletherapy. More recently, Co-60 has been considered as a source for IMRT[2] and tomotherapy delivery,[3,4] with studies showing that the plan quality may rival IMRT treatments delivered with a linac. The Renaissance® System 1000, ViewRay Inc., Gainesville, FL is currently under development and will use Co-60 as a compatible source for MRI-based, image-guided IMRT. Perhaps Co-60 will not go the way of the dinosaur after all.

Rudimentary Co-60 teletherapy units are still making an impact in many parts of the world today (see IAEA, DIRAC database at www-naweb.iaea.org/nahu/dirac); the number of units worldwide is currently estimated at 2386 compared to 8460 clinical accelerators. Many developing countries are now in a position to consider newer technologies and more advanced treatment techniques such as IMRT. Limited capital, technical and physical resources, however, make decisions difficult. The advantages of a Co-60 source over a linac-produced treatment beam can be easily argued from the maintenance and

quality assurance standpoint. Another consideration for advanced radiation therapy is the choice of multileaf collimator (MLC); a conventional MLC is an electromechanical device that must operate under strict positional tolerances during delivery and requires highly trained staff for maintenance and repair. A binary MLC, with ON or OFF states and pneumatic actuators, could be engineered to be inexpensive and robust and may continue to operate (along with the source transfer mechanism) from a small backup power source during outages.

Even in the "developed world," good quality IMRT treatment plans are difficult to achieve without the expertise of highly trained and skilled individuals. Treatment planning methodologies need to be simpler to use and more consistent in terms of plan quality before they become more widely accepted. The tomotherapy inverse planning method is straightforward. Dose from each beamlet, created by the binary MLC openings, is precalculated, making the process of adjusting planning parameters and reoptimization very efficient. There are no machine parameters to optimize at each planning iteration as there are with a conventional MLC, which adds additional layers of complexity to the inverse planning algorithms and methods.

Developing countries have a strong desire for those things that are perceived to be necessary in the "high-tech" world even though they may be totally inappropriate for the local environment. There is no doubt that advanced radiation therapy techniques such as IMRT are being considered by developing countries with limited resources. To ensure success, the technology chosen must be accessible, simple to use, easy to maintain, and reliable. I believe that Co-60 tomotherapy offers the best choice to fulfill these requirements.

AGAINST THE PROPOSITION: Bhudatt R. Paliwal, Ph.D.

Opening Statement

Is cobalt-IMRT really cost-effective radiation therapy? For countries with limited fiscal resources, considerable attention needs to be given to cost/benefit.[1,5,6,7,8,9] A maxim in today's culture of reducing costs is that we need to provide the most effective therapy at the lowest possible cost. The challenge inherent in this thinking is our ability to put a price on the risk of harm a subpar modality contributes for the patient, and the effect it has on security and safety for the public.[10,11]

First, one of the basic principles of medical practice is "First do no harm." I believe that the radiation oncology profession transitioned to the use of higher energy photon beams because Co-60 therapy was not only less effective in controlling cancer, but it also did harm to a significant fraction of patients in terms of increased normal organ and skin toxicity, resulting in poor quality of life. Percent depth dose, dose rate, skin dose, and beam penumbra are some of the well-documented limitations of a cobalt unit.[6] The impact of these factors is not necessarily eliminated by an IMRT plan. Compared to linac-based IMRT, cobalt-60 IMRT will result in a higher radiation dose "bath" to the peripheral regions of the body and therefore result in increased risk of induction of secondary cancers. Dose rate is also an important factor in determining suitability of Co-60 IMRT treatment. A modern linac can produce about 10 Gy/min at the isocenter, whereas the best a cobalt source can provide is about 2.5 Gy/min, a factor of 4 lower. It would mean a factor of 4 longer treatment delivery times. Patient positioning and internal motion are important factors in the efficacy of an IMRT optimized treatment, and these would be compromised. Moreover, compared to Co-60, higher energies are advantageous since the beams are less affected by tissue density and air gap.

Second, radioactive sources pose an environmental hazard while being transported, while in service, and finally at the time of disposal. The source is always emitting radiation, whereas a linac x-ray beam can be switched "off." There is always a risk of a radiation accident such as when a source "gets stuck" in the "on" position. Furthermore, there are numerous accounts of contamination produced by improperly disposed sources. Additionally, a radioactive cobalt source in the hands of poorly trained personnel or an

organization determined to cause serious harm to a large population could be devastating. What price are we willing to pay for such risks?

As the old edict goes: You get what you pay for. One of the key motivations in proposing Co-60 based IMRT is the promise of making the equipment inexpensive, reliable, and simple. Manufacturers claim: "We are producing machines for $1.5 million without service contracts, while our competitors charge $5–$7 million for complicated machines that need service contracts." These claims are exaggerated on both ends. There are hidden costs of frequent source changes, service and maintenance, and the much-needed optional items consisting of hardware and software, patient data record and verify systems, imaging options, etc. On the upper end of the linac units, $5–$7 million would buy you a very high-end machine with trips to Las Vegas and Hawaii included!

Rebuttal: Patrick F. Cadman, M.Sc.

My opponent argues against Co-60 therapy in general and I will attempt to address his points. A 4 MV linac beam is really a "dirty" Co-60 beam (average energy of 1.25 MeV) and this beam energy is very near that used for IMRT with tomotherapy. The studies I have referenced also indicate that the larger beam penumbra associated with a Co-60 source does not significantly impact the quality of IMRT plans. Also, there is no physical reason why there would be a higher "dose bath" or integral dose with arc-type IMRT using Co-60 compared to a linac with approximately the same average energy; any suggestion that secondary cancers will increase is unfounded. A fresh Co-60 source when used in a tomotherapy unit with an 85 cm source-to-axis distance will have an output of ~ 365 cGy/min. The use of multiple sources, a multislice MLC, and larger and more optimal source designs would reduce treatment times further.

The radiation safety issues associated with Co-60 are certainly worthy of serious consideration, but have become a bit of a red herring in the developed world. A database of radiological incidents and related events[12] indicates that Co-60 orphaned sources and accidental dispersions account for a small fraction of total fatalities and injuries compared to other radioactive sources. There are many radioisotopes that might be used in a radiological dispersal device. As medical physicists, we should focus on ways to further limit the risks of transporting, use, and disposal of all radioactive sources in general while allowing society to enjoy the benefits.

Imported Co-60 sources can be expensive; however, power reactors in many countries may produce indigenous sources of moderate activity at low costs. Where technical support and physical resources are limited, a robust, reliable Co-60 tomotherapy machine that can be depended on to operate for long hours would be very cost-effective, perhaps allowing a trip to Hawaii after all.

Rebuttal: Bhudatt R. Paliwal, Ph.D.

We have learned valuable lessons from Co-60 radiotherapy. Its adverse effects and the superior characteristics of high-energy photon beams have led us to linac-IMRT. I find it difficult to justify the "big brother" notion that Co-60 was not good enough for us but it is acceptable for developing countries.

Mr. Cadman cites the technical and fiscal environment of developing countries to support Co-60 IMRT. He overlooks the fact that today a large fraction of medical physicists, computer programmers, and biomedical engineers in developing countries are educated and support the infrastructure in developed countries. Plentiful manpower in the developing countries is an added asset with multiple shifts per day providing higher throughput with the same upfront investment in superior technology.

There is no significant difference in cost between Co-60 IMRT and linac-IMRT. MLC and IGRT systems are equally expensive whether mounted on a linac or a cobalt unit. Mr. Cadman's claim of the Renaissance® System's use of Co-60 as a "compatible" radiation source for MRI-guided-IMRT does not mean a "superior" source. Moreover, in the current sociopolitical environment it is neither trivial nor cheap to provide security and safety for radioactive sources.

A high quality product is seldom “cheaper” initially. The US auto industry’s customers have suffered from the production of less expensive, but also inefficient, unsafe, and less dependable cars for years, whereas Japan’s car industry has produced slightly more expensive, but superior quality cars using better technology to provide a *safer*, longer, effective lifespan, and cheaper in the long run. We need to learn from our past experiences and not promote outdated concepts.

As John Ruskin (1819–1900) once said: “It is unwise to pay too much, but it’s worse to pay too little. When you pay too much, you lose a little money—that is all. When you pay too little, you sometimes lose everything because the thing you bought was incapable of doing the thing it was bought to do.”

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2.6. Only a single implanted marker is needed for tracking lung cancers for IGRT

Xiaodong Wu and Sonja Dieterich
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OVERVIEW

For lung cancer treatments using image-guided radiation therapy (IGRT) it is necessary to image the motion of the tumor during both the planning and delivery of the treatment. A common method to do this is to use implanted markers, sometimes just one and sometimes several. It has been suggested that just one such marker is sufficient and to use more than one puts the patient at increased risk of complications such as pneumothorax, and this is the premise debated in this month's Point/Counterpoint.
Arguing for the Proposition is Xiaodong Wu, Ph.D. Dr. Wu received his B.S. in Theoretical Physics from China's Xiamen University in 1985 and obtained his Ph.D. in Biomedical Engineering in 1996 from the University of Miami. He is certified in Therapeutic Radiologic Physics by the ABR and is Professor and Chief of Physics in the Department of Radiation Oncology, the University of Miami Miller School of Medicine. His main research interest is high precision image-guided stereotactic radiosurgery and radiotherapy.

Arguing against the Proposition is Sonja Dieterich, Ph.D. After completing her Ph.D. in Nuclear Physics at Rutgers University in 2002, Dr. Dieterich received training in Medical Physics at Georgetown University Hospital, Washington DC, from 2002–2003. In 2003 she accepted a faculty position at Georgetown, where she became Chief of the CyberKnife program in 2006. In 2007 she moved to Stanford University Hospital, Stanford, CA, as Clinical Associate Professor and Chief of Radiosurgery Physics. Dr. Dieterich is certified in Therapeutic Radiologic Physics by the ABR and is Chair of the AAPM Task Group 135 (QA for Robotic Radiosurgery). Her current interests are the development of QA/QM programs for new technologies, motion management, and SRS dosimetry.

FOR THE PROPOSITION: Xiaodong Wu, Ph.D.

Opening Statement

Advances in imaging technologies have allowed dose escalation in treating localized soft-tissue tumors that move and deform internally due to respiration and the movement of their adjacent organs. With advanced 4D-CT, both the integrated target volume that accounts for tumor excursion and the transient tumor volume at a particular breathing phase can be obtained. I assert that the transient tumor volume with limited margin should be the preferred approach for ablative types of treatment, that is, stereotactic radiosurgery (SRS) or stereotactic body radiotherapy (SBRT), to minimize normal tissue toxicity. If such a target volume with limited margin is to be used for treatment with high doses, image-guidance based on skeletal structure (commonly used in conventional RT and intracranial SRS) is not adequate for treatment delivery. A tumor volume-specific localization technique with high precision is essential. A widely used technique is to localize soft-tissue tumors indirectly through fiducials, that is, implanted tumor surrogates such as radio-opaque markers or radiofrequency transponders.[1]

It has been a general trend that, when target localization is focused on the tumor volume itself, the six degrees of freedom of the tumor volume are used for treatment guidance. Here we encounter two

difficulties. First, for soft-tissue tumors for which internal motion is of concern, the tumor location and orientation vary and are no longer consistent with the global body orientation. Second, due to the often noncoherent tumor deformation, the accuracy of the rotational parameters computed from the implanted fiducial markers is greatly affected. By following all tumor-specific localization parameters (translational and rotational), dosimetric error will be unavoidably introduced due to the changes in geometric parameters such as SSD and effective computation depths. I believe that, until a fully adaptive 4D planning and 4D delivery system is at hand, both geometric and dosimetric errors should be minimized by using global patient/skeletal rotational parameters and tumor-based translational setup parameters. This reduces the need for multiple fiducial implantations and could save patients from complications due to fiducial placement.[2] In many cases, incorporated with global alignment, a single fiducial marker centrally located in the tumor could result in good accuracy for tumors with size suitable for SRS and SBRT (our upper limit tumor size is usually about 4 cm in average dimension for definitive SRS or SBRT to assure high dose gradient outside the PTV). Single fiducials should be used with careful management to avoid fiducial migration. The fiducial marker (preferably with antimigration features) should be placed inside the tumor. Sufficient time should elapse between the implant and the planning CT acquisition to allow the fiducial to "scar" into position. 4D-CT sets fused to the fiducial marker can be used to construct the tumor volume to account for tumor deformation and rotation. Maximum tumor/fiducial excursion can also be mapped by the planning 4D-CT to assure that during treatment the fiducial's position remains within an acceptable range. Post-treatment CT has demonstrated that there has been no appreciable local migration for any of our patients (over 500) with a single fiducial implanted inside the tumor mass.[3] With the increased use of CT or 4D-CT for treatment delivery guidance, the value of using a single fiducial for intrafractional tumor tracking following initial CT-based setup will become more evident.

AGAINST THE PROPOSITION: Sonja Dieterich, Ph.D.

Opening Statement

With the advance of image-guided real-time respiratory motion management for lung tumors, the potential pitfalls of using external tumor motion surrogates have become apparent.[4,5] Therefore, tumor localization during treatment needs to be introduced into the clinics for precise targeting. This can either be achieved with technology using hybrid tracking models[6] or direct electromagnetic tracking.[7] Excluding novel fiducial-less tracking techniques (e.g., Cyberknife XSight lung), all of the direct localization methods use one or more fiducials as surrogates for tumor localization. In my opinion, multiple fiducials are needed to achieve accurate tumor localization and tracking results. Knowledge of tumor deformation and rotation, which requires multiple fiducials, has been demonstrated to be essential to determine the motion margin.[8] Until better deformation models become clinically available, tumor registration between different 4D-CT phases during treatment planning requires the use of multiple implanted fiducial markers. When breath-hold is used instead of 4D-CT, registration of the end-inhale and end-exhale phases also requires multiple fiducial markers in the tumor.[8]
In addition to assessing deformation/rotation, there can be other problems with using only one fiducial.Fiducials can migrate out of the tumor after implantation, requiring a repeat procedure which doubles the risk of complications and uses expensive resources. Even if the fiducial just migrates within the tumor after simulation, a systematic localization error is introduced to the treatment. Accounting for this would mean increasing the PTV margin, which would result in more normal tissue dose. The use of multiple markers also reduces the localization uncertainty in the tracking algorithm. For imaging systems such as kV imagers, multiple fiducials can provide magnification information adding the third dimension.

One argument against the placement of multiple fiducials is the risk of complications such as pneumothorax. These assertions are based on data from transthoracic needle aspiration biopsies which were initially used for fiducial placement. Procedural advances, such as transbronchial needle aspiration[9] or transesophageal ultrasound guidance,[10] and the use of smaller diameter fiducials, have reduced the pneumothorax risk considerably. A recent publication[11] targeted at radiologists describes the optimum geometry of multiple fiducial placements and will reduce the risk of a suboptimal fiducial configuration. Changes in dose calculation accuracy because of CT artifacts are another concern, especially for smaller tumors. Except for CT artifacts, Monte Carlo dose calculation algorithms can accurately compute the delivered dose to the tissues in the vicinity of high-density metal objects. The CT artifacts can be reduced by using lower-density fiducials such as titanium coils. Most treatment planning systems allow manual density overwrite, which can be used to eliminate the major streak artifacts. Secondary reconstruction algorithms to reduce streak artifacts at image acquisition are under development and are expected to be implemented clinically within less than five years.

Rebuttal: Xiaodong Wu, Ph.D.

Any successful new technical application always depends upon the current status of its surrounding technologies. With the global improvement in technology, a specific "new" application will often become a transitional step toward a longer-lasting modality.

Multiple fiducial 6D tracking with the CyberKnife was first applied to extracranial spinal indications in which the rigid body condition generally holds well. The same fiducial tracking module was then extended for soft-tissue tumor tracking. However, the ambiguity of the rotational information with soft-tissue tumors has not been sufficiently recognized and rotational corrections are still widely used.

Although tumor deformation and rotation will naturally be reflected in the multiple fiducial array paradigm, it is my argument that this information has not been reliably interpreted for valid rotational tracking. Currently no delivery system can compensate for tumor deformation in real time. I concur that the deformation should be incorporated into the treatment margin. But both 4DCT and breath-hold end-inspiration/expiration CT images can provide excellent deformation and rotation information with a single fiducial by coregistering the image sets to the same fiducial. As such, the margin representing tumor deformation and rotation is related to a fixed point, consistent with the beam tracking reference. It is also worth noting that a minimal internal fiducial migration can hardly be differentiated from the indication of deformation. Adding all the uncertainty factors, compared to a carefully managed (to avoid migration) single fiducial approach, any added benefit of a multiple fiducial tracking technique may be minimal.

Rebuttal: Sonja Dieterich, Ph.D.

I agree with Dr. Wu that the transient tumor volume with limited margin should be used for treatment techniques such as SRS or SBRT. However, a paper he cites[3] explicitly states that, to account for rotation, an added margin is used, and that this margin is larger the more elongated the tumor. This approach runs counter to the original intent: Limiting margin size and thereby spare as much normal tissue as possible.

Even though Dr. Wu states that there is "no appreciable migration" of fiducials, there is currently no published evidence as to what extent this statement is correct. If we use expensive technical procedures to target at submillimeter spatial accuracy, fiducial migration also should be assessed on the same level of accuracy.

I concur with Dr. Wu's statement that fiducials in different parts of the tumor may have differential motion as a function of time. In placing one fiducial only, there is an implicit assumption that the location of this fiducial represents the median/average of the tumor volume. Because the optimum location of one fiducial is not analytically determined before implantation, the motion of one fiducial is most likely not the optimum surrogate of tumor motion. This is a situation where less information is not necessarily better information. The same holds for the argument that changes in geometric parameters and SSD will introduce dosimetric uncertainties. It has been shown that these changes are not discernible in the tumor DVH for rotations less than 6°.[12]

I propose that, because we currently cannot assess and follow the rotation and deformation of soft tissue fiducials, we need the information from multiple fiducials to determine if the assumptions made based on the simulation 4D-CT are still correct during treatment, especially if patient-specific margins are created based on the complexity of the tumor shape. In addition, during 4D-CT patients are often asked to "breathe regularly." Shirato *et al.*[13] showed that, for voluntary breathing, tumor trajectories can differ from those for free breathing; therefore, 4D-CT is not always "ground truth."
In conclusion, the minimal risk of multiple implanted fiducials is outweighed by the many benefits, and I recommend using multiple fiducials for tumor tracking in SRS/SBRT.

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2.7. It is not appropriate to “deform” dose along with deformable image registration in adaptive radiotherapy

Timothy E. Schultheiss and Wolfgang A. Tomé
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OVERVIEW

For adaptive radiotherapy it is common to collect images of the patient throughout the course of therapy. Because of temporal variations, however, it is usually necessary to deform images so as to merge them into a cohesive dataset. This image registration makes the accurate merging of dose distributions difficult, if not impossible. Some have decided to do this by “deforming” the dose distributions, somewhat analogous to deforming the images, but it has been suggested that this is not appropriate. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Timothy E. Schultheiss, Ph.D. Dr. Schultheiss received his Ph.D. degree in Physics from Brown University in 1979. He has held faculty positions at M.D. Anderson Cancer Center, Fox Chase Cancer Center (Professor and Director of Radiation Physics), and is now Professor and Director of Radiation Physics at the City of Hope Cancer Center. He is a Fellow of the ACR, AAPM, and ASTRO, and is certified in Therapeutic Radiological Physics by the American Board of Radiology. Dr. Schultheiss has served on many AAPM Committees and Task Groups including as Chair of the Statistics and Biological Effects Committees. During his career he has been involved in the premarket deployment of a number of new technologies. He has published extensively in biological effects of radiation, especially radiation myelopathy, also in prostate cancer, statistical analysis of clinical data, and in large-field IMRT.

Arguing against the Proposition is Wolfgang A. Tomé, Ph.D. Dr. Tomé obtained his Ph.D. in mathematical physics in 1995 from the University of Florida and completed a post doc and two-year residency in radiation oncology physics at the Shands Cancer Center of the University of Florida in 1998. From 1998 to 2012, he served as faculty member in the Departments of Biomedical Engineering, Human Oncology, and Medical Physics of the University of Wisconsin, where was promoted to Professor with tenure in 2009. He is currently the Director of Physics of the Oncophysics Institute at the Albert Einstein College of Medicine of Yeshiva University and the Director of the Division of Medical Physics of Montefiore Hospital, the teaching hospital of the Albert Einstein College of Medicine. He also holds appointments as Professor of Radiation Oncology at the Albert Einstein College of Medicine and as Visiting Professor of Medical Physics at the Centre of Medical Radiation Physics of the University of Wollongong, Australia. He is board certified by the American Board of Radiology in Therapeutic Radiological Physics and is a Fellow of the AAPM. Dr. Tomé’s research interests are bio-mathematical modeling of cancer treatments, biologically guided radiation therapy, adaptive radiation therapy, deformable image registration, 4D patient management, image guided stereotactic body radiotherapy, image guided fractionated stereotactic radiotherapy, and radiosurgery. He has been a member of many AAPM Task Groups and Committees and currently serves on the ASTRO Radiation Oncology Institute Information Technology Infrastructure Committee and the ASTRO Council on Health Policy: Evaluation Subcommittee of the Emerging Technologies Committee.

FOR THE PROPOSITION: Timothy E. Schultheiss, Ph.D.

Opening statement

For decades, physicists have striven to increase the accuracy of dose calculation and dose display in radiation therapy treatment planning. Although the leaders in this effort have been amazingly successful, the success of these efforts gives some physicians (and physicists) too much confidence in the dose distributions we see displayed. In fact, we have become far too credulous regarding the barrage of computer output in our field.

Although long in coming, the day of deformable image registration (IR) is upon us. The reason it was long in coming is that it is very difficult.[1] Each image source will have its own inaccuracies due to distortion, artifacts, resolution, interference, motion, etc. We all have seen rigid IR algorithms find some entirely unexpected (and wrong) solutions. Generally, registration software allows manual adjustment after optimization because the human brain processes gray scale images so much better than a computer.[2] However, manual adjustment of the registration is not really possible with deformable registration. With different images, the optimal registration is not objectively definable. That is, there are no objective metrics for assessing the registration one gets when one image is registered and deformed to match another image.

Rigid IR alone is fraught with error. Deformable IR is yet more error prone. Now some would add deforming the *calculated* dose distribution along with the deformed image. With deformed images (or the accompanying contours) we can at least choose to accept or modify them. But when the dose is deformed we have nothing upon which we can base a visual evaluation.

Of course, the deforming of dose is well-intentioned.[3] The absorbed dose, being a local phenomenon, essentially belongs to the cell that absorbed it. Because cells and tissue move around, we would have to calculate a new dose distribution for each fraction if we want to achieve the greatest accuracy, which is now within our grasp. Then we need some way to merge all of these dose distributions. Enter deformable dose. We *can* deform all these dose distributions onto a single volumetric study. But let us not be so naïve as to believe we have achieved our goal of ultimate accuracy.

The problems are greater than merely those of deformable IR. We are likely to have tissues that simply disappear (along with their dose) during a course of therapy. These include shrinking solid tumors, enlarged lymph nodes, and some normal tissues such as the parotid gland. Some organs may inflate and deflate over time. The lung does this with a period of seconds, but the rectum also does this with a period of hours. The small bowel can slosh about in the abdomen without our being able to tell one loop from another. Finally, tumor growth or inflammation can cause tissues to be present at the end of treatment that were not there at the beginning.

The ultimate problem with deformed dose is our inability to measure it. Comparison with measurement is always the standard in the mathematical modeling of physical phenomena. Until we can deform dose with algorithms that have been validated against measurement, rather than being merely based on image manipulation, we should withhold all commercial use of this misleading process. It is more akin to "Photoshopping" the dose than to dose calculation.

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

Opening statement

The goal of adaptive radiation therapy is, first, to determine if the treatment is being delivered as planned, by acquiring additional image sets throughout the course of treatment (in addition to the planning image) and, second, to adjust the treatment plan if objectives are not being met. Without accurately accumulating the dose over multiple images, it could be hazardous to adjust the treatment plan. Consider the following examples. If the paradigm of uniform PTV dose coverage is employed, an adequate approach to determine delivered target dose would be to register the GTV with the planning CT to form a composite GTV and check if this composite GTV lies within the uniform 3D PTV dose

distribution. Clearly, this approach does not necessitate dose deformation but only image deformation. However, in the case of dose painting where target dose is heterogeneous, dose warping is necessary to ensure dose to corresponding spatial locations are accurately accumulated.[3,4] Not accurately accumulating the dose could be hazardous, as it may lead to treatment decisions being based on incorrect dose distributions. For example, target cold-spots may overlap in reality. Lack of this knowledge could be detrimental to the treatment outcomes, since a significant dose deficit to even a very small portion of a high-risk area within the GTV can have a detrimental effect on the achievable tumor control probability.[5] The same also holds for organs at risk, which by treatment plan design see a highly nonuniform dose distribution. Moreover, organ shape, size, and position can change from fraction-to-fraction due to organ motion and filling, and the fact that the treatment target is realigned to correct for possible interfraction target motion.[6] Hence, if accurate estimation of expected normal tissue complication probability for organs at risk is desired for plan adaptation then it is necessary to warp the dose.

Using image sets acquired just prior to delivery of radiotherapy is, however, only a first order approximation, since things might change during the course of delivery. Before discussing how this point can be addressed, let me just state that the approximation based on a single image set acquired just prior to delivery is still better than assuming that patients are static CT scans and "flying blind." Ultimately, however, we have to go further: ideally one would acquire anatomical image information and record the machine state and dose delivery status at time points during the delivery. This information could then be used, employing deformable dose accumulation across image sets that are highly correlated, to arrive at a more accurate estimate of dose received for both the target and organs at risk for a given fraction. Dose could then be accumulated over the course of treatment by adding to the record new imaging information along with the dose delivery information from each fraction. The realization of this vision of both dynamically deforming the image and accumulating dose is not too far off into the future and will become clinical reality with the introduction of MR-guided radiation therapy.

Rebuttal: Timothy E. Schultheiss, Ph.D.

Professor Tomé has it right. He states that "*without accurately accumulating the dose over multiple images, it could be hazardous to adjust the treatment plan*." The problem is that we *cannot* accurately accumulate dose over multiple images for the reasons stated in my opening remarks. Actually, the problem is worse. There are no metrics upon which to base the accuracy of this dose accumulation. The effort to add doses delivered to the changing anatomy of the patient over a course of treatment is a worthy research endeavor. However, until we are in a position to demonstrate the accuracy of *both* the deformed image registration and the resultant dose accumulation, such unvalidated software should not be implemented in any clinical setting. We must require that the same rigor be applied to deformed and accumulated dose distributions as is applied to calculated dose distributions. FDA take note.

Note that the proposition is stated in the present tense. Only a Luddite would propose that accurately deforming the dose will never be possible or should not be attempted, but it is incumbent upon physicists to ensure that new technologies are deployed with safety as the highest priority. We must be able to test the validity of a deformable image registration—not just that kidney maps to kidney, for example, but that there is voxel-by-voxel agreement. We need measures of the *accuracy* of the image registration, not just the correlation or mutual information.

Like dose accumulation, autocontouring software generally relies upon deformable registration of a target image to a reference image. Extant autocontouring software generally requires significant postprocessing manual corrections or fine tuning of its organ identifications. If we cannot automatically identify entire organs by software, we certainly cannot identify voxels. If we cannot identify and follow voxels, we cannot accurately accumulate dose.

Rebuttal: Wolfgang A. Tomé, Ph.D.

I would like to thank my esteemed colleague for the valuable points he has raised in his opening statement and his call to caution. While I agree with Dr. Schultheiss that accurate deformable image registration (DIR) is a tough clinical problem to tackle, it is incumbent on us to educate our physician colleagues on the limitations and applicability of DIR just as our profession has done successfully in the case of advanced modern dose calculation algorithms over the last two decades. Hence, the clinical implementation of DIR should be pursued carefully, deliberately and, in the beginning, only for suitably selected patient groups. Moreover, in my humble opinion, to simply throw in the towel and say that there are too many uncertainties and complexities associated with DIR for it to be clinically useful, is not an acceptable approach. Rather, we should continue in a prospective manner to explore the usefulness of DIR using *in silico* clinical trials to determine which patient populations and clinical sites could benefit from DIR without actually changing current treatment plans and treatment paradigms. Using this approach will allow one to determine if DIR and deformable dose accumulation (DDA) allows for better prediction of expected normal tissue toxicities. To this end, however, it is essential to have a DDA technique that does not depend on the way dose is accumulated across image sets. Our group has recently presented a DDA methodology that exhibits this property.[7] Clearly, DDA and DIR hold great clinical promise for improved prediction of normal tissue toxicities and have the potential to allow one to escalate the dose to target structures at constant expected normal tissue complication probability (NTCP), i.e., allowing one to pursue iso-NTCP escalation strategies. However, this potential application should be carefully explored in prospective clinical trials.

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2.8. To ensure that target volumes are not underirradiated when respiratory motion may affect the dose distribution, 4D dose calculations should be performed

George Starkschall and John P. Gibbons
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OVERVIEW

How can you calculate the dose to points that move during irradiation such as when points within tumors move due to respiratory motion for treatments in the thorax region? Do you simply calculate the dose assuming no motion, or do you calculate the dose to each specific voxel of tissue, taking into account its movement during respiration (so-called 4D dosimetry)? What if the radiation field intensity varies significantly from one point to another, such as with IMRT? Whether or not 4D calculations are required when respiratory motion is present is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is George Starkschall, Ph.D. Dr. Starkschall obtained his Ph.D. in Chemical Physics from Harvard University in 1972. He is certified in radiotherapy physics by both the ABR and the ABMP and is Professor in the Department of Radiation Physics, The University of Texas M.D. Anderson Cancer Center, Houston. His major research interests include development of respiratory-correlated radiation therapy and methods for acquisition of 4D CT images, radiotherapy dose calculation algorithms, methods for radiotherapy optimization, and PACS for radiotherapy. Dr. Starkschall has served on numerous AAPM committees and task groups; he has chaired the Electronic Media Coordination Committee, and is the current chair of the Education and Training of Medical Physicists Committee. He is Editor-in-Chief of the *Journal of Applied Clinical Medical Physics*.

Arguing against the Proposition is John P. Gibbons, Jr., Ph.D. Dr. Gibbons obtained his Ph.D. from the University of Tennessee-Knoxville in 1991, and completed a two-year residency in Radiation Oncology Physics at the University of Minnesota Hospitals & Clinics, Minneapolis in 1993. He is certified in radiotherapy physics by both the ABR and the ABMP and is currently Chief of Clinical Physics at Mary Bird Perkins Cancer Center, Baton Rouge, Louisiana. His major research interests include treatment planning dosimetry and optimization, and he currently chairs the AAPM Working Group on Radiation Dosimetry and the Task Group on MU Calculations for Photon and Electron Beams. Dr. Gibbons is a member of the Boards of Directors of the AAPM and the ABMP, and is Secretary of the AAPM.

FOR THE PROPOSITION: George Starkschall, Ph.D.

Opening Statement

Four-dimensional (4D) dose calculations are a component of a procedure that accounts for respiratory motion in the planning and delivery of radiation. In performing 4D dose calculations, one typically starts with a 4D computed tomography (CT) image data set, consisting of three-dimensional (3D) data sets, one for each phase of a patient's respiratory cycle. A beam configuration is established on a single phase, identified as the reference phase, and copied to all other phases of the data set. Doses are calculated on each phase. The reference phase dose matrix is deformed to each subsequent phase, and the doses on the reference phase dose matrix are calculated on each phase. The doses are accumulated to give the 4D dose distribution.[1,2,3,4]

The question we are debating is whether or not we should be performing these calculations. I argue that the calculations should be performed. The first issue is whether or not it makes a difference. We recently

performed a study to compare 4D calculations with 3D calculations on a cohort of 15 patients with Stage III nonsmall cell lung cancer.[5] In six of the 15 patients, the difference in clinical target volume (CTV) coverage between 3D and 4D was sufficiently great (>3%) to warrant replanning, and in five of the patients the difference in planning target volume (PTV) coverage was sufficiently great (>5%) to warrant replanning (these are updated data from Ref. 5). The differences are not great, but they are beyond the limits of acceptable accuracy of a modern dose calculation algorithm.[6]

One can argue that it is far more difficult to perform a 4D than a 3D dose calculation, but the increased effort is in the computational load, and not the user intervention. The time-consuming aspects of 4D treatment planning include loading the 4D data sets onto the treatment planning system and delineating the gross tumor volume (GTV) on multiple data sets. These tasks are already being performed as part of 4D target volume delineation; they do not add incrementally to the task of dose calculation. Greater computational resources are required to execute the calculations, but computational power continuously increases and, as new technology develops, treatment planning computers will become powerful enough to execute these calculations in a reasonable amount of time. A calculation that takes an hour to execute today will take minutes in the near future.

Another issue preventing widespread use of 4D calculations is that none of the vendors of commercial radiation treatment planning systems has this capability presently available. At least one vendor, however, has such capability available in a research version, and it is not unreasonable to assume that other vendors will make the capability available in the near future.

4D dose calculations may not be needed for all patients for whom respiratory motion plays a role in the planning process, but present studies have not yet determined a set of guidelines for patient triage. Until sufficient experience is gained with these calculations, it is advantageous to the care of patients to perform 4D dose calculations whenever feasible.

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

Opening Statement

Intrafractional changes in patient anatomy during treatment will affect the dose distribution to both target and normal tissue structures. For tumors within the lung, where respiratory motion maximizes anatomical variations, corrective strategies are necessary to ensure adequate target coverage. However, 4D dose calculations are not required to achieve this goal.

The primary area of concern for respiratory motion is target underdosage in regions near field edges. The motion blurring of a static-field dose distribution may significantly reduce the dose near the target boundary.[7] Three ways are available to correct for this effect using conventional 3D planning techniques. First, the simplest solution is to gate both the planning CT and the treatment. By selecting appropriate gating parameters, one may effectively eliminate respiratory motion, thus removing the need for a 4D dose calculation. Second, it is possible to increase the field margins. Target excursion may be estimated by fluoroscopy or, if available, 4D CT techniques. Appropriate margins may be applied based on the estimated geometrical deviations of the target.[8] While many margin recipes are determined under the assumption of an invariant dose distribution, it is not evident how variations in dose distributions will change the required margins. Furthermore, one may theoretically increase margins as far as necessary to ensure adequate coverage of the target. Although the normal tissue dose in this case will be higher, that is irrelevant to the current proposition. Third, it is always possible to apply 4D optimization strategies to 3D dose calculations. These strategies attempt to deblur the true dose distribution by optimizing the incident energy fluence distribution, typically increasing the fluence at the field edges. Optimized fluences are determined based on the target's probability density function (pdf),[9,10] with more robust solutions incorporating error bars in the predicted pdf.[11] Determination of the pdf does not require a full 4D dose calculation, however, and the resulting optimized treatment fields may be recomputed using 3D techniques.

While 4D optimization techniques may reduce the normal tissue dose, target coverage is very susceptible to the choice of pdf.[12] Thus, the target dose for a 4D dose plan obtained with a poorly chosen pdf may be even worse than that for a conventional 3D plan with margins.

Other concerns include dosimetric changes due to intrafraction variations in tissue density and/or target deformation. However, these effects may be insignificant if 3D calculations are made on CT datasets that incorporate these variations. Improvements in 3D computational accuracy should be achieved through the use of time-averaged CT data, which can significantly improve dosimetric accuracy (e.g., <5%) within the target.[12] Additional error reductions may occur for fractionated treatments, where motion-related dosimetric changes may be washed out over multiple treatments.[13] It is likely that this error is smaller than that due to use of homogeneous calculation algorithms.[14] Finally, it is always possible to increase the prescribed dose to ensure adequate coverage. Again, this problem is avoided entirely with gated treatment techniques.

Rebuttal: George Starkschall, Ph.D.

Dr. Gibbons' assertion that 4D calculations are not necessary to account for respiratory motion is based on techniques for accounting for respiratory motion that are state of practice in selected large institutions. However, new developments in dose calculations that allow determination of dose while explicitly accounting for respiratory motion demonstrate the potential inadequacy of the present calculating techniques.

Dr. Gibbons' statement that “the primary area of concern for respiratory motion is target underdosage in regions near field edges” is based on a calculation methodology that convolves the static dose distribution with a probability distribution function (pdf) that characterizes the respiratory motion.[7] When 4D calculations are done explicitly, however, we have found that in some cases the underdosing may occur in the center of the target volume.

Dr. Gibbons goes on to propose several methods to correct for inadequate dosing resulting from a 3D calculation. One of these, gating the delivery of radiation to the respiratory cycle, has been shown to be of limited effectiveness in reducing the effects of motion, because even with gating, some residual respiratory-induced motion remains.[15] Dr. Gibbons also recommends increasing the field margins to account for motion, but in treating lung tumors we want to minimize the volume of uninvolved lung that is irradiated. Often we use image-guidance techniques to reduce setup uncertainty and decrease field margins. We lose the advantages of these techniques to decrease field margins if we must increase margins to compensate for motion. We already use 4D CT to explicitly account for respiratory-induced tumor motion.

Explicit calculation of 4D dose distributions might not be warranted for all lung cancer patients, but until we obtain a better understanding of how to triage such patients, and once we obtain the capability of routinely performing 4D calculations, we should incorporate them into our tool box. With a reasonable amount of experience, we may be able to set some ground rules to identify situations where a clear advantage can be gained by 4D dose calculations.

Rebuttal: John P. Gibbons, Jr., Ph.D.

Dr. Starkschall's data indicate that 4D dose calculations have determined a 3%–5% underdosage for about one-third of the patients in this study group. I maintain that the magnitude and frequency of this result would be much less if either larger margins or 4D optimization strategies were used for the 3D plans. These differences are not great (as Dr. Starkschall has stated) and may in fact be smaller than the uncertainty of the dose calculation algorithm. I anticipate that physicians will be willing to either ignore these small underdoses, or even slightly increase the prescribed dose to compensate, especially since much greater dose differences occurred when we began planning with heterogeneity corrections. Finally,

dosimetric underdoses are avoided entirely if a gated therapy technique is employed, thus eliminating the need for full 4D dose calculations.

While Dr. Starkschall argues that the additional planning time required will stress the planning computer more than the user, the ability to initiate patient treatments in a timely manner will still be compromised. It is likely to take much longer to perform the calculations since, as he points out, there are no commercial treatment planning systems that currently have the ability to perform 4D calculations. Furthermore, without a clear need, it may be a long time before this capability is commercialized and I, for one, am not "breath-holding."

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2.9. Within the next 10–15 years protons will likely replace photons as the most common type of radiation for curative radiotherapy

Richard L. Maughan and Frank Van den Heuvel
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OVERVIEW

Interest in proton therapy has increased dramatically in the past couple of years, especially in the United States. The obvious physical benefits of protons are offset by the high costs. The promise of innovative new technologies to reduce the cost of proton therapy machines, however, combined with impressive results being accumulated, might make proton therapy not only a feasible alternative to conventional techniques for curative patients, but possibly the treatment of choice at some time in the not-too-distant future. This is the premise debated in this month's Point/Counterpoint.

Arguing for 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 in 1983 where he was responsible for the medical physics aspects of a neutron therapy 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.

Arguing against the Proposition is Frank Van den Heuvel, Ph.D. Dr. Van den Heuvel is Professor at the Katholieke Universiteit, Leuven, Belgium and the Director of Medical Physics in the Department of Experimental Radiotherapy at the University Hospitals Gasthuisberg in Leuven, having previously spent almost 10 years at Wayne State University, Detroit. He obtained his Ph.D. in physics from the Free University in Brussels. His main interests lie in patient and organ positioning, incorporating radiobiological models into clinical planning, use of exotic particles for treatment, and using computers to make his life easier.

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

Opening Statement

Over the past sixty years technical advances in radiotherapy have led to new radiation delivery techniques which have allowed for tumor dose escalation and improved normal tissue sparing. We have progressed from orthovoltage x rays, through ^{60}Co units, high energy linacs, conformal therapy, to intensity modulated radiation therapy (IMRT) and tomotherapy. The clinical efficacy of these advances has been readily accepted by physicians and physicists and the new technologies have been rapidly applied to the benefit of many patients. In no case have controlled clinical trials of treatment outcome preceded the application of the new technologies, yet in all cases efficacy has been demonstrated.[1,2]

Proton therapy was introduced in the 1950's but it was not until 1990 that the first hospital based proton facility became operational (at Loma Linda University). Protons have not received rapid universal acceptance. The slow introduction of proton therapy, in spite of the obvious dose distribution advantages of the Bragg peak, has been due mainly to the high costs of penetrating isocentric proton beams. Recent cost effectiveness studies project that the costs of funding and operating a proton facility over its 40-year lifetime may be approximately 50–300% higher than for conventional therapy.[3,4] Given the relative cost effectiveness of radiotherapy as a cancer treatment modality, these costs are justifiable when set against the potential clinical gains[5,6] from the widespread application of proton therapy.

There are 1.4 million new cancer cases in the USA each year of which ~400 000 are treated with radiation therapy with curative intent. Therefore, if the majority of curative patients are to receive proton therapy by 2023, sufficient facilities to treat >200 000 patients/year are required. Assuming 400 patients/year can be treated in a single proton therapy room, then 500 proton therapy rooms are needed. In the USA in 2008 there are five operating proton facilities with a total of 17 treatment rooms, three new centers will be operational by 2011 raising the room total to 31. Proton therapy is now gaining acceptance with a further 10–12 centers in development which may be operational by 2014 providing 65–75 additional rooms. At this three year doubling rate there will be 500 treatment rooms available by 2023.

Recent experience in radiation oncology, particularly with the introduction of IMRT, demonstrates that, in the internet age, well-informed patients demand the latest technological advances. The vendors respond quickly to provide the necessary equipment. There is reason to suppose that, in coming years, as proton therapy and its superior efficacy are established, demand for this treatment will greatly increase. With five major manufacturers and several companies developing less expensive technologies, there should be ample manufacturing capacity, and potential cost reductions will further improve the viability of proton-therapy business plans in the USA.

I believe the primary reason for growth in proton therapy will be proven superior clinical efficacy and, therefore, I predict that it is highly likely that there will be enough proton treatment capacity in the USA to treat over half of the curative cancer patients by 2023.

AGAINST THE PROPOSITION: Frank Van den Heuvel, Ph.D.

Opening Statement

The Proposition does not take into account the inherent inertia of the radiation therapy community. Also, even though there definitely is an advantage of protons with respect to photon treatment for a number of applications, they are not *that* good.

One might compare the gain by using protons with the gain of IMRT over classical 3D conformal treatment: a possible reduction of complications together with an increased need for patient movement management. IMRT was introduced clinically in 1994, with a much lower economical and technological threshold compared to protons, even if we take into account the possibility of less expensive proton systems in the future,[7] and it is now considered one of the standard techniques. In an average department the majority of the treatments are still classical open beams, while in a progressive department about a quarter of the treatments are IMRT. Most treatments such as large pelvic fields, breast fields with lymph node involvement, and all palliative treatments remain non-IMRT photon based. It is in the specialized IMRT applications that there might be room for proton therapy to make its mark.

Ignoring the time-frame problems, there are a few other reasons why even in the long run protons are not as great as we should like. There is little inherent biological advantage of proton therapy: an RBE of the order of 1.1 is regularly quoted,[8] most likely due to the contribution of slow protons. There is also the problem of stray neutrons which have to be minimized.[9,10,11]

This brings us to its only real claim to fame: the innate possibility of protons to deliver dose to the target while decreasing the amount of dose in adjacent organs. This will only have a benefit in treatments where the target is located very close to a critical structure. In other cases there is no apparent planning advantage in using protons.[12] The study mentioned here did conclude that the dose to healthy tissue was lower with protons, an argument which makes an impact primarily for treatment of younger patients, not the group we are expecting to populate radiation therapy departments due to the aging demographic.

Another article compares IMRT, tomotherapy and proton therapy for a selection of diseases.[13] The authors conclude: ”*Each technique excels for certain classes of highly complex cases, and hence the various modalities should be viewed as complementary rather than competing.*” I can only but agree.

The above arguments are for planning cases alone. Any advantage would only be theoretical. The treatment has to be delivered! With protons this is more complex and error prone than with photons. Indeed, for a given field only in-plane errors are critical for photons, while out-of-plane errors have less impact. For protons all the directions become critically important, including changes in composition of tissue between surface and target. Changes in the latter might yield differences of more than 100% from the intended treatment. Furthermore, an out of plane rotation of the target volume can also change the perfect coverage.[14] Indeed, the less than stellar results of proton therapy so far might find an explanation in inferior coverage. Solutions for this problem exist but are labor intensive, thus reducing the number of possible treatments.

In summary, there certainly is a place for proton therapy in the arsenal of cancer treatments but, due to its lack of robustness, it will not replace the other modalities. Its low toxicity makes it the perfect partner for photons and other treatments.

Rebuttal: Richard L. Maughan, Ph.D.

Recently in the USA, the radiation therapy community has responded rapidly to advances in technology. Many progressive academic departments and community hospitals already treat large numbers, sometimes the majority, of curative patients with IMRT. The strength of proton therapy is its superior dose distribution. Its low-LET characteristics are also advantageous, since high-LET modalities are only proven for a small number of anatomical sites.

Protons do have the ability to deliver dose to the target while decreasing dose to adjacent critical organs. The full impact of the superior dose distribution offered by proton therapy on radiation oncology has yet to be realized. Not only may these advantages be exploited for dose escalation in selected sites, but already results suggest that normal tissue toxicity in patients undergoing chemotherapy may be considerably reduced with protons. With many patients receiving combined modality treatments which are toxicity limited, such an advance may have a large impact on the practice of oncology.[15] Also the ability to retreat recurrent tumors originally treated with conventional therapy is considerably enhanced.[16] In future many patients will have originally received dose sparing proton therapy thus offering even more aggressive retreatment possibilities. The aging population and increasing longevity will boost the need for retreatment.

There are difficulties in delivering proton therapy particularly related to target coverage and critical structure avoidance. These problems are understood and work is in progress to define more robust treatment planning solutions which minimize the effects of potential errors related to range uncertainty and target/organ motion.[17,18]

Obviously, with few proton centers currently operational, predicting that proton therapy will be the predominant treatment for curative patients is highly speculative. However, with proven superior clinical efficacy it is likely that this situation may be achieved in the USA by 2023.

Rebuttal: Frank Van den Heuvel, Ph.D.

The opening statement of my distinguished colleague is based on three arguments:

1. a theoretical advantage;

2. a rosy cost-benefit analysis;

3. the possibility of having enough centers to treat all curative cases using protons given the current rate of growth of such treatment centers.

I cannot but agree that an advantage exists. However, it is not a miracle cure. The physics of the Bragg peak makes it possible to reduce the dose to surrounding organs better than possible with photons. In some cases, however, the treatment becomes hopelessly complex. For example, treatment of the breast with involved nodes will become excruciatingly difficult to plan and execute. Such treatments gain from

the larger dose fall-off and loco-regional character of photon therapy, something which is lost when using protons unless such treatments are carefully planned and applied.

Even if we allow for difficult planning, execution seems to be harder than first imagined. This is most likely the reason why currently the benefits have not yet materialized. The increase in setup complexity leads to a negation of the second argument above. The cited cost-benefit analyses are based on very optimistic patient selection and limited overhead costs. For example, increased labor intensiveness is not taken into account in most predictions, and the added cost of decommissioning centers, which is a hidden cost, is ignored. A source cited by Prof. Maughan states:[4] "*The differential is estimated to be* ~1.5 *provided there were to be no charge for the original facility and that there were sufficient patients for operating on an extended schedule* (*6-7 days of 14-16 h*) *with* $\geq$ *two gantries and one fixed horizontal beam*." This means that if initial costs are not taken into account we need an additional 1.5 times the cost for a gain which probably does not amount to a factor of 1.5.

I do agree that, should proton therapy be shown to be as fruitful as predicted, the number of centers needed might be built in this short time. However, if heavy ions are shown to be even better than protons, we might need to also build a number of heavy ion centers, yielding several decades of interesting work for us physicists.

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2.10. We do not need randomized clinical trials to demonstrate the superiority of proton therapy

Hideyuki Sakurai and W. Robert Lee
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OVERVIEW

Despite the very significant costs involved, proton therapy centers are opening up all over the world. Yet no clinical trials have been conducted to demonstrate that proton therapy is superior to much less expensive photon treatment. It is claimed that such trials are not necessary because it is obvious that protons are better and this is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Hideyuki Sakurai, MD, PhD. Dr. Sakurai obtained his M.D. and Ph.D. (Radiation Oncology) degrees from Gunma University, Gunma, Japan, where he worked in the Radiation Oncology Department until 2008. He then moved to his current position as Professor and Chairman in the Department of Radiation Oncology and Director of the Proton Medical Research Center, University of Tsukuba, Ibaraki, Japan. He has published extensively in radiation oncology with his major research interests being gynecological, gastrointestinal and pediatric therapy, proton beam and carbon ion therapy, brachytherapy, and hyperthermia.

Arguing against the Proposition is W. Robert Lee, M.D. Dr. Lee completed his M.D. degree at the University of Virginia, Charlottesville, and his residency in radiation oncology at the University of Florida, Gainesville. He subsequently held faculty positions at Fox Chase Cancer Center and Wake Forest School of Medicine, Winston Salem, North Carolina. During this period, Dr. Lee completed two masters' degrees, one in Clinical Epidemiology and another in Adult Education. In 2006, he was recruited to Duke University, where he is currently Professor of Radiation Oncology, Associate Professor of Urology, and Director of the Radiation Oncology residency program. His major research interests are development of novel fractionation schedules in the treatment of prostate cancer and measures of quality in prostate brachytherapy. He is currently working on development of a curriculum devoted to improving medical decision making for patients and healthcare professionals.

FOR THE PROPOSITION: Hideyuki Sakurai, M.D., Ph.D.

Opening Statement

Before this discussion, it is important to compare the interactions of photons and protons. First, there is very little difference in the biological effects of photons and protons. The relevant differences are only physics. Second, due to these physical differences, protons generally deliver a lower dose to surrounding normal tissues in almost all cases.[1]

To consider randomized clinical trials (RCTs), an important factor should be ethics. The ethical point of randomization is whether or not the patient can accept the result of a flip of a coin.[1,2] In other words, the two arms must appear to be substantially equivalent from the patient's point of view,[3] with one arm not clearly inferior to the other from the professional's viewpoint. In the field of radiation oncology, for instance, RCTs are appropriate to compare fractionation schedules or to determine which chemotherapy agent is the best in combination with radiation for the treatment of specific tumors. Additionally, we can also accept RCTs that compare treatment techniques with different mechanisms, for example, surgery vs radiation for early stage cancer or carbon beams vs protons for radioresistant tumors.[4] However, for RCTs comparing protons and photons, both treatments have similar mechanisms, so we would be comparing only different dose distributions. There is no medical rationale for such RCTs because it is

known that protons deliver lower doses to nontarget tissues than do photons for the same specified dose and dose distribution to the target.[5] RCTs to provide answers to questions that can be readily answered by simple planning comparisons are not necessary.[6] I think this is the first reason for not conducting RCTs to compare photon and proton radiotherapies.

The second problem with such RCTs is treatment cost. In Japan at present, for instance, national public insurance covers all radiation therapy except particle therapy. Patient payment for early stage lung cancer in surgery, x-ray stereotactic therapy, and proton therapy are (in U.S. $ equivalents) $5400, $2400, and $33 000, respectively. Who pays the treatment fees for the patients randomized to receive protons? RCTs often give important results, but they rarely produce radical changes in treatment, and there is the ethical problem in randomization described previously.[3] Hence, from the patient's point of view, it is difficult to recommend RCTs that are likely to demonstrate no major differences in cure rates with big differences in cost.

The design of such RCTs could involve considerable difficulty, both ethically and socially. Other problems of RCTs are the small number of proton centers available, and hence the small number of patients that can be treated, which makes it impossible to complete these RCTs in a timely manner. For rapid progression of radiation therapy techniques, especially proton therapy, the current approaches are substantial nonrandomized phase II trials,[7] case control studies,[1] prospective cohort studies, and physics and dosimetry studies. Ongoing studies with more patients and longer follow-up will demonstrate the true benefits of proton therapy. Lack of evidence from RCTs is no reason to deny the superiority of protons.

AGAINST THE PROPOSITION: W. Robert Lee, M.D.

Opening Statement

I am arguing against the proposition because it is antithetical to science and it subtly attempts to shift the burden of proof. I will begin my argument by describing the burden of proof.

The burden of proof is the obligation on a party in an epistemic dispute to provide sufficient warrant for their position.[8] The burden of proof is used in legal, political, and scientific disputes. In most epistemic disputes, the burden of proof lies with the claimant. Although not apparent in the proposition, the claim put forward is that proton therapy is superior to photon therapy. The proposition is worded in such a way that it subtly shifts the responsibility or burden of proof to the critic and is, therefore, an example of the fallacy of argument from ignorance (*argumentum ad ignorantiam*).

Perhaps the best example of the fallacy of argument from ignorance is Bertrand Russell's teapot.[9] Russell wrote that if he claimed that a teapot were orbiting the sun, it would be nonsense for him to expect others not to doubt him just because they could not prove him wrong. Russell's analogy illustrates the idea that the burden of proof lies upon a person making claims rather than shifting the burden of proof to others. Russell's example, of course, was used to argue against the existence of God. If you grant that the present conversation is scientific, then the appropriate motion or claim should be framed as a hypothesis. Simply put "Proton therapy is superior to photon therapy." This is a hypothesis that can be tested and the burden of proof lies with the claimants.

More than 2000 years ago, Hippocrates began the long process of dissociating medicine from magic. His lasting contribution remains that he established medicine as a discipline dependent on the laws of nature and, therefore, capable of being studied scientifically. In medicine, by convention and community standards, this burden is met by accumulating evidence. For the better part of 60 years, it has been accepted that randomized controlled trials provide the least biased estimates of treatment effects.[10] To date, there are no randomized controlled trials comparing proton therapy to photon therapy in any clinical scenario. To aver that proton therapy *does not require* this level of evidence when claims of

superiority are made implicitly suggests that proton therapy is supernatural, beyond the limits of the natural world; in short, magic.

This complete absence of level I evidence has not kept proton enthusiasts from claiming that proton therapy is superior. There is a long list of "new" treatments that were widely adopted on weak evidence but, following rigorous comparison, were found to be *inferior* to standard therapy.[11] Statements of superiority in any realm of clinical medicine in the absence of randomized trials should be viewed with suspicion. To assert that proton therapy is superior to photon therapy in the absence of rigorous evidence is to engage in faith-based medicine.

Rebuttal: Hideyuki Sakurai, M.D., Ph.D.

Dr. Lee is clearly an RCT enthusiast and his comments are too abstract to be persuasive. He apparently considers the normal process of development of radiation therapy to be "antithetical to science." I disagree. Consider, for example, the dearth of RCTs comparing conventional radiation therapy with high-tech x-ray therapies such as stereotactic radiosurgery and intensity-modulated radiation therapy. Although numerous phase I and II trials were conducted, there are almost no reports of phase III RCTs with two radiation therapy arms to compare conventional techniques with the new highly encouraging ones.

Additionally, I also regret that Dr. Lee did not propose a practical way to appropriately design an RTC to compare x-rays and protons. To my knowledge, for example, only one phase II RCT to compare x-ray vs proton therapy is ongoing for advanced lung cancer (at the MD Anderson Cancer Center). For this trial, first 20 patients who are suitable for high dose radiation are randomly assigned to either of the two arms. After 20 cases, with a method of Bayesian adaptive randomization, subsequent patients will be more likely to be assigned to receive the type of therapy that the radiation oncologist considers to be better based on the results for earlier patients in the study. This type of randomization has been accepted recently in order to take into consideration any slight inequality of the treatments that may be developing during the study. I think this is an appropriate approach because it considers patient benefit. It illustrates the difficulties involved in the design of such clinical trials.

Hippocrates established medicine (not "*magic*") based on practice and experience. RCTs do not always give a true answer to all medical questions, and conducting RCTs is sometimes inappropriate. We need to recognize that not only RCTs but also non-RCT studies must be science.

Rebuttal: W. Robert Lee, M.D.

I disagree with several elements of the argument put forth.

First, it is not true that there are no biologic differences between protons and photons. More than 30 years ago, Robertson et al. published a paper that indicated the RBE of the proton beam increases beyond the peak.[12] A recent paper from Paganetti et al. describes the phenomenon and states that there is a "local hot region over the terminal few millimeters of the SOBP and extension of the biologically effective range."[13] It is an oversimplification to believe that biology does not matter in proton beam therapy and state that the only "relevant differences" are physics.

Second, it is not prudent to state that RCTs are unnecessary because questions can be "readily answered by simple planning comparisons." Two recent examples of planning comparison are not consistent with one another.[14,15] How can one use studies like this to readily answer the question of whether protons are superior to photons? Given our limited understanding of dose-volume relationships in most contexts, it is unwise to use DVH comparisons as a surrogate; clinical results in patients are what should be important.

I agree with Dr. Sakurai that proton beam therapy is more expensive than photons, and I was surprised by the fact that Japan's public insurance does not pay for particle therapy. It is intriguing that Dr.

Sakurai imagines that some RCTs of protons are “likely to demonstrate no major differences in cure rates with big differences in cost.” It would be wonderful if Dr. Sakurai could list some examples and share them with our American proton enthusiasts!

At the end of the day, the question remains. Are we willing to accept the claim that proton beam therapy is superior in the absence of high-level evidence? I am of the opinion that medicine is a discipline that should be rooted in science. Randomized trials are the best method to test hypotheses, and the proton beam lends itself to many hypotheses that can be tested.

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2.11. The adoption of new technology in radiation oncology should rely on evidence-based medicine

Christopher F. Njeh and Christian M. Langton
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OVERVIEW

New technologies are constantly being introduced in radiation oncology primarily because they are new and not because they are clearly better than the technologies they are replacing. Often there is a "belief" that the new technology "ought" to be better but many believe that they should be widely adopted in the clinic only after evidence has shown that they are at least as safe and efficacious as existing technologies, which are often less expensive. This is the concern debated in this month's Point/Counterpoint.

Arguing for the Proposition is Christopher Njeh, Ph.D. Dr. Njeh obtained his Ph.D. degree in Medical Physics from Sheffield Hallam University, UK, and, after graduation, he worked at the Addenbrooke's Hospital in Cambridge and Queen Elizabeth's Hospital, Birmingham, UK. He then came to the United States as a Visiting Postdoctoral Fellow at the University of California, San Francisco, where he was subsequently appointed as an Assistant Professor of Radiology. He later completed a Medical Physics residency at Johns Hopkins University, Baltimore, and is currently Chief Medical Physicist at Texas Oncology in Tyler, TX, and holds an adjunct faculty position at the University of Texas at Tyler. Dr. Njeh is certified in Therapeutic Radiologic Physics by the ABR. His major research interests include image-guided radiation therapy and accelerated partial breast irradiation. He is author or coauthor of over 50 papers and 10 book chapters and is coeditor of two books.

Arguing against the Proposition is Dr. Christian McDonald Langton. Dr. Langton obtained his M.Sc. degree in Medical Physics from the University of Aberdeen and his doctoral degrees from the University of Hull. After working in industry for two years, he returned to academia in the UK and ultimately attained the rank of Professor of Medical Physics at the University of Hull. In 2008, Dr. Langton was appointed Professor of Medical Physics at Queensland University of Technology in Brisbane, Australia, and Director of the Queensland Cancer Physics Collaborative. Dr. Langton's main research interest has been in quantitative bone imaging and characterization, and his work on the science, technology, and clinical utility of ultrasound assessment of cancellous bone and osteoporosis has resulted in over 1800 publication citations. He holds several related patents and there are seven commercial devices currently available adopting his broadband ultrasonic attenuation technique, with over 12 000 systems utilized worldwide.

FOR THE PROPOSITION: Christopher F. Njeh, Ph.D.

Opening statement

Medical technology encompasses all drugs, devices, and medical and surgical procedures used in medical care as well as the organizational supportive systems within which such care is provided.[1] Radiation oncology has recently witnessed an explosion in innovation including but not limited to: proton therapy, CyberKnife, tomotherapy, IGRT, and IMRT. Efficacy, safety, and cost effectiveness, however, remains the focus in the provision of optimal care to patients. While some of these innovations offer unprecedented breakthroughs for some patients, they have the potential to also result in unintended harm if not used appropriately. It is, therefore, essential that adoption of these new technologies be evidence based.

Evidence-based medicine can be perceived as "*the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients*."[2] Its practice presupposes the integration of individual clinical expertise with the best available external clinical evidence from systematic collection and synthesis of data, including patients' values and expectations.[3] The gold standard for the attainment of level 1 evidence is usually through randomized controlled trials (RCTs) and meta-analysis of such trials.

There are many reported instances in the scientific literature where RCTs refuted evidence from theoretical, observational, physiologic studies or common sense. In the 1890s, Dr. William Halsted, for instance, developed radical mastectomy for breast cancer. His procedure was performed unchallenged for over 80 years. It was, however, not until an RCT was conducted in the late 1980s that it dawned upon the scientific community that radical mastectomy had no advantage over simpler forms of treatment for early-stage breast cancer.[4] Another more recent example is vascular brachytherapy that was used to treat in-stent restenosis until an RCT showed that this therapy yielded comparatively inferior outcomes to polymer-based slow-release paclitaxel-eluting stents.[5]

Opponents of RCTs may be surprised to learn that not all new therapies amount to an improvement compared to the standard of therapy. For example, an analysis of outcome data from 58 RCTs, including a total of 12734 patients, conducted between 1968 and 2002 by the Radiation Therapy Oncology Group, found that, overall, experimental and standard arms were equally successful.[6] They also found that treatment-related mortality and morbidity were, on average, higher in the innovative arm.

In contemplating these facts, we are reminded of the economist who once said "*…man's wants are numerous but his means are limited.*" His view is applicable to national health care. Were one to place the cost of new technology into proper context it would be safe to assert that U.S. health care costs have risen faster than the gross domestic product (GDP), often by a substantial margin. While in 1960 approximately 5% of the GDP of the United States was spent on medical care,[1] by 2004 it accounted for over 15% and is expected to be as much as 20% of GDP by 2015.[7] According to a landmark study by The Kaiser Family Foundation,[8] new technology has been identified as one of the causes of this exponential rise in health care cost. I submit, therefore, that new technology needs to fulfill the triple condition of efficacy, safety, and cost-effectiveness so that our limited resources can be put to the most judicious use.

AGAINST THE PROPOSITION: Christian M. Langton, Ph.D., D.Sc.

Opening statement

Evidence-based medicine is commonly defined as "*the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients*."[9] These are admirable words, but what do they really mean? Are they a realistic aspiration for adoption of new technologies in radiation oncology?

A key factor is the validity of the *evidence*, so variable in reality that a number of category levels are widely utilized. For example, the U.S. Preventative Services Task Force[10] lists three levels of "quality of evidence," the highest level being "*evidence obtained from at least one properly designed randomized controlled trial.*" For the laudable randomized clinical trial, there has been a dramatic expansion in the number of publications associated with "radiation oncology" alone. Considering "Web of Science" publications per year using the topic search category of ("RCT" or "randomized clinical trial" or "randomized control trial") and ("radiation oncology" or "radiotherapy") yields: 1989= 2, 1994 = 32, 1999 = 55, 2004 = 107, and 2009 = 228. How do we arrive at a consensus based upon such a wealth of information?

To consider the feasibility of performing unambiguous high-quality randomized clinical trials associated with new technology in radiation oncology to determine the "evidence-based best-practice," I raise a number of questions that in many cases identify inherent confounding factors:

- Will a comparison be made against an untarnished "gold standard" or with current practice? The latter will inevitably necessitate large cohort numbers in each study arm, often impracticable from a recruitment perspective.
- Is there potential for a high attrition rate?
- Will it be difficult to assign and maintain inclusion and exclusion criteria?
- Will it be difficult to avoid bias? Very few cases are truly "equivalent."
- Noting the understandable need to maintain a primary focus on patient welfare, as circumstances potentially change, will it be difficult to maintain a rigid protocol?
- Will the protocol be readily and reliably transferable multicenter and multinational?
- How long will it be before the technique could be routinely adopted? Technology developments appear at a fast time rate and may evolve during the course of an RCT such that they are used differently at the end of a trial than at the beginning and might even become outdated before the trial is over.
- How important are factors such as quality of life and secondary cancer risk?

Other criticisms of adopting "evidence-based medicine" include stagnation, bland uniformity, and lowering of standards through deskilling practitioners. Instead of using clinical judgment, they will be encouraged to follow protocols that treat all patients as essentially interchangeable.[9]

There is also a threat to the adoption of new techniques in radiation oncology through a growing movement of "lack-of-evidence based medicine" that has been used to restrict access to a number of therapies,[11] particularly by the UK's National Institute of Clinical Excellence.

Perhaps the hottest "new technology in radiation oncology" debate relates to proton verses photon IMRT, with a question raised as to whether large randomized phase III comparative trials should be performed?; that would inherently encompass a significant number of scientific and ethical issues[11,12] — I will end with that thought!

Rebuttal: Christopher F. Njeh, Ph.D.

My opponent has identified some potential shortcomings of evidence-based medicine (EBM), to which I would offer these counter arguments:

- The sheer volume of information available in the literature is more reason for a unified and systematic approach to synthesize them.
- Recruitment bias can be avoided by proper randomization.[13]
- EBM makes decision making more thoughtful and more transparent, providing a stronger scientific backbone to medical practice.
- Not all studies are carried out with the same degree of rigor (quality, quantity, and consistency) hence a need to grade the quality of the research such as required by SORT,[14] GRADE,[15] or the Center for Evidence Based Medicine.
- The FDA is not thorough enough in its technology approval process. Recent studies have shown that the FDA premarket approval process is often based on weak studies.[16]

- Ethical dilemmas in RCTs are eliminated by the acknowledgement of the equipoise principle which assumes that the two arms in a study have an equal chance of performing well.[17] This principle has been validated by the fact that only 25%–50% of new technology is better than traditional technology.[18]
- Another issue with pursuing RCTs has to do with the vested interests of three players if the RCT proves that the procedure is ineffective: the physician (new technology is accompanied by higher reimbursement), the hospital (need to pay for the equipment), and the manufacturer (need to make a profit).[19]

In conclusion, obtaining the relevant high quality evidence is a challenging, demanding, time-consuming, and costly pursuit. Nevertheless, it is a rigorous process, which we must demand of new technology so as to remain accountable to our patients.

Rebuttal: Christian M. Langton, Ph.D., D.Sc.

Having carefully considered my opponent's Opening Statement, I am confident that the arguments provided within my own Opening Statement remain valid and wholly intact. There are two primary components of my opposition to the proposition. First, it is impossible in reality to acquire irrefutable evidence as to whether a "new technology" will indeed improve individual patient care. Second, it is impossible to create a single unifying consensus based upon reported data. Allied to this, there has been a dramatic increase in the number of evidence-based medicine derived "clinical guidelines," so much so that there has been a call for "guidelines for clinical guidelines" within a British Medical Journal Editorial.[20]

A fundamental question that we must address is whether so-called "evidence-based medicine" serves its purpose of helping clinicians make better decisions for the individual patient; related not only to the primary factors of diagnosis and treatment, but also encompassing prognosis, benefit, risk, and cost.

Continuing this somewhat broader perspective, I wish to consider another component of the proposition's title, specifically, what do we really mean by "new technology in radiation oncology"? Are many so-called "new technologies" simply part of a fundamentally evolutionary advancement process? Noting the age-old tenet of "maximally treating the cancer by maximally sparing normal tissue," are we in danger of being distracted away from aspects of radiation oncology that are of greater importance from an individual patient's perspective? For example, are we in need of true "new technologies" that better target regions of a particular tumor or organ that require, or maybe do not require, "treatment;" and to determine how these relate to both static and temporal anatomy?

In summary, while appreciating the ideological paradigm that "the adoption of new technology in radiation oncology should rely on evidence-based medicine," in reality, this cannot be achieved and we should concentrate on the primary role of helping clinicians make better decisions for the individual patient.

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CHAPTER 3

Brachytherapy

3.1. Miniature x-ray tubes will ultimately displace Ir-192 as the radiation sources of choice for high dose rate brachytherapy

Randall W. Holt and Bruce R. Thomadsen
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OVERVIEW

Recent advances in the development of miniature x-ray tubes have made electronic brachytherapy a feasible alternative to conventional high dose rate brachytherapy with high activity Ir-192 sources. Because of the obvious radiation safety and security advantages, it is conceivable that the miniature x-ray tube might displace Ir-192 as the source of choice for HDR brachytherapy. This is the proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is Randall W. Holt, Ph.D. Dr. Holt earned his Ph.D. in Biomedical Engineering at Case Western Reserve University, specializing in 3D-image analysis, after which he received postdoctoral training at the USC Department of Radiation Oncology, specializing in virtual simulation and 3D dosimetry software. Currently Dr. Holt is the Director of Physics for North Valley Radiation Oncology, which provides a broad range of medical physics services to clinics in Northern California. He is board certified by the ABR in radiation therapy physics.

Arguing against the Proposition is Bruce R. Thomadsen, Ph.D. Dr. Thomadsen earned his M.S. and Ph.D. degrees in Medical Physics at the University of Wisconsin—Madison, where he is currently an Associate Professor in the Department of Medical Physics. He is board certified by the ABR in Radiological Physics, by the ABHP in Comprehensive Health Physics, and by the ABMP in Radiation Oncology Physics. His major research interests include all aspects of radiation therapy physics but especially brachytherapy. Dr. Thomadsen currently serves on numerous AAPM committees and task groups and chairs the Radiation Safety Subcommittee and the Special Brachytherapy Modalities Working Group, and is a member of the Board of Editors of *Medical Physics*.

FOR THE PROPOSITION: Randall W. Holt, Ph.D

Opening statement

To displace Ir-192, miniature x-ray sources must deliver therapeutic radiation as well as, or potentially better than, Ir-192, under safer conditions, and with favorable economics.

Current electronic brachytherapy (eBx) source technology provides dose rates comparable to 7-Ci Ir-192 sources, with similar cylindrically symmetric dose distributions, using miniature x-ray tubes small enough to be inserted into the human body via catheter guides.[1] Energy is the distinguishing characteristic, with eBx sources ranging from 20 to 50 kVp, compared to 380 keV for Ir-192.[1] At 50 kVp, eBx sources attenuate as a function of about $1/r^3$ compared to Ir-192 which attenuates roughly as $1/r^2$.[1] Inverse-cubed dissipation can be advantageous. For example, with accelerated partial breast

irradiation (APBI) treatments, the dose to lung and heart is less with eBx.[2] For gynecological treatments, the dose limiting tolerance of proximal organs using Ir-192 is mitigated at 50 kVp.[3] Integral dose, linked to radiation-induced cancer, is reduced with eBx.[4]

Both economics and safety favor the use of eBx over Ir-192. Room shielding is minimal for 50 kVp, for which exposure is reduced by a factor of 10^3 with just 0.51 mm Pb.[5] The therapy team can remain in the room during treatment, behind a rolling shield, increasing patient confidence. Treatments can be conducted in the CT suite, immediately after imaging, without moving the patient and disturbing the applicators, improving the final outcome as well as patient throughput. The regulatory overhead of radioactive materials increases with every passing year.[6] For sound reasons of safety, Ir-192 requires the presence of a physician and a physicist.[7] While Ir-192 adverse events are rare, quick reaction is critical to prevent misadministration.[7] With eBx, even if all electronic and mechanical failsafe mechanisms were to fail, one needs only to pull the power plug. Smaller centers with modest patient loads cannot justify the costs of initial purchase, continual source replacement or physics effort required for Ir-192 sources. The initial cost of an eBx unit is less than that of an Ir-192 remote afterloader and eBx sources can be acquired on an as-needed basis, leading to more readily available treatment and thus to better patient care.

While the previous arguments are sufficient to show that eBx can compete with Ir-192, the reason that eBx will ultimately replace Ir-192 lies in the potential for improved treatment. In general, HDR treatment is limited by the surgical implant quality. Over 10% of APBI treatments fail due to inadequate skin spacing or cavity conformance.[8] Endometrial treatments are limited by proximal organ dose.[4] In such cases, no amount of plan optimization can produce an acceptable result. Electronic brachytherapy could potentially mitigate suboptimal implantation by varying the treatment energy and source anisotropy. From 20 to 50 kVp, a thin metal foil can attenuate dose and produce a noncylindrical anisotropy, which could be shaped to match irregular target volumes. With appropriate 3D planning, dose distributions for suboptimal implants could be improved or irregularly shaped targets could be treated using this method of intensity modulated brachytherapy (IMBT). Ultimately, Ir-192 HDR will be used only for a limited set of specialized treatments, having been displaced by eBx-based IMBT.

AGAINST THE PROPOSITION: Bruce R. Thomadsen, Ph.D

Opening statement

First, I will assume that this discussion addresses only electronic brachytherapy with a stepping source and not rigid units used mostly for intraoperative treatments. Then the reasons I believe electronic brachytherapy will not replace HDR Ir-192 are that, with electronic brachytherapy, regulations will not be simplified, dose distributions within and just outside the target volume will be less uniform, dose distributions will be more affected by inhomogeneities, and the time commitments by physicists will be increased. I will address each of these in turn.

Regulations. While professionals in radiation practices often complain about the Nuclear Regulatory Commission, state radiation regulations have become, or are becoming, very similar. The CRCPD is proposing model regulations for states to apply to electronic brachytherapy. Thus, practitioners will have to deal with regulators one way or the other.

Treatment target dose uniformity. With electronic brachytherapy, the dose decreases more rapidly with distance from the source because the electronic brachytherapy tubes operate at about 50 kVp, compared with the effective energy of about 380 keV for Ir-192. Thus, the dose through the target volume is less uniform. For example, for intracavitary breast irradiation with the same dose at the prescription distance of 1 cm from the surface of a 4-cm diameter balloon, the dose at the surface of the balloon with electronic brachytherapy becomes 1.5 times that with Ir-192. The dose beyond the prescription distance decreases more rapidly with the electronic brachytherapy. The importance of the dose beyond the prescription point is not yet known. It might be that success of intracavitary breast irradiation depends on

the dose to cells beyond the nominal prescription distance and reducing that dose could decrease the efficacy of this form of treatment. This may apply to treatments at some other sites also.

Effects of inhomogeneities. The lower energy of electronic brachytherapy moves most of the interactions into the photoelectric region, so atomic number inhomogeneities will have a greater effect than with Ir-192. Density differences will also result in more inhomogeneity in doses.

Time commitment. Compared with HDR Ir-192, electronic brachytherapy requires more time on the part of the medical physicist on two fronts. First, because each tube is used for only one patient, a complete calibration is required for each patient when initiating that patient's treatment. If two patients are treated consecutively, the tubes must be changed between patients, and this requires new quality assurance measurements. This becomes even more burdensome with twice-daily treatment: while a single patient under treatment would require only one set of QA measurements per treatment day, with two BID patients, there may be four sets of measurements.

In conclusion, there is clearly no compelling reason to replace Ir-192 with electronic sources.

Rebuttal: Randall W. Holt, Ph.D

My opponent makes a series of minor arguments, mostly valid, but insufficient as a whole to derail widespread adoption of eBx technology. I will address each of these in order.

Regulations. Medical physicists should provide a quality effort regardless of which regulatory body is watching, but the difference between the regulatory overhead of an x-ray tube versus an isotope is considerable and can be measured in inches of paper and days of effort.

Treatment target uniformity. Granted, tissue nearer the source will receive higher doses with eBx than with Ir-192, But, outside of dose regions of necrotic potential, it is typically the doses to critical organs that govern our prescriptions and fractionation schema. PTV margins are established for good scientific reasons and an argument that dose beyond the PTV could be somehow beneficial is anathema to a four decade long program in medical physics to image, target, and deliver dose to medically directed areas and minimize dose everywhere else.

Effect of inhomogeneities. Absorbed dose to lung and bone is energy dependent, but the clinical impact in brachytherapy is unclear. However, the potential for IMBT opens the possibility for conformal dose shaping around critical structures. Now that we know that it is physically possible, IMBT seems inevitable.

Time commitment. It is correctly asserted that currently, since each patient must be treated with a new tube, a complete calibration is required for each eBx patient. However, we need to convince the FDA that a more appropriate safety limit is that of cycles, rather than limiting one-source-per-patient. Ir-192 sources have a limit on number of extraction/retraction cycles and a limit on tube-on/off cycles would also seem a reasonable specification for eBx.

Rebuttal: Bruce R. Thomadsen, Ph.D

The following is my response to the claims made by my opponent regarding potential advantages of eBx over Ir-192 for HDR brachytherapy.

Advantages due to energy. While the more rapid attenuation of the x rays can reduce doses to neighboring structures, the uniformity of the target dose suffers.[9] With breast brachytherapy, the skin is only a problem for intracavitary treatment with single catheter applicators. Newer multichannel applicators address the skin dose while allowing the superior penetration of Ir-192. Contrary to my opponent's assertion, endometrial treatments are not limited by proximal organs.[10] The success of both eBx and Ir-192 HDR brachytherapy may be due to dose beyond the prescription point. Reducing the integral dose may be laudable but not at the expense of cures.

Radiation Protection. Granted, electronic brachytherapy units require markedly less shielding and allow personnel to be present during treatment. However, with Ir-192 HDR brachytherapy we have not had any problems due to personnel leaving the room for treatments. The minimization of concern about loss of control of the source is also a benefit, but given the number of events of that nature, which can be handled easily, the benefit is questionable.

Regulation. Despite security not being an issue for the electronic sources, it is unlikely that regulations in general will be much different. Proposed regulations, and good practice, require calibration of each x-ray tube (one for each patient), and a calibration check when the tube has been changed (between patients): a significant burden for medical physicists.

Costs. Whether the cost of a new radionuclide source is an allowed billing line item has changed over time, just as it may for x-ray tubes. The costs of replacement sources are built into the HDR charges, so there is no economic advantage to either source based on source costs. Regarding readiness for treatments, the sources in Ir-192 HDR units are always ready with no chance of being out of stock.

Applicator shielding. Concerns expressed about possible applicator shielding apply only to intracavitary treatments, since electronic brachytherapy sources cannot be used for interstitial implants due to the tube size. Ir-192 HDR vaginal cylinders currently accommodate shielding. In cervical cases, where additional shielding would be useful, the rapid decrease in dose with distance for eBx could compromise the deep dose and the effectiveness of the treatment.

In conclusion, while electronic brachytherapy offers definite advantages and will find a place in brachytherapy, it is unlikely that it will replace conventional Ir-192 HDR brachytherapy.

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3.2. Intensity modulated electronic brachytherapy will soon become the brachytherapy treatment of choice for irregularly shaped tumor cavities or those closely bounded by critical structures

Edward S. Sternick and Dorin A. Todor
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OVERVIEW

Brachytherapy treatment of irregularly shaped tumor cavities or those closely bounded by critical structures can be a challenge with conventional radionuclide sources due to the isotropic nature of the dose distribution around each source. One proposal to address this problem is to use miniature x-ray sources instead of radionuclides and to intensity-modulate the radiation emitted, much as with IMRT in teletherapy. The proposition that this approach might become the treatment of choice for such lesions is debated in this month's Point/Counterpoint.

Arguing for the Proposition is Edward S. Sternick, Ph.D. Dr. Sternick obtained his Ph.D. in Medical Physics from UCLA in 1968 and subsequently joined the faculty of the Dartmouth-Hitchcock Medical Center, where he founded the Medical Physics Section and co-founded the Biomedical Engineering Program at Dartmouth's Thayer School of Engineering. He is currently Medical Physicist-in-Chief, Professor, and Vice Chair of Radiation Oncology at Rhode Island Hospital/Brown University Medical School, Providence, RI. Dr. Sternick has been active in several organizations, especially the AAPM in which he has been a member and/or chair of 39 Committees and Task Groups. He has served as President of the AAPM and the ABMP. His many honors include Fellowships of the AAPM, the ACMP, and the ACR, and the Marvin M.D. Williams Professional Achievement Award of the ACMP.

Arguing against the Proposition is Dorin A. Todor, Ph.D. Dr. Todor obtained his Ph.D. in Physics from Old Dominion University, Norfolk, VA, and subsequently completed a medical physics research fellowship at Memorial Sloan-Kettering Cancer Center, New York. He is currently Assistant Professor at the Medical College of Virginia, Virginia Commonwealth University, Richmond, VA. His major research interests include development of real-time imaging of catheters during placement for HDR partial breast irradiation, clinical validation of intraoperative planning, delivery and dosimetric assessment of LDR prostate brachytherapy, and modeling radiobiological effects in prostate and breast brachytherapy.

FOR THE PROPOSITION: Edward S. Sternick, Ph.D.

Opening statement

A proposition recently debated in a Medical Physics Point/Counterpoint article deals with the possible ultimate replacement of conventional Ir-192 HDR brachytherapy by miniature x-ray tubes.[1] The technological alternative referenced, in which a 50 kVp x-ray source is employed to deliver the radiation, has been termed electronic brachytherapy (EB).[2,3] Available miniature x-ray sources are small enough to be introduced into a body cavity through a catheter and provide dose rates comparable to those from radionuclide brachytherapy sources. Initial EB clinical studies have been reported for the treatment of breast and endometrial cancers[4,5] with a number of other tumors under consideration.

EB has several immediately identifiable advantages: (1) because of the relatively low energy of the x rays, treatments can be delivered in an unshielded room in contrast to the significant protective shielding required for Ir-192 brachytherapy; (2) the low exposure rate allows staff to remain near the treatment couch during dose delivery where they can provide comfort and encouragement to the patient; and (3)

since x rays are produced electronically, safety and security concerns associated with the transport and storage of radioactive material are unnecessary and Nuclear Regulatory Commission oversight is not mandated.

There are additional advantageous dosimetric properties to consider. Low-energy miniature x-ray source characteristics can be uniquely exploited with an approach called Depth Dose Modulation (DDM).[6] This procedure combines source collimation and microindexing to selectively modify the depth-dose characteristics of the source and create customized dose distributions for a variety of brachytherapy applications. A close fitting, two-section adjustable collimator, consisting of a cylindrical band around the lower portion of the source and a cap over its tip, provides predefined aperture settings that can generate controllable beam hardening and attenuation. Microindexing the source using variable step sizes, when combined with modification of the collimator gap width, facilitates the selection of optimal depth-dose characteristics for a given clinical situation. For example, the depth dose can be made to fall off rapidly near critical structures or, conversely, it can be adjusted to fall off less rapidly in the absence of these structures, thereby achieving a more homogeneous dose distribution.

Furthermore, the selectable shielding capability that is readily achievable only with a low energy x-ray source provides a powerful tool for developing Intensity Modulated Electronic Brachytherapy (IMEB)[7] plans. This capability should make possible the production of more conformal brachytherapy dose distributions in irregularly shaped tumor cavities or those closely bounded by critical structures. This property will potentially permit dose escalation to achieve increased cure rates while reducing normal tissue toxicity.

AGAINST THE PROPOSITION: Dorin A. Todor, Ph.D.

Opening statement

The proposition is provocative, but there is limited evidence to support it. A proof of principle has been offered that electronic brachytherapy (EB) could be “modulated” by collimating and stepping the source.[7] The immediate effect of collimation would be the significant prolongation of the treatment time. It is not obvious how a collimated but still cylindrically symmetrical source would improve conformance for irregular targets using a single lumen, when the irregularity would be—as often it is—in the radial direction. Given the large source size (5.4 mm assembly diameter compared with 0.59 mm for Ir192 VariSource), any multi-lumen applicator would be prohibitively large and the inability to travel through curved applicators will severely limit possible applications.

There are other more general and important considerations worth mentioning. The proposition mentions “*tumor cavities*,” implying that the breast is a major site of application. In an evidence-based paradigm, one must remember that virtually all of the long-term accelerated partial breast irradiation (APBI) experience has been acquired in an Ir-192 based delivery setting. The question is: can this experience be used to validate and justify EB, given the significantly different depth dose distribution? A review of clinical data reveals that in 90% of patients with initial negative margins, residual disease was confined to $\leq$ 10 mm from the edge of the cavity wall.[8,9] Most clinical trials, however, require only D90 $\geq$ 90%,[10] making “coverage” with the prescription dose significantly smaller than 1 cm. However, because the observed elsewhere recurrence rate is less than 1%,[11] the radiation effect likely extends beyond the 1 cm of the *assumed* target. Simply placing a prescription constraint at an arbitrary distance of 1, 1.5, or 2 cm from the surface of a device or from the lumpectomy cavity wall does not stop the dose distribution at that distance. A more or less arbitrary dose of 3.4 Gy/fraction at 1 cm, results in about 2 Gy at 1.5 cm or 1.8 Gy at 2.0 cm. We simply do not know what exact dose or margin is appropriate for various sites but we do know that *in tandem* the values used today are clinically meaningful. Mimicking only the 1 cm prescription point behavior, which is how EB has been used so far,[12] completely ignores the paradigm under which most clinical data have been acquired. The issue of prescription becomes even

more complicated when the RBE of low energy x rays, compared to that of the Ir-192 radiation,[13] is taken into account.

It has been shown[4] that V200 and V150, as well as the dose homogeneity index (DHI), correlate with side effects observed in interstitial multi-catheter APBI. In the balloon-based treatment, for example, 200% is likely the highest dose present in the "target," whereas EB would create a large V300 or higher! It is difficult to understand how such hot spots, previously nonexistent, would be an improvement over the current paradigm.

The technical ability to simply produce vastly different dose distributions (the means are irrelevant) is of little use unless, through carefully scrutinized clinical trials, one proves that the new modalities have equivalent or better clinical outcomes. Since most of the side effects associated with high dose regions need many years to be fully realized (also true for treatment "failure"), the word "*soon*" used in the title is rather misleading.

To conclude: It is not clear how the "modulated" version of EB works in real life, or how it would be applied and with what clinical consequences. To extend this to "*soon to become the treatment of choice*" would be, in the words of A. Greenspan, "Irrational exuberance."

Rebuttal: Edward S. Sternick, Ph.D.

In the words of Albert Einstein, "Knowledge of what is does not open the door directly to what should be." As is typical of most major technological advances in radiation oncology, the current early stage development of IMEB does not negate its genuine potential for widespread utilization in the near future. When external beam IMRT first moved from theory to clinical practice in the 1990s, it was readily acknowledged that the IMRT treatment planning and delivery systems available early on would profit significantly from continued development to improve their operational functionality. This progress was soon realized. Within a remarkably short time following its introduction, IMRT became widely adopted and is today regarded as an indispensable treatment modality. We can anticipate that IMEB, now in its formative period, will evolve similarly over the next few years into a robust alternative for diverse brachytherapy scenarios.

With substantial improvements in EB x-ray source technology currently underway, these miniature devices are becoming smaller and more adaptable to support a wider array of treatment options beyond those restricted to just breast and endometrial sites. The ability to selectively and controllably alter depth-dose profiles by variable collimation and microindexing will overcome the most significant dosimetric disadvantages of EB and open the field to a broad range of applications. Although actual beam-on time might increase somewhat using IMEB because of the source output modulation, just as it does with most IMRT treatments, this temporal increment represents only a fraction of the total time associated with a course of brachytherapy, whether it is intensity modulated or delivered in a more traditional manner. With either approach, there is often much greater time allocated to setup and applicator placement in a patient than that required for the radiation delivery itself.

Intensity modulated electronic brachytherapy challenges traditional conventions, mindsets, and prejudices. But the IMEB methodology, which enables the conformality of high dose to a specified tumor volume while maintaining low doses to neighboring sensitive tissues, promises to become a valuable and preferred tool in the radiation oncologist's brachytherapy armamentarium.

Rebuttal: Dorin A. Todor, Ph.D.

Electronic brachytherapy is without doubt a novel technique in search of interesting applications. The idea of DDM, presented only as an abstract,[7] is intriguing. A compelling and detailed explanation of how DDM would actually be applied to increase the homogeneity of dose distribution in irregularly shaped structures while sparing others is now due. There are foreseeable technical difficulties: the lack of control/feedback over the actual dose rate during delivery and the control of microindexing and of the

collimator gap. There is currently significant resistance to the idea of optimization in brachytherapy, in part due to subpar planning software and in part due to the belief of some physicians and physicists that planning "by hand" is better. Optimizing a plan using DDM would be significantly more difficult; nonoptimizing would render it useless! But while the technical problems can probably be solved with expenditure of sufficient resources, only time and carefully controlled clinical trials will validate this new technology. The enthusiasm for the development of a novel source has to be balanced by a healthy skepticism regarding its clinical application. The lack of shielding and regulations for EB has the potential to make brachytherapy more available. A generous goal indeed, but we should remember that so was the government's vow a few years ago to spread the dream of homeownership.

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CHAPTER 4

Imaging: mammography, CT, PET, molecular imaging, MRI

4.1. Cone beam x-ray CT will be superior to digital x-ray tomosynthesis in imaging the breast and delineating cancer

Andrew Karellas and Joseph Y. Lo
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OVERVIEW

Recent advances in cone beam CT and digital x-ray tomosynthesis suggest that three-dimensional (3D) systems may soon replace conventional planar mammography as the modality of choice for imaging the breast and delineating cancer. Both of these new technologies exhibit clear advantages over planar mammography but which one of these two is most likely to dominate is debatable. This is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Andrew Karellas, Ph.D. Dr. Karellas received his Ph.D. in Medical Physics from UCLA in 1984 and is currently Professor of Radiology in the University of Massachusetts Medical School, Worcester, MA. He is a Diplomate of the ABR in Diagnostic Radiologic Physics and a Fellow of the AAPM. His interests include digital mammography, tomosynthesis, and tomographic and 3D imaging of the breast. He is a member of the Medical Physics Board of Editors and serves as a Deputy Editor, and has been the Chairman of the AAPM Diagnostic X-ray Imaging Committee and TG 15 on Digital Mammography for Stereotactic Localization. He is a Past President of both the New England and Southeast Chapters of the AAPM.

Arguing against the Proposition is Joseph Lo, Ph.D. Dr. Lo received his Ph.D. in Biomedical Engineering from Duke University, Durham, NC. Between 1993 and 1995 he was a postdoctoral research associate in the Department of Radiology, Duke University Medical Center. He is currently Assistant Professor of Radiology and Biomedical Engineering, and serves on the faculty of the medical physics graduate program at Duke. His interests cover many aspects of breast cancer research including breast tomosynthesis and CT, bioinformatics, computer-aided diagnosis, and digital image processing.

FOR THE PROPOSITION: Andrew Karellas, Ph.D.

Opening Statement

The general concepts of digital breast tomosynthesis (DBT) and dedicated breast computed tomography (DBCT) have been known for many years, but they could not be practically implemented without advanced flat panel detectors of the type that are now used for digital radiography and mammography.[1,2,3,4,5,6] Recent advances in flat panel detector technology have provided a strong impetus for the development of improved and computationally efficient image reconstruction algorithms for DBT and DBCT.[7] In parallel, research and development efforts in digital mammography have been directed toward improvements in the physical aspects of planar imaging of the breast. However, imaging in planar mammography is limited by the inability to visualize tissues in a tomographic or three-

dimensional mode. Therefore a suspicious abnormality can be obscured by interfering breast tissue because the three-dimensional anatomy is represented in a two-dimensional image. DBT and DBCT hold considerable promise in overcoming the limitations of mammography, particularly in dense breasts, but DBT may be viewed as a limited tomographic extension of digital mammography rather than a true tomographic and 3D imaging modality. Breast tomosynthesis can be performed in a number of ways by varying the projection geometry, detector characteristics, exposure technique, reconstruction algorithm, and mode of image display. Developers of the technology may claim unique advantages of a particular tomosynthesis approach based on the implementation of various improvements. For example, we are likely to see improvements in radiation dose efficiency, speed of acquisition, image reconstruction speed, and reconstruction artifacts. Despite such advances, DBT is fundamentally limited by its constraints in the projection geometry. In DBT the tomographic slice is not well defined, which can cause loss of resolution in the axial direction that can affect visualization of subtle features such as amorphous microcalcifications.

Dedicated computed tomography can image the entire breast in a more complete tomographic approach and with essentially isotropic resolution. This technology is in its infancy and several improvements have yet to be made that relate to parameters like voxel size, cone beam reconstruction, x-ray scatter suppression, radiation dose, and breast coverage. Dedicated breast CT can generate true tomographic and 3D images of the breast hitherto unavailable by any other x-ray imaging technique of the breast, and it does not require physical compression of the breast. It is likely to be of particular value for imaging dense breasts and breasts with implants. Given the choice between limited tomography with breast compression offered by tomosynthesis and full tomography with 3D imaging of the breast without compression, dedicated breast CT offers a more powerful alternative to tomosynthesis. Although I am strongly in favor of continued research on DBT, we should make an even greater commitment in DBCT because of its true tomographic and 3D capability.

AGAINST THE PROPOSITION: Joseph Lo, Ph.D.

Opening Statement

Digital tomosynthesis will replace mammography, and soon, while breast CT will not. This strong claim is justified because tomosynthesis (often abbreviated as “tomo”) has all the advantages of mammography, while providing 3D images to address mammography's main problem of overlapping tissue.

Breast tomo is based upon modifications to existing full-field digital mammography (FFDM) systems. The result is high resolution in the *x-y* plane parallel to the compression paddle, with lower but acceptable resolution (e.g., 1 mm) in the *z*, or depth, direction. In comparison, breast CT resolution within each slice is likely to be several times worse, possibly affecting the ability to detect and characterize calcification morphology. Even for masses where resolution is likely not the limiting factor, one study showed no significant difference in performance between breast tomo and CT.[8] Although research continues in order to optimize tomo acquisition[9,10] and reconstruction,[11,12,13,14] clinical trials with federal and industrial funding are already in progress involving multiple sites/vendors and well over 3000 subjects to date.

Tomo is technically just limited-angle cone beam CT, but angular range is not the only important difference between the modalities. Tomo compresses the breast in a standing position just like mammography, while breast CT uses no compression and thus requires prone positioning. This distinction is actually a very big deal for many clinically relevant reasons. First and foremost, tomo provides far better posterior tissue coverage than CT. Because the patient lies on a table with finite thickness and there is no compression to pull the breast into position, the chest wall and axilla cannot be effectively imaged. Moreover, just getting some patients into the prone position will slow down the

workflow or just be impossible, such as for women who may be arthritic, morbidly obese, or otherwise infirm. For these women, posterior tissue coverage will be even more challenging.

Breast tomo also has several practical advantages. Minimal re-training is necessary for technologists (as positioning and operation are virtually the same as for FFDM) or radiologists (because tomo images already resemble mammograms). In contrast, breast CT is a whole new modality and may require substantial re-training. Consider as well infrastructure and cost. While a tomo system can do double duty as a conventional FFDM system, a breast CT unit cannot, which means hospitals would need to buy both mammography and CT units. The unit cost for breast CT is also likely to be much greater than that of a much simpler FFDM/tomo system. Finally, the larger footprint of the breast CT table may not fit into existing mammography rooms, which would require even more costly renovations and downtime.

In summary, although breast CT will play some role in future breast imaging, it is not practical for primary screening. Breast tomo will have comparable performance and much wider clinical acceptance than breast CT. Ultimately, breast tomo will likely replace mammography, at least for screening and, perhaps, for diagnostic examinations as well.

Rebuttal: Andrew Karellas, Ph.D.

Breast tomosynthesis is not likely to provide the final solution to circumventing the limitations of planar mammography. Tomosynthesis systems are not likely to evolve as simple upgrades of existing digital mammography systems. Major redesign with regard to the mechanics of the motion of the x-ray tube and detector must be made and the beam quality (kVp, target, filtration) is likely to be different from that in planar mammography in order to maintain low radiation dose. This would also require modifications of the detector in the form of larger pixel size, pixel binning and thicker x-ray detector that would result in lower spatial resolution than in digital mammography. The adaptation of breast tomosynthesis systems to a dual function for digital mammography and tomosynthesis is attainable but such systems will not deliver true tomographic and 3D information. Breast tomosynthesis relies on limited projections (typically about 10–25) and the reconstructed images are inherently prone to artifacts that may render some features difficult to interpret. Its spatial resolution in the depth (z) direction presents a particular concern in depicting the geometry and morphology of clustered microcalcifications due to its non-isotropic resolution and propensity to artifacts.

By comparison, dedicated breast CT delivers isotropic spatial resolution for true tomographic and 3D depiction of anatomic detail, and it is less prone to image reconstruction artifacts in the absence of highly attenuating tissues and large cone beam angle. DBCT is critically dependent on advances in detector and electronics technology for attaining good spatial resolution, fast data acquisition and lower radiation dose. Slip ring technology can be implemented for fast acquisition in order to avoid any motion effects. In view of recent advances in detectors and electronics and gantry design and rotational mechanics, further improvements in DBCT are very realistic. Simultaneous imaging of the axial and medial aspects of the breast presents a significant challenge with DBCT but, with innovative gantry design, rotational mechanics and patient positioning techniques, this challenge can be met. Finally, unlike tomosynthesis, DBCT does not require physical compression of the breast and this represents a radical departure and a great improvement over existing techniques.

Rebuttal: Joseph Lo, Ph.D.

I agree with Dr. Karellas that the limited angle acquisition of tomosynthesis is a limitation. I disagree, however, on its impact. Tomo consistently provides compelling images that have radiologists clamoring for the technology. In a recent clinical study, tomosynthesis outperformed mammography in sensitivity and specificity.[15] Radiologists do not mind the artifacts or depth resolution. They *are* concerned, however, with workflow implications of interpreting dozens of images per breast for tomo and possibly 200 or more for breast CT.

Breast CT will probably play an important role as a diagnostic adjunct to mammography or tomosynthesis. I agree that CT will image implants far better. As for 100% dense breasts, tomo can often image them quite well already, but CT may do even better. CT may also facilitate future quantitative applications such as contrast enhanced imaging.

Microcalcifications are a controversial issue for both modalities. Tomosynthesis has higher in-plane resolution but may suffer from artifacts. Clinical results to date are mixed, and this is an active area of research. Others have suggested hybrid scan sequences which avoid the whole problem by acquiring a conventional FFDM in mid-tomosynthesis scan.[16] In comparison, breast CT's lower in-plane resolution may make calcification detection and characterization quite challenging.

At this moment, neither of these modalities has received approval in the US or elsewhere. This may change quickly, of course, but clearly both are nascent technologies and there is much potential for improvement. On this point, my colleague and I certainly agree.

In conclusion, while breast CT yields "true" 3D images, it has important practical limitations including prone positioning, poor posterior coverage, and likely higher cost. Tomosynthesis delivers practical and effective 3D images without such limitations. From the patient's point of view, we may use slightly less compression to achieve dose reduction, positioning, and immobilization while avoiding pain. Tomosynthesis is therefore likely to become the new standard for screening and perhaps diagnostic breast imaging.

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4.2. Molecular breast imaging will soon replace x-ray mammography as the imaging modality of choice for women at high risk with dense breasts

Michael K. O'Connor and Georgia Tourassi
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OVERVIEW

X-ray mammography has been the mainstay of breast cancer screening for decades, with excellent results. There is a problem, however, with detection of cancers in women at high risk and/or with dense breasts. For this population of patients, other modalities are being studied and some, such as molecular breast imaging (MBI), have shown sufficient promise to encourage some to suggest that MBI will soon replace x-ray mammography as the imaging modality of choice for women at high risk with dense breasts. This is the proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is Michael K. O'Connor, Ph.D. Dr. O'Connor graduated with a Ph.D. from the Department of Clinical Medicine, Trinity College, Dublin in 1978. He worked as a medical physicist in Dublin for ten years before moving to the United States in 1986, where he was appointed Assistant Professor of Radiologic Physics at the Mayo Clinic, Rochester, MN, where he is currently Professor in the Division of Medical Physics. His major research interests include molecular breast imaging, SPECT/CT, and bone densitometry.

Arguing against the Proposition is Georgia Tourassi, Ph.D. Dr. Tourassi graduated with a Ph.D. in Biomedical Engineering in 1993 from Duke University, Durham, NC and completed a residency in the Radiology Department at Duke in 1995. She is currently Associate Professor of Radiology and Medical Physics at Duke University. Her major research interests include computer-assisted radiology, especially mammography, breast elemental composition imaging, receiver operating characteristics analysis, and applications of artificial neural networks.

FOR THE PROPOSITION: Michael K. O'Connor, Ph.D.

Opening Statement

In some respects, the pertinent question in this debate should not be whether MBI will replace x-ray mammography in women at high risk with dense breasts but rather *what* imaging modality will replace mammography in this subpopulation. While the overall sensitivity of mammography ranges from 71% to 96%, the sensitivity drops to <60% in women at increased risk of breast cancer[1] and to <50% in women with mammographically dense breasts,[2] groups in which considerable overlap exists. In the United States, about 25% of women 40 and older have dense breasts and about one to two million women are at increased risk of breast cancer, hence the number of women impacted by the limitations of mammography is substantial.

Modalities that have been explored as possible replacements for mammography are digital mammography, ultrasound, and MRI. A large multicenter study of digital mammography (DMIST) failed to demonstrate a clear advantage over film mammography in women with mammographically dense breasts,[3,4] and the recent ACRIN 6666 trial showed that whole breast ultrasound was no better than mammography in women at high risk with dense breasts.[5] Studies on breast MRI have shown that it performs significantly better than mammography in this population[1] and the American Cancer Society has recommended breast MRI screening for women at high risk. In doing so, however, it acknowledged

that breast MRI has some drawbacks, including variable specificity (50%–90%) and high cost. These may prove to be significant impediments to its widespread use as a screening modality.

MBI is a nuclear medicine technique that utilizes small semiconductor-based gamma cameras that have significantly better spatial and energy resolution than conventional gamma cameras, permitting improved detection of small breast tumors.[6] In MBI, four to eight images are acquired, making interpretation significantly less complex than MRI. Using light pain-free compression, the breasts are imaged in a similar configuration to mammography, thus simplifying correlation between the two modalities. A recent study has shown that this technology has a similar sensitivity to MRI.[7] More importantly, preliminary results from a large screening study have shown MBI to have comparable or better specificity than mammography while detecting two to three times more cancers in women at high risk with dense breasts.[8]

Hence MBI appears to have many of the characteristics required for a screening test: High sensitivity, high specificity, low cost, and limited number of images allowing for rapid interpretation. From the patient's perspective, elimination of the painful compression associated with mammograms should increase willingness to undergo annual screening. Current studies utilize Tc-99m sestamibi, which is an FDA approved radiopharmaceutical for breast imaging. A number of new molecular imaging agents under development, however, promise to further improve the diagnostic capability of MBI. Given the current results with MBI and the promise of better radiopharmaceuticals, I believe that MBI will soon replace x-ray mammography as the imaging modality of choice for women at high risk with dense breasts.

AGAINST THE PROPOSITION: Georgia Tourassi, Ph.D.

Opening Statement

Women at high risk of developing breast cancer due to genetic factors, family history, and/or dense breasts are the Achilles heel of x-ray mammography, reducing its sensitivity to as low as 33%–68% compared to the 80%–90% overall sensitivity typically quoted for screening mammography.[2,9,10,11] Yet, after considerable advances in breast cancer imaging, mammography remains the mainstay screening modality due to its proven efficacy: Approximately 25% reduction in breast cancer mortality at a modest cost of $20 000–$30 000 per quality-adjusted life year saved.

With the development of high-resolution, small field-of-view dedicated detectors, molecular breast imaging has emerged as a promising alternative for detecting tumors even smaller than 10 mm.[6,12] The most-up-to-date study and the premise for this debate reported a threefold increase in sensitivity over mammography at a comparable specificity in high-risk women with dense breasts.[13] I believe that MBI will be limited to playing an adjunct role to screening mammography for this subgroup of patients, however, due to some serious shortcomings as well as other formidable competitors.

First and foremost, MBI struggles with the issue of radiation dose. MBI delivers eight to ten times the radiation of a standard mammogram, an unacceptable proposition for screening. Second, the effectiveness of MBI is still unexplored for the detection of microcalcifications, and it is questionable for obese women for whom false negative interpretations are more common.[6] Third, there are also some practical obstacles with MBI such as long acquisition times (at 40 min per study), need for careful breast positioning by specially trained technologists to ensure maximum coverage of the breast region, and challenges with gamma-guided breast biopsy.

Although creative solutions could be found with ongoing research for many of the above limitations, MBI will still have to compete with other interesting developments in breast imaging that are potentially more palatable. For example, digital breast tomosynthesis is expected to be more sensitive than 2D mammography in women with dense breasts, providing effective coverage of the chest wall and axilla, with no limitations on imaging obese or otherwise infirm patients, and at the same radiation dose as 2D

mammography.[14] With MRI already recommended in 2007 by the American Cancer Society as an adjunct modality for screening high-risk women, and dedicated CT breast imaging (CTBI) rising as a lower cost alternative with better visualization of calcifications and more precise CTBI-guided needle core biopsies than MRI, there are many promising alternatives to MBI for consideration.

It should be noted that much of the reported promise relies on small-scale studies that focus on the number of detected cancers as the end point. However, the true benefit of a new alternative can only be measured with respect to patient outcomes. Large-scale, multi-institutional studies are essential to provide the necessary statistics so that the true cost benefit of MBI vs the current standard and other reasonable options can be clearly delineated.

In conclusion, although with expected technological developments MBI will probably find its place for personalized breast cancer imaging, current evidence is not sufficient to support a paradigm shift by making MBI the mainstay breast cancer screening modality in high-risk women with dense breasts.

Rebuttal: Michael K. O'Connor, Ph.D.

My colleague's primary argument against MBI is the high radiation dose associated with the technique. Our research team is acutely aware of this issue and I agree with Dr. Tourassi that MBI cannot progress to being a screening tool with current doses. To this end, we have been working on a variety of techniques for dose reduction, including collimator optimization,[15] and algorithms to both reduce noise and combine opposing dual-head images. To date we have achieved a factor of about 5 reduction in dose (from 20 to 4 mCi sestamibi) with the eventual goal of about a tenfold reduction. These dose reductions would yield an MBI technique with comparable radiation exposure to a mammogram, about three times the sensitivity, and minimal discomfort to the woman at a cost only slightly greater than that of a digital mammogram.

The other main argument against MBI focuses on detection of microcalcifications (and presumably DCIS). While we have yet to do a definitive comparison between MBI and mammography in patients with microcalcifications, the published results to date show that MBI can detect DCIS with a sensitivity of about 90%.[6] In response to the comment regarding special training of technologists and the need for careful breast positioning, the training requirements for MBI are no different from those for mammography. Our MBI system is located in the breast imaging division and all the technologists are fully trained in breast positioning techniques.

We agree that there are many new promising techniques under development. I would propose that the future of breast imaging may move in a similar direction to oncologic imaging where PET/CT is the dominant technology. A combined MBI/digital tomosynthesis unit would marry functional and anatomical imaging of the breast and would work off the strengths of both technologies to provide the definitive tool for the detection of breast cancer.

Rebuttal: Georgia Tourassi, Ph.D

My colleague's opening statement paints a gloomy picture for the future of x-ray mammography as the screening modality of choice for women at high risk with dense breasts. I agree that preliminary studies comparing MBI vs digital mammography in this patient subpopulation make a strong case in favor of MBI in terms of detection accuracy.[13] As such, more research in MBI should be encouraged. However, digital mammography is also a relatively young modality that continues to evolve and improve. It is not difficult to imagine that in the near future ongoing research efforts on new detector technologies and optimized target/filter combinations, coupled with computer-assisted detection software and possibly the application of tomosynthesis, could dramatically improve the detection accuracy of digital mammography, particularly when imaging dense breasts.[16]

Nevertheless, our research efforts for better screening practices should focus on true societal benefit. It will be challenging to find a screening tool as operationally efficient and cost effective as x-ray

mammography. Given the numerous practical limitations of MBI that I pointed out in my opening statement, promise without strong evidence is not enough to support a change of screening practice. Multi-institutional randomized controlled trials are essential. Moreover, we need to understand the behavior of breast cancers that are typically detected by MBI (or any other alternative under consideration) but missed by mammography. Some breast cancers are slow growing and successfully treatable even if detected later. Other cancers are aggressive from the beginning and not amenable to the benefits of early detection. As medical imaging modalities advance, we will have to face the consequences of overdiagnosis and overtreatment.[17]

In conclusion, our society will continue to struggle balancing ever-increasing costs with the need to meet the health care needs of our population. Premature enthusiasm often leads us to embrace changes in patient management that in the long run are shown to be less beneficial than originally expected. It is, therefore, entirely premature to give up on digital mammography as a screening tool.

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4.3. Ultrasonography is soon likely to become a viable alternative to x-ray mammography for breast cancer screening

Carri K. Glide-Hurst and Andrew D. A. Maidment
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OVERVIEW

With heightened concerns about radiation exposures and the cost of medicine, this is an opportune time to be seeking less expensive, nonionizing procedures for mammographic screening. Recent developments and impressive results with automated 3-D whole-breast ultrasound in combination with x-ray mammography, using lesser trained personnel and thus more efficient use of physician time, have given hope that it may be possible in the future to use ultrasound as a standalone mammographic screening modality. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Carri K. Glide-Hurst, Ph.D. Dr. Glide-Hurst obtained her Ph.D. in Medical Physics from Wayne State University in 2007, focusing her efforts on breast ultrasound tomography and utilizing acoustic parameters for breast density evaluation at the Karmanos Cancer Institute. She then spent two years in postdoctoral training in the Department of Radiation Oncology at William Beaumont Hospital, with an emphasis on motion management techniques in lung cancer, and is now Senior Associate Physicist at Henry Ford Health Systems in Detroit. Her current interests include a hybrid of teaching, clinical duties, and translational research.

Arguing against the Proposition is Andrew D. A. Maidment, Ph.D. Dr. Maidment is Associate Professor of Radiology and Chief of the Physics Section at the University of Pennsylvania in Philadelphia. He received his Ph.D. in Medical Biophysics from the University of Toronto in 1993 for developing a scanned-slot digital mammography system. From 1993 to 2002, he was Director of Radiological Physics and Assistant Professor of Radiology at Thomas Jefferson University. Dr. Maidment has more than 200 peer-reviewed journal articles, book chapters, proceedings papers, and abstracts. He is active in the ACR and AAPM, including chairing the AAPM Mammography Subcommittee. His research interests include digital mammography, 3-D x-ray imaging of the breast, contrast-enhanced breast imaging, and digital radiography detector physics.

FOR THE PROPOSITION: Carri K. Glide-Hurst, Ph.D.

Opening statement

X-ray mammography, the current standard of care for breast cancer screening, has reduced women's overall breast cancer mortality by ~ 16%.[1] However, in younger women with dense breasts, mammography has significantly reduced sensitivity due to the difficulty in detecting small tumors in a background of dense parenchyma. Also, some women are reluctant to get mammograms due to the pain and anxiety associated with breast compression. Finally, the radiation dose associated with mammographic screening, although low, is of concern. To address these limitations, magnetic resonance imaging (MRI) has emerged as an additional breast screening modality, with improved sensitivity (98%) over mammography (48%).[2] However, the costs, limited availability, exam length, and contraindications (i.e., implanted metal clips and pacemakers) have prevented the widespread acceptance of MRI for routine breast screening. As a result, the American Cancer Society currently recommends MRI breast screening only for women with ~ 20%–25% increased lifetime risk of breast cancer.[3]

Such limitations in the current state of the art provide compelling evidence that a nonionizing, noninvasive, efficient, and accurate methodology with reasonable costs would be ideal for breast cancer

screening. Whole-breast ultrasound fulfills all of these needs. The current role of ultrasound in breast cancer screening is mainly through adjunct imaging, primarily for the discrimination of cysts, with improved sensitivity using mammography combined with ultrasound (63%) when compared to mammography alone (48%).[2] However, a direct benefit has been observed for ultrasound screening in asymptomatic women with dense breasts—*after* negative mammographic findings—and resulted in a diagnosis of 15–34% of the total detected cancers in the studies described.[4] Further, the detection benefits of screening ultrasound have been validated in a large, multicenter trial (ACRIN 6666), which revealed slightly increased diagnostic accuracy of ultrasound screening when compared to mammography in a high-risk population with similar screening sensitivities between the two modalities. While ultrasound presents an increased risk of false-positive results (8.1%, negative biopsy or short-term follow up),[5] this is also true for MRI, where increased sensitivity leads to higher call-back rates.[3]

Previous generations of conventional B-mode ultrasound scanning were once criticized for their operator-dependence, limited penetrating ability, and small fields of view. However, advances in ultrasound transducer assembly, namely, through added elements, cylindrical geometry, and ring/linear arrays, have addressed these shortcomings and permitted larger region-of-interest scanning or, in some cases, automated whole-breast scanning.[6,7,8] Many of the recent ultrasound systems introduced are multimodality, yielding attenuation, sound speed, reflection, and other mutually registered images that provide more quantitative tissue characterization than previously available with reflection-based ultrasound.[6]

Ultrasound poses a practical and affordable solution for screening younger women with dense breasts, pregnant females, and those who do not meet the risk level requirements of breast MRI screening. Overall, whole-breast ultrasound is advantageous because it is volumetric, noninvasive, and nonionizing, and the current literature supports the routine implementation for breast cancer screening, particularly for women with dense breasts.

AGAINST THE PROPOSITION: Andrew D. A. Maidment, Ph.D.

Opening statement

At the current time, there are no compelling data to support the use of ultrasonography as an alternative to x-ray mammography for breast cancer screening. While studies in combined mammography and ultrasound screening suggest a possible benefit in combined screening, the data do not support independent use of ultrasound for screening due to poor specificity. In the ACRIN 6666 screening study of 2637 women, Berg et al.[5] have shown that mammography and ultrasound each identified cancers in 20 women, while combined screening identified cancers in 28 women. In that study, the positive predictive value (PPV) of mammography was 22.6%, while ultrasound was only 8.9%. Thus, ultrasound required nearly three times as many biopsies to achieve the same cancer yield as mammography. The results of Weinstein et al.[9] showed similar trends in PPV and sensitivity for ultrasound—digital mammography identified seven cancers from 20 biopsies in a group of 569 women and ultrasound identified three cancers from 20 biopsies in the same group.

The ACRIN 6666 study also illustrates another shortcoming of ultrasound. In that study, the median time to perform bilateral ultrasound was 19 min. The ultrasound examinations were all performed by skilled radiologists with extensive ultrasound experience. The total study time could easily exceed 30 min if one considers the time for comparison to prior studies, discussion of results with the patient, creation of a report, prep and clean-up time, etc. Thus, a single radiologist could not scan more than two patients per hour. Admittedly, this time is long compared to the 5–10 min reported by Kolb et al.[10] and Kaplan;[11] however, those two trials were simpler to perform, as the ACRIN 6666 trial required compounding and Doppler measurements to achieve the reported sensitivity and specificity.

Additional concerns include the cost and availability of quality ultrasound screening. In 2008, the global Medicare reimbursement for breast ultrasound (billed as CPT 76645) was $85. Given the extended

amount of time for physician-operated screening ultrasound image acquisition and interpretation, this reimbursement level seems insufficient. There is the additional concern that currently, there are not enough radiologists to perform breast ultrasound screening. Assuming a radiologist could perform 4000 ultrasound studies a year (16 per day), nearly 10 000 trained radiologists would be required to screen the approximately 36 million women who get mammograms annually.

Since ultrasound can distinguish solid tumors from fluid-filled cysts, it has a clear clinical role as a diagnostic tool in breast imaging. However, ultrasound does not appear useful for routine screening because of lower sensitivity and specificity compared to mammography, the suboptimal imaging of microcalcifications with ultrasonography, and the projected costs.

Rebuttal: Carri K. Glide-Hurst, Ph.D.

My esteemed opponent poses a valid argument regarding the shortage of radiologists to perform routine ultrasound screening. While this may be true, automated whole-breast ultrasound, where the entire breast is scanned via computer-driven transducers operated by technicians, will reduce the dependence on physicians to perform ultrasound screening.[8,12] In addition, automated scanning reduces exam time, which should effectively lower overall costs, and thereby address concerns regarding current reimbursement levels. Although it should be noted that while the average global Medicare reimbursement for breast ultrasound is $85, similar reimbursement levels also exist for film-screen mammography ($83).

Ultrasound has been widely supported for breast cancer screening of high-risk populations, including those with a personal history of breast cancer. The ACRIN 6666 study revealed that for 1400 women with this risk factor, 28 were found to have cancer, with nine of these cases seen *only* on ultrasound.[5] Moreover, the benefits of ultrasound breast screening have been further illustrated through a combined analysis of over 42 000 ultrasound exams across six institutions, where 150 cancers, the majority of which were <1 cm in size, were identified in 126 women through the use of *ultrasound alone*. Clearly, screening ultrasound has the potential to detect occult cancers not visible with mammography, particularly in the early stages of disease. Furthermore, while the ACRIN 6666 study demonstrated a lower PPV for ultrasound, a more recent whole-breast ultrasound screening study of 6425 high-risk cases found insignificant differences in the PPV of biopsy between mammography and ultrasound (39.0% and 38.4%, respectively).[12]

The benefit of screening ultrasound has been shown to increase breast cancer detection yield by 4.2 cancers per 1000 high-risk women.[5] Overall, ultrasound is likely to become a viable alternative to mammography for breast cancer screening, particularly for high-risk women.

Rebuttal: Andrew D. A. Maidment, Ph.D.

In her opening statement, Dr Glide-Hurst argues correctly that improved breast imaging is needed for young women and women with dense breasts. However, the cited work only supports breast ultrasound when used in conjunction with mammography. Standalone whole-breast ultrasound screening lacks sensitivity and substantially lacks specificity.

The use of ultrasound in combination with mammography will naturally increase cancer yield, but will concomitantly increase the costs and decrease the PPV. Consider breast MRI. MRI is more sensitive than mammography, but has poorer specificity, much like ultrasound. At the current time, the increased cost and low specificity do not justify using MRI as a strict alternative to mammography. Rather, MRI is currently performed in combination with mammography in only a small subset of women at high risk of breast cancer, for whom the cost is commensurate with the benefits.

Unfortunately, there is no research to demonstrate that the combination of mammography and ultrasound is cost-effective, nor does it appear that the small increase in sensitivity achieved with the combination is worth the decrease in specificity. After the widespread implementation of the breast MRI

guidelines, mastectomy rates increased significantly without obvious clinical benefit.[13,14] There is no reason to think that the situation with ultrasound will be different.

As MRI also illustrates, specific triage strategies must be developed when implementing new screening methods to identify the population(s) of women for whom the new modality is superior to mammography. These data do not currently exist for ultrasound imaging. This should be a focus for breast ultrasound researchers in the near-term.

In summary, an appropriate standalone imaging modality to replace mammography does not currently exist for any subgroup of women. Whole-breast ultrasound screening may have benefit in combination with mammography in selected populations. However, studies to identify an appropriate screening strategy for any such population are lacking.

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4.4. Recent data show that mammographic screening of asymptomatic women is effective and essential

Marcia C. Javitt, R. Edward Hendrick, John D. Keen, and Karsten Juhl Jørgensen
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OVERVIEW

Screening mammography is employed widely both in the United States and abroad. Several recent publications, however, have claimed that screening does not reduce breast cancer mortality and causes over-diagnosis resulting in unnecessary mastectomies. Others claim that mammographic screening of asymptomatic women is effective and essential. This controversy is debated in this Point-Counterpoint by four of the world's leading experts in screening mammography.

Arguing for the Proposition are Marcia C. Javitt, M.D. and R. Edward Hendrick, Ph.D. With more than 25 years of experience including Director of Women's Imaging, Body MRI, and Genitourinary Radiology, Dr. Javitt is Adjunct Professor of Radiology, Uniformed Services University of the Health Sciences, Walter Reed Army Medical Center, Washington, DC, where she leads education and teaching in Urology and Obstetrics and Gynecology. She is the Section Editor of Women's Imaging for the American Journal of Radiology (AJR), President of the Society for the Advancement of Women's Imaging, Chair of the American Board of Radiology (ABR) Core Exam Subcommittee for Reproductive Endocrinology, Chair of the American College of Radiology (ACR) Appropriateness Criteria Committee on Women's Imaging, and Chair of the Radiology Resident Curriculum Committee for the Society of Uroradiology. Dr. Javitt is co-founder and co-editor of the AJR "*Masters of Radiology Series*." She has authored two textbooks and multiple book chapters and her main research interests are women's and genitourinary imaging, and preoperative staging of gynecologic malignancies. Dr. Hendrick is Clinical Professor of Radiology at the University of Colorado–Denver, School of Medicine. A board-certified diagnostic medical physicist, he helped establish the ACR's Mammography, Stereotactic Breast Biopsy, MRI, and Breast MRI Accreditation programs, and currently serves as Co-Chair of the Breast MRI Accreditation program. He helped define both ACR and Federal Drug Administration (FDA) standards for mammography equipment and quality control, is the lead author on all four editions of ACR's Mammography Quality Control Manual, and was co-principal investigator of the NCI-sponsored ACRIN DMIST trial of digital mammography.

Arguing against the Proposition are John Keen, M.D. and Karsten Juhl Jørgensen, M.D. Dr. Keen received co-terminal AB/BS degrees in Economics and Chemical Engineering from Stanford University in 1985. He worked as an economist and consumer advocate for several years with the state of California, and received an MBA from the University of California, Berkeley in 1989. He obtained his M.D. degree from the University of Illinois where he did graduate research in microwave spectroscopy. He completed a residency in diagnostic radiology at Cook County John H. Stroger Jr. Hospital in Chicago in 2000, and currently works there as an attending radiologist. His research interests include economic analysis and consumer awareness in radiology. Dr. Jørgensen received his medical degree from the University of Copenhagen, Denmark in 2003. Since completing his internship at the University Hospital in Herlev, Copenhagen, he has been employed as a researcher at the Nordic Cochrane Centre in Copenhagen. His research training includes a stay at the Johns Hopkins Bloomberg School of Public Health, Baltimore, MD in 2006. His main research interest is breast screening, including systematic reviews, epidemiological studies, and ethical aspects of invitations and informed consent. His research has also included research methodology and general health checks.

FOR THE PROPOSITION: Marcia C. Javitt, M.D. and R. Edward Hendrick, Ph.D.

Opening statement

Although screening mammography is hotly debated, recent randomized controlled trial (RCT), case-control (comparing women who had developed breast cancer with matched control subjects who had not), and service screening (women invited to a screening service) data confirm that screening mammography saves women's lives.

A 29-year follow-up of the Swedish two-county trial showed that women aged 40–74 "invited to screening" had a statistically significant 31% fewer breast cancer deaths than uninvited women.[1] This is consistent with the first published results from this study that showed a significant 30% reduction in breast cancer mortality among women invited to screen.[2]

Three other population-based trials in Sweden (1976–1990) compared groups of women invited to screening mammography to a usual-care (non-invited but may or may not have received mammograms as part of their normal health care) control group. While all four Swedish trials differed in numbers of rounds of screening (2–5), screen intervals (18–33 months), numbers of mammographic views (1 or 2), and ages of women at entry to the study (39–74 years), the four trials combined showed a statistically significant 23% reduction in breast cancer deaths in the "invited to screen" group compared with uninvited women (95% confidence interval: 12%–33%).[3,4] Two other population-based RCTs, the Health Insurance Plan of New York (HIP) and Edinburgh trials, each demonstrated statistically significant benefit from "invitation to screening."[5,6,7,8] Recent analysis of RCTs done for the U.S. Preventive Services Task Force yielded a statistically significant mortality benefit from screening mammography in women of each age decade from 40 to 69 years.[9,10]

RCTs underestimate the true benefit of screening because not all women randomized to "invitation to screening" attend screening, but all breast cancer deaths in this group count toward mortality in the "invited" group, whether they attended mammography or not. Of women invited to screening in the HIP trial, only 67% attended the first round, 53% attended the second round, and less than half attended 3rd and 4th rounds.[5,6,7] Similarly, women randomized to the uninvited group can receive mammography outside the trial, but their breast cancer deaths are counted as mortality among the control group. It was estimated that 20%–30% of control group women in RCTs had at least one mammography exam outside the trial.[11]

Most RCTs had longer screening intervals than the ACR recommendation of annual screening, some used only a single view per breast rather than two as ACR recommends, and all were performed with old technology.

More recent case-control and service screening studies have assessed the benefit of mammography among women who actually received screening compared to women who did not. A case-control study of the Dutch population-based screening program showed that mammography screening reduced breast cancer deaths by 49% compared to unscreened women.[12] These results are consistent with service screening programs showing that women screened regularly have 40%–76% fewer breast cancer deaths than unscreened women.[13,14,15]

Ironically, increased criticism of screening mammography is occurring just when we are starting to get mammography "right" with high technical quality, improved interpretation, and minimally invasive breast biopsy. The real question is not whether we should be screening U.S. women with mammography, but how we can overcome socio-economic barriers[16] and extend the proven benefits of mammography screening to all U.S. women over age 40.

AGAINST THE PROPOSITION: John D. Keen, M.D. and Karsten Juhl Jørgensen, M.D.

Opening statement

Over the past few years, multiple papers have questioned the benefit of mammographic screening[17,18] and have shown that screening causes over-diagnosis (diagnosis of disease that would never cause symptoms), leading to increased mastectomy use.[19,20]

The premise of mass screening is that earlier intervention will prevent advanced disease and therefore reduce breast cancer deaths. However, an overview of seven countries with long availability of breast screening, including the United States, found no reduction in late stage disease since screening started.[21] This is not surprising. Screening detects breast cancers that are a little over 1 cm in diameter on average, rather than 2 cm for clinically detected disease.[22] This represents a reduction of 1–2 volume doublings of the 32 necessary to reach 2 cm (Ref. 22) and is equivalent to a few months growth for aggressive, fast-growing cancers[22] which therefore easily "slip through the screen." On the contrary, screening effectively detects slow-growing and dormant tumors, resulting in over-diagnosis.

Screening advocates usually cite trials from Sweden. But despite high participation since screening started in the mid-1980s, the breast cancer mortality reduction in Sweden has been only 16% from 1989 to 2006 in women aged 50–69 years, much less than in Denmark (−26%) and Norway (−23%), which had only limited screening, e.g., only 20% of women aged 50–69 years were offered screening in Denmark.[24] The average reduction in breast cancer mortality in Europe has been almost twice as large in younger, non-screened age groups as in those screened, and equally large in countries with and without screening.[24] The primary cause of improvements in mortality has been more effective therapy, not screening.[25]

Screening's effect on the recorded incidence of ductal carcinoma *in situ* and early stage invasive breast cancers has been massive, both increasing several-fold since screening began.[25] This is due to the detection of cancers which would never become clinically evident, let alone lethal, without screening (over-diagnosis). Screening participation turns thousands of healthy women into breast cancer patients, whom we treat with surgery, radiotherapy, and possibly chemotherapy, as we cannot tell which cancers are over-diagnosed. If screening reduces breast cancer mortality by 15%, which is optimistic, ten times as many women receive unnecessary treatment as will benefit.[25]

The U.S. status quo, aggressive annual screening starting at age 40 that our colleagues continue to advocate,[26] likely costs close to one million dollars for every life-year saved, 10–20 times more than we accept for other interventions.[27] Independent panels in both the United States[9] and Canada[28] found that screening women in their 40s is questionable and that biennial screening starting at age 50 is preferred, in agreement with policies in Europe. Hubbard et al. have shown that annual screening does not reduce the proportion of advanced cancers. Furthermore, the cumulative false-positive rate after 10 years for women ages 40–59 was 61% with annual versus 42% with biennial screening.[29] Certain professional groups benefit from the status quo,[30] while many doctors are reluctant to change established beliefs about cancer biology. Currently, the United Kingdom is reviewing the rationale for breast screening because of the new evidence.[31] We question if screening mammography is justifiable at all, but especially the aggressive annual screening of younger women.

Rebuttal: Marcia C. Javitt, M.D. and R. Edward Hendrick, Ph.D.

Screening mammography saves lives.[1,2,3,4,5,6,7,8,9,10,12,13,14,15] Our colleagues distract readers from this fact by raising issues such as over-diagnosis, irrelevant population mortality data, and misstated RCT data. They confuse over-diagnosis with overtreatment (mastectomy). The great majority of cancers, including high-grade DCIS (the DCIS predominately detected by mammography), will progress to metastatic breast cancer (distant metastases) if untreated. Recent estimates of the rate of over-diagnosis by screening mammography range from less than 1% to 10%.[9,10] Since no marker exists to identify the few cancers that would not progress, it would be irresponsible to advise against treating a diagnosed breast cancer. Breast cancer treatment in the United States is now highly personalized, taking into account

cancer biology, patient age, and health. The vast majority of women with mammographically detected breast cancers are offered breast conserving therapy. Mastectomy is reserved for women who are not candidates for, or decline, breast conservation.

In the United States, at diagnosis less than 5% of breast cancers are stage IV (distant metastases) and less than 6% are stage III (locally advanced) (SEER Cancer Statistics Review, 1975–2008, and SEER Survival Monograph, 2007)). It is faulty logic to criticize screening mammography by pointing to a lack of reduction in late stage cancers in a population where more than one-third of eligible women are not screened. In truth, mammography screening yields a significant decrease in late stage breast cancers, decreasing morbidity as well as mortality, and empowering more women to benefit from breast-conserving treatment.

Our colleagues' statement "If screening reduces breast cancer mortality by 15%, which is optimistic, ten times as many women receive unnecessary treatment as will benefit" is incorrect. They inappropriately apply RCT results for women 40–49 to all women age 40 and over, underestimating lives saved by screening by as much as two-fold.[1,2,3,4,5,6,7,8,9,10] Case control and service screening results show that women attending screening have mortality reductions ranging from 28% to 65%.[11,12,13,14,15]

The consequences of less screening are later stage breast cancers and increased breast cancer mortality. Failure to provide screening mammography puts women's lives at risk.

Rebuttal: John D. Keen, M.D. and Karsten Juhl Jørgensen, M.D.

Evidence-based medicine is about relying on the best available evidence and discarding that which is flawed. Our opponents seem to prefer the most optimistic results without assessing their validity, and to disregard unwelcome ones.

The Edinburgh trial is widely recognized as untrustworthy. It randomized 87 general practices, which led to substantial baseline imbalances. Twenty-six percent of the controls belonged to the highest social group versus 53% of the intervention group, leading to a spurious 26% reduction in cardiovascular mortality in those screened, which obviously cannot be a screening effect. The Swedish Two-County trial randomized only half as many clusters, but we cannot know if this led to similar baseline imbalances, as only the age distribution has been published, where there was a difference between groups. The lead investigator has not accommodated requests for supplementary baseline data. Long follow-up cannot compensate for fundamental flaws, and trials of high methodological quality (the Malmö and Canadian trials) did not find an effect of screening.[28]

Reports have repeatedly pointed out that case-control studies should not be used to assess cancer screening because the small possible effect is prone to substantial bias that favors screening.[32] These studies compare breast cancer mortality in attendees with non-attendees, but the attendees are predominantly the affluent and healthy. When the Malmö randomized trial was analyzed as a case-control study, it showed a 58% reduction in breast cancer mortality after 9 years when in fact the trial found only a 4%, non-significant, reduction.[32]

Benefits should be presented in context. A 15% relative risk reduction for ages 40–49 is 0.047% in absolute terms.[28] Increased screening participation also means proportional increased over-diagnosis, while increased screening frequency does not provide further benefit.[28]

Flawed studies have determined our current screening policy. We must stop uncritically accepting results we like and face the facts: comparisons between screened and non-screened countries and age groups clearly show that better treatment, not screening, has caused the decline in breast cancer mortality.

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FOOTNOTE

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Department of the Army, Navy, Department of Defense, nor the US Government.

4.5. Computer-aided detection should be used routinely to assist screening mammogram interpretation

Robert M. Nishikawa and Joshua J. Fenton
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OVERVIEW

Computer-aided detection (CADe) is used for the interpretation of screening mammograms in many institutions, especially in the United States. Some suggest that the time is ripe to use it routinely for *all* mammographic screening programs worldwide. Others, however, question its routine use because they claim that there is no convincing evidence that it has any mortality benefit. This is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Robert M. Nishikawa, Ph.D. Dr. Nishikawa received his B.Sc. degree in Physics in 1981 and his M.Sc. and Ph.D. degrees 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 at the University of Chicago where he is Director of the Carl J. Vyborny Translational Laboratory for Breast Imaging Research. He has served on many AAPM committees and is currently Co-Chair of the Working Group on computer-aided diagnosis. His research interests are computer-aided diagnosis, breast imaging, and evaluation of medical technologies. Dr. Nishikawa discloses the following potential conflicts of interest: receives royalties from and shareholder in Hologic, Inc. (Bedford, MA).

Arguing against the Proposition is Joshua J. Fenton, M.D., M.P.H. Dr. Fenton is Assistant Professor of Family and Community Medicine at the University of California, Davis. A family physician, Dr. Fenton conducts research on the accuracy, utilization, and clinical impact of cancer screening and other diagnostic tests. Current research focuses on the dissemination and clinical impact of mammography innovations, validation of Medicare mammography claims data, the appropriateness of osteoporosis screening and treatment in primary care, and interventions to avert inappropriate diagnostic testing by primary care physicians. Dr. Fenton graduated from the University of California, San Francisco School of Medicine and completed his residency at San Francisco General Hospital. He was a Robert Wood Johnson Clinical Scholar at the University of Washington. Dr. Fenton serves on the Editorial Board of the *Journal of the American Board of Family Medicine* and is Associate Editor of *Evidence-Based Medicine*.

FOR THE PROPOSITION: Robert M. Nishikawa, Ph.D.

Opening Statement

Let me begin my argument with the underlying assumption that breast cancer screening with mammography is effective at all six levels of effectiveness as outlined by Fryback and Thornbury.[1] Mammographic screening is effective because it can detect breast cancers early enough for them to be treated effectively. Computer-aided detection can help radiologists to reduce their cancer miss rate and thereby promote earlier detection. The DMIST study showed that ~50% of women who have breast cancer have their mammograms read as normal.[2] Computer-aided detection could, therefore, have a large impact on the false-negative rate of mammography.

In a Point/Counterpoint debate published in 2006, I argued that the effectiveness of CADe in screening mammography was unproven.[3] Since then, several additional clinical studies have been published but, more importantly, our understanding of CADe and how to measure its effectiveness has improved.

Compared with 2006, research on the effectiveness of CADe, while still not definitive, clearly shows that its use can reduce radiologists' miss rate but, on the negative side, it increases the radiologists' recall rate. However, the increase in number of cancers detected (~10%) is comparable to the increase in recall rate (~12%).[4] I believe that this recall rate is slightly elevated because radiologists are still learning how to the use the system effectively.

The ratio of the number of cancers detected to the number of recalls is the positive predictive value of screening (PPV_1). If PPV_1 is essentially unchanged—a 2% decrease (1.10/1.12)—and screening mammography is effective, then screening mammography with CADe must also be effective, since the number of recalls for every cancer detected is the same whether CADe is used or not. Further, since mammography is "cost effective" at this PPV_1, finding more cancers at a fixed PPV_1 must increase the benefit of screening when CADe is used.

Perhaps the strongest evidence for CADe allowing earlier detection of cancer is from the two studies published by Fenton et al.[5,6] In these studies, the fraction of cancers that were detected as DCIS increased when CADe was used, with a corresponding decrease in Stage 1 invasive cancers. Note that all cancers a radiologist detects because of using CADe are mammographically visible. This means that the cancer will eventually be detected mammographically—unless it is detected as an interval cancer (a cancer that is detected nonmammographically between screening exams)—whether or not the radiologist uses CADe.[7] Therefore, CADe is unambiguously detecting a cancer at an earlier stage.

While CADe is an effective tool for screening mammography, an increase in sensitivity of 10%, in light of a 50% miss rate when CADe is not used, is moderate at best. New approaches to implementing CADe clinically and better training of radiologists in how to use CADe, however, can potentially enhance its benefit.

AGAINST THE PROPOSITION: Joshua J. Fenton, M.D., M.P.H.

Opening Statement

Breast cancer screening is performed among healthy, asymptomatic women with the goal of reducing their risk of dying from breast cancer. Before recommending routine application of CADe during screening mammography, one must be confident that its use in mammography is helping, not hurting, women. While consideration of patient harms and costs are important, fundamentally we must be confident that CADe augments screening mammography's impact on breast cancer mortality.

Within this framework, one cannot soundly recommend routine use of CADe during screening mammography. There are no data showing that CADe use during screening mammography is associated with reduced breast cancer mortality, and analyses of national mammography data suggest that CADe use is associated with little if any change in mammography performance or in the stage or size of detected breast cancers.[6] Under optimal conditions,[8] CADe may incrementally increase the detection of noninvasive breast cancers (ductal carcinomas *in situ*). But mammography's mortality benefit largely derives from early detection of invasive breast cancers,[9] so even optimal CADe use is unlikely to reduce breast cancer mortality risk.[10]

Indeed, finding more ductal carcinoma *in situ* of ambiguous lethal potential is a potential harm of mammography, as many *in situ* carcinomas may be overdiagnosed and unnecessarily treated, particularly in older women. Computer-aided diagnosis also clearly increases the false-positive rate of screening mammography. Leading to considerable anxiety in most women, false-positive mammography constitutes a substantial aggregate harm of CADe when multiplied by the millions of women now exposed to CADe in U.S. practice.[11]

Routine CADe use also comes with significant monetary costs. Although CADe is already widely used in the United States,[11] if CADe use were extended to all of the 31×10^6 screening mammograms performed/year in the United States, CADe-attributable costs from added insurance payments

(~$12/mammogram) and diagnostic testing after additional false-positive mammograms (~$450/false-positive) would exceed $550 × 10^6 annually.[5]

One might argue that mammography is poorly reimbursed, and CADe fees represent an essential revenue stream for mammography practices. But Congress did not add the coverage for CADe to the Medicare benefit as a means of subsidizing mammography practice. Rather, CADe coverage was the result of adroit industry lobbying and a Congress that was poorly prepared to evaluate the limited evidence of CADe's effectiveness.[12] Reimbursement incentives explain the broad and rapid adoption of CADe in the United States as compared to other developed countries, and Congress would be wise to rescind Medicare coverage for CADe, removing the incentive for its routine use in the United States.

Some may argue that theoretical benefits of routine CADe use justify its harms and costs. Similar arguments were made in support of routine self-breast examination until large randomized trials demonstrated harm without benefit.[13] An analogous adverse risk–benefit ratio may be the ultimate truth with CADe. While large randomized trials of CADe use may be impractical, CADe should ideally be used only in the context of research protocols and certainly not routinely, as is regrettably the case in U.S. practice.

Rebuttal: Robert M. Nishikawa, Ph.D.

I concede to my colleague that the broad adoption of CADe in the United States is a result of reimbursement, and the decision to approve reimbursement was not based upon clinical evidence demonstrating its effectiveness. Nonetheless, this does not mean that CADe is ineffective and should not be used routinely. Let me address two points from Dr. Fenton's opening statement.

Dr. Fenton argues that CADe should not be used routinely because no study has shown that its use can reduce breast cancer mortality. Given that argument, screening with breast MRI or digital mammography should not be performed. In fact, conventional screening mammography was common long before there was consensus on a mortality benefit, which occurred 20 years after it became used routinely. While there is merit to Dr. Fenton's argument, the end result would be a stifling of innovation and many new imaging techniques would never see the light of day. To study the impact of any screening technology on breast cancer mortality requires tens of thousands of women, tens of millions of dollars, and over 10 years of follow-up. Clearly, some figure of merit other than mortality needs to be used as a criterion for clinical implementation.

One possible surrogate end point could be cancer stage. Dr. Fenton argues that the only change in cancer characteristics is an increase in the detection of DCIS with a reduction in Stage I cancers. As I pointed out in my opening statement, CADe will not lead to overdiagnosis, because all cancers detected by CADe are mammographically visible and will be detected eventually without CADe. Therefore, based on Dr. Fenton's data, CADe is clearly leading to earlier detection.

Since cancer stage alone does not predict mortality, I believe further clinical studies are needed to evaluate the effectiveness of CADe. These studies can only be done if CADe is being widely used clinically.

Rebuttal: Joshua J. Fenton, M.D., M.P.H.

Dr. Nishikawa implies that our work with the Breast Cancer Surveillance Consortium (BCSC; Ref. 6) demonstrated a favorable shift in breast cancer stage with CADe. In unadjusted analyses, CADe use was associated with a reduced rate of detection of invasive breast cancer but no change in the rate of detection of DCIS. In adjusted analyses, however, CADe was associated with a nonsignificant trend toward increased detection of DCIS but no differences in rate of detection of invasive cancer or in the diagnosis of early stage invasive cancers. As discussed in my opening statement, any increase in the detection of DCIS is of uncertain clinical significance in light of the ambiguous relationship between early DCIS detection and reduced breast cancer mortality.[9] More importantly, it is misleading to state

that “CADe is unambiguously detecting a cancer at an earlier stage” when adjusted analyses suggested little, if any, impact of CADe on breast cancer stage.

Citing his own work,[4] Dr. Nishikawa states that CADe reduces the “miss rate” of screening mammography by 10%, implying that CADe improves the sensitivity of screening mammography. However, BCSC data and a meta-analysis suggest little if any impact of CADe on screening sensitivity or breast cancer detection rates.[6,14]

Similarly, Dr. Nishikawa states that the PPV_1 is “essentially unchanged” with CADe.[4] On this basis, he reasons that CADe must be effective, given that screening mammography is also effective. The preponderance of other evidence, however, suggests that CADe is associated with reduced PPV_1 (about a 16% relative decline from 4.3% to 3.6% in the BCSC data), increased recall rates and little, if any, improvement in cancer detection rates.[6,14]

The effectiveness of CADe should ultimately be based on whether it reduces breast cancer mortality in community practice. Evidence to date suggests that a breast cancer mortality benefit from current CADe technology is highly unlikely.[10] Absent a mortality benefit, routine use of CADe during screening mammography cannot currently be justified.

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4.6. Office-based cone-beam and digital tomosynthesis systems using flat-panel technology should not be referred to as CT units

Stewart Carlyle Bushong and Stephen Balter
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OVERVIEW

Several vendors have recently introduced relatively small digital imaging systems designed for in-office use by head and neck physicians. Although they produce reconstructed digital tomographic images, they are much less expensive than conventional CT systems, yet they are marketed as CT machines that will pay for themselves in a very short time since reimbursements are the same as for CT units. Concern has been expressed that they should not be called CT systems and this is the claim debated in this month's Point/Counterpoint.

Arguing for the Proposition is Stewart Carlyle Bushong, Sc.D. Dr. Bushong received his Master's and Doctorate degrees from the University of Pittsburgh, Pennsylvania. He is Professor and Chief, Section of Radiologic Science, Department of Radiology, Baylor College of Medicine, Houston. He is certified by the American Board of Health Physics, the American Board of Radiology, and the American Board of Medical Physics. Dr. Bushong has served several organizations in many capacities, including as Chairman of the American College of Medical Physics, Chairman of the Texas Board of Licensure for Professional Medical Physicists, and Chairman of the Houston Community College System Foundation. He has published 138 journal articles, 35 book chapters, and 29 books.

Arguing against the Proposition is Stephen Balter, Ph.D. Dr. Balter obtained his M.S. degree in Radiological Physics from Columbia University, New York and his Ph.D. in Physics from the Polytechnic Institute of Brooklyn. He is currently medical physicist at Columbia-Presbyterian Medical Center and Clinical Associate Professor, Radiology and Medicine, Columbia University, New York. Dr. Balter is certified by the American Board of Radiology in Radiological Physics and the American Board of Medical Physics in Diagnostic Radiological Physics. He has served many organizations in numerous capacities, including as Director of the 2002 AAPM Summer School, Vice President of the Radiological Society of North America, and member of the AAPM Board of Directors. Dr. Balter has published 80 journal articles and 33 books and chapters.

FOR THE PROPOSITION: Stewart Carlyle Bushong, Sc.D.

Opening statement

At all Radiological Society of North America Annual Meetings, specialty physicians are introduced to, and encouraged to purchase, advanced medical imaging systems such as computed tomography (CT), magnetic resonance imaging, positron emission tomography, and more. Recently, three new systems[1,2,3] have been promoted to head and neck physicians as in-office, patient-friendly, CT machines that will greatly increase revenue because CT reimbursement codes may be used. These codes are approximately ten times those that apply for radiography, even digital radiography.

The three systems that are the subject of this debate closely resemble dental panoramic imaging machines. They are designed principally for use by ear, nose, and throat physicians. Patients sit upright in the imaging system, which creates cross-sectional images of the paranasal sinuses and temporal bones. There are several major vendors of CT imaging systems and their technical specifications, described in peer-reviewed scientific papers,[4,5,6] are rather similar. None of these descriptions resemble the three systems under consideration here.

The significance of this discussion is clear since approximately 37×10^6 Americans are affected by sinusitis each year as reported by the Centers for Disease Control and Prevention. Americans spend $5.8 billion each year on costs related to this pathology.[7] Prior to the introduction of these so-called CT imaging systems, sinusitis was easily diagnosed with screen-film radiography, which is being rapidly replaced by digital radiography and even digital radiographic tomosynthesis because of its better contrast resolution.

These newly introduced imaging systems are not the same as conventional CT for the following reasons:

1. **X-ray beam**: Characteristic of projection radiography, these systems use an area-beam and not a cone-beam. In contrast, CT uses a smaller or cone-shaped beam, resulting in reduced Compton scattering and consequently improved contrast resolution.

2. **X-ray tube**: Similar to dental radiography, some of these systems use a stationary anode x-ray tube. In contrast, CT requires a much more robust design to yield a heat capacity often exceeding 6 MJ.

3. **Image receptor**: Similar to digital radiography, these systems use a flat-panel image receptor. In contrast, CT employs a structured assembly of individual radiation detectors consisting of a ceramic or scintillation phosphor married to a silicon photodiode configured into a multislice array to respond to the narrower x-ray beam of CT.

4. **Imaging time**: These systems require up to 40 s to produce each image. In contrast, CT produces subsecond images, reducing the degradation caused by patient motion and thereby improving both spatial and contrast resolution.

5. **Dynamic range**: Most of these systems employ an eight-bit dynamic range yielding 256 gray levels. CT has a 12-bit range yielding 4096 gray levels and superior contrast resolution and image postprocessing.

The description of these three imaging systems[1,2,3] as CT is simply not true. And, for sure, more such imaging systems will be introduced because they represent a considerable income source for the physicians who own them and control the patients. I have no problem if they are identified as digital radiographic tomosynthesis systems and compensated as such. When the area-beam and flat-panel image receptor are incorporated into CT, the resulting system will surely follow something such as that described in the recent literature[8] and be quite different from the office-based systems debated here.

AGAINST THE PROPOSITION: Stephen Balter, Ph.D.

Opening statement

Consistent naming of imaging equipment is important. There are no proposed naming restrictions if the imager is located anywhere but in an office or anywhere at all if the imager is a variant with only a different detector.[9] “What’s in a name? That which we call a rose by any other name would smell as sweet.”[10] Do all roses smell equally sweet? Is an “eirigh” a rose? Where would one find such a thing?

Should the name of any machine be required to change depending on its current location? This only makes sense if its functionality significantly changes when it is moved. Frankly, I cannot imagine this happening to imaging equipment.

What is or is not a CT unit? Both cone-beam computed tomography and digital tomosynthesis (DT) provide cross-sectional images of patients with a range of properties.[11] Traditional CT is a form of reconstruction imaging that collects and uses a mathematically complete set of x-ray transmission data.[12] DT uses an incomplete data set.[13] However, many CT scanners are capable of reconstructing images even if some data are missing. At some point, missing projection reconstructions could be called DT. Data acquisition, image utility, and radiation factors will favor different technologies under different circumstances.[14]

Should the name of anything be required to change depending on its current mode of operation? An imaging system with a flat-panel detector and cone-beam geometry can be relatively small and inexpensive. Such systems are designed and used for projection radiography (PR), DT, or CT imaging. In principle, a CT-capable system can also provide DT and PR images. At least one commercial cone-beam flat-panel system provides all these modes.

Should different machines have the same name? Different names for exactly the same device used in different locations will certainly add unnecessary confusion. Different imagers might be given the same name either because they produce similar images or simply by virtue of historical progression.[6] Naming is deceptive when the major intent is to imply the same type and quality of examination. The latter point may influence referral patterns and therefore has clinical and economic significance.

A name may or may not be descriptive of its object: "Humpty Dumpty said with a short laugh; 'my name means the shape I am, and a good handsome shape it is, too. With a name like yours, you might be any shape, almost.'"[15] Generic descriptive names, (e.g., bicycle or CT scanner) are meaningful only if they provide useful information. In any event, it is irrational to change either the generic or trade name of the same thing or even what the same thing is referred to, dependent on where it is located.

Rebuttal: Stewart Carlyle Bushong, Sc.D.

Usually I would agree with Dr. Balter regarding "What's in a name." However the current situation involves clever marketing of the three imaging systems to nonimaging physicians to be used in the same manner as in-office radiographic imaging systems have been used so successfully for a century.

The paranasal sinuses are hollow air cavities in the bones of the head surrounding the nose. They consist of

1. Ethmoid sinuses, just behind the bridge of the nose and between the eyes;
2. Frontal sinuses over the eyes in the brow area;
3. Maxillary sinuses inside each cheekbone; and
4. Sphenoid sinuses behind the ethmoid sinuses.

Each sinus has an opening into the nose for the free exchange of air and mucus and each is joined with the nasal passages by a continuous mucous membrane lining. Therefore, anything that causes a swelling in the nose, such as an infection or an allergic reaction, can affect the sinuses.

Sinusitis occurs when the sinuses are inflamed and may be associated with discomfort and pain. Sinusitis may be categorized as

1. Acute, lasting 4 weeks or less;
2. Subacute, lasting 4–12 weeks;
3. Chronic, lasting at least 12 weeks and occasionally for months or even years; and
4. Recurrent, consisting of several acute attacks within a year.

Sinusitis is clearly a widespread malady, affecting approximately 37×10^6 Americans annually. When a physician employs one of these systems and identifies it as CT, the applicable CPT code is in the \$500–\$1000 range rather than \$50–\$100 for radiography including digital tomosynthesis radiography. Therefore, overutilization is assured.

Radiography is perfectly capable of diagnosing maxillary or ethmoidal sinusitis. Suspected acute frontal or sphenoidal sinusitis is more difficult to diagnose and indeed would be helped by digital tomosynthesis radiography and may require CT examination. When such is the case, the patient should be referred for conventional CT rather than to one of the systems discussed here.

Rebuttal: Stephen Balter, Ph.D.

Dr. Bushong is concerned that "so-called CT imaging systems" in office practice will increase healthcare costs. Name constraints will not help. Quoting Alice again,[15] "The name of the song is called 'Haddocks' Eyes'. … The name really is 'The Aged Aged Man'. The song is called 'Ways and Means'. The song really is A-sitting on a Gate.'" Irrespective of name, technology, or point of service, performance and cost are important to payers.

Sinusitis is an example of the poor performance of conventional radiography. Predictive values range from about 80% in the maxillary sinus down to single digits in other sinuses.[16] CT scanning has its place if the diagnosis cannot be made by history and physical examination (including the use of an endoscope where indicated).

Detectors are not the fundamental issue. Dr. Bushong already concedes that flat-panel detectors will replace dedicated CT detectors in large systems. That this will happen can also be inferred from the specifications of flat panels currently used for image-guided radiation therapy and fluoroscopy. Conventional scanners have scan widths up to 16 cm and long detector arrays. The irradiated volume is larger than that found in dedicated head and neck scanners. Compton scatter is not less.

X-ray tube and scan time are selected together. A subsecond scanner needs a powerful tube, weighs more than a ton, and is expensive. Not all examinations are degraded by multisecond acquisition. Equipment design includes cost, reliability, and clinically appropriate image quality. Not meeting requirements either by overdesign or underperformance usually results in commercial failure.

Not calling office-based devices "CT scanners" will help them avoid regulatory and medical physics oversight. Payers are free to use any available information to set reimbursements based on clinical indications and performance irrespective of technology. It is up to the clinical community to provide decisions on clinical justification and acceptable performance for individual procedure types. The American College of Radiology appropriateness guidelines and accreditation programs provide excellent examples. Developing and evaluating procedure-specific technical performance are parts of medical physics. We need to routinely do much more of this.

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4.7. PET/CT will become standard practice for radiotherapy simulation and planning

Tinsu Pan and Lili Chen
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OVERVIEW

The use of CT to define and localize anatomical structures for radiotherapy simulation and treatment planning has become standard practice over the past decade, but CT images alone are often not sufficient for delineation of cancers. In contrast, positron emission tomography (PET) is often excellent at imaging cancers but is poor with respect to definition of anatomy. It is common, therefore, to fuse CT and PET images in order to obtain the best of both modalities. Accurately combining the two images is, however, a challenge, especially with regard to precise patient positioning for the separate imaging procedures. This is not a problem with a single integrated PET/CT unit, which is why PET units are no longer marketed alone. How important PET/CT will be in simulation and treatment planning is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Tinsu Pan, Ph.D. Dr. Pan received his Ph.D. in Electrical Engineering and Computer Science from the University of Michigan in 1991. He received postdoctoral training in Nuclear Medicine at the University of Massachusetts Medical Center from 1991 to 1993 and continued doing research on quantification of SPECT until 1996. He then joined the Applied Science Laboratory of GE Healthcare, Waukesha, WI, where he designed the two commercial products of cardiac CT and 4D CT for GE LightSpeed CT. Since 2003, he has been an Associate Professor in the Departments of Imaging Physics and Radiation Physics in the University of Texas, M.D. Anderson Cancer Center. His current interests are imaging tumors and cardiac motion in the thorax with CT and PET/CT. He has published 5 book chapters, 18 patents, and 65 papers. Dr. Pan is certified by the ABR (Diagnostic Radiological Physics) and the ABSNM.

Arguing against the Proposition is Lili Chen, Ph.D. Dr. Chen received her Ph.D. in medical physics and biophysics from the Institute of Cancer Research and Royal Marsden Hospital, University of London, U.K. in 1994. She was a postdoctoral fellow at Toronto University and a postdoctoral fellow and staff member at Stanford University. She joined Fox Chase Cancer Center in 2001. Her major research interests are treatment planning for IMRT, image guidance and assessment for radiotherapy, high intensity focused ultrasound surgery, and enhancement of drug delivery for gene therapy and chemotherapy in combination with radiotherapy. She has 34 peer-reviewed papers and is the principal investigator for research awards from U.S. federal agencies and nonprofit foundations.

FOR THE PROPOSITION: Tinsu Pan, Ph.D.

Opening Statement

PET/CT combines the complementary information of functional PET images and anatomical CT images in a single imaging session. It has an advantage over PET-only scanners in hardware registration of the PET and CT data, as compared with less accurate software registration of data taken on separate PET and CT scanners. The first commercial PET/CT scanner became available in 2001 and, since then there have been over 2000 PET/CT scanners installed worldwide. No PET-only scanners have been produced since 2006.[1] The widespread use of PET/CT has been supported by its efficacy for the diagnosis, staging, and restaging of cancer patients and has been shown to alter patient management.[2] Today, ^{18}F-FDG is used in a majority of PET/CT procedures to image the glucose uptake in tissues, which is

correlated with an increased rate of glycolysis in many tumor cells. New molecular targeted agents are being developed to improve the accuracy of targeting different disease states and assessing therapeutic response.

If CT simulation helps radiation therapy (RT) in target definition, PET/CT simulation can only further improve the accuracy of such delineation. Application of ^{18}F-FDG PET for gross target volume (GTV) delineation has been demonstrated for head and neck cancer and nonsmall cell lung cancer.[2] PET/CT holds promise for characterization of the efficacy of RT by assessing the immediate biological response of tumor cells rather than relying on surrogate measures of dose maximization and uniformity.[3] PET/CT is also potentially useful for assessing hypoxia, which makes tumors resistant to radiation and can impede the success of RT.[4] It has been estimated that GTV delineation needs to be changed in 30% to 60% of patients[5] due to functional information from PET. The most prominent changes in GTV have been reported in cases with atelectasis and with incorporation of PET-positive nodes in otherwise CT-insignificant nodal areas.[5] PET/CT improves standardization of volume delineation with respect to interobserver variation, changes the treatment strategy from curative to palliative by revealing distant metastases, reduces the risk of geometrical misses, and minimizes radiation dose to nontarget organs.[6]

New developments of 4D-CT and 4D-PET have also been incorporated in PET/CT to improve the imaging capability for lung tumors influenced by respiratory motion.[7,8] New tools for improving the registration of CT and PET images in the thorax from data acquisition rather than software registration for PET/CT have become available.[9] Many of the tools developed for CT simulation since the 1990s, and 4D-CT simulation introduced recently for inclusion of multiple data sets in RT, will help the integration of PET/CT into RT. Continuing improvement of PET/CT instrumentation by utilizing time-of-flight information of coincidence events with fast detectors will further improve the image quality of PET/CT. The time is right to utilize PET/CT in RT.

AGAINST THE PROPOSITION: Lili Chen, Ph.D.

Opening Statement

I agree that PET and CT make significant contributions to radiation oncology. Indeed, CT has played a revolutionary role in the establishment of 3D conformal radiotherapy by providing a 3D geometry model of the patient for target and critical structure delineation, beam placement, dose calculation, and plan evaluation. PET has added biological and metabolic information to the radiotherapy process to facilitate target definition and treatment assessment. The availability of an integrated PET/CT unit has further provided a common platform for both imaging modalities to reduce image misregistration and improve patient convenience.[10] However, hybrid PET/CT scanners are expensive systems with limited capabilities; they are unavailable in most cancer clinics; and payment issues affect cost-effectiveness. PET/CT probably will not become standard practice for radiotherapy treatment planning since it is unnecessary for palliative treatments and sometimes insufficient for curative treatments in modern radiotherapy.

Although CT can provide useful anatomical information for radiotherapy planning it has poor soft-tissue contrast that is often inadequate for target and critical structure delineation. In comparison, magnetic resonance imaging (MRI) provides superior image quality for soft tissue delineation compared with CT. The target volumes obtained with MRI are often significantly different from those furnished by CT.[11,12] MR/CT has been widely adopted for accurate anatomical delineation (using MRI) and dose calculation (using CT). MRI can even be used alone for prostate treatment planning to avoid redundant CT scans, which in turn will reduce cost and avoid unnecessary radiation exposure to the patient.[13,14] In this regard, an integrated PET/MR unit may be more advantageous than a PET/CT unit.[15] Furthermore, a high-end MR unit is also capable of performing functional MRI, diffusion-weighted MRI, and MR spectroscopy to provide information about vasculature change, blood flow, oxygen use, and metabolic environment, which can be used for target definition and treatment assessment.

PET imaging in radiation oncology has been performed exclusively with ^{18}F-deoxyglucose (FDG), which is effective in evaluating malignant tumors in the lung, breast, head and neck, esophagus, pancreas, colon and rectum, as well as for melanoma and lymphoma.[16] Unfortunately, FDG-PET has not been successful in detecting other malignancies such as early prostate cancers, which comprise a large fraction of radiotherapy treatments. Due to intrinsic limitations the spatial resolution of FDG-PET is poor. The standard uptake values do not correspond to the tumor cell densities because of many confounding factors,[17] especially in the presence of tissue heterogeneity. PET is useful qualitatively, e.g., in staging and nodal assessment but not quantitatively in determining the exact clinical target volume (CTV). PET helps delineate CTV more consistently but not necessarily more accurately. The bottom line is that the CTV depends on the extent of microscopic disease that cannot be seen with PET. Multiple imaging modalities must be used in modern radiation therapy to minimize the uncertainty in CTV delineation and PET/CT will be a part of this process, at least for some cancers but not the entire process.

Rebuttal: Tinsu Pan, Ph.D.

I agree with most of my opponent's assertions. As with any new technology, there is a learning curve, and there are issues to overcome. PET/CT is no exception. PET/CT is great for many cancers but has limitations for prostate and brain. In addition, PET may not reveal microscopic disease because of its limited spatial resolution. PET/CT for RT is still limited principally to academic hospitals and a single pharmaceutical ^{18}F-FDG.

Today, reimbursement by insurance is the biggest obstacle for the adoption of PET/CT for RT. It was not until insurance reimbursement for PET started a decade ago in the United States, did the sale of PET scanners and, later, PET/CT scanners increase significantly. The benefits of having a PET and CT scan in the same imaging session facilitated the adoption of PET/CT over stand-alone PET. Today, many patients, before they are admitted to RT, already have a PET scan as part of their diagnostic workup. Most radiation oncologists will use the patient's PET data to help define the tumor volume even though there is no standard for determining the tumor boundary with PET, and registration of separate PET and CT data may not be ideal.

My colleague raises the important issue of consistency, not accuracy, of PET to CTV definition. I believe that consistency is a prerequisite before the efficacy of a treatment can be evaluated, and that more clinical data will emerge to support PET/CT. This is even truer today with the ever increasing accuracy and precision required for intensity-modulated and image-guided RT. Due to its excellent soft tissue contrast over CT, MRI is an indispensable imaging tool. Nonetheless, PET/CT may have an advantage over PET/MR in cost and general oncology applications, although PET/MR may have a niche in the brain application. In summary, PET/CT is just CT with additional contrast from PET. It can only help CT based RT.

Rebuttal: Lili Chen, Ph.D.

As I pointed out previously, CT and MRI provide essential information for target and critical structure delineation, dose calculation, and treatment plan evaluation, and these have been used as primary imaging modalities for RT treatment simulation and planning. Many other imaging modalities to complement CT and MRI have played important roles in target determination, critical structure avoidance, treatment design, and assessment. These include FDG-PET, SPECT, MR spectroscopy, functional MRI, ultrasound, receptors, electroencephalography, and optical imaging, to name just a few. PET/CT units are still not widely available in radiotherapy clinics, and PET/CT images from a radiology department may be impractical for radiotherapy planning if the system is not set up for radiotherapy simulation. New molecular-targeted agents offer great potential, e.g., for hypoxia imaging, but their clinical impact on radiation oncology remains to be demonstrated. Reimbursement for PET/CT scans is declining while the cost for a CT/PET unit is not, making it less cost-effective from an administrative point of view. The standard of practice for radiotherapy simulation and planning is evolving and it is

likely to involve multiple imaging modalities depending on the body site, disease type, beam modality, treatment technique, dose scheme, and other factors affecting treatment outcome.

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4.8. PET-based GTV definition is the future of radiotherapy treatment planning

Salahuddin Ahmad and Slobodan Devic
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OVERVIEW

In treatment planning, the gross tumor volume (GTV) is most commonly defined using CT, sometimes supplemented by MRI. It has been suggested that in the future such volumes will likely be defined primarily with the use of positron emission tomography (PET). This is the claim debated in this month's Point/Counterpoint.

Arguing for the Proposition is Salahuddin Ahmad, Ph.D. Dr. Ahmad received his Ph.D. degree in Physics from the University of Victoria, Canada in 1981 followed by postdoctoral training in Medical Physics from UT MD Anderson Cancer Center. He has been a faculty member at Rice University and Baylor College of Medicine, and the Chief Physicist at the Houston VA Medical Center. He is currently Director of Medical Physics and the Medical Physics Residency Program and Full Professor in the Department of Radiation Oncology at the University of Oklahoma Health Sciences Center. He is an Editorial Board Member of the *JACMP* and *Medical Dosimetry*, Bangladesh Liaison for the AAPM, a Fellow of the ACMP, and an ABR Diplomate.

Arguing against the Proposition is Slobodan Devic, Ph.D. Dr. Devic obtained his B.Sc., M.Sc., and Ph.D. degrees in Physics from the University of Belgrade, Belgrade, Serbia, and subsequently completed a Medical Physics Residency at McGill University, Montreal, Canadain 2002. Since then he has worked as a Medical Physicist at McGill University, first, in the Department of Medical Physics, Montreal General Hospital and, currently, in the Radiation Oncology Department, Jewish General Hospital, where he is an Assistant Professor. His major research interests are PET/CT-based treatment planning for lung and rectal carcinomas, new treatment techniques for GI cancers, and GafChromic film dosimetry. Dr. Devic is a Member of the *Medical Physics* Editorial Board.

FOR THE PROPOSITION: Salahuddin Ahmad, Ph.D.

Opening statement

PET is a functional imaging method that has become widely used in radiation simulation over the last decade. The most critical component of radiotherapy treatment planning (RTP) is delineation of the GTV, which is essential to deliver a high dose to the malignant tissue, while keeping the dose to surrounding tissue low. FDG-PET is also routinely used for diagnosis and staging of several types of cancers including nonsmall cell lung cancer (NSCLC).

Conventional CT simulation for GTV delineation introduces uncertainties into RTP because of difficulties in determining tumor margins, especially in NSCLC with atelectasis, pleural effusion, pneumonitis, or normal tissue displacement, and its limitations in identification of tumor-involved local lymph nodes. Also, neither CT nor MRI is well suited for distinguishing if hilar and/or mediastinal lymph nodes are involved. These factors contribute to marked variability in GTV delineation among even experienced radiation oncologists. In lung cancer staging, FDG-PET has proven to have greater sensitivity and specificity than CT or MRI. PET data complement anatomic data provided by CT, help distinguish tumor from normal anatomy and consequently lead to a more consistent delineation of the GTV with the reduction of inter- and intraobserver variation.

PET image quality improvements and tools for accurate segmentation and quantification have been developed recently. Among various segmentation methods, the gradient-based technique best estimated true tumor volume, out-performing threshold-based techniques in accuracy and robustness for delineation of primary tumor volumes in NSCLC.[1] For the quantitative implementation of PET data into GTV delineation, the differences in reproducibility of segmentation technique-based contoured volumes, however, should be kept in mind.[2]

Respiratory motion of lung tumors during PET image acquisition causes artifacts affecting quantification of FDG uptake and determination of tumor size. Respiratory gating using 4D-PET, such as 4D CT, can show us where the tumor is at a given time and how it moves. This capability removes image degradation associated with the partial volume effect, allowing us to see involved lymph nodes and other tumor activity where it may have been blurred out in 3D-PET. 4D-PET provides biological characterization of tumors, e.g., regions of hypoxia or necrosis, in sharp detail. This provides greater treatment efficacy, improves tumor edge definition, defines the full physiologic extent of moving tumors, and thus improves RTP for lung tumors. In addition, reduction of blurring from free-breathing images may reveal additional information regarding regional disease.[3]

Use of PET for GTV definition in RTP, which has been validated for lung, head, neck, and brain tumors, was found to be beneficial in colorectal cancer,[4] and influenced CT-based RTP for locally recurrent nasopharyngeal carcinoma by changing target volume definition.[5] Recently, PET/CT derived tumor volumes were found smaller than those derived by CT, with nodal GTV contours changed in 51% of patients.[6] PET signals may now be used to define a subvolume in a CT-derived GTV to deliver escalated doses inside the GTV for more radio-resistive areas. In summary, PET for GTV delineation appears beneficial and has tremendous promise to impact RT planning and treatment.[7]

AGAINST THE PROPOSITION: Slobodan Devic, Ph.D.

Opening Statement

Over the last decades, radiotherapy treatment planning has been based on an anatomical object, namely the gross tumor volume (GTV), from which the clinical target volume (CTV) and the planning target volume (PTV) are derived. Because of its superb spatial reproducibility and the ability to provide information on electron density, computed tomography (CT) was, and still is, the backbone of three-dimensional radiotherapy treatment planning (RTP). Since the inception of the PET/CT scanner as a single imaging modality, numerous studies have reported on possible changes to the GTV as defined on anatomical images.[7,8] Following the initial attempts for target thresholding,[7,9,10,11] numerous variations of the PET-based GTV definition approaches were developed over the years.[12,13] However, an undeniable drawback of such approaches is that they tend to create a single PET-based target volume to replace the traditional CT-based GTV.

Thus far clear guidelines on how to incorporate PET data into the RTP process have not emerged from either clinical or phantom studies. MacManus[14] suggests that the “best judgment” of the radiation oncologist is the guideline to be followed for GTV definition using PET in patients with lung cancer, while Nestle et al.[15] stated that “… at this time we can only rely on the qualitative visual approach interpreted by a well-trained nuclear medicine specialist.” However, such conclusions deny the specific role of quantitative physiological information contained in functional images such as FDG-PET that could have a role in radiotherapy treatment planning through definition of biological target volumes (BTVs).

Instead of replacing the CT-based anatomical information with PET-based functional data, another approach would be to integrate both datasets in such a way that they complement each other. While such harmonization of PET and CT data into the radiotherapy treatment planning process is becoming evident, methods to actually put this complementation in place are not apparent yet. One of the possible scenarios, elaborated by Ling et al.,[16] would be creation of BTVs embedded within the previously

defined gross-tumor volume. According to his recommendations, a GTV defined by inherently low spatial resolution functional imaging such as PET should not be a surrogate for a CT-based GTV. The frame for one or several BTVs should be gross tumor volume defined with CT, which has superior spatial resolution and reproducibility and, if possible, with MRI for enhanced soft tissue contrast. Once this general frame is delimited, different functional sub-volumes (tiles) can be added to the mosaic. The incorporation of regions with increased FDG uptake as, for example, the glycolytic BTV,[17] within the CT-based GTV, may lead to escalated radiotherapy doses being delivered to specific parts of the tumor in order to improve the probability of cure.

Rebuttal: Salahuddin Ahmad, Ph.D.

I agree with Dr. Devic that CT is the backbone of RTP and guidelines to incorporate PET data are not clear. However, PET identifies additional gross disease and detects significant tumor extension outside GTV delineation on CT that needs to be incorporated to enhance GTV precision. Objective approaches to tumor segmentation have been developed where tumor is either defined based on the standardized uptake value (SUV) and auto contouring all areas with a value at or above that marker, or defined as the area enclosed in the 40%–50% intensity level relative to the tumor maximum. Recently, a gradient-based algorithm is being incorporated to aid PET-based GTV definition.

I also agree with Dr. Devic that optimal definition of GTV is dependent on integration of multimodality imaging. CT provides morphological information whereas PET offers information about metabolism, physiology, and molecular biology of tumor tissue, improving GTV delineation. PET/CT is becoming a routine imaging tool for radiation oncology because of its combined benefits of improved staging and tumor delineation provided by PET, and high-resolution 3D anatomic display by CT. Together these allow better treatment with precise targeting. The continuing innovations in PET/CT technology, along with increasing availability of these scanners, is rapidly becoming an accepted and routine clinical tool in RTP for anatomic and biologic tumor targeting. Recently, integrated or hybrid PET-CT scanners have become available. These have been shown to be superior to CT alone, or a combination of PET and CT acquired separately.

In conclusion, PET images used for RTP improve GTV delineation and offer additional information about tumor biology and physiology. Improvements in PET image quality, segmentation, and quantification are essential components for future biologically based image-guided radiotherapy, the aim of which is to modify dose distributions to particular regions according to voxel intensities identified by functional imaging.

Rebuttal: Slobodan Devic, Ph.D.

Dr. Ahmad's arguments are related primarily to the use of PET in redefinition of CT-based CTV (inclusion of proximal nodes) and not GTV. While this role is undeniable, contemporary clinical practice only uses PET data to localize positive nodes or suspicious proximal tissue to be included into CTV definition, which is still performed on CT images. However, replacement of CT-based GTV by PET-based GTV is far from being widely accepted clinical routine, with published data showing no clear clinical importance of such a change. My colleague also points out the importance of image acquisition gating for RTP, and rightfully concludes that it will have the same impact on both PET and CT image quality and interpretation, and I have no problem with that.

Taking into account the specific image properties of contemporary medical imaging modalities, the frame of the biological PTV should be ideally defined with both CT, having superb spatial resolution and spatial reproducibility, and MRI, owing to superb soft tissue contrast characteristics. While the CT and MRI provide an overall spatial uncertainty of the order of 2 mm, the spatial resolution of the current commercially available PET/CT systems is more than double this.[18] Once the frame of the mosaic (GTV) is set on the radiation treatment planning easel, different subvolumes (tiles) can be added.

Tumor and normal tissue physiology, together with the nature of the radiopharmaceutical used, must be taken into account for both quantitative PET signal interpretation and its incorporation into the treatment planning process. It should be remembered that the single intensity value for a given voxel is based on the catabolic activity of more than 10^5 cells and it is unrealistic to expect that the domains of the subvolumes with different physiological characteristics will be defined by sharp boundaries within the tumor volume. Even if it would be possible to define certain target subvolumes within the predefined GTV, these would be characterized only by the relatively greater abundance of a certain type of cell or metabolic condition. This would not imply exclusion of other biological situations coexisting within the same volume.

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4.9. Genomics, functional and molecular imaging will pave the road to individualized radiation therapy

Joseph Stancanello and John E. Bayouth
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OVERVIEW

There has been considerable progress recently in the development of genomics and functional and molecular imaging using tools such as whole-genome arrays, fMRI, magnetic resonance spectroscopy imaging (MRSI), and 4-D high-definition PET. Many of these new technologies are just beginning to find their way into radiotherapy treatment planning and evaluation of treatment response, and it is possible that these might eventually make it feasible to devise optimal radiation treatments for each specific patient. The potential for such individualized radiation therapy is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Joseph Stancanello, Ph.D. Dr. Stancanello graduated with a Ph.D. in bioengineering from Politecnico di Milano, Italy, also attending an Executive MBA program at the same institution. His research fields were medical image registration in radiosurgery and the competitive advantage in the radiotherapy marketplace. He also taught mathematical analysis at Padova University, Italy. He has worked in the Medical Physics Department at Vicenza Hospital, and Bracco Imaging, where he specialized in medical image post-processing and conducted research on functional and molecular imaging. He is currently managing European collaborative research for Siemens Healthcare Oncology.

Arguing against the Proposition is John E. Bayouth, Ph.D. Dr. Bayouth graduated with a Ph.D. from The University of Texas Health Science Center at Houston/M.D. Anderson Cancer Center in 1993, and is currently Director of the Medical Physics Division in the Department of Radiation Oncology at the University of Iowa. His areas of research interest include image-guided radiation therapy, four-dimensional radiotherapy, magnetic resonance imaging and positron emission tomography in radiation therapy for tumor target delineation and response to therapy, treatment delivery time and radiation biology effects of extra high dose rates during gated delivery, and benchmark photon beam data for improved accuracy in radiotherapy. He serves and has served on numerous committees of the AAPM and is a member of the Board of Directors.

FOR THE PROPOSITION: Joseph Stancanello, Ph.D.

Opening Statement

The assumption by Parmenides on the unity and immutability of the Being was challenged by Democritus, who opposed a definition of the Being as made of several and finite atoms. This would make the Being still finite but mutable, dependent upon the various combinations of the atoms themselves. In other words, what is supposed to be just one, is no longer one when considering its phenomenology. *Mutatis mutandis*, this concept has been discovered to be true also for: (a) the nature of a given disease, which now is considered rather a collection of different diseases, and (b) the individual response to treatments, that we know to be equally as applicable in the field of pharmacogenomics as in radiotherapy. In the past, the evaluation of individual response to pharmacological treatment depended upon statistical approaches based on population outcomes. Modern drug discovery programs utilize tools consisting of functional and molecular imaging combined with genomics, transcriptomics and proteomics, to predict patient response to treatment. These same tools can now be applied to

radiotherapy treatment. In order to maximize the success rate of treatments, while minimizing patient morbidity, one can exploit the individual genetic profile and its actual expression. Thus, not only at the beginning of treatment may the optimum approach be selected, but also the treatment strategy may be modified according to early prognostic indicators.

Examples of functional imaging applications that have been proposed include BOLD-fMRI-based brain radiosurgery[1] and 18F-FLT-PET-based radiotherapy, by planning target volumes incorporating infiltrated lymph nodes. Other applications of molecular imaging have been reported such as the use of MR-spectroscopy imaging in prostate radiotherapy[2] and receptor-based imaging in many types of tumors which over-express particular receptors. These new developments have been shown to add substantially to our knowledge of individual radiotherapy response, even if their current complexity and cost are a deterrent to their widespread adoption. Proteomics is likely to play a major role in this field, suggesting how to successfully tailor treatment to patients on the basis of the information related to post-translational modifications that cannot be fully characterized at the gene level. Examples of information on DNA repair, normal-tissue radiosensitivity, oxidative stress and apoptosis-related genes have already been reported,[3] as well as the genetic determinants of long-term toxicity in breast cancer radiotherapy treatments.[4]

As a whole, all these new scientific tools are currently supporting the development of individualized radiotherapy and, in the near future, their contributions will grow rapidly. Technological advances such as higher field strength MRI scanners, high-definition PET, new contrast agents for molecular imaging,[5] and high throughput whole genome and protein microarrays, will allow high-specificity, sensitivity and spatial resolution methods to be routinely applied to radiotherapy and these will additionally link diagnostics to therapy in the value chain of the patient-outcome-oriented process.[6]

Information technology is expected to support the removal of barriers like increased information load and complexity. Additionally, we need to create robust pathways to translate these theranostic tools from research to clinical domains, responding to international variations in healthcare policy and reimbursement systems.

AGAINST THE PROPOSITION: John E. Bayouth, Ph.D.

Opening Statement

Individualized therapy is a rational goal to further advance radiation therapy. Genomics, functional, and molecular imaging are exciting new tools, but to enable individualized therapy they will require *physics*.

Evidence shows that physics has paved, and continues to pave, the road in radiation oncology through the discovery of man-made and natural sources of radiation, and the development of therapeutic-energy x-rays machines, linear accelerators for megavoltage photons and electrons, CT, PET, MRI, IMRT, IGRT, particle and heavy ion therapy, and so on. These accomplishments continue to dramatically change radiation therapy and enable us to further individualize therapies.

Individualized radiation therapy remains elusive; we do not know with clinically acceptable certainty the precise dose needed to produce a desired response of the tumor in any specific patient or the dose that will cause unacceptable normal tissue damage, and cannot modify treatment based on assessment of that patient's real-time response. Even the simple is not so simple. PET utilization for individualized tumor delineation is technically impeded by dependence on sampling and spatial resolution, image reconstruction kernels, tumor uptake to background ratio, and tumor motion. Even with an ideal marker, significant advances in physics are still needed before we can clinically exploit molecular imaging. In a study in which eight experienced physician users were required to contour the gross tumor volume for head and neck cancers using each one of three imaging modalities separately, Breen *et al.*[7] showed that metabolic imaging (PET/CT) had the highest inter-observer variability. Objective physics metrics are needed. A recent review of the literature reveals a spectrum of conclusions regarding the impact of PET

on delineation of target volumes.[8] The challenges in using MRSI to individualize radiation therapy are even greater, as QA is poorly implemented or absent and files are not in a format that can be used routinely for RT applications. In spite of more than a decade of research, clinical application remains restricted due to local susceptibility requiring case-specific shimming, and problems caused by chemical shift misregistration artifacts, spatial distortion, re-scaling of pixel values in each 2D image to create a meaningful 3D map, image registration, image re-sampling, and interpolation.[9,10]

The challenges of using genomics to determine tumor and normal tissue response for each patient are orders of magnitude beyond those of functional and molecular imaging. Current review articles show the use of the human genome (DNA) or its products (RNA and proteins) holds promise, but scores of studies have demonstrated that the most promising markers (ATM, TGF, and single nucleotide polymorphisms) are inconsistent in their correlation with response.[11] The interpretation of data is laborious and time consuming and may change with tumor burden, and patient-to-patient variability introduces complex dependencies of multiple genes and gene products. One estimate suggests 30,000 patients would be required to achieve the necessary statistical power to demonstrate a significant correlation with clinical response; patient and treatment heterogeneity are too great. The information will be useful for population statistics, but is far too imprecise for individualized therapy. To advance this area the authors call for the collection of "high quality physics" to be correlated with clinical and outcome data.[12] The delivered radiation dose must be accurately known along with a quantitative measure of response to facilitate establishment of response prediction produced by genomics.

Physics will be needed to make genomics, functional, and molecular imaging another vehicle on the road to individualized radiation therapy, a road paved by physics.

Rebuttal: Joseph Stancanello, Ph.D.

I share Dr. Bayouth's healthy skepticism about the challenges on the road to individualized radiotherapy driven by genomics, functional and molecular imaging. I agree that "high quality physics" will be needed to ensure correct exploitation of the new information. But the road is about to be paved as a result of the interplay of new knowledge and tools.

There is ongoing research to investigate promising automatic source-to-background algorithms to allow more objective PET-based target delineation. The spread of cyclotrons will allow radiotherapy to use a wider range of radioisotopes with higher spatial resolution, while 4D high-definition PET scanners are becoming available on a wider scale. Additional efforts are necessary to link the high and low level individual data to established and emergent radiobiological models.

As to genomics, the introduction of high-throughput whole-genome arrays will dramatically increase the efficiency of the analyses, allowing the expression of several genes to be investigated. Moving from the domain of gene expression to protein production and metabolic activity eliminates much of the uncertainty associated with molecular genetics in translational radiobiology. As a result, smaller rationalized studies can be performed to provide clinical correlates for bioeffect-based treatment planning.

As a historical parallel, let us think of the classical theorems in mathematics proving the existence of solutions to problems for which no analytical form was known. The authors of the theorems appreciated that solutions existed, but no tool to identify their analytical forms was available. Recently, the advent of computers and sophisticated numerical methods has offered us the opportunity to find approximate forms of these solutions to an adequate level of precision. This has allowed us to understand the behavior of complex systems. In the same way, we now have a clearer understanding of the biology captured in these new investigative modalities. We simply need to develop the correct tools to exploit them.

Rebuttal: John E. Bayouth, Ph.D.

Dr. Stancanello indicates that the modern drug discovery programs will be capable of predicting patient responses to treatment, independent of statistical approaches. Current techniques are far too imprecise for individualized therapy. To be independent of a statistical approach for individualized therapy would require the same accuracy with which we calibrate our linear accelerators—having only a significant correlation between the monitor unit and radiation absorbed dose is inadequate.

Dr. Stancanello points to publications that show the potential benefit of these emerging technologies, but to date they have failed to provide individualized radiation therapy because of the inability to establish robust quantitative imaging tools, techniques, and quality assurance. The U.S. National Institutes of Health (NIH) has announced a multi-million dollar funding initiative (PAR-08-225) to support tool and technique development by medical physicists and other imaging scientists, addressing what they believe to be a significant impediment to using molecular and functional imaging clinically. The AAPM recently formed TG-174 to help identify the limitations of FDG-PET in radiotherapy, and establish guidelines for consistent FDG-PET usage.

Just as I have heard for more than 20 years, again I hear that the future of radiation oncology research, development, and now individualized therapy will come from biology. Although I believe genomics, functional imaging, and molecular imaging holds great potential, without accurate methods to determine the delivered radiation dose it represents half the story at best. The manifestation of individualized radiation therapy will be born out of the efforts from physics.

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4.10. The physics components of the ACR MRI Accreditation Program are overly tedious and beyond what is needed to ensure good patient care

Wlad T. Sobol and Moriel S. NessAiver
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OVERVIEW

MRI systems, like any other imaging technologies, suffer from loss of good image quality if not properly tested and maintained. Also, like other imaging systems, this reduction in image quality might be too subtle to be realized by the users, yet could be sufficient to put patient care at risk. The assurance of good image quality is the goal of the physics tests prescribed in the American College of Radiology (ACR) MRI Accreditation Program. These physics tasks were initially simply recommendations but, over the years, they have evolved into requirements which some believe are overly tedious and beyond what is needed to ensure good patient care. This is the topic debated in this month's Point/Counterpoint debate.

Arguing for the Proposition is Wlad T. Sobol, Ph.D. Dr. Sobol received his Ph.D. degree from the Jagiellonian University in Cracow in 1978 and is currently Professor of Radiology in the Department of Radiology at the University of Alabama in Birmingham. 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. Dr. Sobol is a Diplomate of the American Board of Radiology in Diagnostic Radiological Physics and the American Board of Medical Physics in Magnetic Resonance Imaging Physics and is a Fellow of the AAPM.

Arguing against the Proposition is Moriel S. NessAiver, Ph.D. Dr. NessAiver received his Ph.D. in Biomedical Engineering in 1988 from the University of Southern California where his research focused on MRI surface coil intensity correction methods. From 1989 to 1994 he was a senior scientist at Picker responsible for developing their cardiac MRI program and holds six patents on cardiac imaging techniques. In 1994 he joined the University of Maryland School of Medicine. While there he authored the book "All You *Really* Need to Know About MRI Physics." He is a past member of the ACR MRI Accreditation Physics committee. His company, Simply Physics, has been providing MRI quality control services for the past seven years.

FOR THE PROPOSITION: Wlad T. Sobol, Ph.D.

Opening Statement

Let me start by saying that I am not against ACR accreditation programs. To the contrary, while I have never been a part of an official ACR body in charge of an MRI accreditation program (MRAP), I have stayed very close to the project since its onset and helped nurse it along in various ways. Thus, I am quite familiar with both its structure and history. When the MRAP started, it did not require a physics expert's participation. Periodic system testing was recommended, but scope and methods were left entirely to the judgment of the local team. As time went by, the program requirements[1] evolved dramatically and physics components went from recommended and descriptive to required and prescriptive. This worries me.

The origins of the tests, currently required by the ACR MRAP as components of yearly physics surveys, date back to the late 1980's when a group of starry-eyed enthusiasts set out to formulate descriptions of basic MRI performance tests.[2] At about the same time, the manufacturers developed some specifications

for basic assessment of MRI equipment's performance.[3] From today's point of view, most of these efforts look quaint and obsolete, dwarfed by 20 years of spectacular progress in MRI technology. This is okay, since these tests were never meant to be prescriptive; they were intended to provide helpful suggestions and guidance. This point of view has always been clearly stated in the ACR's own standards.[4]

The structure of all current ACR accreditation programs is based on the ACR mammography accreditation program. This has some serious consequences for the ACR MRAP. While mammography machines in use today have a very uniform design and offer only a few user-adjustable parameters, MRI scanners are vastly more differentiated and require scores of user-defined parameters to operate. Most of these parameters are platform-specific and are not implemented even across vendors' own product lines. Furthermore, neither the ACR nor MRI manufacturers provide tools needed to run the ACR-prescribed tests. As a result, “MR physicists” are forced to devise their own methods *ad hoc*. This is a challenging task because, at a user level, these tests are trivial to implement on some MR machines, but they prove very difficult, if not downright impossible, to run on others.

Finally, MR vendors' own internal test tools and tests have evolved, over the years, into a set vastly superior to anything that an end user can accomplish using a scanner graphical user interface (GUI) and a simple phantom. This leads to an interesting *gedanken* scenario: what is supposed to happen when the physicist's test, performed using methods that might be unsuitable for the evaluated unit, fails? Obviously, the system engineer will then run a set of tests using internal service tools. What if all these tests pass? A showdown is bound to expose the embarrassing inadequacy of the physicist's methods.

Given this situation, it is best to leave the authority over the scope and methodology of MRI system testing to the MRI experts in the field. The ACR MRAP guidelines may define recommended tests and demand written explanation from the expert for any observed variances, but the accreditation body should stay away from prescribing tests for which it has no authority to ensure proper implementation.

AGAINST THE PROPOSITION: Moriel S. NessAiver, Ph.D.

Opening Statement

Not only are the requirements for the physics components of the ACR MRI Accreditation Program as outlined in the most recent ACR's MRI Quality Control Manual[5] not overly tedious, I submit that they do not go far enough to ensure both good patient care and a good return on investment for the owner of the MRI scanner. The single most time-consuming task required of the MRI physicist is the yearly performance test. It is the goal of this yearly task to ensure that the magnet has good homogeneity, the gradients are properly calibrated, each and every RF coil is working at peak performance, and all of the components work together as a harmonious whole.

The single biggest omission by the ACR Accreditation Program is not requiring that each channel of every phased array RF coil be tested. Today's phased array coils can have up to 64 channels and can cost upwards of $100 000. If one channel is not working properly, an image can look “OK” but the small region covered by the bad channel can have significantly reduced signal-to-noise ratio (SNR). Most physicists only look at a single composite image which can result in problems being missed. As a case in point, I once tested a four-channel knee coil which produced a very uniform composite image with an SNR of 274. However, when I examined the individual channels, two channels had SNR values of 200 while the other two channels had SNR values of only 45. The coil was replaced and the new coil had SNR values of 220 in each channel and a composite SNR of 430. This gain in SNR would allow the site to use a 14 cm FOV instead of a 17.5 cm FOV.

Over the last 3.5 years I have performed 174 yearly performance tests on 98 different magnets. I performed more than 3000 separate tests on roughly 1500 different RF coils, half of which were phased array coils. Of those 174 system tests, in only 18 (10.3%) did I encounter no deficiencies of any kind. An additional 19 (for a total of 21.3%) only had minor deficiencies that did not affect image quality,

meaning that a full 78.7% of all of the systems I tested had deficiencies that directly affected image quality. I encountered a total of 144 phased array coils (19.2%) with significant problems. Utilizing software I wrote for analyzing phase difference images, I found 22 systems (12.6%) with homogeneity problems. Between 10 and 20% of the scanners suffered from each of the following problems: excessive RF noise, excessive ghosting, poor gradient calibration, poor hard copy (film) and soft copy performance. I also found that one vendor's turbo spin-echo (TSE) sequences had slice thicknesses that were all 18-23% thicker than specified while another vendor's were 20%–25% thinner.

A thorough yearly performance test can take 8–14 h but this is a small price to pay to ensure the highest quality images that patients, and magnet owners, have every right to expect.

Rebuttal: Wlad T. Sobol, Ph.D.

Somewhat to my surprise, my fellow debater appears to argue for the same solution, namely, that the physicist testing MRI equipment should be allowed to select both the scope and methodology of yearly surveys and acceptance testing. However, while Dr. NessAiver argues for the right to *expand* the testing methodology, I argue for the rights to *narrow* the scope and *modify* the methodology.

It is no secret that MRI coil management is currently in bad shape due to rapid transition into the complex domain of multichannel, phased array designs. Unfortunately, currently there are no public algorithms for testing the multichannel coils, no accepted baseline performance specifications, no established tools, and no adequate phantoms. Thus, it is impressive to see a testimony of a skilled MRI expert who advocates devising (undocumented) proprietary interfaces, forging through data extraction protocols, and developing custom software tools to analyze the results. But to require such performance from an average MRI physicist is unrealistic at best.

Then there is an issue of economics. Routine coil configuration management and performance testing is included in most service PM programs. Few facilities would consider it fiscally responsible to ask the physicist to replicate this task. I, for one, would prefer to have an option of *checking* the service engineer's PM results, making sure that all coils perform within the vendor's own standards.

I believe Dr. NessAiver may be leaning a little towards the infamous “academic bias,” as he seems to advocate an environment where nothing matters but the performer's virtuosity. I just want to help people by making their jobs a little easier and making the scanners perform a little better. To do this effectively, I need the freedom of tailoring the scope of my services to the environment in which I find myself. My dream is to be a part of the solution, not a part of the problem.

Rebuttal: Moriel S. NessAiver, Ph.D.

I certainly agree with many of the points that Dr. Sobol raised. MRI scanners are more complicated to operate than any other modality and the manufacturers do not provide adequate tools for typical users to evaluate scanner performance. This is why I perform all data analysis on my laptop using software that I have personally developed. While it is true that some manufacturers have developed sophisticated testing tools, it has been my experience that their specs are often so generous as to be nearly useless. I also agree that the scope and methodology of MRI system testing should be left to the MRI experts in the field, however those experts *should* be MRI physicists with years of actual hands-on experience.

Dr. Sobol proposed a thought experiment where the physicist performs a test of his own design in which the system fails while the service engineer, using the vendor's tools, says it passes. This has happened to me. I use a 32 cm sphere and my own software to map out magnet field homogeneity and one time I claimed that a certain magnet failed this test. The service engineer, however, using only a 24 cm sphere, said it passed. After the engineer reviewed my analysis, he agreed to bring in a shim rig and measure it over a 40 cm volume. The magnet *then* failed the vendor's spec.

It is incumbent upon us, the MRI physicists, to be the sites' third-party advocates to the manufacturers. The very fact that close to 80% of all scanners that I have tested have had problems that adversely affected image quality is enough of a reason to justify the periodic evaluations required by the ACR. If we need to develop our own tools, so be it. Just because a task is difficult, doesn't mean we shouldn't do it.

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CHAPTER 5

Ionizing Radiation Protection, Standards and Regulations

5.1. Exposure limits for emergency responders should be the same as the prevailing limits for occupational radiation workers

Rebecca H. Kitchen and Eric G. Hendee
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OVERVIEW

The reactor accident at Chernobyl drew the world's attention to the terrible dangers that emergency response workers face when exposed to high levels of ionizing radiation. Many of these responders received doses way in excess of the legal limits established for radiation workers and, as a consequence, about 30 of them died acutely and possibly several hundreds of them will eventually die of radiation-induced cancer. It could be argued that emergency responders deserve the same protection and have the same radiation exposure limits as radiation workers. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Rebecca H. Kitchen, M.S. Ms. Kitchen obtained her M.S. degree in Medical Physics from the University of Wisconsin, Madison. While studying she served in the National Guard as a medic and is now a physicist in Radiation Oncology and the RSO at Aurora BayCare Medical Center in Green Bay, WI, which is the hospital in the region designated to care for radiological emergency patients. She has served as the Secretary/Treasurer of the AAPM North Central Chapter and is certified by the American Board of Radiology in Therapeutic Radiological Physics.

Arguing against the Proposition is Eric G. Hendee, M.S. 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 the Chief Physicist in Radiation Oncology at Waukesha Memorial Hospital, WI, and is certified by the American Board of Radiology in Therapeutic Radiological Physics. He has served on the Wisconsin expert panels for decontamination and hospital response to radiation emergencies. He is also chair of the recently formed AAPM working group on Medical Response to Radiation Incidents.

FOR THE PROPOSITION: Rebecca H. Kitchen, M.S.

Opening Statement

Unplanned radiation exposures include smaller incidents, uncontrolled sources, and serious accidents.[1] The radiation emergency assistance center/training site (REAC/TS) in Oak Ridge, TN maintains an extensive database of radiation incidents involving significant radiation exposures.[2] The associate director of REAC/TS, Doran Christensen states, "*We have information in the REAC/TS Registries that have over 2,000 cases from around the world over the past 60 years. In that Registry, we have no history of a medical worker receiving a significant dose of ionizing radiation or having been significantly contaminated with radioactive materials while caring for victims of radiological or nuclear incidents.*"[3]

The largest dose on record for an emergency healthcare provider at REAC/TS was 2.49 mSv.[4] The majority of incidents have occurred with primary responders receiving very little dose and do not show justification for an increased limit.

Determining health risks to emergency workers from exposure to radioactive sources is difficult due to nonuniform dose distribution and many other factors. However, if one knows that a radioactive source is involved, appropriate protective measures can be taken.

Accidents involving significant risk of radiation exposure are extremely rare. The best example would be Chernobyl. This has been called the "most serious accident in the history of the nuclear industry" by the IAEA.[5] Of the 200 000 workers called to contain the contamination, the average dose was 100 mSv.[5] Acute radiation syndrome was diagnosed in 134 cases and 28 individuals died. Do we advocate an occupational dose limit that allows for this, or do we realize that in certain cases all the rules go out the window?

Many agencies have advocated the use of "turn back" doses.[1] Some have even listed this as a function of how many potential lives would be saved. Receiving a dose of *X* to save 10 000 lives is a pretty good exchange no matter what *X* is, but implementation of this would be difficult at best. Should the person turn back if you estimate only 500 people saved? If you are going to save 10 000 people, why have a limit at all? If a firefighter reaches that new limit, will they really walk away? At what point do you just list what limit is safe and then leave the rest to the conscience of the individual?

Many people in many careers save lives—radiologists and cardiologists for example. On rare occasions they come close to the legal radiation dose limit (varying by specialty and training, of course). Do we increase the legal limit because it may save more lives? You could take this argument to silly extremes. Popular magazines are full of estimates of deaths attributed to particulates and air pollution from coal power plants. One recent estimate is that 20 000–30 000 premature deaths per year can be attributed to our nation's use of coal.[6] According to this argument, the annual occupational limit for nuclear power plant workers should be raised if this would result in more power produced via nuclear means. Occupational limits should be based on safety, not on occupation. If a dose is considered unsafe for an individual in one profession, why would it be considered safe for an individual in a different profession?

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

Opening Statement

"I will never allow personal feelings, nor danger to self, deter me from my responsibilities as a firefighter."[7]

In an emergency involving first responders arriving on the scene, their training and experience will determine their actions. As evidenced by the above statement for firefighters, this will focus on the safety of others, even when there is potential for personal harm. For an event involving radiation, it is unrealistic to expect that their mission should be any different from what it would with fire or any other hazard. By nature of being first responders, little to no information would be available regarding radiation exposure levels at the scene. It is also unlikely they would have time or resources to monitor exposure in the initial phases of a response. An awareness of the possible presence of radiation would certainly encourage the principles of time, distance, and shielding, but this is the common theme for most situations they face. The risk level associated with radiation should be consistent with other risks in an emergency in that it should pertain primarily to short-term consequences, with less concern for long-term effects.

Setting a level based on occupational dose limits is potentially counterproductive to the mission of first responders. These limits (50 mSv/year, 5 mSv/year ALARA) are designed for those who work with radiation regularly as part of their job so as not to significantly increase the lifetime risk of cancer. This does not apply to infrequent exposures of first responders in an emergency where lives and property are

at risk. However, acute radiation effects are a concern. Up to around 1000 mSv, the responder may experience acute affects which are not life threatening if correctly managed.[8] The training that first responders receive is based on these acute effect levels, on the order of 5–20 times the occupational limits (50–200 times the ALARA limits). For example, the current emergency worker "turn back" guidance from the IAEA is 1000 mSv for life-saving actions, and 500 mSv for actions to prevent severe health effects or injuries.[1] The FEMA training center at the Nevada Test site recommends an exposure limit of 250 mSv, and after that it is voluntary.[9] The voluntary aspect simply means the responder should be informed of the personal risks above 250 mSv, but that they are able to continue their actions with no specified upper limit.

There is no question that first responders should do their best to minimize personal risk in any situation, but it makes no sense to recommend overly conservative occupational radiation exposure levels to individuals with such an important role in time of emergency. NCRP Report 138 states that "*special individual exposure guidance, often in excess of exposure limits, is required for emergency response because the benefits associated with establishing control at the scene of a large radiological disaster are so great.*"[10] Once additional help and proper monitoring equipment arrives on the scene, decisions can be made as to how best to protect both responders and the general public.

Rebuttal: Rebecca H. Kitchen, M.S.

My colleague's opening statement that (a firefighter) "*will never allow personal feelings, nor danger to self, deter me from my responsibilities*" describes the courage of a firefighter eloquently. First responders will do whatever it takes to protect others—these are people who run *into* burning buildings, after all. The fact that firefighters will not allow danger to themselves to prevent them from doing their job is not an argument in and of itself for higher radiation exposure limits. That would be like saying that firefighters do not have to follow established guidelines for personal protective gear because it may slow them down in the performance of their duties.

I agree "*it is unlikely that a first responder would have time or resources to monitor exposure in the initial phases*." This again would not be an argument for increasing the allowable limit. Why increase a limit that is not likely to be measured until after the fact?

I also agree that there is a very small amount of "danger" associated with the current guidelines. However, I am not discussing what dose is "safe" or what dose could be tolerated in a single exposure. If a dose is considered unsafe for an individual in one profession, then why would it be considered safe for an individual in a different profession?

Think of the speed limit. People routinely go over the speed limit when trying to rush someone having a heart attack to the hospital. We do not post on our signs "65 unless medical emergency, then 85." We post the limit that is generally considered to be safe to drive and then deal with exceptions as they occur.

Rebuttal: Eric G. Hendee, M.S.

Ms. Kitchen raises several questions that I will endeavor to answer.

I believe we both share the view that unnecessary radiation exposure to anyone is undesirable. However, the bottom line for emergency responders is when to "turn back" from the scene. I agree that, since the risk to emergency responders is very low, there is no need to increase the limit beyond currently accepted values. These values are those recommended specifically for emergency responders by the IAEA (and others).

By her statistics, the acute radiation syndrome (ARS) risk for the 200 000 who responded to Chernobyl was only 0.07%, while the average exposure (100 mSv) was twice the annual occupational limit (20 times ALARA). While complicated by socioeconomic factors, the increased risk of radiation related death to emergency responders at Chernobyl over 12 years following the incident is on the order of 4%

(approximately 200 out of 4000 deaths[5]). Therefore, a turn back exposure significantly higher than the occupational dose limit corresponds to a very low risk of ARS, and a relatively low increased long-term death risk.

Regarding whether or not first responders would walk away, the answer if there are lives at risk is simply no. If it is property at risk, then the decision is more difficult and they will quickly weigh risk versus benefit on the scene with or without radiation measuring equipment and the knowledge to use it. This requires a general understanding of risk associated with what they are about to do, i.e., receive a one-time exposure. This is exactly the point where we list what limit is safe and the rest is left to the conscience of the individual. Confusing the issue with occupational dose limits directed at those who spend an entire career working with radiation will not help them make an informed decision.

I wholeheartedly agree with her final point that "occupational limits should be based on safety, not on occupation." Safety is based on risk, and the risk of a one-time exposure for emergency responders is not the same as the risk associated with occupational exposure. For this reason, the recommended levels are not, and should not, be the same.

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5.2. The use of bismuth breast shields for CT should be discouraged

Cynthia H. McCollough, Jia Wang, and Robert G. Gould
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OVERVIEW

One way to reduce the dose to the breasts of women during CT examinations has been to cover the breasts with bismuth shields. This practice has come under increased criticism, however, and it has been suggested that it should be discouraged. This is the premise debated in this month's Point/Counterpoint. [Note that, although single authorship only is allowed normally, we have co-authors arguing in support of this proposition. This was not realized by Drs. McCollough and Wang until after they had completed their manuscript since this was not specifically addressed in the Instructions for Authors. These instructions have now been modified to specify that single authorship only is allowed normally].

Arguing for the Proposition is Cynthia H. McCollough, Ph.D., and Jia Wang Ph.D. Dr. McCollough is Professor of Radiological Physics and Biomedical Engineering at Mayo Clinic, where she directs the CT Clinical Innovation Center. Her research interests include CT dosimetry, advanced CT technology, and new clinical applications such as dual-energy and spectral CT. She chairs the AAPM Working Group on Standardized Nomenclature and Protocols, is vice-chair of the CT Subcommittee, and is a member of the Imaging Physics Committee. Dr. McCollough is a fellow of the AAPM and the ACR. She received her doctorate from the University of Wisconsin in 1991. Dr. Wang works with Dr. McCollough at the CT Clinical Innovation Center as a research fellow. His research interests include dual energy CT technology and related clinical applications, as well as CT dose reduction technology. Dr. Wang received his doctorate from Dartmouth College in 2009.

Arguing against the Proposition is Robert G. Gould, Sc.D. Dr. Gould obtained his doctoral degree from Harvard University in 1977 and then took an appointment at the University of California San Francisco, where he has stayed for his entire career and is currently Professor of Radiology. He is a Past-President and Fellow of the AAPM and has served on or chaired numerous AAPM committees. His major research interests are developments in molecular imaging, small animal and high-resolution SPECT, and artifact and dose-reduction strategies in CT.

FOR THE PROPOSITION: Cynthia H. McCollough, Ph.D., and Jia Wang, Ph.D.

Opening Statement

Because of the relative radiation sensitivity of the female breast, it is desirable to reduce the breast dose from CT scanning of the thorax. Placing a bismuth shield on the anterior chest surface, over the breasts, has been promoted as a straightforward way to achieve this goal,[1] because "the shield attenuates x-ray photons before they reach the breast." Sounds like a good idea, right? Wrong. When both image quality and dose are considered (instead of only dose), it is clear that use of bismuth shielding is actually a bad idea. Medical physicists must consider the complete picture and, rather than promoting the use of bismuth shielding, should actually discourage its use. The three primary disadvantages of bismuth breast shields are as follows:

1. Breast shielding wastes radiation already delivered to the patient. The dose reduction from breast shields is due to the attenuation of x-rays coming from the anterior direction. When the tube rotates to the posterior and lateral positions, the shield absorbs photons exiting the patient—x-rays that would have otherwise reached the detector. This increases image noise without any commensurate reduction in radiation dose, which is clearly inconsistent with the ALARA principle. Simply by decreasing the tube

current, one can reduce not only anterior (breast) dose by the same amount but also reduce dose to the entire scan volume.[2] Even though the tube current is reduced, image noise is equivalent to when bismuth is used.[3]

2. Breast shielding degrades image quality and CT number accuracy. Bismuth shielding increases image noise across the entire image, not just directly under the shields.[3,4,5] It also causes streak and beam hardening artifacts, which can artifactually increase CT numbers, again not just below the shield, but throughout the entire image.[3,6] If the increase in image noise caused by bismuth shields is diagnostically acceptable (as claimed by proponents of the method), it is better to simply decrease the tube current to reduce breast dose. This avoids the artifacts and CT number errors caused by the shields. Furthermore, technologists do not have to spend time positioning the shields carefully and cleaning them between patients.

3. Using bismuth shielding in conjunction with automatic exposure control (AEC) systems leads to unpredictable and potentially undesirable dose and image quality performance. AEC is widely used to adapt tube output according to the specific patient's attenuation profile and diagnostic task. Placing a shield on the patient before the CT radiograph is acquired will lead to overestimation of patient attenuation and result in an increase in tube current, thereby defeating the purpose of using the shield.[7,8] If the shield is placed after the CT radiograph is acquired, the image quality prescribed by the user will not be obtained due to the unanticipated attenuation of the shield. Either way, the sophisticated "phototiming" algorithm is thwarted; the prescribed dose or the prescribed image quality is not delivered. Thus, we strongly advocate that medical physicists discourage the use of bismuth breast shields.

AGAINST THE PROPOSITION: Robert G. Gould, Sc.D.

Opening Statement

Many improvements have been made in CT scanners that lower radiation dose and many methods to reduce patient dose during scanning have been published.[9,10] Bismuth shields placed over the patient during CT imaging are shown to reduce the dose to the region immediately below the shields by 30% or more.[6,11,12,13,14] Both the thyroid and breasts are considered stochastically sensitive organs and have individual weighting factors for calculating effective dose. Indeed, the ICRP weighting factor assigned to the breast equals the highest of any organ (0.12).[15]

Bismuth shields used to protect the breast are commercially available at modest cost and can be placed in sterile plastic bags and reused. They are positioned on the patient after the scout image is acquired because many CT scanners use the scout image as the basis for the adjustment of tube current during scanning. If the bismuth is placed prior to scouting, the algorithm for current adjustment may compensate for the attenuation of the shields, reducing their effectiveness. On CT scanners that adjust the tube current based on a direct measure of the radiation intensity during scan acquisition, notably those made by Siemens, the use of shields is not recommended.

Care must be taken in placement of the shields since they produce streaks, which should not be allowed to project into the patient's anatomical image. This is accomplished by offsetting the shields from the patient's surface by several centimeters and positioning the shields so that their surface is tangential to the curvature of the torso. Placement is not difficult and a few minutes of technologist training is sufficient.

Bismuth shields affect the CT number of the tissue, most noticeably immediately below the shields. The CT-number increase in soft tissue can be quite significant close to the shield, more than 100 HU, but the effect decreases rapidly with distance from the shield.[6] If the shields are offset from the skin by 2 cm, the CT number increase is 40–50 HU near the skin, less centrally, and a few HU near the skin opposite the shield.[6] The offset does not significantly affect the dose reduction that is achieved.[6] When breast

shields are used on adult women, the effect is primarily seen outside the ribs. While inaccuracy of the CT numbers may be offensive to medical physicists, it does not seem to bother most radiologists nor has it been shown to have a deleterious clinical effect.[13] Shields should not be used whenever quantitative assessment of CT numbers is needed, such as when used to quantify the amount of coronary artery calcium. Bismuth shields also increase noise in the image, but again this effect is greatest near the shield and lessens quickly with distance.[6] This effect has not been shown to result in reduced diagnostic effectiveness.[13]

A significant drawback of bismuth shields is that, while they reduce the beam intensity entering the patient, they also reduce the intensity of the beam exiting the patient. Thus, information-carrying photons are attenuated between the patient and the detectors. However, dose is reduced regionally, and radiation sensitive organs can be spared significantly. Bismuth shields are not a substitute for using low dose techniques and methodologies that reduce patient dose in CT.

In summary, I would encourage the use of bismuth shielding as a methodology proven to reduce local dose that is easily implemented, inexpensive, and widely available. Bismuth shields are not perfect, they simply work.

Rebuttal: Cynthia H. McCollough, Ph.D. and Jia Wang, Ph.D.

In response to some of Dr. Gould's statements apparently in support of bismuth shields, we make the following comments:

1. When AEC is used on Siemens scanners, the use of shields is not recommended.

We agree and extend this warning to Philips systems, which also update the tube current during the scan, responding to the bismuth shield by increasing the current and, hence, countering its intended benefit. For systems without real-time tube-current adjustment (e.g., GE and Toshiba), the prescribed image quality is not achieved. Hence, shields should not be used with *any* AEC techniques. Turning off AEC, however, is not advised; z-axis AEC reduces dose to the breast and improves image quality, especially in the shoulders and hips.

2. Shields should not be used whenever quantitative assessment of CT numbers is needed.

In Ref. [6] cited by Dr. Gould, the CT number was increased by about 10 HU in the center of the phantom (lung and heart), even though the shield was offset by 6 cm. Also, image noise was increased across the entire thorax. Both effects represent degradation of image quality and quantitative accuracy.

3. A significant drawback of bismuth shields: wasting dose to the patient.

We completely agree. Use of bismuth shields should be replaced by globally reducing the tube current; the overall number of photons reaching the detector, and hence image noise, is the same between the two methods when the reduction in tube current is matched to the dose reduction achieved by bismuth shielding. In reducing tube current, however, dose is reduced to the entire volume, not just the anterior surface, CT numbers remain accurate, and potential streak artifacts are avoided.

In conclusion, we find no compelling reason to use bismuth shields and, as Dr. Gould assists us in pointing out, many reasons to avoid them.

Rebuttal: Robert G. Gould, Sc.D.

Noise is never constant within a clinical image just as dose is not uniform. Bismuth shields do increase noise within the scan volume but not uniformly, and it is difficult within the complexity of the anatomy to detect this increase. Since use of an AEC mechanism is desirable (and shields are not a substitute), adjustments to the milliamperes proposed as an alternative can be difficult to implement and, furthermore, will result in degradation of the images globally, not regionally. When more than the chest is imaged in a single acquisition (e.g., chest and abdomen), every image will be degraded by a lowering

of the AEC-determined milliamperes, not just those through the chest. As noted, bismuth shields should not be used on all scanners or in all applications.

If the shields have been positioned correctly, artifacts are usually not noticeable or are minimal inside the rib cage at typical window and level settings used for viewing CT chest images. To my knowledge, there is not a single report of a missed diagnosis due to bismuth shields! I encourage readers to look at some clinical images where shields have been used and judge their quality.

Positioning and care of bismuth shields is neither difficult nor time consuming. It does not interfere with or slow workflow. Training technologists in the use of shields is important but is neither difficult nor extensive. When used correctly, shields do not cause the "phototiming" algorithm to run amok.

Notwithstanding the drawbacks, bismuth shielding is an easily implemented, inexpensive and effective method to reduce breast dose.

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5.3. Radiation therapists should not have to wear personnel dosimetry badges

Scott Dube and R. Paul King
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OVERVIEW

Most radiation therapists work outside treatment rooms which are heavily shielded. Their personnel dosimetry badges typically indicate that they have received minimal radiation exposures, yet they are still required to wear these badges. Consequently, it has been suggested that radiation therapists should not be required to wear personnel dosimetry badges, and this is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Scott Dube, M.S. Mr. Dube received his M.S. degree in Radiological Sciences from the University of Colorado in 1979. Subsequently he worked for Rocky Mountain Medical Physics, Mid-Pacific Medical Physics, Northwest Medical Physics Center, and The Queen's Medical Center in Honolulu. In 2006, he became the solo physicist at Queen of the Valley Medical Center in Napa, CA. Mr. Dube is certified by the American Board of Radiology in Diagnostic Radiologic Physics, Medical Nuclear Physics, and Therapeutic Radiologic Physics. In the AAPM, he has served as a member of the Clinical Practice and Professional and Public Relations Committees.

Arguing against the Proposition is R. Paul King, M.S. Mr. King earned degrees in Medical Physics and Electrical Engineering from the University of Florida and is nearing completion of a degree in Health Administration at the University of Southern Mississippi. He has worked in diverse settings in Florida, California, and Texas, and is currently Chief Physicist and RSO at the Anderson Regional Medical Center, Meridian, Mississippi. He is certified in Therapeutic Radiologic Physics by the ABR and has served on the Biological Effects Committee of the AAPM.

FOR THE PROPOSITION: Scott Dube, M.S.

Opening Statement

I would like to first address the question whether radiation therapists are or are not currently *required* to wear personnel dosimetry badges. Unfortunately, the answer varies from state to state. So let me address the question in general by turning to the gold standard of radiation protection regulations, namely, the Suggested State Regulations for Control of Radiation as developed by the Conference of Radiation Control Program Directors (CRCPD).[1] The pertinent sections include the following:

(1) Section D.1502.a.1 states that badges are required for individuals likely to exceed 10% of the annual limit.

Response: It has been my experience that radiation therapists receive much less than 10% of the annual limit. Certainly they must wear badges if their exposure history indicates otherwise. But the majority of therapists work in heavily shielded control areas with minimal exposure levels. Therefore, badges are *not* required.

(2) Section D.1502.a.iv states that badges are required for individuals entering a high or very high radiation area.

Response: Radiation therapists do not enter a high or very high radiation area. They wait until the beam is terminated before entering the room. Therefore, badges are not required.

So we have established that badges are not required. Next, let us consider why others have recommended that radiation monitoring badges be provided to radiation therapists.

(1) The badge provides evidence of null exposure.

Response: A comprehensive area survey is always conducted for each new linear accelerator to determine exposure levels in the environs. Also, the best practice is to install area monitors for six months to document exposure levels at pertinent locations. These data provide all the documentation necessary to prove that there is a low exposure environment.

(2) The badge will provide exposure data in the unlikely event that a therapist is present in the linear accelerator room when the beam is energized.

Response: The exposure to the individual can be easily determined using the beam parameters documented in the Record/Verify system and the recollection of the incident by the exposed individual. Phantom measurements with appropriate instrumentation can provide an accurate estimation of the exposure.

(3) Badge data are better than historic area survey results or event specific dosimetry should the individual bring a lawsuit against the hospital for untoward effects.

Response: I doubt this is true but I admit that this could be a valid point.

Finally, let us consider the reasons why I advocate not providing badges to radiation therapists.

(1) There is a savings (admittedly small) in the cost to provide badges.

(2) There is a savings (again, admittedly small) in the effort to manage the badge program.

(3) Reason dictates that there is no benefit served by providing a badge. If anything, there is a detriment in that it sends the message that there is likely danger in working around a linear accelerator. This is simply not true, especially since physicists always employ the ALARA principle.

AGAINST THE PROPOSITION: R. Paul King, M.S.

Opening Statement

Seeking improved efficiency in the management of healthcare organizations, industry leaders sometimes turn to manufacturing practices such as the Toyota lean philosophy, with its emphasis on the elimination of practices that do not create value for the customer.[2,3] The question of whether radiotherapists should wear dosimetry badges is related to the development of a lean process. In managing a radiation protection program, we benefit three customers. The first is our society, which values demonstrable safety in the workplace. The second is our institution, which values its reputation in the marketplace. The third is our employees, who value protection from radiogenic illness and who look to us to provide that protection. By requiring that radiotherapists use personnel dosimetry badges, we serve each of these customers.

Because they think it to be important, policymakers require that we individually measure occupational doses received by those we either expect may receive a large dose or who work in areas where high dose rates occur.[4] Though it does not protect in the same way as a concrete shield, a radiation dosimetry badge is crucial to a radiation protection program and protects against radiation in the way that a speedometer protects against speeding tickets; enabling correction by indicating problems when they exist. Legalistic arguments might be made that we need not monitor radiation therapists because they are unlikely to occupy a high radiation area concurrent with the radiation. While this may arguably meet the letter of the requirement, society’s interest is better served when we meet both the requirement’s letter and its spirit.

This serves the institution's interest as well. Seeking ways around the requirement may draw unwelcome scrutiny. Any expense saved on dosimetry badges could be offset by the value lost in tarnishing the organization's reputation. Healthcare organizations spend great sums to build and protect their reputations.[5] Dosimetry monitors inexpensively demonstrate an organization's commitment to safety, both for its employees and the community. The value of a radiation protection program's reputation becomes apparent when there is an adverse event, misadministration, or violation. Regulators often approach an event quite differently in the context of an institution that "does the right thing" than one that "gets away with what it can."

The value of individual measurement to a therapist can be confusing because it differs from that of a radiographer. In contrast to diagnostic radiographers, for whom nontrivial doses are routine, radiotherapists normally receive inconsequential doses which, even if doubled, would remain inconsequential. A radiographer's dose can escalate slowly and, if it doubled, could become quite significant. For therapists, the greater concern is for an anomalous high-dose accident. Conditions that might produce an accidental overexposure might put the radiotherapist at risk of a second overexposure if the accident is not recognized and corrective actions are not taken. Preventing this second accident is the main goal of radiation monitoring. That such exposures are rare does not mean that measurement lacks value. Rather, it documents the ongoing adequacy of existing radiation control practices in radiotherapy.

Rebuttal: Scott Dube, M.S.

This debate actually began in November 2009 in the medphys listserver (medphys@lists.wayne.edu). There was such a lively exchange that my opponent and I were asked to participate in this Point/Counterpoint.

My motive for suggesting that therapists should not have to be provided badges had little to do with cost. I acknowledge that this would be unjustified. Rather, it is largely because I abhor giving into fear, such as fear of radiation, fear of repudiation, and fear of litigation.

Let me go back to the fundamental question as to whether badges should be required. To help me adequately address this question, I sent a copy of my Opening Statement to the CRCPD, as well as all 50 State Program Directors, and asked whether radiation therapists do, in fact, enter a high radiation area.

The CRCPD did not reply officially but I did hear from 11 directors. Some said therapists must wear badges without explaining why. Others said therapists may be required to enter the linear accelerator room while the beam is on during an emergency, and hence there is the potential for inadvertent exposure; therefore, badges *are* required. Only one said (unofficially) that badges should not be necessary since accelerators are controlled from outside the room and automatic shut-off systems are adequate.

It seems that the majority opinion is that the principle of providing badges only to those who are *likely* to exceed 10% of the annual limit does not apply to therapists. Rather, it is essential for therapists to be badged because of the *highly unlikely possibility* of an exposure that exceeds 10% of the annual limit if the therapist has to enter the treatment room during an emergency.

It is hard for me to argue against this so, in the end, I have to concede. Radiation safety policy generally errs on the side of safety for all the reasons my opponent has discussed. The linear-no-threshold model is a good example.[6] This is prudent given the pervasive fear of radiation held by so many. The recent articles in the New York Times only fuel that emotion. Certainly, the provision of a personnel monitor to a radiation therapist is a small but worthwhile act to alleviate that fear.

Rebuttal: R. Paul King, M.S.

My colleague is concerned that, by requiring radiotherapists to wear film badges, we send the message that a medical linear accelerator is dangerous to operate. I agree that, because ours is a leadership role, we must be cognizant of the messages that we send; both explicit messages and implicit. However, I contend that any message of danger that we communicate by issuing a dosimetry badge is both correct and helpful. Consider that the Clinac iX vendor's Safety Guide provides the following statements and instruction:[7]

(1) "The Clinac can produce a lethal radiation dose in a very short time."

(2) "Radiation exposure can cause serious illness or death, though not instantaneously."

(3) "When working on or near the machine, wear radiation monitoring devices approved by the cognizant (sic) regulatory agency."

This manufacturer sends the clear, and I contend, accurate message that the radiation produced by a linear accelerator introduces a measure of danger into its operation. In guiding the attitudes and directing the habits of radiation therapists, we should nurture their healthy respect for this danger.

Commonly encountered attitudes toward occupational radiation exposure span a continuum from "unreasoning anxiety," through "healthy respect," and into "disdainful contempt." If the goal of withholding dosimetry badges from radiotherapists is to temper an unreasoning anxiety into healthy respect, then the merits of this goal are clear. However, the greater risk is that this policy might corrode a healthy respect for the danger inherent to the delivery of therapeutic radiation into disdainful contempt. Returning to our automotive analogy, we need radiation therapists to exhibit some of the characteristics of long-haul truckers; to be attentive, calm, alert, and confident. If they are white-knuckled, sweating, and afraid of the road, they will be unsafe. But while we want them to be calm and confident, they must be neither so calm nor so confident as to fall asleep.

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5.4. The use of effective dose for medical procedures is inappropriate

Caridad Borrás and Walter Huda
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OVERVIEW

The quantity "effective dose" was originally introduced as a way to quantify the potential detrimental stochastic (cancer and hereditary) effectiveness of nonuniform radiation exposures of populations of workers and the general public for radiation protection purposes. It was not intended to be used to represent patient exposures, yet over the past decade, it has become commonplace to specify doses to patients and patient populations undergoing imaging procedures in terms of effective dose. It has been proposed that this is not appropriate, and this is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Caridad Borrás, D.Sc. Dr. Borrás earned her Doctor of Science degree in Physics from the University of Barcelona, Spain. She did her doctoral thesis at Thomas Jefferson University, Philadelphia, PA as a Fulbright scholar. Subsequently, she worked as a radiological physicist at the West Coast Cancer Foundation, San Francisco and then, for 15 years, directed the radiological health program at the Pan American Health Organization/World Health Organization in Washington DC. Currently, she is in Recife, Brazil, as Visiting Professor in the Federal University of Pernambuco. Dr. Borrás is certified by the American Board of Radiology in Radiological Physics and by the American Board of Medical Physics in Medical Health Physics. She is a Fellow of the AAPM and the American College of Radiology, and has received the Gold Medal of the Spanish Medical Physics Society

Arguing against the Proposition is Walter Huda, Ph.D. Dr. Huda earned his Ph.D. in Medical Physics at the Royal Postgraduate Medical School (Hammersmith Hospital) at the University of London. From 1976 to 1981, he worked as a physicist at Amersham International, a commercial company specializing in radioactive products. He has worked as a diagnostic medical physicist at the Manitoba Cancer Treatment and Research Foundation in Winnipeg, Canada (1982–1990), University of Florida in Gainesville, FL (1990–1997), and at SUNY Upstate Medical University in Syracuse, NY (1997–2007). He is currently Professor of Radiology at the Medical University of South Carolina in Charleston, where his research interests are in medical imaging and radiation dosimetry. He is board certified by the Canadian College of Physicists in Medicine and by the American Board of Medical Physics.

FOR THE PROPOSITION: Caridad Borrás, D.Sc.

Opening statement

In 1991, the International Commission on Radiological Protection (ICRP) published ICRP 60[1] to replace the Recommendations published in 1977 as ICRP 26. Among the changes, "equivalent effective dose" was called "effective dose," a term retained in the latest ICRP Recommendations, published in 2007 as ICRP 103.[2] Effective dose is a risk-related radiation protection quantity designed to take into account the radiobiological effectiveness of different types of radiation at low doses and dose rates and the contribution of these risks in individual organs and tissues to overall detriment from stochastic effects such as cancer and hereditary effects. Over the years, as the knowledge on radiation effects on humans improved, the number of organs/tissues considered and the numerical values of the tissue-weighting factors (w_T) used in calculating effective dose changed. However, the concept and its intended use did not change. Effective dose is to be used in planned exposure situations to show regulatory compliance

with dose limits and constraints for workers and the public. It is applied to a reference person and it was never intended to provide a measure of risk to individuals.

ICRP 105[3] clarified this by stating that effective dose is not appropriate for medical exposures because "*The age distributions for workers and the general population (for which the effective dose is derived) can be quite different from that of the overall age distribution for the population undergoing medical procedures using ionizing radiation, and will also differ from one medical procedure to another depending on the age-and-sex-prevalence of the individuals for the medical condition being evaluated.*"

In spite of these caveats and published uncertainties of more than 40% for a reference patient population,[4] the scientific literature, including AAPM reports, abounds in the use of effective dose for patients, regardless of patient age and whether deterministic effects may be present, such as after radiotherapy. Brenner[5] reported that "*less than 1/3 of the 2008 PubMed citations on radiation 'effective dose' refer to radiation protection, the rest are for clinical patient dosimetry*." Furthermore, many authors do not specify the set of w_T values used, thus making intercomparisons across publications often meaningless.

In recent years, the use (or misuse) of effective dose has been debated, and an alternative quantity called "effective risk" has been proposed.[5] While disagreeing on which set of risk factors better express health detriment, all the authors debating this issue agreed that effective dose should not be used for medical exposures![5,6]

What is wrong with just determining organ doses for which measurement methodologies[7] and risk estimates[8] are readily available?

AGAINST THE PROPOSITION: Walter Huda, Ph.D.

Opening statement

Deterministic effects in medical imaging are rare, with serious skin burns currently estimated to occur in only ~ 0.01% of all interventional radiological procedures.[9] Accordingly, radiation risks to patients exposed to ionizing radiation in medical imaging examinations primarily relate to the stochastic processes of carcinogenesis and the induction of genetic effects.[2] The effective dose quantifies the (approximate) amount of radiation that a patient receives in a radiological examination and is directly related to the stochastic risk.[10,11] Effective doses can be obtained for any type of radiological examination including radiography, fluoroscopy, CT, and nuclear medicine.[12,13] Effective doses are employed by the medical imaging community to understand the amount of radiation used in radiological examinations and appreciate the significance of this radiation exposure, as well as for optimizing protocols so that patient radiation risks are minimized.

In radiological imaging, it is essential that practitioners understand how much radiation a patient may receive from any given procedure. A chest CT examination (effective dose 5 mSv) makes use of about 100 times more radiation than a chest x ray (effective dose 0.05 mSv). A ventilation perfusion scan performed to investigate a possible pulmonary embolism (effective dose 2.5 mSv) uses about half the radiation of a chest CT examination. No other radiation dose parameter (e.g., organ doses and energy imparted) comes close to conveying the information that is encapsulated by the effective dose.

The effective dose is also used to quantify natural background radiation exposures and for regulatory purposes. In the United States,[14] effective doses from any radiological examination can be compared to those from ubiquitous natural background radiation (~ 1 mSv/yr), average radon exposures (~ 2 mSv/yr), as well as regulatory dose limits for occupational exposure (50 mSv/yr) and members of the public (1 mSv/yr). Comparing natural background and regulatory effective doses with effective doses from diagnostic tests helps put medical exposures into an appropriate perspective.

It is possible to attempt to convert effective doses into (approximate) radiation risks. A uniform whole body dose of 100 mGy, which corresponds to an effective dose of 100 mSv, has a cancer risk of ~ 0.7% in 30 yr old males and ~ 1% in 30 yr old females.[15] Risks in young children would be higher, and in older individuals would be lower. Such radiation risk estimates in diagnostic radiology may be compared to other hazards in medical imaging (e.g., use of iodinated contrast agents), medicine (e.g., surgery), or everyday life (e.g., of dying in automobile accidents).

Optimization of diagnostic imaging involves finding x-ray techniques that offer the lowest patient dose when image quality is kept constant. Plotting effective dose as a function of x-ray tube voltage (kV) at constant image quality in CT permits identification of the kV value that minimizes patient risks. Importantly, CT optimization using alternative dose metrics (e.g., $CTDI_{air}$ or $CTDI_{w}$) has been shown to be inappropriate.[16]

My experience in medical imaging convinces me that the effective dose is (by far) the most appropriate way to quantify the "amount" of radiation patients receive in any radiological examination, as well as explain the "significance" of such exposures.[17] I also believe that there are no alternative metrics that could meet the current needs of the medical imaging community, as outlined in this Opening Statement, with the simplicity and succinctness of the effective dose.

Rebuttal: Caridad Borrás, D.Sc.

I agree with Dr. Huda that "*in radiological imaging, it is essential that practitioners understand how much radiation a patient may receive from any given procedure*." Indeed, effective dose has been used to quantify stochastic risk in many radiological procedures, as Dr. Huda so aptly documented. But to use publications from the NAS/BEIR,[8] the ICRP,[2] and the NCRP[14] to support his claim that "*there are no alternative metrics that could meet the current needs of the medical imaging community*," is misleading. The BEIR VII Report[8] calculates cancer risks from *organ*, not *effective*, doses. The ICRP Report 105[3] recognizes the role effective dose may have, but advises caution regarding the referred population: "*Effective dose can be of value for comparing doses from different diagnostic procedures and for comparing the use of similar technologies and procedures in different hospitals and countries as well as the use of different technologies for the same medical examination provided the reference patient or patient populations are similar with regard to age and sex*." Many calculations are done not only disregarding the latter consideration but also, if comparisons are performed using different w_T values, significant differences may result. To illustrate this point, NCRP 160[14] calculated the effective dose resulting from a mammogram consisting of two views of each breast and a mean glandular dose to the total breast tissue of 1.8 mGy per view. Using a w_T for breast of 0.05 (ICRP 60),[1] the effective dose was 0.18 mSv; using a w_T of 0.12 (ICRP 103),[3] it was 0.42 mSv!

I fully agree with the ICRP that "*for planning the exposure of patients and risk-benefit assessments, the equivalent dose or the absorbed dose to irradiated tissues is the relevant quantity*."[3] This approach permits both deterministic and stochastic risks to be quantified. Dose thresholds for deterministic effects are known (mainly) from radiotherapy experience,[3] and BEIR VII has calculated stochastic risks for many organs/tissues exposed to low doses of low LET radiations.[8] Also, there is no reason why equivalent doses from internal and external exposure cannot be added for a given organ.[18]

Finally, if the purpose is to reduce patient dose, effective dose is not needed. Diagnostic reference levels are always expressed in machine parameters, such as incident air-kerma for radiography/fluoroscopy and CT air-kerma index and air-kerma length-product for CT.[7]

Rebuttal: Walter Huda, Ph.D.

Consider a retrospectively gated coronary computed tomography angiogram (CTA) examination performed on the author of this Rebuttal, who is a 59 yr old male weighing 88 kg. This examination on a representative 64 slice CT scanner would likely use a $CTDI_{vol}$ of 60 mGy and be 17 cm long. Doses in

88 kg patients are ~ 13% lower than doses in the 70 kg phantom[19] used by the ImPACT CT Patient Dosimetry Calculator.[20] Accordingly, my organ doses from this examination would be 59 mGy to the lung, 13 mGy to the red bone marrow, and 16 mGy to the stomach, with dose values for 21 additional organs. I do not believe that such a list of a total of 24 "organ doses" is either required or helpful to medical imaging practitioners.

Combining these 24 discrete organ doses in Walter Huda's coronary CTA according to the ICRP 103 rules shows the effective dose to be 23 mSv, which is very informative. This cardiac CTA, for example, results in an exposure that is three times higher than for a cine cardiac catheterization.[13] One can easily convert this effective dose of 23 mSv into a cancer induction risk, which is independent of organ tissue weighting factors.[20] My hypothetical cardiac CTA would have a cancer incidence risk estimate of 0.087%,[20] with quantifiable contributions from the lungs (60%), red bone marrow (12%), stomach (4%), and liver (4%).

In summary, effective doses are not risks *per se*, but a practical way of dealing with nonuniform doses in medical imaging. When necessary, effective doses for any type of radiological examination can easily be converted into radiation risk taking into account patient demographics. I therefore have little doubt that the effective dose will (rightly) continue to be one of the most important patient dose metrics in medical imaging.

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5.5. Backscatter x-ray machines at airports are safe

Elif Hindié and David J. Brenner
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OVERVIEW

Both backscatter x ray and millimeter-wave-based whole-body scanners are used at security check points at airports. Because the former involves ionizing radiation, it has been suggested that their use should be discontinued because of the potential biological hazards of x ray exposures. Others argue, however, that these hazards are negligible at the low exposure levels used, and that backscatter x ray body scanners are safe. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Elif Hindié, M.D., Ph.D. Dr. Hindié received his Board in Nuclear Medicine from Paris XII University in 1987. During his Ph.D., he worked on the development of new techniques for localization of molecules at the subcellular level such as imaging with secondary ion mass spectrometry. He is currently Professor in Biophysics and Nuclear Medicine at Bordeaux University Hospital, University of Bordeaux, France. His research interests include cellular dosimetry, parathyroid imaging, thyroid cancer treatment, and the use of 18FDG-PET/CT in oncology.

Arguing against 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, the cellular, the tissue, and the organism levels. He divides his research time roughly equally between the effects of high doses of ionizing radiation (relating to radiation therapy), and the effects of low doses of radiation (relating to radiological, environmental, and occupational exposures).

FOR THE PROPOSITION: Elif Hindié, M.D., Ph.D.

Opening Statement

Wide consensus exists that the effective dose of radiation delivered by airport backscatter x ray scanners is exceedingly low. Direct measurements from several independent sources, including the U.S. Food and Drug Administration,[1] Johns Hopkins University,[2] and the U.S. Army,[3] showed that a single scan is associated with a range of roughly 0.015–0.1 μSv. To put this in context, this dose is similar to that absorbed during 1–2 min of flight.

Some have argued that the dose to the skin may be “dangerously high,” even if effective doses are low. Skin (and lens) doses are, however, only two to four times higher than effective doses[3] and a traveler would have to be screened several hundred thousand times per year before reaching the dose limits.

Radiation-induced cancers have only been demonstrated for doses exceeding 100 000 μSv. No epidemiological study will, therefore, ever be able to prove a carcinogenic effect for the range of doses delivered by backscatter scanners. Nevertheless, very precise estimates of the number of cancers induced by backscatter scanners are sometimes publicly given, leading to a false impression of mathematical certainty. The crucial information often not presented to the public is that these cancers are purely hypothetical, and would never even have been hypothesized without the linear no-threshold (LNT) model. The LNT model postulates that every dose of radiation, no

matter how small, increases the probability of getting cancer. This highly speculative hypothesis was introduced on the basis of flimsy scientific evidence more than 50 years ago, at a time when cellular biology was a largely unexplored field. Over the past decades, an ever-increasing number of scientific studies have consistently shown that the LNT model is incompatible with radiobiological and experimental data, especially for very low doses.[4,5,6]

The LNT model was mainly intended as a tool to facilitate radioprotection regulations and, despite its biological implausibility, this may remain its *raison d'être*. However, the LNT model is now used in a misguided way. Investigators multiply infinitesimal doses by huge numbers of individuals in order to obtain the total number of hypothetical cancers induced in a population. This practice is explicitly condemned as "incorrect" and "not reasonable" by the International Commission on Radiological Protection,[7] among others.

Airport backscatter x ray scanners are safe. One reason to discontinue their use would be if they were ineffective against competing techniques. They should not be dismissed solely on the basis of an old speculative hypothesis that has been both severely questioned by modern scientific findings and used erroneously.

AGAINST THE PROPOSITION: David J. Brenner, Ph.D.

Opening Statement

What do we mean by safe? The most direct interpretation of "safe" refers to an exposed individual. One may ask what the best estimate of the lifetime cancer risk is to an individual receiving one or more x ray backscatter scans. Using the standard "5%/Sv" cancer mortality risk formula, this would result in an estimated lifetime cancer mortality risk estimate of about 10^{-7} for two 1-μSv screening scans.[8] "Safe" by almost any standard!

Of course this individual risk estimate is exceedingly uncertain. Some have argued that the risk at very low doses is zero. Others have argued that phenomena such as tissue/organ microenvironment effects, bystander effects, and "sneaking-through" immune surveillance, imply that low-dose radiation risks could be higher than anticipated. The bottom line is that individual risk estimates at very low doses are extremely uncertain.

But when extremely large populations are involved, with up to 10^9 scans per year in this case,[9] risk should also be viewed from the perspective of the entire exposed population. Population risk quantifies the number of adverse events expected in the exposed population as a result of a proposed practice,[10] and so depends on both the individual risk and on the number of people exposed. Population risk is described by ICRP as "one input to … a broad judgment of what is reasonable,"[11] and by NCRP as "one of the means for assessing the acceptability of a facility or practice."[12] Population risk is considered in many other policy areas where large populations are exposed to very small risks, such as nuclear waste disposal or vaccination.[13]

It has been claimed that moving from individual risk to population risk is "bad science." In fact there is *no* science at all here. An individual cancer risk of 1 in X is just another way of saying that if X people are exposed to that risk, the expected number of induced cancers is 1; and if (say) 100 times X people are exposed to that risk, it is essentially certain that there will be some induced cancers. One can argue what the individual risk actually is, but one cannot argue about the average population consequences of a given individual risk–-it is simply what we mean when we talk of individual risk.

So x ray backscatter scanners are associated with very small but very uncertain individual risks. This uncertainty is irrelevant for an individual–-whether the individual risk is 0, or 10^{-8} or 10^{-6}, these are all small enough risks for any individual not to be concerned. But if 10^9 scans per year

are performed,[9] the uncertainties in individual risk mean that we have little idea whether the population consequences of this activity will be 0 or 10 or 1000 cancers per year.

If there were no practical alternatives, it could be argued that any such population risks would be more than balanced by the benefits of reducing the risk of a terrorist event. Millimeter-wave-based whole-body scanners,[14] however, currently function equally well in airports, do not involve ionizing radiation, and are associated with essentially no mechanistic or experimental evidence of biological risks.[9,15]

X ray backscatter scanners are probably "safe" from an individual perspective, but their population safety, if they are to be used up to a billion times annually, is unknown. Given available practical alternatives, it would be prudent to curtail their use.

Rebuttal: Elif Hindié, M.D., Ph.D.

I am pleased that Dr. Brenner agrees that backscatter scanners are safe on an individual basis. However, he then goes on to compute the effect of trivial doses delivered to huge populations to obtain a population risk, an approach I strongly dispute. In support of my position, such calculations have been unequivocally condemned by the major scientific associations as "incorrect,"[7] illegitimate,"[16] "without any scientific validity,"[17] known to produce a "distorted image of risk, completely out of perspective with risks accepted every day,"[12] and "should not be used for the purpose of estimating population health risks,"[18] and "predictions of hypothetical cancer incidence and deaths in patient populations exposed to such low doses are highly speculative and should be discouraged.[19] Generally, the misuse of the LNT model may create in the public unfounded fears of small radiation doses, which often lead to nonsensical individual choices, such as avoiding necessary medical examinations.

The carcinogenic effects of very low doses of radiation are obviously uncertain. They are not even amenable to scientific assessment. The LNT model postulates that risk increases linearly with dose. However, defense mechanisms are qualitatively dose-dependent and are highly effective in the range of natural background dose levels,[4] which is not surprising from an evolutionary perspective. Notably, no cancer excess has been observed in areas with naturally high radiation levels, where individuals absorb the equivalent of a screening dose every minute or less.

The screening dose of 1 μSv (or, more precisely, 0.88 μSv) cited by Dr. Brenner was indirectly obtained in one study by extrapolation from image characteristics.[8] However, several other studies that used direct measurements consistently showed the dose to be about 0.05 μSv or less.[1,2,3]

I wish to make it clear that I am *not* endorsing the use of backscatter scanners; I do not know how truly useful they are in the context of airport safety, or whether better alternatives exist, though at least some reports suggest that millimeter-wave scanners are less reliable.[20] My point is made from a purely medical perspective. A machine that delivers a dose equivalent to 1–2 min of flight is not a public health hazard. Contrarily, anxiety and fear engendered by irrational health scares can certainly take a toll on public mental health.

Rebuttal: David J. Brenner, Ph.D.

In the absence of direct data on radiation carcinogenesis at very low doses, it is hard to see how Dr. Hindié can be so certain that there are zero population risks associated with performing a billion x ray backscatter scans.

Lacking epidemiological data, Dr. Hindié cherry-picks some references to suggest "ever-increasing" numbers of laboratory studies questioning the LNT extrapolation of risks to very low

doses. But one can equally well cite laboratory studies suggesting that LNT may underestimate risks at very low doses.[21,22,23] In truth, we do not have credible laboratory models of radiation-induced cancer, and it follows that we do not have any hard evidence, one way or the other, as to the status of LNT at very low radiation doses.

Surprisingly, Dr. Hindié implies that, even if there is indeed a very small individual risk from x ray backscatter scans, the overall population risk is still zero. This suggests a misrepresentation of what individual risk actually means. An individual cancer risk of, say, one in a million, is just another way of saying that if one million people are exposed, we expect about one cancer to be induced. Here there is nothing to debate.

So we return to the question: In the complete absence of relevant data, how can one be so certain what the long-term population risks actually are? In the presence of such uncertainty, and given the availability of equally efficient whole-body screening tools which do not use x rays (millimeter-wave scanners), is it wise to base policy solely on wishful thinking?

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CHAPTER 6

Education

6.1. A professional doctoral degree that does not require dissertation research is an appropriate alternative to a Ph.D. as preparation for a career in medical physics

John D. Hazle and Dennis Mah
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OVERVIEW

A hot topic among medical physicists in the United States these days, especially for those involved in the education and training of medical physicists, is the proposed new Doctorate in Medical Physics (DMP) degree. Unlike the traditional Ph.D., with its considerable research component, this new doctorate degree would replace most of, if not all, the research requirement with a 2-year period of clinical training (although guidelines on the requirements for this degree have not yet been established and, presumably, this is one of the tasks of the new Professional Doctorate in Medical Physics Working Group that has been formed by the AAPM Education and Training Committee). The premise that this new doctorate degree is an appropriate alternative to a Ph.D. is the proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is John D. Hazle, Ph.D. Dr. Hazle is Professor and founding Chairman of the Department of Imaging Physics at The University of Texas M. D. Anderson Cancer Center. He obtained his B.S. degree in physics and M.S. in medical physics from the University of Kentucky and his Ph.D. in biophysics from The University of Texas Graduate School of Biomedical Sciences in Houston. His primary research interests are the development of magnetic resonance imaging techniques to monitor minimally invasive therapies. He is the Principal Investigator of an NCI program to develop new imaging technologies for research using small animals. Dr. Hazle also directs the NCI funded Small Animal Imaging Facility at M. D. Anderson. Dr. Hazle has over 75 publications and has held leadership positions in several national medical physics organizations. He is currently President of CAMPEP.

Arguing against the Proposition is Dennis Mah, Ph.D. Dr. Mah began his career at the University of Toronto, at both Princess Margaret Hospital and Sunnybrook Health Sciences Center. Upon graduating in 1997, he took a clinical fellowship at Memorial Sloan Kettering Cancer Center in New York. He was certified by the ABR in Therapeutic Radiologic Physics in 2000. Dr. Mah has authored numerous papers on organ motion and image guidance and is currently interested in applications to adaptive therapy and stereotactic body radiosurgery. He served on the faculty of Fox Chase Cancer Center and Columbia University before moving to his current position at Montefiore Medical Center & Albert Einstein College of Medicine in the Bronx, NY, where he is the Director of Clinical Physics and Associate Professor.

FOR THE PROPOSITION: John D. Hazle, Ph.D.

Opening Statement

According to the 2006 AAPM Salary Survey, 88% of master's level and 66% of doctoral level medical physicists identified their primary appointment as clinical. Overall, 77% of medical physicists considered their primary job function as clinical. The increasing demand is perceived to be for clinical physicists in radiation therapy. However, we still train most medical physicists in research-oriented programs.

Currently, the minimum requirements to take the ABR examinations in radiological physics are a master's degree and 3 years experience. In 2014, 2 years of this experience must be from a CAMPEP accredited residency. The AAPM ABR trustees are considering a proposal to allow graduates of 2-year CAMPEP accredited residencies to sit for the Boards, effectively reducing the experience requirement by 1 year. There are currently about 100 residency slots in U.S. programs producing about 50 graduates per year. Manpower projections suggest that approximately 250 residency graduates per year will be required by 2014. Achieving a fivefold increase in the number of residency slots in the next 6 years will be difficult. The main impediment to growth of residency output appears to be faculty mentoring time.

This 4-year minimum training process is similar to the training of dentists and veterinarians, and not so different from our physician colleagues. However, a significant difference is the lack of "doctoral level" degree status with the resulting benefits and stature. At M. D. Anderson, the clinical productivity expectations for clinical staff (M.S.) and nontenure track clinical faculty (Ph.D.) do not differ significantly. However, those with Ph.D.s are considered faculty and their salaries are benchmarked against a higher salary scale, and they receive superior benefits.

Further, in this time of dwindling federal funding for research several issues must be considered. First, how many research trainees can be supported by grant funds? Would a more focused investment of our limited research resources be better spent on a smaller number of truly research oriented graduate students who intend to pursue careers in medical physics related research? Even more importantly, how many of these "research trained" scientists can future research funding projections support as research faculty?

By differentiating the professional (clinical) and academic (research) pathways, we can develop a more sustainable and appropriate model for training. While I acknowledge that our professional practice is rooted in science, I believe that what defines the profession of medical physics is the postgraduate training specific to the application of physics in medicine.

Therefore, a new professional training pathway has been proposed: Doctorate of Medical Physics, or DMP. While the Ph.D. plus residency pathway would remain for those seeking academically oriented careers in clinical medical physics, the DMP could become the primary professional training route for clinical medical physicists. While the details of this new pathway have yet to be determined, general discussions have included 2 years of didactic training followed by 2 years of clinical training, resulting in a 4-year program.

A significant difference would be the implementation of a professional school training model where the trainees pay for most of their education, with a much higher stipend than that traditionally paid by graduate students. This would be necessary to support the faculty resources required for the additional clinical training slots needed to meet manpower needs. For example, five new students per year into a 4-year program paying $20,000 in tuition would result in program income of $400,000 per year. This revenue would allow programs to hire additional faculty and to develop the infrastructure necessary for clinical training. It should be noted that this tuition is still below that for other professional degrees, while our graduates would have some of the highest initial earning potential. Finally, upon completion of a 4-year DMP program the trainee would have incurred about $80,000 in tuition debt while the Ph.D. students would have earned about $125,000 during their 5-year Ph.D. program and another $80,000–90,000 during their residency. However, looking at the 7-year postbaccalaureate situation, the DMPs

would have earned approximately $300,000 in their first 3 years of professional practice, pretty much leveling the playing field financially between the two pathways at that time.

So, will the DMP degrade the Ph.D. degree? I do not think so. The stature of academically oriented medical physicists is based on their achievements and innovation, not their training. Will the DMP improve the position of our primarily clinical masters level colleagues? I hope so. In my opinion, they deserve the same compensation and recognition for their clinical effort as their Ph.D. counterparts.

AGAINST THE PROPOSITION: Dennis Mah, Ph.D.

Opening Statement

A new doctorate of medical physics (DMP) degree has been suggested so that we can have professional schools with 2-year didactic programs followed by a 2-year clinical program, thus mimicking our physician colleagues. After the DMP, the graduate would be eligible to sit for the ABR board exams (although this is yet to be finally approved by the ABR).

This program is neither viable nor necessary and could fundamentally harm developments in medical physics. In terms of viability, let us consider how it competes with masters degrees. From 2014 onwards, the ABR will require that any medical physicist must have completed a CAMPEP-accredited residency in order to be eligible to sit for the Board exam.[1] Prospective students can elect either to pursue an M.S. degree followed by a CAMPEP residency, or they can elect to obtain a DMP degree from a CAMPEP-accredited program. If they select an M.S., the tuition rates would be anything from a waiver (i.e., zero) to ~$10 K/year.[2] They then complete a residency, which pays a median salary of ~$47 K/year for 2 years.[3] After residency, they will have grossed ~$74 K. In comparison, DMP tuition will likely be more than that for an M.S. since it is a professional degree. However, for the sake of argument, let us assume that it is equal to that for an M.S., i.e., $10 K/year. The DMP candidate will come out with roughly the same experience as an M.S. candidate, but ~$40 K in the hole. If the DMP is to be a "professional" degree like an M.D., then the tuition will likely be tripled to ~$30 K/year (Ref. 4)—as cash starved universities are likely to do. The difference in "cost" between a DMP and an M.S. with 2-year residency is thus somewhere between ~$114 K and $194 K. In a market driven economy, the only way the proposed DMP degree might be successful would be if M.S. physicist positions were to be eliminated. If the only difference between an M.S.+2-year residency and a DMP is to be called "doctor," to save a minimum $114 K, please call me "mister."

If the DMP were to become the standard for a clinical medical physicist, ultimately there would be fewer people interested in pursuing medical physics Ph.D.s and, as a result, progress and innovation could be reduced.

"If it ain't broke, don't fix it." The medical physics profession is healthy and growing. Over the last 6 years, medical physicists have enjoyed an average 9% annual rate of salary increase in the United States[5] compared to an average 2.7% increase in inflation.[6] Creating the DMP will inevitably lead to higher tuition and increased regulation, without any benefit to the patient or the profession. Improvements in the quality of medical physicists should be addressed through other means (e.g., credentialing, certification), not by creating a new degree so that more of us can be called "doctor."

Rebuttal: John D. Hazle, Ph.D.

In general, I think responses to most of Dr. Mah's opening statement are already included in my opening statement. In the end his rationale to "don't fix it if it ain't broke" is only valid in times when external forces are negligible. However, in the words of that great poet Bob Dylan, "the times they are a-changing." While the need for a professional doctoral degree was debatable before the ABR announced its 2012 and 2014 initiatives, I believe that the only way we can meet the need for formal clinical training in medical physics is to change the paradigm for our clinically focused professionals. We need financially viable and sustainable programs to generate somewhere between 200 and 250 new practicing

clinical medical physicists per year. The current model for "research oriented" training will not meet this need.

Rebuttal: Dennis Mah, Ph.D.

Dr. Hazle proposes that the DMP will increase funding for training programs and equalize compensation between M.S. and Ph.D. physicists. While the number of training programs is currently insufficient, the demand is for clinical physicists, not necessarily Ph.D.s. Dr. Hazle's comparison between the proposed DMP and Ph.D. ignores the M.S. physicists who do not necessarily require research funding support at any time in their training. To meet the shortages, we should be training more M.S. physicists with CAMPEP-approved residencies and educating the gatekeepers (administrators) about the projected labor shortage to increase the number of training slots. Money can be found from tuition as Dr. Hazle suggests, as well as other channels such as private grants, industrial and government sources.

Dr. Hazle also states that a DMP would reduce the disparity in compensation between M.S. and Ph.D. physicists citing M. D. Anderson as an example. However, M. D. Anderson may not be representative of the industry since academic institutions value Ph.D.s. The result is both higher pay and differences in hiring patterns. The majority of Ph.D. physicists work in academic centers and most M.S. physicists work in private practice.[3] The 2006 AAPM survey indicates that board certified M.S. physicists, on average, make 7% less than board certified Ph.D. physicists.[3] However, this signal may be lost in the noise. The range from the median to the 20th and 80th percentiles is much larger than 7%, so there are likely M.S. physicists with equal experience to Ph.D. physicists, who are making more money. In other words, "you're not paid what you're worth, but what you negotiate."

There is no reason to establish the DMP and, personally, I feel that, if it is tried, it will fail. Developments in research, accreditation and training will improve the stature of medical physicists, not new degree programs.

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6.2. All graduate medical physics programs should have an original research component

David W. O. Rogers and Janelle A. Molloy
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OVERVIEW

With the rapid rise in the number of medical physics residency programs, most of which provide no opportunity to do research but, instead, deliver intensive clinical training, there is a fear that most M.S.-level physicists entering the field will have done so without any exposure to research. This, along with the threat of emerging Doctorate in Medical Physics programs that have little or no research requirements, has led some to question whether it is appropriate for medical physics graduate programs to allow students to graduate with no research experience. This is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is David W. O. Rogers, Ph.D. Dr. Rogers received his Ph.D. in experimental nuclear physics from the University of Toronto in 1972. After a postdoctoral fellowship in Oxford, he joined the National Research Council (NRC) in Ottawa in 1973 in what is now the Ionizing Radiation Standards Group. At the NRC, Dr. Rogers headed the radiation dosimetry program until he took up a Canada Research Chair in Medical Physics in the Physics Department at Carleton University in 2003. Dr. Rogers has served on numerous committees and Task Groups in the AAPM, including the Board of Directors, and is currently a Deputy Editor of *Medical Physics*. As program Director of the Medical Physics program at Carleton University, he has supervised 15 graduate students and 17 research associates. He received the William D. Coolidge Award in 2010 for his contributions to medical physics.

Arguing against the Proposition is Janelle A. Molloy, Ph.D. Dr. Molloy obtained her Ph.D. from the University of Virginia in 1990 and subsequently worked in the Department of Radiation Oncology, University of Virginia, Charlottesville, where she attained the level of Associate Professor. In 2008, she moved to the Department of Radiation Medicine, University of Kentucky, Lexington, where she is Director of Medical Physics and of the Medical Physics Graduate Program. Dr. Molloy has served on numerous committees and Task Groups of the AAPM, including the Board of Directors, and is the current Treasurer. She has served on CAMPEP since 2002, where she is a member of the Residency Education Program Committee.

FOR THE PROPOSITION: David W. O. Rogers, Ph.D.

Opening statement

This debate is really about whether or not all medical physicists should be expected to do research, a question that is not new.[1,2] The answer is that they must do research or our profession will die out and our nonresearch oriented clinical roles will be filled by technicians who are paid much less. If I can convince you of this argument, then it becomes obvious that all graduate medical physics programs must have an original research component—how else are upcoming medical physicists going to learn how to tackle a research problem? Research is a skill and an attitude, which is only learned by doing.

Medical physicists have created almost all of the major advances in radiation oncology and in imaging for medical diagnosis and intervention. This historical fact means that medical physicists have been recognized as an essential part of radiotherapy and imaging teams. As the equipment becomes more and more complex, it is tempting to think that only highly skilled and very highly paid medical physicists can keep the equipment running smoothly. This is self-delusion. I recently reviewed a university BSc

program for radiation technologists and these students were very well educated, learning lots of Physics, Mathematics, and Statistics as well as getting all sorts of hands-on experience with clinical equipment (e.g., their laboratory had a dozen Pinnacle treatment planning systems and they spend many months in clinical placements—sounds like some Medical Physics MSc programs). This is the future. As the equipment gets more and more complex, it will become more and more automated, as well as more and more amenable to highly skilled technicians handling it well.

So, what is the role of a clinical medical physicist going to be if it does not include doing research? Certainly, many highly paid medical physicists do no research today—but the high pay came about because of the historical role of medical physicists as researchers and will not continue without on-going research.

The research I am talking about for clinical physicists will not necessarily change the world—not everyone can develop a new treatment technique or a new class of imager. However, useful research can be as incremental, but nonetheless complex, as investigating how well some new technology works (not just running the standard acceptance tests), finding new and different ways to use the technology, or demonstrating the effectiveness of a new way to do routine tasks. Perhaps this research will not lead to publications, but it should lead to interesting presentations at conferences. This is real research, and the only way to learn how to tackle a research problem is to struggle with a significant problem as part of one's graduate training.

Mark my words, if we do not regain the attitude that medical physicists are also researchers, our role in clinical practice will slowly erode, and no amount of job protection via licensure and other quasi-union means will protect our high paying jobs since they will be taken over by the upcoming generation of highly trained and competent technologists who are significantly less costly to the health care system.

If we must do research in our clinical practice, and if we have not learned how to do it by having a substantive original research component in our graduate programs, when are we going to learn it?

AGAINST THE PROPOSITION: Janelle A. Molloy, Ph.D.

Opening statement

Medical physics graduate programs must be allowed to focus their training in a way that is consistent with their strengths and resources. I am therefore opposing the proposition so that programs that focus on clinical training can educate their students in an effective and efficient manner.

Research training does not possess a monopoly in terms of teaching critical thinking or instilling intellectual courage. Appropriate clinical education will teach these higher cognitive capacities but, in addition, it will yield specific technical skills and directly relevant experience. For example, it is not infrequent for quality assurance tests to return results that fail the acceptance criteria. Resolution of such situations requires understanding of the characteristic behavior of subsystems, critical thinking, context-appropriate judgment, and prioritization. Within this context, all of the skills traditionally credited to research training are taught but, in addition, students acquire valuable experience in many others aspects of clinical medical physics that will be directly applicable in their careers.

We must not disparage the teaching of specific and useful technical skills in favor of vague "critical thinking." A clinical physicist must possess very specific technical skills in order to function effectively. Those who lack this knowledge will have limited value in a clinical setting. We should consider the acquisition of specific technical skills as a necessary but not sufficient condition of medical physics education.

The medical physicist is the person tasked with safely applying technologies that have been commercially developed. This is not science. For example, commissioning a new treatment planning system is, by necessity, an exercise in "black box" testing.[3] Detailed knowledge of the source code and

specifics of the algorithm flow are impossible to obtain due to complexity, proprietary concerns, and time constraints. Knowledge of the theoretical calculation algorithms is necessary, but the skill required for this is more similar to that of a diligent student rather than that of an independent researcher.

The mindset required to properly implement new clinical technology requires diligent consideration of failure modes and human factors.[4] In a laboratory experiment, it is sufficient to simply get the equipment working long enough to collect data. This is insufficient in a clinical setting, where the *robustness* of the technical and human systems is of paramount importance. Medical physicists must recognize likely failure points and develop robust QA strategies. These are skills that are typically not acquired during focused research training.

There is, however, significant overlap between clinical practice and research. Perhaps both supporters and opponents of the proposition have much in common. Scholarly activities are abundant in the clinical environment. For example, implementation of new radiation treatment modalities is often accompanied by comparisons of new treatment plans to those using conventional methods. The exercise of collecting these data and drawing conclusions could be considered science or it could be considered clinical practice. Regardless, I believe that all medical physics graduate programs should prepare their students to engage in such activities. However, I believe that the best way to do this is to mentor students through the resolution of authentic and timely clinical problems.

Rebuttal: David W. O. Rogers, Ph.D.

I agree with most of what my opponent has said. However, in almost every instance, one could replace "medical or clinical physicist," with "new generation of radiotherapy technician" and it would be applicable. This observation is the underlying threat to our profession. Without an emphasis on the research nature of our profession, it will surely decline. Without a significant original research component in our graduate medical physics programs, the next generation of medical physicists will not be researchers.

It is the role of the soon-to-be-mandatory residency programs to ensure that a minimum set of "specific technical skills" are acquired. This is not the role of the graduate programs which should ensure a broad base of knowledge and teach how to do research. At the same time, it must become mandatory that research be part of all residency programs since we must make clear to all entry-level physicists that research is an essential part of clinical practice. In addition, a 2-year break from research during residency would mean the research edge is lost forever. If one feels there is not enough time for research during training, then this is again delusion. There can never be enough time to learn all the specific skills of a medical physicist in a 2-year residency. Maintaining research capability is certainly as important as the skills missed, since research capability implies an ability to continuously learn the skills needed, either those missed in training or the new ones invented the day after the residency is completed.

To summarize the stature of medical physics as a profession is based on our research contributions, and unless we maintain these research contributions, the profession as we know it will die out because we are so costly to the health care system. If we are to continue with research, it is essential that research be a significant component of all graduate medical physics programs.

Rebuttal: Janelle A. Molloy, Ph.D.

Mindless technical practice as the only alternative to research is an unfounded assertion. Clinical medical physicists provide value that a technician cannot. Moreover, research performed in the clinical setting is a luxury that compromises our ability to address important clinical issues.

Dr. Rogers asserts that the value clinical physicists enjoy is based on their indirect association with researchers. We work in an unforgiving, market-driven economy. Medical physicists receive high salaries because we provide services that require a unique skill set. We provide a deep understanding of

physical and technical processes so that these processes can be applied over a wide and appropriate range of scenarios.

Physics education, more than research, is responsible for our clinical success. Physicists are trained to understand basic principals over memorization, to scrutinize the behavior of systems, and to think critically. Physicists are intelligent and have a strong work ethic. These are attributes that are correlated with, but not caused by, research training.

The educational standards for our profession are progressing. There is an irony, however, in that the more directly relevant the training, the more suspicion is evoked in terms of its intellectual integrity. We are concerned that the farther we move away from "real" physics backgrounds, the more our brand equity will degrade.

Our practice requires some repetitive data collection that, in fact, could be delegated to technicians. We must not assume however that the ability to efficiently perform these tasks degrades our ability and willingness to think. We will not be skilled problem solvers if our understanding of the equipment we use is theoretical. The clinically valuable physicist is one who is fluent with the details of specific technologies and who can lead a treatment team through clinical problem solving. This is not research; it is the practice of clinical medical physics.

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6.3. Most residency programs for radiation oncology physicists do not reflect the heightened importance of medical imaging

X. Ronald Zhu and Rupak K. Das
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OVERVIEW

With the widespread application of highly conformal radiotherapy techniques, imaging has taken on increased importance both in planning and delivery. Radiation oncology physicists increasingly have to use imaging systems without necessarily having in-depth knowledge as to how these systems work. This is due to the educational programs they attended, which allowed students who planned to specialize in radiation oncology, to graduate without the same level of detailed knowledge of imaging required of their counterparts who wanted to specialize in imaging. It might be hoped that current radiation oncology physics residency programs have remedied this situation by including sufficient education in all the imaging modalities used in therapy, but it has been suggested that this is not the case for most programs. This is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is X. Ronald Zhu, Ph.D. Dr. Zhu obtained his Ph.D. in Chemical Physics from the University of Utah and completed a Radiation Oncology Physics Residency Program at Washington University, St. Louis. He is currently Professor of Radiation Physics at the University of Texas MD Anderson Cancer Center and Director of the Radiation Oncology Physics Residency Program. He is a member of the Commission on Accreditation of Medical Physics Educational Programs (CAMPEP) Residency Education Program Review Committee. Dr. Zhu is certified by the American Board of Medical Physics in Radiation Oncology Physics and has served on numerous American Association of Physicists in Medicine (AAPM) Committees and Task Groups including the Education and Training of Medical Physicists Committee, the Therapy Imaging Subcommittee, and the Work Group on Coordination of Medical Physics Residency Programs.

Arguing against the Proposition is Rupak K. Das, Ph.D. Dr. Das obtained his Ph.D. in Physics from Ohio University, Athens, Ohio and subsequently did postdoctoral research at the University of North Carolina and the Department of Radiation Oncology, Washington University, St. Louis, before completing a medical physics residency at the University of Florida, Gainesville. Dr. Das is a Professor and Director of the Radiation Oncology Physics Residency Program in the Department of Human Oncology, University of Wisconsin, Madison. Dr. Das is Board certified by the American Board of Radiology (ABR) in Therapeutic Radiological Physics and serves as an examiner on the Board. He has served on many AAPM Committees and Task Groups including the *Medical Physics* Editorial Board and the Work Group on Coordination of Medical Physics Residency Programs.

FOR THE PROPOSITION: X. Ronald Zhu, Ph.D.

Opening Statement

Medical imaging plays an increasingly important role in radiation oncology.[1] Magnetic resonance imaging (MRI) and positron-emission tomography (PET), together with computed tomography (CT), have become a part of the standard imaging tools used for radiation therapy treatment planning and tumor response monitoring. Intensity modulated radiation therapy has significantly improved dose conformity and has led to more stringent requirements for immobilization and localization in radiation treatment delivery. Image-guided radiation therapy (IGRT), which enables in-room target localization, has been developed to meet these challenges. Imaging technologies available for IGRT include

electronic portal imaging, ultrasound-based techniques, kilovoltage (kV) x-ray imaging, integrated CT/linear accelerator systems, tomotherapy with megavoltage (MV) CT, and cone beam CT (CBCT) using kV and MV x rays. Clinical radiation oncology physicists ought to have in-depth knowledge of these imaging technologies.

Radiation oncology physics residency programs are the formal training programs for future clinical physicists. Recognizing the need for structured clinical training for physicists wishing to practice professional medical physics, the AAPM published a report on essentials and guidelines for hospital-based residency training programs in 1990,[2] with an updated version in 1996 (AAPM Report No. 90).[3] The CAMPEP (Ref. 4) has accredited medical physics residency programs based on AAPM Report No. 90 (Chapter 3). Section 3.4.4, Training Content, of the report does not explicitly include imaging modalities that are important to radiation oncology except radiographic/fluoroscopic and CT images for simulation, although Sec. 3.5.4.A3 on IGRT does briefly mention MRI, PET, ultrasound, and image registration and fusion in addition to CT. Unless individual residents have had previous training in imaging physics, the current curriculum of radiation oncology physics residency programs based on the AAPM Report No. 90 does not provide the in-depth training in imaging physics which is critical to IGRT. For example, radiation oncology physics residents do not have sufficient training to understand factors affecting image quality for CBCT, commonly used for in-room IGRT, and MRI, widely used for defining target volume and soft tissues.

One could argue that radiation oncology physicists do not need to have in-depth knowledge of imaging physics: When needed, they could seek help from their colleagues who specialize in imaging physics. But radiation oncology physicists trained in all aspects of the radiation oncology workflow have a better appreciation of the effects of image quality on the planning and delivery of radiation dose distributions. They are responsible for the problems that can prevent them from planning, and safely and accurately delivering doses. Radiation oncology physicists with a better understanding of imaging physics can make better clinical judgments. Therefore, residency programs for radiation oncology physicists should provide an in-depth training in medical imaging in this era of IGRT.

AGAINST THE PROPOSITION: Rupak K. Das, Ph.D.

Opening Statement

It is true that during the past decade, it has become increasingly common to use multiple imaging modalities to define and localize the treatment volume. All treatment planning systems are able to use multiple imaging modalities such as CT, PET, MRI, or U.S. for external beam and brachytherapy planning. Also, all treatment delivery systems can be purchased with some form of built-in imaging modality such as cone beam CT (kV or MV) to localize the treatment volume. But currently, most clinics use just CT imaging for external beam treatments or U.S. for prostate brachytherapy. Direct use of other imaging modalities in treatment planning systems is still quite limited.

The topic of how much a radiation oncology physicist should know about imaging will be debated for years. The AAPM Task Group Report on academic programs for graduate degrees in medical physics recommends that “To some degree, image science is required knowledge for any medical physicist, but details of magnetic resonance image science are more pertinent to the specialist.”[5] The same can be said for radiation oncology physics residents. End users of imaging modalities in treatment planning do not need to know the imaging system in detail. What they need to know is how to administer a comprehensive quality assurance (QA) program for different imaging modalities such as those presented in AAPM Task Group Reports.[6,7] Graduate and residency programs for radiation oncology physicists do not have to cover in detail how each modality functions, but should instead teach how to perform QA for these imaging modalities.

Ultimately, it is up to the ABR to tackle this issue rather than individual programs. In the Part I: General section of the Examination Study Guide for Radiologic Physics,[8] two imaging modalities, nuclear

magnetic resonance and ultrasound, are already included. Moreover, for the Oral Examination[4] in Radiologic Physics, out of the five subject categories included, one is "image acquisition, processing and display." So the requirement for a practical understanding of medical imaging for radiation oncology physicists is already in place. The case for increasing the imaging component of radiation oncology physics residency programs is premature at best.

Rebuttal: X. Ronald Zhu, Ph.D.

Dr. Das acknowledges the importance of medical imaging in the era of IGRT but suggests that radiation oncology physics residents only need to learn how to establish and manage a comprehensive QA program for the imaging devices used in radiation oncology, and do not need to have in-depth knowledge about how each imaging modality functions. I beg to differ. First, simply administering a comprehensive QA program for imaging devices used in the clinic is not sufficient. As asserted in my opening statement, radiation oncology physicists should know more about medical imaging than currently required in residency programs because only they have an appreciation of the effects of image quality on the ability to plan and deliver radiation treatments appropriately. Second, even if just for establishing an effective QA program, radiation oncology physicists should know more about how each imaging modality functions. Without sufficient knowledge, they will not be able to establish an effective and efficient QA program for the imaging devices used.

I agree with Dr. Das that the curriculum for an individual program should not be drastically changed until the AAPM, CAMPEP, and the ABR have established new guidelines. It is also true that there is a medical imaging component for radiation oncology physicists in the current ABR examinations. But I would argue that in this era of IGRT, with the heightened importance of medical imaging, the medical imaging component of the exam is insufficient in terms of depth of knowledge required and, therefore, current training of radiation oncology physics residents in imaging is inadequate.

Rebuttal: Rupak K. Das, Ph.D.

Dr. Zhu states that if radiation oncology physicists have a better understanding of imaging physics, they can make better clinical judgments. I could not disagree more. Clinical judgments should be made by radiation oncologists and not by radiation oncology physicists. Since radiation oncologists are using these imaging modalities to derive the planning target volume and localizing it for daily treatment, they should consult their imaging counterparts, the radiologists, in making these decisions. A physicist should provide them with information on uncertainties associated with these modalities. Physicists should also be extensively involved in QA for these imaging devices, thereby instilling confidence in the definition and localization of targets and normal tissues.

Dr. Zhu's claim that residency programs should provide an in-depth training in medical imaging for residents in radiation oncology physics is not practical. Other than a handful of large academic institutions, most radiation oncology physics departments/sections do not have experts in imaging. In my institution (University of Wisconsin), there are three courses on imaging (CT, MRI, and ultrasound) offered each year. Each of these courses is three credit hours. Each credit hour corresponds to one hour of class per week for a semester. Graduate students interested in specializing in imaging physics are required to take these courses for better understanding and in-depth knowledge. So a total of nine credit hours will be required to give a radiation oncology resident an in-depth training on these imaging devices. Enlarging the curriculum of a radiation oncology physics training program to imaging physics at this level will be burdensome for the training institutions.

I still believe that implementation of a comprehensive QA program on the imaging modalities used in a radiation oncology clinic might be all that we need. Not only will it give some insight to the residents on the imaging modalities that are being used in the clinic, but it will also teach them the importance and benefits of such a QA program.

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6.4. Medical Physics residency programs in nonacademic facilities should affiliate themselves with a university-based program

Jatinder Saini and Jason R. Sherman
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OVERVIEW

With the requirement that, by 2014, graduation from a Commission on Medical Physics Educational Programs (CAMPEP) accredited residency program will be necessary in order to become certified in Medical Physics by the American Board of Radiology, the number of such residency programs has been increasing dramatically. Although most of these programs are in universities, some are in practices that are not university-based. It has been suggested that such residencies need to be affiliated with university-based programs, and this is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Jatinder Saini, M.S. Mr. Saini obtained his MS degree in Radiological Physics from Wayne State University in 2010 and, upon graduation, became a Medical Physics intern at the Swedish Cancer Institute, Seattle, WA. He subsequently moved to his current position as a radiation oncology physics resident at Central Arkansas Radiation Therapy Institute, Little Rock, AR.

Arguing against the Proposition is Jason R. Sherman, M.S. Mr. Sherman obtained his MS degree in Medical Physics from the Toshiba Stroke Research Center, Department of Biophysical Science, State University of New York at Buffalo in 2008. During this time, he was Assistant Radiation Safety Officer at the Erie Community Medical Center, Buffalo, New York and, upon graduation, he became a diagnostic radiology physics resident at Upstate Medical Physics, Inc., Victor, NY, where he became the first to graduate from this residency program in 2011 and is now a full-time employee.

FOR THE PROPOSITION: Jatinder Saini, M.S.

Opening statement

As the new 2014 board certification requirements approach, the number of medical physics residencies is rapidly increasing. While most of these residencies are based in large academic institutions or comprehensive cancer centers, a small number have opened in private practice or community hospital settings. The latter variety of residency may be problematic for the field of medical physics. Though accredited by CAMPEP, they cannot provide their residents with the same breadth of experience obtainable in academic residency programs.

A private practice residency may indeed provide a suitable amount of clinical exposure. Even so, there are clear benefits to training in a large institutional setting where experts in a broad range of fields practice and do research. Generally, in an academic environment there are multiple ongoing research projects in which residents can participate, giving them the opportunity to learn and practice cutting-edge technologies. Residents are able to collaborate not only with faculty physicists and physicians, but also with medical residents, graduate students, and postdoctoral scholars. Moreover, opportunities for collaboration extend well beyond a resident's particular institution, as academic institutions frequently participate in scientific conferences and journal clubs. For all these reasons, the academic residency program provides the medical physics resident with a comprehensive training environment.

We also need to ask how nonacademic physics residencies might affect the perception of our profession. How often do we see physicians' residencies in private practice settings or community hospitals? In radiation oncology, for example, most medical residency training takes place in a university

environment or in comprehensive cancer centers. Do we really want the public to think that medical physicists require a lesser degree of training than physicians? While having such residencies, we are relegating the training of medical physicists to the level of medical dosimetrists or radiation therapists rather than keeping it at a level comparable to that of physicians. Most medical specialties listed on the American Board of Medical Specialties (ABMS) do not train their residents in a private practice environment. The medical physics specialty, being part of ABMS, should also have similar pathways to practice.

Nonuniversity-based residency programs are addressing the pressing shortage of residency programs. In that sense, they are a step in the right direction. But these programs should associate themselves with established, university-based programs in their respective regions. In this way, a resource-sharing arrangement can be developed so that residents in these programs can participate in the activities of the large institution.

In conclusion, I believe that all private practice and small clinic-based medical physics residencies should become affiliated with larger institutions in their regions and, further, that the AAPM and CAMPEP should facilitate the development of such relationships for the greater good of our profession.

AGAINST THE PROPOSITION: Jason R. Sherman, M.S.

Opening statement

With a limited number of CAMPEP-accredited imaging residencies that are not affiliated with a university-based program, I feel it is appropriate that I discuss my experience at Upstate Medical Physics, the first and, thus far, the only CAMPEP-accredited Diagnostic Imaging Residency in a private practice consulting group. Not only was this program deemed by CAMPEP reviewers to be strong in both didactics and clinical experience, but it is unique in that it prepares medical physicists for work in the rapidly-growing consulting environment.

Some may claim that a lack of affiliation with university-based programs limits the educational component of the residency and is thus more focused on revenue-generating work. Having completed my three-year medical physics residency with Upstate Medical Physics, I can attest that this is not the case. This unique program goes above and beyond simply training each resident to perform medical physics surveys. There is also a significant emphasis on the assurance of competency, continuing education, professional maturation, and development of the ability to handle any situation in a confident and ethical way.

All residents have a list of educational requirements they must adhere to throughout their three-year program. They are obligated to read and review four journal articles a month, including one continuing education credit from the AAPM Virtual Library. They are required to deliver quarterly presentations on a peer-reviewed article, participate in monthly staff meetings and attend monthly presentations by invited radiologists who share their knowledge, experience and collection of clinical images. Through the consulting practice, the Upstate Medical Physics resident has the unique opportunity of experiencing a diverse group of hospital and outpatient medical center settings, with a wide range of equipment. Additionally, residents learn how to conduct other essential professional duties which include participation in professional societies (AAPM, RSNA, etc.), teaching, contract negotiations, participating in Radiation Safety Committee meetings, working with regulatory and accrediting bodies, and assisting in the planning process for growing departments.

The Upstate Medical Physics Residency Program was designed as a three-year program in order to provide the broad clinical experience necessary to fully develop clinical medical physics expertise. The clinical training schedule begins with the fundamentals in radiation safety and radiologic and fluoroscopy work, then builds upon that foundation as the modules progress through the more complex modalities. A significant differentiating strength of this residency program is that the resident continues

to work in each modality after each training module is completed. Over the three-year residency, this approach builds heightened competence through consistent experience.

Upstate Medical Physics has created a diverse residency program that incorporates all of the necessary ingredients to mold highly competent medical physicists.

Rebuttal: Jatinder Saini, M.S.

Mr. Sherman presents a solid case for the educational quality of his own residency. But it would be a mistake to assume that his admittedly unique program is representative of nonacademic medical physics residencies in general. Moreover, as strong as his residency might be, I maintain that it would still benefit from affiliation with a university or other research-oriented institution.

Reading journal articles, attending presentations and other such educational activities, are a great way to keep oneself abreast of the latest developments in the field, but they cannot provide the same depth of understanding as actual participation in research projects under the guidance of mentors. The practical nature of our field typically requires hands-on experience as well as theoretical understanding in order to acquire true mastery. Participation in a consulting practice like that associated with Mr. Sherman's residency can fulfill this requirement to some extent but many of the duties in such a practice are routine and do not develop the strength of insight one can acquire by helping to stretch the boundaries of knowledge with a research project. Thus, it will be ideal to have some research component in each residency program, most likely resulting in a publication.

It is also worth noting that the accreditation of any program by CAMPEP only ensures that the program meets certain minimum *clinical* training standards. According to the CAMPEP website, "*The goal is to ensure that a residency program provides rigorous and thorough clinical training in a similar fashion to that provided by medical residency training programs*." Thus, CAMPEP accreditation does not evaluate institutions for any research training provided to residents.

Additionally, I would like to reiterate my original point about the public perception of the medical physics profession. There is more prestige involved with graduation from a university whose reputation extends beyond the local region. A private practice or community hospital may have a great local presence, but when graduates from such associated residency programs go out to work outside the local region, their expertise may not be valued as much as that of those who were trained in a university-affiliated program.

Rebuttal: Jason R. Sherman, M.S.

Mr. Saini raises some important points, a number of which I feel have been addressed in my opening statement using my own residency experience here at Upstate Medical Physics to support my case. With 100+ client facilities, the residents here are given the opportunity to work with cutting-edge technologies, participate in research projects, and consult with a wide variety of medical personnel. The structure of our residency program conforms to the recommendations of the 1990 AAPM report "Essentials and Guidelines of Hospital-Based Medical Physics Residency Training Programs."[1] We have then taken it a step further to ensure that the program not only meets but exceeds these standards in the private consulting practice setting. Competency and experience is tracked using software called TYPHON (see Ref. 2), which is used by radiology residents across the country.

We have observed that most hospitals and private imaging centers use medical physicists in private consulting practices rather than full-time employees for their imaging physics services. Clearly, with the large proportion of jobs in the private practice service model, a residency program which is based in a private practice group is highly valuable to the residents since it is specifically suited to meeting the current and future needs of the diagnostic imaging medical physics community.

While being unaffiliated with an academic institution may change the “perception of our profession,” why must it be in a negative way? A CAMPEP-accredited residency, university-affiliated or not, satisfies all of the requirements set forth by the accrediting body and should be equally valued. As with anything new, there is always skepticism and scrutiny, which is certainly warranted as we want to ensure that we are not settling for a “lesser degree of training.” The requirements for what is needed to become a medical physicist are changing. It is only logical that medical physics residency programs evolve accordingly and offer the support needed to ensure the success of our profession.

The need for CAMPEP-accredited residency programs in the near future is a certain fact. I have shown that if designed properly, affiliation with a university-based program should not be required.

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CHAPTER 7

Professional Issues

7.1. Bright young physicists should be advised to avoid careers in radiation therapy

Robert J. Schulz and Matthew B. Podgorsak
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OVERVIEW

Many physicists who entered the radiotherapy field 30–40 years ago were told that their careers would be short lived because developments in genetics and chemotherapy would soon make radiotherapy obsolete. Since then, the number of physicists specializing in radiotherapy has increased about tenfold, so these doom-and-gloom forecasts were flawed. However, recent progress in genetic understanding of cancer and its treatment and prevention has caused some to believe that the heyday of radiotherapy is over, and that young medical physicists should consider careers in other subspecialties. This is the premise 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.

Arguing against the Proposition is Matthew B. Podgorsak, Ph.D. Dr. Podgorsak joined the faculty of Roswell Park Cancer Institute (RPCI) in 1993 and has been Chief Physicist in the Department of Radiation Medicine since 1998. He serves as Associate Professor in the Department of Biophysics in RPCI's Graduate Division of the State University of New York. Dr. Podgorsak earned his doctorate in medical physics from the University of Wisconsin, Madison, in 1993. He is Board-Certified in Radiation Oncology Physics by the American Board of Medical Physics and is licensed by the State of New York to practice Therapeutic Medical Physics. Dr. Podgorsak has served on the AAPM Board of Directors and currently is a member of the Development Committee and the Meeting Coordination Committee, where he is Chair of the Education Program subcommittee. Dr. Podgorsak is Director of RPCI's Medical Physics Residency and Medical Dosimetry Training Programs.

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

Opening statement

From a casual reading of Scientific American, it is clear that bright young physicists have innumerable opportunities to contribute to the advancement of science and industry as well as medical research. Therefore, it should come as no surprise that many are attracted to apply their unique skills to enhancing the cure rates of radiation therapy (RT). However, before making such a commitment, which would take them far outside the mainstreams of physics research, a few observations about cancer treatments and RT, in particular, may be enlightening.

As for cancer treatment, consider that surgical excision of tumors goes back over 200 years, that John Adams' daughter had a mastectomy in 1811,[1] that the first radical prostatectomy was performed in 1904,[2] and that to this day surgery remains the first treatment for upwards of 70% of all cancers.[3] Similarly, consider that the irradiation of tumors began about a century ago, and that RT is still one of the mainstays of cancer treatment. Although both surgery and RT have undergone major technical refinements, their basic rationales remain unchanged: For surgery, excise tumors, leaving no positive margins; for RT, irradiate the tumor until the fraction of surviving malignant cells is reduced to the point where, for whatever reasons, they no longer pose a viable threat to the patient's well being. As for clinical progress, mortality (deaths per 100 000) for all cancer sites decreased from 205 in 1975 to 195 in 2004, and the 5 year relative survival increased from 50% to 66% over this same period.[4] More often than not these gains can be attributed to multimodality treatments consisting of surgery supplemented by pre- or post-op RT plus adjuvant chemotherapy. Without doubt, future gains will come from improved chemotherapeutic agents and earlier tumor detection as opposed to technical refinements in surgery or RT.

One of the major contributions of physicists to RT has been the improvement of dose distributions, i.e., shaping, intensity modulating, and directing x-ray and charged-particle beams so as to more uniformly irradiate tumors while minimizing the dose to surrounding normal tissues. Despite the potential advantages of proton and carbon-ion beams,[5] however, there is a dearth of clinical data to suggest that *further* refinements to the dose distributions already provided by modern x-ray systems will have a detectable impact on mortality or morbidity. The main reason for this is that nine out of ten cancer deaths are attributable to metastases[6] even when local control of the primary has been achieved.

Clearly, the future of physicists in RT depends upon the future of that medical specialty. As with surgery, all available evidence suggests that RT has gone about as far as it can in reducing cancer mortality, and that only minor reductions in morbidity associated with aggressive treatments may now be achieved. This is not to suggest that RT will soon be replaced but only that its role will gradually but steadily diminish, to be replaced by drug-based therapies. As this inevitable transition proceeds, RT physicists will morph into system engineers, concerned mainly with overall quality assurance while looking over their shoulders as biological solutions are found to what are basically biological problems.

AGAINST THE PROPOSITION: Matthew B. Podgorsak, Ph.D.

Opening statement

I interpret the Proposition to assert that aspiring young physicists can somehow have their full potential quantified through a “brightness” scale and that those at the high end of the scale should not consider a career in radiation therapy physics. Presumably, their exceptional academic talents would be wasted were they to become radiation therapy physicists, and other branches of medical physics or even other physics specialties would better satisfy their career aspirations.

I reject this elitist assertion for the following two reasons. First, there are many illustrious members of our radiation therapy physics profession, my opponent included, who have distinguished themselves not only in clinical practice but also in academics through research, teaching, and authorship of textbooks. Simply reviewing the list of authors in this edition of *Medical Physics* and reflecting upon our own mentors or perusing our personal bookshelves will remind us of many others that enjoy inclusion in the category of great leaders. Second, opportunities for exceptional academic contributions, paralleling those achieved by our senior colleagues early in their careers, continue to develop as the technology of delivering radiation therapy evolves. In fact, the recent renaissance of radiation therapy technology has been driven largely through contributions made by our academically oriented colleagues. There is no reason to believe that these opportunities will cease to be available to our young colleagues any time soon. While my opponent has recently questioned the clinical impact of some new technologies,[7] whether or not any future modalities or treatment paradigms yet to be discovered will have any impact

on a patient's treatment outcome remains unclear. This question, however, is not being debated in this exchange.

I believe that physicists with strong academic aspirations, rather than being discouraged from entering radiation therapy, should instead be advised to begin their career in large, academic centers rather than in small radiation therapy clinics. It is at academic centers where our young colleagues will be empowered to follow their academic aspirations and make significant contributions to our field. Are we to suggest that only those physicists with lesser brightness should be encouraged to join the field of radiation therapy and drive its future evolution? I think not!

I am a second generation radiation therapy medical physicist with approximately 15 years of clinical and academic experience. Although work and professional life have been very challenging at times, I can honestly say that I have enjoyed immensely most aspects of my career, and I would not hesitate to encourage my children or any aspiring young physicists to consider choosing a similar path for their own future. From a purely pragmatic point of view, the need for therapy physicists will continue to increase for the foreseeable future. With a balance of clinical responsibilities and protected time for academic work, I believe that physicists can find gainful employment in radiation therapy. Their clinical work will be coupled with an opportunity to satisfy their academic goals and they will benefit society and enjoy excellent job satisfaction through their clinical and academic efforts.

Rebuttal: Robert J. Schulz, Ph.D.

In his opening statement Dr. Podgorsak suggests that because I used the term “bright young physicists,” I must have a brightness scale in mind, and that those at the top of this imaginary scale should avoid careers in radiation therapy. Let me state unequivocally that this brightness scale is news to me, and that my opening statement is aimed at *all* physicists who are on the verge of making decisions that will affect their careers.

Unfortunately, Dr. Podgorsak did not address the main points I raised in my argument. These are that the efficacy of radiation therapy has reached a plateau, further improvements in dose distributions and dose delivery will have an undetectably small impact on patient outcomes, and the role of radiation therapy, and of surgery as well, will be gradually eclipsed by new and better drug therapies that result from basic biological and clinical research. These points accepted, then young physicists who enter radiation therapy today could very well, in 20 years time, find their radiation oncologist colleagues dispensing drugs far more often than approving treatment plans while they (the physicists) devote more of their time to conducting evermore demanding quality assurance programs for a steadily diminishing number of radiation therapy patients.

In closing, one caveat: At the moment radiation therapy seems recession proof, and a well-paying job is very attractive compared with no job at all. But as budgets are inexorably reduced, the Centers for Medicare & Medicaid Services (CMS) will have to make more evidence-based decisions for its reimbursement rates than it has in the past. Evidence showing that the outcomes of proton-beam therapy are superior to those of IMRT or that those of IMRT are superior to those of 3D-CRT is at best shaky or at worst nonexistent.[8,9,10] This does not bode well for further research on dose distributions and dose-delivery systems or for the future of physicists in radiation therapy.

Rebuttal: Matthew B. Podgorsak, Ph.D

I agree that radiation therapy will be superseded by other clinical approaches and ultimately be documented in medical history as “the best available treatment of the time,” much like the craniotomies and bloodletting used to treat some of our ancestors' afflictions. Where we disagree is on the time line and what to do as we wait.

We have two choices. The first is to simply accept *status quo* in anticipation of the development of a new treatment paradigm at some point in the future. The second, and the choice I advocate, is for our

profession to continue striving to improve radiation dose delivery, either through better targeting or by implementation of more efficient radiation beams and techniques. As my opponent states, a large scale improvement in tumor control is unlikely. However, most clinicians will nevertheless acknowledge the benefit of conforming dose according to biological need, consequently resulting in improved clinical outcomes through fewer treatment-related sequelae. These further refinements will require the dedication and significant talent of our upcoming junior colleagues. Improving our patients' quality of life is certainly worth the effort.

If our senior peers had accepted *status quo* just a few short years ago, we may have never experienced IMRT, image guidance, increased access to proton therapy, and other modern approaches that have benefited so many of our patients. We must remember that these techniques, considered state of the art right now, are recent developments for which we have our academically inclined colleagues to thank. As our senior leaders retire, I look forward to working with aspiring young physicists as our profession continues to evolve and treatments are further refined. Patients will continue to appreciate our efforts, even as we wait for "the next best thing." If we give up now, who knows what potential developments on the horizon may never come to be.

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7.2. The 2014 initiative is not only unnecessary but it constitutes a threat to the future of medical physics

Gary D. Fullerton and Kenneth N. Vanek
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OVERVIEW

The AAPM Board recommendation that, by 2014, in order to be eligible for American Board of Radiology certification, candidates must complete a Commission on Accreditation of Medical Physics Educational Programs (CAMPEP) accredited residency program, has raised a number of concerns. It has even been suggested that this so-called 2014 initiative is not only unnecessary but also it constitutes a threat to the future of medical physics. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Gary D. Fullerton, Ph.D. Dr. Fullerton obtained his Ph.D. in Radiologic Physics from the University of Wisconsin, Madison in 1974. He worked at the University of Texas Health Science Center at San Antonio for 35 yrs, where he was Professor and Chief of the Radiological Sciences Division and Vice-Chair in the Department of Radiology, and Chair of the Resident MD/Ph.D. Graduate Program in Human Imaging. In 2009 he moved to the University of Colorado Denver, where he is Professor and Vice-Chair of Radiology. He has served as an Officer in several national and international societies including President of the AAPM, President of the Society of Magnetic Resonance Imaging (SMRI), Secretary of the AAPM, Secretary-General of the International Organization for Medical Physics, and Secretary-General of the International Union for Physical and Engineering Sciences in Medicine (IUPESM). In 2009 he received the IUPESM Award of Merit for Outstanding Achievements in Physical and Engineering Sciences in Medicine. Dr. Fullerton is certified by the ABR in Radiological Physics and is a Fellow of the AAPM, the SMRI, the American Institute of Medical and Biological Engineering, the International Society of Magnetic Resonance in Medicine, and the American College of Radiology.

Arguing against the Proposition is Kenneth N. Vanek, Ph.D. Dr. Vanek obtained his Ph.D. in Nuclear Engineering Sciences/Medical Radiation Physics from the University of Florida, Gainesville in 1976. After serving in the United States Air Force for 20 years, he joined the H. Clay Evans Johnson Cancer Treatment Center, Memorial Hospital, Chattanooga, Tennessee and then, in 1988, the Department of Radiation Oncology, Medical University of South Carolina, Charleston, where he is currently Associate Professor and Director of Medical Physics and New Technology, Associate Professor in the Department of Neuroscience, and Director of the Radiation Oncology Medical Physics Residency Program. Dr. Vanek has been active in several societies, having served as Chairman of the ACMP, Chair of the AAPM Annual Meeting Coordination Committee, President of the Deep South Chapter of the Health Physics Society, President of the AAPM Southwest Chapter, and a member of the AAPM Board of Directors. He is certified by the ABR in Therapeutic Radiological Physics and by the ABMP in Radiation Oncology Physics, and is a Fellow of the ACMP, the AAPM, and the American College of Radiology.

FOR THE PROPOSITION: Gary D. Fullerton, Ph.D.

Opening Statement

Debate over the relative importance of **research, education, and professional** practice of medical physics, which has generated heated arguments over the entire five-decade history of the AAPM, reached a fever pitch following the AAPM Board recommendation to focus exclusively on CAMPEP

residency training to qualify for ABR certification. *This so-called 2014 initiative is not only unnecessary but also it constitutes a threat to the future of medical physics*.

Research

Medical physicists have traditionally led teams designing tests to validate new technologies for radiology and radiation oncology ranging from computed dosimetry, linacs, MRI, PET, US, and PET/CT among many others. Each technology needed objective research to validate patient benefit. Medical physics research training in Ph.D. programs provided intellectual tools and methods supporting these important leadership roles. Traditional undergraduate and professional doctorate degrees are inadequate as they teach students to seek solutions to problems by recapitulating the work of others from books, journals, and professional references.

Graduate Education

North American graduate programs in medical physics evolved primarily in research-oriented graduate schools with an increasing fraction of programs becoming CAMPEP-accredited providing a more uniform level of clinical education. They provided large numbers of both MS (professional focus) and Ph.D. (research focus) graduates well versed in medical physics to integrate with graduates of traditional physics programs to provide strong multidisciplinary physics teams in clinical practice. The financial underpinnings typically included graduate research fellowships from host universities, return of tuition from undergraduate and MS level students to provide teaching assistantships, and research grant funding to provide research assistantships. Due to the 2014 initiative, programs in Graduate Schools must close and reopen as degree programs in Professional Schools. Medical Physics graduate programs with large research portfolios cannot move, however. This induces financial instability by fracturing academic medical physics into separate schools with entirely different demands and practices.

Professional Practice

Presently many regulatory agencies demand Qualified Medical Physicists (QMPs) for critical roles in the implementation of complex clinical technologies for patient care. Demand for QMP services with required qualifications has caused healthy increases in salaries and respected positions in the health care infrastructure in both Canada and the United States of America. Reducing didactic education to 2 yrs followed by 2 or 3 yrs of clinical (practical) training reduces the range of medical physics capabilities and responsibilities. The idea that new technology can be learned from a book without using research methods seems patently ridiculous when one reviews the past 20 yrs.

Intent Versus Reality

The intent of the AAPM Board of Directors was to improve the practice of clinical medical physics using established paradigms for physician training. This laudable goal ignores the fact that medical physicists must be educated differently than physicians to do jobs for which physicians are untrained. The physician is responsible for patient care. The medical physicist is responsible for assisting the physician to use technologies that physicians do not understand in sufficient detail to implement by themselves. The AAPM needs to make a course correction and time is growing short.

AGAINST THE PROPOSITION: Kenneth N. Vanek, Ph.D.

Opening Statement

The 2014 initiative may be separated into two components: (1) the ABR eligibility requirement for completion of a CAMPEP residency program and (2) the 2014 effective date. The purpose of ABR certification is reflected in its mission statement[11] "*to serve patients, the public, and the medical profession by certifying that its diplomats have acquired, demonstrated, and maintained a requisite standard of knowledge, skill, and understanding essential to the **practice** of diagnostic radiology, radiation oncology, and radiologic physics.*" The importance of clinical training has long been

recognized. The ABR requires 4 yrs of residency for both diagnostic radiology and radiation oncology certification. The American Board of Medical Specialties (ABMS) web page "About Board Certification"[22] states "*Before a doctor can become Board Certified, each must complete: 4 yrs of premedical education in a college or university; a course of study leading to an MD or DO degree from a qualified medical school* and *3 to 5 yrs of full-time experience in an accredited residency training program.*" Clearly, residency training is an inherent component of the overall education required to become certified by a medical specialty board. Will physicists be able to maintain their status of being certified by the ABR without residency training? I contend that this is neither a sustainable situation nor is it in the best interest of patient safety.

As medical professionals, we have a commitment to patients and our physician colleagues not only for the quality of our practice but also for insuring that future clinical physicists are well trained. The consequences of poorly trained physicists are life threatening and may adversely impact a considerable number of patients before clinical symptoms appear and the cause is discovered. Graduate academic programs should provide a firm basic foundation of knowledge that a medical physicist can utilize in clinical practice as well as important research experience. Even if clinical courses and a few weeks in a clinic are included in the curriculum, academic programs are not a substitute for 2–3 yrs of full-time structured and focused clinical training. The old-school method of hit and miss on-the-job-training is no longer adequate to train new medical physicists. Today, in order to fully prepare future medical physicists to independently practice in the clinic with increasingly complex technology, we must offer, in addition to a solid academic education, clinical training through an accredited residency program that offers a broad variety of procedures with state-of-the-art equipment and a sufficient number of faculty and patients to acquire the necessary clinical training and experience.

The implementation date of 2014 is also a necessity. Prior to 2007 when the 2014 initiative was announced, there were only 12 CAMPEP radiation oncology and two diagnostic residencies. From 2007 to 2010, 31 radiation oncology and four diagnostic residencies have been added. Also, one diagnostic and 11 therapy programs are currently awaiting CAMPEP approval. Would this dramatic increase in residency programs have occurred without the 2014 initiative? I think not.

In conclusion, the 2014 initiative is not only necessary but also mandatory for the future of medical physics, the safety of patients, and the quality of future clinical physicists. The risk to our profession is to falter on this initiative.

Rebuttal: Gary D. Fullerton, Ph.D.

Dr. Vanek's opening statement recalls the tale of blind men asked to describe the elephant.[33] He identifies a version of truth with his description of the physicianlike patient care role of medical physicists. It is one truth among many. Expert clinical medical physics requires recognition of other truths such as those that involve regulatory functions, technical support, radiation safety, research programs, and development engineering. The medical physics team will be stunted by exclusive focus on the clinical training methods designed for physicians.

While nodding to the importance of academic education in medical physics, Dr. Vanek does not see the impact of elimination of CAMPEP graduate medical physics education. Medical physics programs and departments in graduate schools will be forced to turn away from courses suited to clinical training toward topics more suited to fundamental medical research. Medical physics programs post-2014 must redirect activities toward their only remaining funding sources from general medical physics education (tuition income) and research (federal grants).

While Dr. Vanek doubts that the ABR would continue to certify medical physicists with CAMPEP-accredited Ph.D. education in medical physics with on-the-job (nonresidency) experience in the clinic, he ignores the fact that the 2014 change in rules relative to admission to the ABR was proposed by the

AAPM Board not by the ABR. The ABR Commissioners may have serious concerns about our ability to meet clinical needs post 2014 but are unwilling to contradict the AAPM on such an important decision.

Physicians care for humans who evolve only slowly. Medical physicists care for the introduction and operation of technologies evolving so rapidly that no one today can predict the coming decade. We must not forget the differences in our zeal to excel.

Rebuttal: Kenneth N. Vanek, Ph.D.

I disagree with Dr. Fullerton's speculative statement that graduate programs must close and reopen as programs in professional schools because of the 2014 initiative. The 2014 initiative requires graduation from a CAMPEP residency to be eligible to take ABR Part 2. Nothing in this initiative mandates the creation of programs in professional schools. Most statements by my opponent apply to academic program issues, which may indeed warrant review by both academic programs and CAMPEP. Since residency training will soon be mandatory for ABR certification, perhaps the amount of clinical training required in graduate school versus the need for more core courses and research should be reevaluated.

A misconception seems to exist that residency programs simply teach residents technical procedures. In reality, a broad spectrum of challenges is encountered daily in the clinic and many require rapid as well as accurate decisions. Problem solving skills under clinical stress and urgencies must be learned on the front line. Although a solid theoretical foundation and analytical reasoning enhanced through research are invaluable in this decision process, so is that critical factor called clinical experience, which is best taught through a formal residency program. The irreplaceable importance of clinical training is well established and recognized throughout the health professions. It cannot be ignored by our profession.

I must reemphasize that the 2014 initiative is essential for the future of medical physics, ABR certification, the safety of patients, and effectively teaching future medical physicists who choose a clinical career. We must not waver from this resolve.

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7.3. The 2014 initiative can have potentially unintended negative consequences for medical physics in diagnostic imaging and nuclear medicine

Ehsan Samei and Terry M. Button
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OVERVIEW

The AAPM Board recommendation that, by 2014, in order to be eligible for American Board of Radiology certification, candidates must complete a Commission on Accreditation of Medical Physics Educational Programs (CAMPEP) accredited residency program, was intended as a means to raise the standards of care by ensuring that those entering the field were adequately educated. There is a shortage of medical physics residencies in imaging, however, and it has been suggested that this 2014 initiative might actually *negatively* impact the quality of care in diagnostic imaging and nuclear medicine. This is the claim debated in this month's Point/Counterpoint.

Arguing for the Proposition is Ehsan Samei, Ph.D. Dr. Samei is Professor of Radiology, Medical Physics, Biomedical Engineering, Physics, and Electrical and Computer Engineering at Duke University. He was a cofounder of the Duke Medical Physics Graduate Program and currently serves as the Director of the Duke Imaging Physics Residency Program, Carl E. Ravin Advanced Imaging Labs, and Clinical Imaging Physics at Duke. His research interests include quantitative imaging, molecular x-ray imaging, and image assessment and optimization. He is the current President of the Society of Directors of Academic Medical Physics Programs (SDAMPP), and Past-President of the Southeast Chapter of the AAPM (SEAAPM). He is certified by the ABR in Diagnostic Radiologic Physics and has served on, or been Chairman of, numerous AAPM Committee and Task Groups, including the *Medical Physics* Editorial Board.

Arguing against the Proposition is Terry M. Button, Ph.D. Dr. Button started in Medical Physics as a Masters level physicist in Radiation Safety and Radiation Oncology in the late 1970s. He obtained his Ph.D. in Biophysics from the State University of New York at Buffalo (Roswell Park) in 1989, with his research focused on magnetic resonance. Upon graduation, he worked as an Imaging Physicist at Columbia Presbyterian until he moved to Stony Brook University in 1991. He established a graduate Medical Physics Program at Stony Brook with Dr. Lawrence Reinstein in 2002, which recently obtained CAMPEP accreditation. He also established an Imaging Physics Residency Program at Stony Brook, which has been accredited since 2009. He is an Associate Professor of Radiology, Biomedical Engineering, and Health Sciences. He oversees the undergraduate Radiological Sciences Program at Stony Brook and is the Chair of the University Radiation Protection Committee (URPC). He has served the ABMP for the past decade as a member of the Board, Panel Chair for Part I and, currently, as Panel Co-Chair of the MR Examinations. He is certified by the ABR in Diagnostic Radiologic Physics and by the ABMP in Diagnostic Physics and Magnetic Resonance.

FOR THE PROPOSITION: Ehsan Samei, Ph.D.

Opening statement

Diagnostic imaging (DI) and nuclear medicine (NM) have been intertwined with medical physics dating back to the discovery of x-rays and radioactivity. As imaging technologies continue to advance and expand into new applications, they increasingly require skilled expertise to understand the delicacy of their operation, monitor their performance, design their effective use, and ensure their overall quality

and safety. Even though the ACR accreditation process has highlighted the clinical role of physicists in imaging operations, that role has largely remained a severely untapped resource. Most imaging centers fail to appreciate this potential, with medical physics groups either nonexistent or highly understaffed and their services poorly integrated into the patient care process. As a field, we have yet to define how these clinical physicists can engage as active, effective, and indispensible members of the clinical team, and how the services that they provide can be financially supported. Physicists do, and always will, contribute to research and development. However, their contributions to *clinical* operations in DI/NM have not been adequately established.

In the face of the challenge of unleashing the real potential of clinical physics in DI and NM operations, we now further face the challenge of the new ABR requirement for the completion of an accredited residency to become eligible for board certification. The basis of this requirement is a well-justified desire to enhance and standardize the clinical competencies of physicists. However, the number of accredited residencies in the US, six in DI and none in NM at the time of this writing, is well below what can be considered adequate to meet the demand. Whilst we wish to expand the role of clinical physicists in DI/NM, the enactment of the ABR requirement by 2014 would bring about a move in the opposite direction. This is because ABR-certified physicists will not be available in adequate numbers to meet the demand in DI/NM and, as a result, even the subpar role that medical physicists currently play in the clinic will be outsourced to other specialists without sufficient physics training, clinical or not. Hence, the objective of enhancing clinical skills will not be served and ABR certification will no longer be considered essential. The result will be a further weakening of the clinical role of physicists in DI/NM and a reduction in their numbers.

What we are facing is no simple challenge. On the one hand, we indeed wish to enhance the standard of practice in clinical medical physics through accredited residencies. On the other hand, however, a premature mandate might actually undermine this very objective. Recognizing that physicists are skilled at finding solutions to hard problems, I believe a solution can be found if we allow our inspiring idealism to meet practical realities.

AGAINST THE PROPOSITION: Terry M. Button, Ph.D.

Opening statement

An initiative is an introductory step leading to action. The 2014 initiative leads all Medical Physics clinical training program directors to act to conform to the CAMPEP approved format. The guidelines that are available to do this are clear and easy to implement.[1,2] It is also essential for program directors to act now if there is hope for their candidates to sit for the Boards in 2014!

The first mission of the AAPM (Ref. 3) is to promote the highest quality medical physics services for patients. From this, follows the fourth mission:[3] to foster the education and professional development of medical physicists. So what is the best training available for medical physicists? An excellent indicator of performance is the “pass rate” of candidates on their Board examinations. For example, to 2005, 95% of candidates who had completed a CAMPEP accredited residency program passed the full board examination on their first attempt compared to the average pass rate of 53% over the same period.[4] More recent data for the oral examination, though not quite so impressive for CAMPEP residency program graduates, still showed a significant advantage for residents: over the period 2003–2008, the oral examination pass rate for first time takers ranged from 47 to 59% while the pass rate for those from CAMPEP accredited residencies ranged from 80 to 90%![5]

The primary reason for improved performance is obvious. A CAMPEP accredited residency is required to be carefully structured to cover the entire spectrum of the appropriate Medical Physics disciplines. To be accredited, the program must be complete; there can be no missing components. Unfortunately, as recently as 2008, AAPM Task Group #133 reported that more than half of all clinical medical physics training (54%) is done on the job, while only 14% of clinical training takes place in a CAMPEP-

accredited residency program.[2] Current Imaging Physics statistics are probably similar given that there are only six CAMPEP approved residency programs.[6]

The financial implementation of a residency program is challenging. Who is going to pay for this training? Program directors need to be creative to get funding for residency slots. In my program, for example, I have added a clinical affiliate and catered to the needs of my Department by planning to focus on strong MR candidates for an additional MR fellowship component.

Clearly there are obstacles in the path of the goal of excellence that is the 2014 initiative but we must find solutions. Since the largest benefactors of clinical training are the candidates, the cost of this training may, in the future, increasingly be the responsibility of the candidates themselves. We physicists have generally been spoiled by the availability of graduate student support. Maybe those days are gone for medical physics.

Rebuttal: Ehsan Samei, Ph.D.

I agree with my respected colleague that, in an ideal world, completion of a residency can ensure a consistent level of competency for practicing clinical medical physicists. However, with only a handful of residencies in DI/NM, enforcement of the new eligibility requirement in less than two years from now would lead to an insufficient number of board-certified physicists, at a time when we need such individuals more than ever to support clinical practice.

Hospitals need technical support to maintain image quality and manage radiation dose, but regulations do not require them to employ ABR-certified medical physicists for this purpose. An alternative workforce of engineers or specialized technologists is used around the world to answer this need. If insufficient ABR-certified physicists are available, hospital administrators will resort to the next available (and less expensive) alternative. This trend, once initiated, may become a permanent and irreversible fixture of American medicine. A critical fact is that our profession currently does not have the financial means to bring the needed number of residencies into existence. The curricular expectations of a CAMPEP-accredited program are too extensive to enable a level of clinical productivity on the part of residents sufficient to claim much compensation from clinical sources; at the same time, the responsibilities of current physicists are too extensive to allow the significant donation of time and attention needed for quality training. Meanwhile, healthcare reform intends to reduce the so-called “overuse” of expensive diagnostic imaging procedures, and to curtail associated charges and fees. Simultaneously, NIH extramural research funding is falling. Who can or will cover the burden prescribed by our professional idealism?

As much as I value and support accredited residencies, enforcing a premature deadline of 2014 without strategic actions years in advance, and without considering the particularities of DI/NM physics, will not produce the desired outcome. We need to go after the crux of the problem (i.e., inadequate funding). Requirements and regulations can only do so much without addressing the fundamental limitation at hand.

Rebuttal: Terry M. Button, Ph.D.

Since the discovery of x-rays by Roentgen, physical scientists have played an essential role in clinical Radiology and have been the backbone of growth and proliferation of new imaging technologies. While it is true that the revenue sources to support imaging medical physicists are not as clearly defined at it is for our oncology medical physics colleagues, the services required of imaging medical physicists have never been more clearly defined. Moreover, these services are mandated by virtue of the reimbursement implications of accreditation and compliance.

It is true that only a handful of CAMPEP accredited Imaging Medical Physics residency programs exist. However, until now there has been little incentive to formalize existing imaging post doctoral programs to meet CAMPEP requirements. With the 2014 initiative looming, however, there is plenty of incentive!

Residency program accreditation is relatively easy to obtain and having it should provide the best students available. I feel that the number of accredited programs will greatly increase over the next few years.

It is important to remember that at the beginning of World War II biplanes were still in use. By the end of the war, jet planes were being placed into service. Necessity can force remarkable advances. I feel that the 2014 initiative will greatly enhance the standard of imaging medical physics practice.

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7.4. The shortage of radiation oncology physicists is addressable through remote treatment planning combined with periodic visits by consultant physicists

Darwin Zellmer and Eric Klein
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OVERVIEW

The recent influx of highly physics-intensive new technology into radiation therapy has created an acute shortage of radiation oncology physicists. This has led to an increase in the employment of consulting physicists and physics groups serving smaller centers remotely, using the internet to access local treatment planning systems and to communicate with in-house staff. It could be argued, however, that these high-tech systems make it even more important to have physics staff available in-house at all times due to the increased complexity of the equipment and the tasks that the physicists have to perform. Whether-or-not this is an appropriate way to address the physicist shortage problem is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Darwin Zellmer, Ph.D. Dr. Zellmer received his doctorate in radiation biophysics from the University of Kansas and has held faculty positions at Rockhurst College, University of Kansas, Medical College of Wisconsin, Fox Chase, and Wayne State University. His areas of research include microdosimetry and radiobiological effects of low-LET radiations. He is currently Chief of Medical Physics at the Anchorage Radiation Therapy Center which is linked by virtual private networks to several treatment sites, one of which is 320 miles from Anchorage and has completely paperless electronic treatment planning, charting, and medical records. This network allows for the remote monitoring of daily QA, CT simulation, treatment planning, and the review of medical/treatment records.

Arguing against the Proposition is Dr. Eric Klein. Dr. Klein is Professor of Radiation Oncology at Washington University, St. Louis, where he has been for 18 years. He has published 64 papers, half as first author. Many publications deal with quality assurance issues. Dr. Klein served as the AAPM's Annual Meeting Scientific Program Director from 1999 to 2001. He is very active in the AAPM and ASTRO, currently serving as Chair of the AAPM's Quality Assurance and Outcome Improvement Subcommittee and Chair of TG-142 (Linear Accelerator Quality Assurance), and he serves on AAPM's Therapy Physics Committee, ASTRO's Physics Committee, and many others. Dr. Klein has been involved with CAMPEP's Residency Review Committee since 1995, and directs the longest standing accredited residency program.

FOR THE PROPOSITION: Darwin Zellmer, Ph.D.

Opening Statement

Remote high-speed internet access to computers has created the potential for greatly improving the productivity of clinical medical physicists and thereby has the potential of partially mitigating the medical physics shortage in radiation oncology. Software from major treatment planning system (TPS) vendors provides for not only remote treatment planning and review, but also simultaneous multiclient access through secure virtual private networks. The advent of the electronic medical record (EMR) allows for review of patient charts from anywhere in the world. These advances in technology can significantly enhance medical physics productivity.

Radiation oncology physicists can be divided into three groups: (1) highly specialized and employed at large institutions; (2) providing consultation for a single task, e.g., commissioning machines or shielding calculations; and (3) "generalists" performing all aspects of clinical medical physics and often serving one or more institutions. Physicists in groups 1 and 2 can perform much more efficiently than those in group 3 who often serve a distributed network of institutions requiring travel time. This third group, which is quite large in the United States, can reap major benefits in efficiency with remote access technology.

The need for coverage of several sites is due to the existence of satellites (or free standing centers) of a larger center. These typically treat 30 patients/day or less and are located miles apart. Professional and market forces exert pressure to implement highly technical procedures that are, by nature, physics intensive, while the general workload does not support the need for a full time physicist. A case in point is intensity modulated radiotherapy (IMRT), for which treatment planning and associated QA requires a day or more per case.

Remote computer access can afford the necessary physics commitment with significant gains in productivity. The IMRT treatment planning process requires several iterations often separated by long time intervals. Each iteration requires the intervention of the medical physicist. Through remote control of the TPS the physicist can consult with the dosimetrist and/or physician after each iteration and, if need be, personally generate optimized treatment plans while being offsite. Through the use of standard protocols and the assistance of a dosimetrist or technologist onsite, the associated necessary quality assurance can also be performed by the physicist offsite. Data collected from a planar array of dosimeters can subsequently be compared with TPS-generated "planar doses" from the remote location. A secondary monitor unit check can then be performed remotely from segmentation data read from the TPS or the record and verify system.

Other tasks such as chart checks using the EMR can also be performed offsite with the same ease and security afforded the TPS. Routine QA as defined in TG-40 (and more recently in TG-100) can also be performed remotely with the assistance of ancillary personnel using written protocols. In addition, hardware/software that can be remotely operated continues to be developed and this will further increase the productivity of the radiation oncology physicist.

AGAINST THE PROPOSITION: Eric Klein, Ph.D.

Opening Statement

Our profession is at a critical crossroad. The ABR is about to mandate that in order to sit for the boards a candidate must have successfully completed a CAMPEP accredited Physics Residency Program.[1] This will elevate our profession significantly in the eyes of our physician colleagues. The number of Physics Residency programs, especially in Radiation Oncology, is increasing dramatically, with likely 30 accredited programs by the end of 2008. Also, the number of resident candidates continues to remain strong (for our institution's single position for this year, we had 72 applications, most quite strong). The manpower demand will be met, and in the most ideal way, with properly trained physicists. Admittedly, the current demand will not be met overnight, or even within the next 1–2 years. So what do we do in the meantime? At first thought, remote capabilities could facilitate remote treatment planning, but at what penalty.

Treatment planning is no longer limited to strategic beam placement/weighting/energy/modification to achieve idealized plans. The treatment planning process now involves image registration, fusion, critical contouring, treatment- and organ at risk-margins, decisions on optimization parameters, beam placement/weighting/energy decisions, creation of images for localization, careful review by physicians, careful review by physicists before data/image/contour transfer, review of the transfers, communication with the therapists, etc. Performing these steps without direct communication among physicists, physicians, dosimetrists, and therapists is not only unproductive, it is also dangerous. This is not easily

remedied by telephone or remote PC access. Combining remote planning with periodic visits by consulting physicists only exacerbates the problem.

The physicist's role in the modern clinic has changed dramatically. Many anticipated that direct data and image transfer would reduce errors and reduce the need for constant physics availability within the clinic. However, due to incompatibility of systems, the ever-changing versions of hardware, along with the increased role that the physicists must play as trainer and problem solver, physics presence is more important than it has ever been. In addition, today's patients are being treated with monitor units that can be in the thousands for IMRT. Therefore errors can be catastrophic. To ensure that the radiotherapy community acknowledges the importance of the presence of well trained physicists, the last thing our profession wants to do is degrade itself with short-term, short-cut solutions. Though there are very reputable consulting physicists and consulting groups, there are examples of visiting physicists who do not take ownership of occasionally visited clinics. Therefore, other manpower solutions to guarantee patient safety and professional credibility are needed. For example, technical personnel rather than clinical physicists can perform tasks such as IMRT quality assurance. And rather than hiring untrained physicists or no-one at all, physics assistants that provide relevant skill sets, such as engineering and IT professionals, could be hired. In addition, time saving measurement equipment must be purchased by hospitals. In conclusion, remote treatment planning and periodic physics visits may have been appropriate in 1987, or even 1997, but not in 2007.

Rebuttal: Darwin Zellmer, Ph.D.

What is implied in my colleague's discussion is that use of remote access is not a proper surrogate for physical presence and compromises quality, and that remote access need not be embraced because new educational programs will alleviate the dearth of qualified physicists. His discussion of education programs seems to evade the discussion of efficiency and quality afforded remote access as it pertains to the shortage of medical physicists, which is paramount to this debate. Explicit counterpoints to Dr Klein's other assertions follow.

Dilution of direct communication: Currently, we successfully use conference calling while shadowing a TPS work station with one or more terminals simultaneously and find that it enhances “direct communication” rather than dilutes it. We have also found access to physicians in general is increased, because their physical presence for discussion and consultation is not mandatory.

Direct intervention and training: There are indeed times when “incompatibility of systems and changing versions of hardware” warrant direct intervention and training by physicists. However, once a system is functioning, the need for intervention by the physicist is minimized and incidental daily problems can most often be addressed remotely. Training, on the other hand, is most efficient person-to-person and can be scheduled for the next regular visit.

Lack of ownership and quality: Well-delineated tasks supplemented with written protocols separate those to be addressed by a physicist from those to be performed by ancillary personnel (see the discussion in my opening statement). Such protocols circumvent any lack of “ownership” and ensure required quality.

Treatment planning systems and electronic medical records accessible through a virtual private network offer remote, secure access not only to treatment planning, but also to images, patient diagnoses, and treatment records. To contend that the use of remote access is inappropriate, would fail to embrace the advancements in telecommunications used by a significant proportion of society, and would thus prevent the potential increase in efficiency afforded by remote electronic access to EMR and TPS systems.

Rebuttal: Eric Klein, Ph.D

Undoubtedly, advances in remote high speed internet access can increase productivity by providing the ability to remotely review treatment charts, plans, and quality assurance tests. But this comes at a cost.

By not having physicists on-site, the chance of error for patients receiving treatments with exorbitant monitor units and localized by complex and incompatible systems only increases. If the physics community demonstrates to our clinician partners and administrators that we can do the current job with insufficient FTEs, then when the current shortage is over, as will probably be the case in a few years, our profession could be subjected to a surplus by having more physicists than jobs available. Instead we must work to increase the physics FTEs needed for today's IMRT/IGRT clinics. In addition, removal of the dedicated physicists from the process chain of dosimetrist-physicist-physician-physicist-therapist will be severely broken and many processes and procedures will be developed without physics input. In Dr. Zellmer's opening statement, he defines three categories of physicists, namely: a single task physicist, specialized physicist, and roaming specialist. He is missing the fourth and most important category, the physicist who is able to handle most of the tasks either as a solo physicist or as part of a small group dedicated to that facility. As physicists we must ask the question: "Are consulting groups potentially hurting our endeavor to appropriately increase the number of qualified FTE physicists?" This may be a *slippery slope* since consulting groups often place less than the needed number of FTEs at a facility and, unfortunately, often with undertrained people. Our physics community needs to be patient until properly trained physicists enter the job market. Our profession will then be elevated as we work alongside our physician partners on equal footing and with pride that we take our profession very seriously, demonstrating dedication to our patients.

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7.5. The terminal M.S. degree is no longer appropriate for students interested in a career in clinical medical physics in the United States

Michael D. Mills and Howard R. Elson
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OVERVIEW

Entry into the medical physics profession in the United States is at a crossroads. In the past, the simplest and most common way to enter the field was to obtain a Medical Physics M.S. degree and to become certified as soon as possible thereafter. With the new American Board of Radiology examination requirements, however, this will no longer be possible: All applicants will have to be enrolled in or have graduated from an accredited medical physics residency program. No longer will entry into the profession be in the hands of graduate program directors; this responsibility will be transferred to the directors of residency programs. The concern has been expressed that these directors might accept trainees into their programs who have doctoral degrees in preference to those holding the M.S. and that many, if not most, M.S. graduates might not be able to secure residency positions. Consequently, it has been suggested that the terminal M.S. degree is no longer appropriate for students interested in a career in clinical medical physics in the United States. This is the Proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is Michael D. Mills, Ph.D. Dr. Mills obtained his Ph.D. in Biomedical Science from the University of Texas Graduate School of Biomedical Sciences, Houston, Texas, in 1980. Since then, he has held clinical and faculty appointments in a number of institutions and is currently Chief of Physics and Associate Professor in the Department of Radiation Oncology, Brown Cancer Center, University of Louisville, Kentucky. He has served on or chaired numerous committees and Task Groups in the AAPM and the ACMP and is currently Chairman of the ACMP Commission on Credentials and Vice-Chairman of the AAPM Professional Council. He has served on the Board of Directors and as Chairman of the Board of the ACMP. He is a Fellow of the ACMP and the AAPM and has received the Marvin M. D. Williams Award of the ACMP. Dr. Mills is certified by the ABR in Therapeutic, Diagnostic, and Nuclear Medicine Physics and by the ABMP in Radiation Oncology Physics.

Arguing against the Proposition is Howard R. Elson, Ph.D. Dr. Elson obtained his Ph.D. in Biomedical Nuclear Engineering from the University of Cincinnati, Ohio, in 1978 and has subsequently worked his entire career in the University of Cincinnati College of Medicine where he is currently Professor of Radiation Oncology in the Department of Radiation Oncology. He has served on several AAPM Committees and the Board of Directors and is certified by the ABR in Therapeutic, Diagnostic, and Nuclear Medicine Physics. Dr. Elson is the Director of the CAMPEP-accredited Medical Physics Graduate Program in the Radiology Department of the University of Cincinnati College of Medicine. He has been the Advisor or on the Research Committees of 28 M.S. and 8 Ph.D. students.

FOR THE PROPOSITION: Michael D. Mills, Ph.D.

Opening Statement

"Dad! I've been accepted to Medical School!" How exciting! But wait; the Medical School is out-of-state! More investigation reveals some distressing information. There are 200 entry slots, 50 for in-state and 150 for out-of-state students, but only 50 clinical rotation slots! At the beginning of year three, 150 of the students are dismissed! Of the 50 rotation positions, 40 are reserved for in-state students! There

are 50 in-state students who therefore have an 80% chance of landing a clinical rotation slot. However, there are only ten rotation slots for the remaining 150 out-of-state students; only a 7% chance of your daughter actually landing a clinical rotation slot and finishing! “I’m sorry. You just can’t go to this school. This medical school seems to be running a racket! They are collecting money to run a big program on the promise of training you to be a doctor but they are not keeping that promise! Fewer than ten percent of students in your position will actually enter rotations and Medical practice. And you will waste two years of your life if you fail to make this almost impossible cut. I cannot recommend that you try to become a physician there. You will need to look for another opportunity.”

While no analogy is perfect, if you replace Medical School with the M.S. program in Medical Physics; the clinical rotation slot with a medical physics residency position; the out-of-state students with M.S. medical physics students; in-state students with Ph.D. medical physics students; medical doctor with medical physics professional, then the analogy of terms and numbers is complete.

“But wait, Dad! I can always be a physician’s assistant, or sell pharmaceuticals!” Oh, the other employment alternatives! Yes, we can justify that the M.S. Medical Physics students can always go on for a Ph.D., work for industry, or work as dosimetrists or physics assistants. However, M.S. medical physics students entered our academic programs expecting to become clinical medical physicists, just ask them! And ask your graduates if they are happy working in a medical dosimetry position they landed by agreeing to work for $10K less than the Certified Medical Dosimetrist (C.M.D.). While you are at it, ask the unemployed C.M.D.s what they think as well!

Two years graduate academic training plus two years training in a clinical residency is a Professional Doctorate. Examples are Physicians, Dentists, Podiatrists, and Optometrists. Medical Physics must credential its professionals accurately as Professional Doctorates in Medical Physics (D.M.P.). Continuing to award the M.S. degree in Medical Physics without guaranteeing entry into an appropriate residency program is a catastrophic disservice to our students and our profession. We are forcing our best candidates to choose other professions.

We must create D.M.P. programs now to be fair to our future students. I therefore urge the immediate elimination of all M.S. Medical Physics programs to be replaced by D.M.P. programs. CAMPEP should accredit only D.M.P. and Residency programs, and immediately set a date beyond which M.S. Medical Physics programs will no longer be accredited.

AGAINST THE PROPOSITION: Howard R. Elson, Ph.D.

Opening Statement

To advocate that “less education is adequate” rather than “more education is better” in a field that values education puts us at a disadvantage. We will make the case that the Medical Physics Master’s degree continues to be of value. This justification is based on four claims: The M.S. physicist plays a valuable role in clinical departments, requiring a more advanced degree would not advance the level of performance, the profession does not demand the elimination of the degree, and the profession does not control the degrees granted by educational institutions.

Much of the work that we perform is relatively routine in which diligence and attention to detail is more important than the ability to perform independent research. How do we measure the value of the M.S. physicist? One measure of value is an employer’s willingness to pay. A review of the 39 positions recently advertised in the AAPM Placement Service list showed only 17 required a Ph.D. Of the 17, the majority were academic positions. With the profession’s history of service by M.S. educated physicists, nonacademic employers feel confident that M.S. physicists are competent in clinical positions. The same conclusion is apparent in the small salary difference between the holders of the two degrees.

Would raising the entrance requirements beyond the M.S. have prevented the recent well-publicized radiation events? No! In fact, many of the incidents occurred in environments staffed by physicists

educated beyond the M.S. Physicians, administrators, and regulators have not demanded an increase in educational experience for medical physicists to furnish a more sophisticated pool of physicists.

If the profession invoked a new minimum of the doctorate of medical physics (D.M.P.) or the Ph.D. for entry into the profession, what would be the potential consequences? Would the students entering the field through M.S. programs suddenly matriculate into the alternate programs? Would the alternated programs expand to accommodate increased populations? Would the present M.S. program be able to convert to granting a more advanced degree? At many institutions presently granting the M.S., including ours, it is not economically feasible to convert to the more advanced degree. Would the AAPM, ABR, or CAMPEP be able financially to overcome the economic barriers for conversion of these programs?

If there were an insufficient number of graduates, what would be the response of the employers in need of the services of our profession? Our clinical work would still have to be done to support patient care. A likely result of a shortage of physicists, caused in part by additional impediments to entry into the field, is that the work would be performed by *less* qualified individuals.

In conclusion, the aims of the medical physics graduate education are fourfold: (1) To provide the knowledge required to provide medical physics services in patient care, (2) to develop the skills necessary to implement new technologies, (3) to accomplish medical physics research and development, and (4) to produce the next generation. My position is that the first two can be satisfied by "well-trained" M.S.-educated physicists, while the latter two might better be suited to Ph.D.-educated physicists.

Rebuttal: Michael D. Mills, Ph.D.

We agree that every aspiring medical physicist must master the content currently contained within the M.S. degree curriculum, and the student must complete a CAMPEP-accredited residency to be eligible for entry into the profession. The debate is over what we *name* this education pathway and *fairness* to those that enter the education path to become medical physicists. Let us examine these claims to see if they stand up to scrutiny:

1. The argument is not over *value*, but *proper valuation*. Medical physicists have mastered a body of clinical knowledge radiation oncologists or radiologists do not and cannot master. The medical physicist's role has proper value only if the naming of accomplishments (D.M.P. or Ph.D.) recognizes this and puts the medical physicist in proper standing with physicians.

2. The level of performance required for medical physics practice *increases* every year. Routine medical physics practice is often more complex than routine medical practice and no one would argue that because much of radiation-medical practice is routine, an M.D. (professional doctorate) degree is not required in order to practice as a radiologist or radiation oncologist.

3. The debate is *whether* the profession should demand the elimination of the M.S. Medical Physics degree. Training 140 M.S. medical physicists that cannot enter CAMPEP residencies each year benefits none of these individuals, nor does such training benefit radiation oncology or radiology, or the patient. In the long run, it will not benefit the program directors either.

4. The profession *does* control which programs are CAMPEP accredited and therefore recognized as a pathway into clinical practice. The M.S. in Medical Physics fails in this regard.

Those who advocate continuing the M.S. in Medical Physics must consider the immediate and irreparable harm that is being done to our profession, our graduates, and our patients. We should eliminate CAMPEP accreditation for all M.S. Medical Physics programs immediately.

Rebuttal: Howard R. Elson, Ph.D.

As was stated by my opponent: "No analogy is perfect," but let us consider the analogy in the *inverse*. Years ago, a medical residency training system was set in place, which resulted in an excess of clinical

spots and an insufficient number of medical school graduates to fill them. Did the creators of this system envision the large number of clinical spots being filled by foreign medical graduates? Did they predict the number of Americans matriculating in foreign medical schools? Did they envision the effect on medical care in this country and the brain drain on the rest of the world? What would have been the consequences if a rigorous system for regulating physicians' licensure had not been in place?

Although this scenario is obviously different from the present medical physics issue, is there a lesson to be learned? What might be the unintended consequences of a drastic reduction in the number of individuals entering the field by the M.S. route, bearing in mind that we do *not* have the protection of rigorous licensure requirements? Furthermore, we do not control the number of institutions granting the D.M.P. We can, and should, encourage the creation of new D.M.P. programs. However, at this time, do we understand the consequences of adding another impediment for entry into the field?

The discussion raised in this Point/Counterpoint may be of interest to the field in general but ultimately at this point in time, the fate of the M.S. is in the hands of the medical physics residency program directors. Will those directors grant admission to applicants holding the M.S. at a rate sufficient to warrant the continuation of M.S. programs? If not, the only option will be the elimination of the M.S. as a mode of entry into the field.

7.6. Medical physics graduate programs should adjust enrollment to achieve equilibrium between graduates and residents

John E. Bayouth and Jay W. Burmeister
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OVERVIEW

Beginning in 2014, to be eligible for American Board of Radiology (ABR) certification, candidates must have completed a Commission on Accreditation of Medical Physics Educational Programs (CAMPEP) accredited residency program. Currently the number of available accredited residency positions is substantially lower than the number of students graduating from medical physics graduate programs, however, and it has been suggested that enrollment in graduate programs should be adjusted to be proportional to the number of residency openings. This is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is John E. Bayouth, Ph.D. Dr. Bayouth received his Ph.D. in Medical Physics and did his postdoctoral training in Radiation Physics at the University of Texas Health Science Center, M. D. Anderson Cancer Center, Houston. He is currently Associate Professor and Director of Medical Physics in the Department of Radiation Oncology, University of Iowa, where he directs a CAMPEP-accredited medical physics residency program. He has served as a member or chair of numerous AAPM committees and task groups. He is currently chair of the Education and Training of Medical Physicists Committee and a member of the AAPM Board of Directors.

Arguing against the Proposition is Jay W. Burmeister, Ph.D. Dr. Burmeister received his Ph.D. in Medical Physics from Wayne State University and is currently Chief of Physics for the Karmanos Cancer Center/Wayne State University, and director of the CAMPEP-accredited Medical Physics graduate program and Radiation Oncology Physics residency program. He is chair of the AAPM Medical Physicists as Educators Subcommittee and has been a member of many other AAPM committees, work groups, and task groups, including the Editorial Board of *Medical Physics*.

FOR THE PROPOSITION: John E. Bayouth, Ph.D.

Opening statement

Medical physics education in the United States is undergoing substantial transformation. Several organizations are influencing the process, which, beginning in 2014, will require clinical training from a CAMPEP accredited residency program to be eligible for ABR certification. Currently, the number of CAMPEP accredited graduate programs, and the number of students within them, are growing, thereby creating an excess of graduates who need clinical experience to achieve board-eligibility.

Some suggest that the solution to this inequity is removing or postponing clinical experience requirements for those pursuing clinical practice careers. This would be a disservice to patients. Others argue that we cannot create an adequate number of residency slots for the graduates. These suggestions fail to consider both the assumption of supply (number of programs) and demand (number of clinical positions). From July 1, 2001 through July 2010, the number of accredited residency programs has grown (4, 5, 6, 9, 12, 13, 18, 23, 31, 42) with a doubling rate of 2.67 years ($r^2 = 0.988$).[1] Meanwhile, the number of clinical positions for graduates has declined: jobs listed by the AAPM Placement Service have decreased dramatically for those with $\leq$2 years experience, from 286 in 2003 to 112 in 2010 (data compiled through the AAPM Placement Service database and provided by the AAPM Headquarters staff).

Graduate education programs are growing while graduate student research is shrinking. Twenty seven of 52 Medical Physics graduate programs identified by the Society of Directors of Academic Medical Physics Programs (SDAMPP) responded to a survey last year, indicating that they have admitted 352 applicants and have 833 graduate students currently enrolled (survey conducted by Edward Jackson, Ph.D. on behalf of SDAMPP and disseminated through e-mail to SDAMPP members).

Most of their graduates (~65%) have pursued clinical employment; far too many for the market to absorb. Meanwhile, the current clinical direction of graduate education programs has likely contributed to the 3:1 M.S./Ph.D. enrollment ratio, resulting in less research.

Our educational mission should be to produce the most talented and qualified medical physicists. The patients we serve will not benefit from an explosion of trainees in either graduate education or residency programs. Graduate programs need "birth control" for two basic reasons: (i) too many graduates are being produced for the market and (ii) research training infrastructure is not expanding to support additional trainees. During his 2010 Coolidge Award acceptance speech, David W.O. Rodgers[2] said: "*While talking about students and post-docs, I want to finish with a note of caution about the future of our field. While I fully realize that patient care is the bottom line of all clinical medical physics, I believe that the reason medical physicists are seen as essential to the radiotherapy and diagnostic processes is because we were the ones doing the cutting edge research* …I *firmly believe that we are on the road to nowhere unless research is further emphasized and given a high priority by all medical physicists*." The importance of developing research skills for all medical physicists cannot be overstated, even for those working in purely "clinical" positions. They will need these skills to diligently implement emerging technologies. Further, it is unethical to require students to commit themselves to years of hard work and financial stress in the hope of finding work in an already saturated market place. Funding graduate students through research naturally regulates growth and serves our mission; the current environment calls for limiting graduate program enrollment.

AGAINST THE PROPOSITION: Jay W. Burmeister, Ph.D.

Opening statement

Is the sole purpose of medical physics graduate education to provide a specific skill set required for professional practice or is it more than this? If medical physics is a "science" to be taught for its own sake then there is no reason to couple enrollment with professional metrics. Moreover, I will argue here that even if you believe medical physics is merely a "practice," it is not in the interest of our profession or patients to calibrate graduate program enrollment with the number of residency positions.

Recent estimates of annual clinical need for new Radiation Oncology Physicists (ROPs) range from 150 (Ref. 3) to 150–300 (TG-133 estimates that the annual need for medical physicists is in the range of 200–400; if we assume that approximately 75% of new entrants practice in radiation oncology, the estimated need is about 150–300 ROP/year).[4] The U.S. Department of Health and Human Services predicted a 22% increase in demand for physician services between 2005 and 2020,[5] and Smith et al. predict the number of radiation therapy patients to increase by 22% from 2010 to 2020.[6] Thus, demand for ROPs in the near future is likely to increase. The 35 residency respondents to the 2010 SDAMPP survey offered a total of 47.5 ROP residency slots per year.[7] While this number does not include all ROP residency positions, the number of slots is clearly far short of our clinical needs. Calibrating graduate enrollment to it will leave hospitals without adequate medical physics resources. I have concentrated only on radiation oncology here but the residency situation is far worse for diagnostic imaging.

If enrollment must be calibrated, it should be to clinical demand, so let us assume that there *are* enough residency positions to meet clinical needs and reconsider the Proposition. The real question then is whether graduate students should be entitled to a residency position by virtue of being accepted into a graduate program. It is difficult to gauge the success of graduate students based on admission statistics, and restricting the number of matriculating students would eliminate many potentially successful

physicists. Preserving current matriculation levels will allow us to continue casting a wider net to assure that our graduate programs produce the highest quality output.

Let us also consider some of the logistics involved in implementing this proposition. Would we require uniform enrollment reductions by all programs? Would this effectively eliminate smaller programs? And, if we calibrate graduate program output to residency positions, how do alternative pathway entrants to the profession fit into the equation?

Graduate programs must be honest and forthright with prospective students about the realities of the job market, and there is clearly a real and ethical problem if this information is withheld. Understanding the risk involved in pursuing a career and achieving a desired outcome, however, is the responsibility of the student.

Those of us involved in graduate medical physics education would very much like to provide a residency spot for all graduates who desire one. However, the proposition presented here implies that medical physics education is only a means to a clinical job, would result in an inadequate supply of clinical physicists, and would likely lower the quality of this supply.

Rebuttal: John E. Bayouth, Ph.D.

I strongly support several elements of Dr. Burmeister's argument. Medical physics should be a science taught for the sake of science and to enhance the quality of clinical support. Graduate programs should be honest with their students regarding prospects for residency, which should not be an entitlement. But I do not believe the data supports the assumption that hospitals will be left without adequate medical physics resources if the number of graduate students were to be decreased. Although anecdotal, I received more than 40 applications for a Medical Physics staff position within two weeks of posting the advertisement. Hopefully the job market will improve and, as I expect, the trend of increasing residency positions will continue as well. Because the number of medical physicists completing their education exceeds market demand, today's equilibrium occurs at the end of the training process. This is clearly suboptimal for our students.

Dr. Burmeister questions the logistics of implementing the Proposition, and I agree that directly coupling enrollment in graduate programs to the number of residency slots would be counterproductive. We all strive to produce the highest quality of education. If graduate student enrollment were supported through and governed by the quality and magnitude of research in our training programs, those who seek a clinical career could establish clinical skills in residency, while maintaining a research priority within our field. This approach would also provide a pathway for those seeking careers in academia or industry. All of these career pathways would benefit from the scientific training.

Rebuttal: Jay W.Burmeister, Ph.D.

I agree with Dr. Bayouth that medical physics education is (or at least should be) about more than just clinical instruction. Albert Einstein said that "Education is what remains after one has forgotten everything one learned in school." Physicists bring to medicine more than knowledge, they bring understanding. This highlights the difference between instruction and teaching, and research is a key ingredient in science teaching. I also agree that removing clinical requirements would be a disservice to patients and that it is possible to create enough residency spots to meet clinical demand (although not by 2014). I further agree that the shrinking Ph.D./M.S. ratio is detrimental to our profession and to patient care. However, many candidates in Ph.D. and postdoctoral programs left research for clinical positions during the IMRT/IGRT boom. We may actually enjoy more success retaining future researchers in the current market. My opponent is correct that more graduate students will not address declining research. Neither will calibrating the number of graduates to the number of residency spots, however.

Dr. Bayouth states that there has been a decrease in entry-level positions based on AAPM Placement Service listings. However, since residents perform clinical services, one would expect the number of

entry-level positions to decrease as residencies increase, so this does not necessarily indicate a decrease in demand for medical physics services. In fact, the need for medical physics services will likely continue to increase with our aging population. Moreover, with the increased media exposure and changing safety culture in Radiation Oncology and Radiology, institutions should view investment in medical physics resources as more important than investment in technology.

Finally, I believe that a student's choice to enter this field of study is generally a result of the desire to apply science to medicine, not the expectation of a guaranteed job or residency upon graduation. Graduate programs should continue to welcome these students and to produce graduates sufficient to meet demand for medical physics research and clinical service and should emphasize educational components such as research which define our value to the medical community.

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7.7. Authorization to practice as a medical physicist is sometimes better achieved by registration rather than licensure

Douglas E. Pfeiffer and Jeffrey P. Masten
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OVERVIEW

The American Association of Physicists in Medicine (AAPM) advocates licensure of medical physicists in order to assure that only qualified individuals practice the profession. For well over ten years, the AAPM has provided financial, staff, and member support for the establishment of licensure in several states yet, so far, only four states have enacted licensure laws. Consequently, it has been suggested that maybe registration of medical physicists rather than licensure might be a more efficient way of assuring appropriate qualification of medical physicists, at least in some states, and this is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Douglas E. Pfeiffer, MS. Mr. Pfeiffer received his MS degree in Applied Science from the University of California, Davis and is certified in Diagnostic Radiological Physics by the American Board of Radiology. He is currently Medical Physicist and Radiation Safety Officer at Boulder Community Hospital. Mr. Pfeiffer has served on numerous American Association of Physicists in Medicine (AAPM) Committees and Task Groups, and has chaired the Government and Regulatory Affairs Committee, Task Group 128, and the Medical Physics Education of Health Professionals Committee. He has served as President of the Upstate New York and Rocky Mountain Chapters and on the AAPM Board of Directors. He is also actively involved in various accreditation programs of the American College of Radiology.

Arguing against the Proposition is Jeffrey P. Masten, MS, JD. Mr. Masten obtained his law degree from the University of South Dakota, Vermillion in 1976 and worked as a lawyer until he transferred into radiological physics in the late 1990s. He was awarded his MS in Radiological Physics by the University of Colorado, Denver in 2000, and is currently Chief Physicist at MedXRay, PC, Sioux Falls, SD. He has served on numerous AAPM committees, including as Chair of the Legislation and Regulation, and Government Affairs Committees.

FOR THE PROPOSITION: Douglas E. Pfeiffer, MS

Opening statement

There is little doubt that ensuring appropriate credentials of clinical medical physicists would elevate the quality of medical physics practice. Almost all other health professionals, and most nonhealth professionals, have some sort of credentialing requirement. Such credentialing must include the following components:

- Certification by an appropriate certification board,
- Scope of practice,
- Continuing education,
- Adherence to practice standards, both ethical and behavioral, and
- Due process for revocation of the credential.

A comprehensive regulatory approach to medical physicist credentialing can provide many of the benefits of licensure without the cost and complexity associated with legislating professional licensure.

Currently, 30 states have some form of registration of medical physicists.[1] Where registration exists, the path is direct with the cooperation of the State Regulatory Authorities. For example, in Colorado, a very direct statement was adopted that specific tasks in radiation therapy shall be performed by a registered medical physicist, where the term "registered" is equivalent to the term "qualified" as used by AAPM and ACMP in the definition of a qualified medical physicist (QMP). This simple approach established acceptable credentials and scope of practice.

Regulations can be written to provide audits for QMPs to ensure continued competency, as has been accomplished in Colorado. It can be specified that any decisions to deny or revoke registration are to be performed by a selection of peers. It is already common to require continuing education within a regulatory framework.

The path to regulatory changes can be much more direct and less expensive than the legislative approach, depending on the wording of the enabling act. The governing radiation control office is often given broad authority to regulate the use of radiation within the state. This usually includes rules for the training and experience of radiation workers, including medical physicists. Rather than money, the capital required is an excellent working relationship between the regulatory authority and the medical physicists of the state. No lobbyists are required, no time vying for the attention of busy legislators, trying to convince them that medical physicists exist. Instead, regulators and physicists work together toward a common goal.

It is also important to remember that a "suggested" national regulatory structure already exists through the Conference of Radiation Control Program Directors (CRCPD) and their suggested state regulations.[2] Many states have it in their authorizing legislation that they must adopt the SSRs in whole or with some exceptions. The CRCPD is currently close to adopting language regarding the qualifications of medical physicists; efforts can then move to trying to get the organization to adopt other features as discussed above.

In short, almost any line item of a licensure act can be incorporated into a regulatory structure. It is most often less expensive and less difficult to achieve regulatory changes than to establish new legislation and a new recognized license. The AAPM must look at a regulatory approach as an adjunct to achieving the goals of medical physicist licensure.

AGAINST THE PROPOSITION: Jeffrey P. Masten, MS, JD

Opening statement

The rather tangled legal status of the clinical practice of medical physics in the United States was highlighted recently by our AAPM President, Dr. Herman, in his remarks before the House Subcommittee on Health when he pointed out that "*Medical physicists are licensed in four states (TX, NY, FL, and HI) and regulated at widely varying levels in the other 46 states*."[3] The fact that a congressional committee convened a hearing, prompted by a series of articles in The New York Times detailing radiation therapy accidents across the country, means that the discussion in our profession of licensing and regulation is no longer an academic pursuit; there will be consequences, both sooner and later. For that reason we need to clearly understand what licensing is, what it is not, and what alternatives may exist.

Stated most broadly, a license is a form of permission granted by some competent authority which awards the holder with the privilege to do some act that is otherwise proscribed by law. Although there are forms of licenses that are private or that involve copyright or patents, we will focus on government licenses in this discussion. Through the grant or denial of a license, a government is able to regulate many different areas of human endeavor.

A number of consequences flow immediately from the definition of a license. One way to view a requirement for a license to undertake an activity is that it is in fact the grant of a monopoly to an

individual, or a group, in exchange for certain obligations. Stated another way, the holder of a license to practice medicine, for example, can practice medicine as it is defined in the statutes, and *no one else can*. Governments (local, state, and federal) have seen fit to create this type of restriction particularly in areas thought to pose significant risks to members of the public. Medicine, law, accounting, engineering, and insurance are just a few examples.

There is the suggestion that the goal of restricting the practice of medical physics to competent individuals can be more easily achieved by a simple registration process with some well-defined education and training criteria. My objection to this approach is that it is essentially "license-lite" and ultimately fails to achieve the goal of effective regulation of the practice of clinical medical physics.

Note that both law and medicine have specific education and training requirements as a part of the licensing (and registration) process. If one did not look any further than the possession of a degree from an accredited school and the appropriate postgraduate training, there is no difference between a law/medical license and "registration." What is different is that both professions possess specific Codes of Ethics which govern how the professions are practiced, and are enforceable within the membership. Both types of professional licenses similarly have specific legal rights, both statutory and constitutional, that are granted to the license holders to protect them from arbitrary action terminating or suspending their license. A simple registration requirement does not offer that protection.

For me, the concept of a formal license is preferable because it fuses the idea of enforceable ethical practice with training and education, and further offers protection from arbitrary adverse action to the holder of that license. Registration might restrict the field to qualified individuals in the sense of training and education, but not much past that.

Rebuttal: Douglas E. Pfeiffer, MS

In an ideal world, universal licensure of medical physicists could ensure all of the goals that both my worthy colleague and I agree are important to achieve. We live in a less than an ideal world, however.

Four states currently require licensure of medical physicists: New York, Texas, Hawaii, and Florida. Of these four, only Florida requires certification by a nationally recognized board.[4] New York does not require certification; licensees must only pass ABR Parts I and II.[5] Texas does not require certification at all, just their own exam.[6,7] It is the stated policy of the AAPM that a qualified medical physicist is certified by an appropriate certification board.[8] Practical and political realities reduce ideal licensure language to something palatable by the given state legislature.

My colleague in this discussion has identified one of the most challenging aspects of registration, that of assuring adherence to ethical standards. I cannot argue that this is not difficult to achieve. However, the number of recorded instances of ethical misconduct in those states currently having licensure is small, as is the number of cases that have come before the Ethics Committee of the AAPM. Thankfully, this appears to be the least of our concerns compared to ensuring that qualified individuals are doing the work. Just as licensure cannot ensure complete adoption of our goals, neither can registration.

We must recognize that there are some states in which licensure is not practicable. Prime examples reside in the Mountain West. These states are sparsely populated and will never have enough physicists to sustain the expense of a licensure program. Other states are simply not proponents of creating additional professional licensures. What is the answer in such states? Registration allows medical physicists to obtain some of their clinical practice goals, if imperfectly.

The AAPM should work to make the registration regulations as strong and comprehensive as possible in parallel with efforts to achieve licensure.

Rebuttal: Jeffrey P. Masten, MS, JD

There is a very significant flaw in the suggestion that any line item of a licensure act can be incorporated into a regulatory structure. That might be true in principle, but it is not correct in fact. A regulatory agency can only do those things which are within the *scope* of its grant of authority. This is a fundamental principle of administrative law. Any proposed new regulation needs to withstand not only review by the legislative committees charged with supervision of agencies in the jurisdiction, but also review by the courts. The first place the challenge will focus on is the scope of the original grant when that regulatory body was created.

The second challenge faced by any attempt to extend the jurisdiction of a regulatory agency is financial. Who is going to pay for this registration? If the taxpayers foot the bill through agency expenditures, that requires the approval of the legislature and its appropriations committees. If the physicists have to cover that bill, it may be just this side of oppressive in a state such as South Dakota, with fewer than a dozen physicists to pick up the expense.

The credentialing requirements offered in my opponent's Opening Statement fit exactly into the definition of a license. It excludes all except a certain class of individuals from doing a particular set of activities backed by a penalty enforced by the state. A license by any other name is still a license.

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7.8. Medical physicists should be allowed by States to image and treat, just like radiologic technologists

Michael S. Gossman and Lisa A. Burgess
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OVERVIEW

With imaging and treatment equipment becoming increasingly more technologically complex, it has been suggested that medical physicists are better qualified to operate these machines than radiologic technologists. State regulations, however, prohibit physicists from operating equipment for patient procedures. It has been argued that because of their superior scientific knowledge and technological expertise, medical physicists should be allowed to image and treat just like radiologic technologists. This is the claim debated in this month's Point/Counterpoint.

Arguing for the Proposition is Michael S. Gossman, M.S. Mr. Gossman received his B.S. and M.S. Physics degrees from Indiana University and the University of Louisville, followed by medical physics education at Vanderbilt University, and was certified in Therapeutic Radiologic Physics by the ABR in 2003. He currently serves as a member of AAPM TG-180, the Peer Review Clearinghouse Subcommittee, the Working Group on Response to Radiation Incidents, the Clinical Practice Committee, and the Therapy Physics Radiation Safety Subcommittee. He also serves as an Associate Editor for *Medical Dosimetry*, Section Editor for the *JACMP*, and as a Medical Consultant to the U.S. Nuclear Regulatory Commission. Mr. Gossman is the Chief Clinical Medical Physicist and RSO at the Tri-State Regional Cancer Center in Ashland, KY.

Arguing against the Proposition is Lisa A. Burgess, M.S. Ms. Burgess obtained her B.S. in Radiation Therapy Technology in 1986 and her M.S. in Radiological Physics in 1991, both from Wayne State University, Detroit. She was certified in Radiation Oncology Physics by the ABMP in 1995. She initially worked from 1986–1991 as a dosimetrist at Harper and Henry Ford Hospitals, Detroit. Since 1991 she has been a radiation oncology physicist at Oakwood and Henry Ford Hospitals, Detroit and, currently, the William Beaumont Hospital, Royal Oak, MI. Ms. Burgess has served the AAPM as Treasurer, Secretary, and President of the Great Lakes Chapter.

FOR THE PROPOSITION: Michael S. Gossman, M.S.

Opening Statement

Most states consider medical physicists to be unqualified to image or treat, regardless of whether they are registered as Qualified Medical Physicists (QMPs). The issue debated here is not about the *need* for medical physicists to perform such duties. Instead, it is entirely about the *allowance* to do so.

A brief reflection on the history of radiation therapy confirms the appropriateness of imaging and treatment by QMPs. For the first 60 years after the first patient was treated by radiation, physicists or nurses trained by physicists performed imaging and treatment tasks. It was not until the 1960s that the profession of the radiation therapy technologist emerged. Both nursing and radiotherapy technologist staff were found throughout the United States having the same radiation treatment duties until the late 1970s. The formation of a few radiotherapy technology schools in the mid 1980s drove the transference of treatment duties away from nurses and over to technologists.

This was precisely the occupational scenario that occurred at the M.D. Anderson Cancer during that period, as related by former AAPM President (1971), Peter R. Almond,[1] as well as his colleague and former ASTRO (1993) and American Radium Society (2002) President, J. Frank Wilson.[2]

Unfortunately, we now find that regulatory bodies fail to recognize the advanced qualifications of the medical physicist by prohibiting them from imaging or treating patients. For example, in some States, radiologic technologists (now called radiation therapists) certified in radiation therapy are the only professionals allowed to activate high dose rate remote afterloaders for patient treatments.[3,4] Dr. Wilson commented: "We are seeing radiologic overregulation by the literal interpretation (*of regulations*)." He stated: "It is just a matter of time before dosimetrists are the only medical professionals allowed by regulation to perform dosimetry tasks." Dr. Wilson further stated that, "A clinically oriented medical physicist should be allowed to image and treat."[2] I agree with these observations entirely. Although this is especially true for radiation therapy, I believe that it is also applicable in diagnostic imaging.

Former Radiological Society of North America President (2002) R. Nick Bryan,[5] commenting on the technical skill of medical physicists, stated: "Medical physicists are understood to be superior to technologists for radiation safety and the physics of imaging. This is why medical physicists are asked to teach these skills to technologists in their program."

I believe that the issue of qualification is paramount. I support the need to have the medical physicist's qualifications better understood by the States and recognized as superior to those of the technical staff that they supervise daily. The AAPM should take the initiative to inform state regulatory bodies that QMPs are highly trained scientists who have adequate skills to image and treat if necessary. I advocate for this recognition for only those individuals deemed "qualified" by the definitions established by the AAPM, and only for the specialization for which they are certified.

AGAINST THE PROPOSITION: Lisa A. Burgess, M.S.

Opening Statement

The scope of practice of medical physics according to the ACMP and AAPM states: "The essential responsibility of the Qualified Medical Physicist's clinical practice is to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result as prescribed in patient care."[6] In the following, I will address the situation in radiotherapy only, but most of my arguments apply equally well to diagnosis.

In order to assure safe and effective delivery, medical physicists routinely deliver radiation "treatments" to phantoms to obtain data needed for machine commissioning, implementation of new technologies, and verification of treatment plans. However, medical physicists do not image or treat just like radiologic technologists. Even though medical physicists deliver the "radiation treatment" to the phantom with the utmost precision, and spend copious amounts of time setting up the radiation treatment to the phantom, they are not treating like radiation therapists. When therapists treat patients, they are not just performing the technical task of beam delivery, they are also managing the patients' care.

The scope of practice for radiation therapists is very different from that for medical physicists. The therapist's education not only provides the technical training required to deliver radiation but also provides the psychological training needed to care for the patient.[7] The technical training includes operation of equipment other than just the treatment machines, along with the execution of various other technical responsibilities. These include starting IVs for CT studies with contrast, tattooing the patient, lifting and positioning patients, monitoring side effects and blood values, and dealing with medical emergencies. The didactic curriculum and two years of clinical experience in the professional radiation therapy program includes communication with patients and their family, dealing with death and dying, providing nutritional care, and providing emotional support and care. This prepares the therapist to not only treat the patient but to also meet the social, emotional, psychological, spiritual, and physical needs of the patient.

The academic program curriculum for graduate degrees in medical physics does not include patient care.[8] Similarly, guidelines for physics residency programs again do not include clinical training to

prepare the medical physicist to deliver radiation treatments "just like a therapist."[9] The didactic and clinical education of medical physicists is structured to prepare them to oversee the treatment process so as to ensure that the treatment prescribed by the radiation oncologist and the resultant treatment plan is delivered in a safe and effective manner.

If the States were to allow medical physicists to image and treat just like radiation therapists, then additional education and training would have to be included in their curriculum to give the background necessary to deliver the same quality of care to patients as provided by therapists.

Rebuttal: Michael S. Gossman, M.S.

Although I agree with many of the points made by my esteemed colleague, I assert that individuals designated as Qualified Medical Physicists are more skilled than technologists to perform any and all technical work. Due to the vast array of machines used in the field, no single technologist will come out of school knowing how to operate all the equipment they are assigned to use. Parallel to that, there should never be a time when a new piece of equipment arrives in a department for imaging or therapy that a Qualified Medical Physicist does not provide acceptance testing on it (thereby learning its functionality), commission it prior to use, creating policies and procedures for its uses, and providing in-service training for those who will operate it. Departments which function otherwise do not adequately follow AAPM Task Group recommendations (TG-40, TG-45, TG-5, TG-2, and TG-74) in therapy and imaging and should be deemed out-of-compliance under accreditation review.[10,11,12,13,14]

The designation "Qualified Medical Physicist" ensures that the individual has had the education, training, and experience necessary to direct and facilitate imaging studies and treatments. Such assurance is not always true for technologists. For example, most radiation therapists have insufficient education and training to qualify them to deliver treatments involving the application of radioactive materials such as prostate seeds, HDR, LDR, etc. For HDR especially, hospitals and physicians should not be forced to pay therapists to simply press the "ON" buttons. Any emotional and psychological duties related to patient needs can be entirely addressed by a more qualified physician or nurse present in the department.

The problem here is with the definitions of "*imaging*" and "*treatment*" in many State regulations. States need to correct the definitions to include the Qualified Medical Physicist within the scope of treatment and imaging, and further remove the scope of treatment involving brachytherapy from therapists entirely.

Rebuttal: Lisa A. Burgess, M.S.

I agree that we are not debating the need for medical physicists to image or treat. However, *allowing* physicists to image or treat implies they have all the necessary skills to do so. The field of radiation therapy and imaging has changed drastically since its first inception. The technical demands of the fields have necessitated specialization by certain professionals. The education of different staff reflects the changes in the field and provides the necessary skills needed to perform all the tasks. For example, it is not reasonable to expect one person to have the technical expertise necessary to perform MRI, CT, and nuclear medicine studies.

I agree that we may be on the path to "radiologic overregulation" as Mr. Gossman stated. However, there is a distinct difference between planning patient treatments and delivering them. The planning of treatments does not involve interaction with the patient. It is the medical physicist's responsibility to curtail overregulation through education of the regulators to distinguish between patient interactions, such as in treatment delivery, and nonpatient interactions, such as treatment planning. The statement made by Dr. Wilson: "A clinically oriented medical physicist should be allowed to treat" could lead to an entirely new Point/Counterpoint debate. We have QMP in our vernacular but a definition of

Clinically Oriented Medical Physicist currently does not exist and, I am sure, would lead to much debate in order to specify the qualifications.

Even though according to R. Nick Bryan, "Medical physicists are understood to be superior to technologist for radiation safety and physics of imaging,"[5] there is no mention of the patient care aspects of treatment delivery. I agree that qualification is paramount and though medical physicists are highly trained scientists, they are not caregivers—The care of the patient needs to be left in the hands of the therapist. It must be remembered that patients have individual needs and each individual's care not only involves a technical delivery but is very much an emotional and psychological delivery; one that I feel the physicist is not superior to the technologist in delivering.

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7.9. Radiotherapy physicists have become glorified technicians rather than clinical scientists

Howard I. Amols and Frank Van den Heuvel
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OVERVIEW

With the advent of the requirement for graduation from an accredited medical physics residency program in order to become certified and the emergence of Doctorate in Medical Physics, there has been some concern that radiotherapy physicists are becoming more like "trained" professionals, or even "glorified technicians," than "educated" scientists. This is the concern debated in this month's Point/Counterpoint.

Arguing for the Proposition is Howard I. Amols, Ph.D. Dr. Amols was awarded his Ph.D. in Physics by Brown University in 1974. He then became an NCI postdoctoral fellow at Los Alamos Laboratory and subsequently has held professional positions in therapy physics at the University of New Mexico, Brown, and Columbia Universities, and (according to him) used to be a scientist. Since 1998, he has been Chief of the Clinical Physics Service at Memorial Sloan Kettering Cancer Center, where he directs the activities of about 50 other physicists. He is certified by the ABMP and is a Fellow and past President of the AAPM. Someday (so he says), he hopes to become a scientist again.

Arguing against the Proposition is Frank Van den Heuvel, Ph.D. Dr. Van den Heuvel is Professor at the Katholieke Universiteit, Leuven, Belgium, and the Director of Medical Physics in the Department of Experimental Radiotherapy at the University Hospitals Gasthuisberg in Leuven, having previously spent almost ten years at Wayne State University, Detroit. He obtained his Ph.D. in Physics from the Free University in Brussels. His main interests lie in patient and organ positioning, incorporating radiobiological models into clinical planning, and using computers to make his life easier.

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

Opening Statement

Unlike most Point/Counterpoint columns which debate the pros and cons of something (e.g., PET scanning is or is not useful, etc.), this column is a semantic debate. What are the definitions of "technician" and "scientist," and which more accurately describes most medical physicists? Let us start with the dictionary. Okay, nobody under the age of 107 uses a dictionary anymore, so let us consult Wikipedia.[1]

Scientist: *Any person who engages in a systematic activity to acquire knowledge; an individual that engages in such practices and traditions… linked to schools of thought or philosophy… who uses the scientific method.*[1]

Physicist: *A scientist who studies physics. Physics… deriving from the Greek "φύσις" meaning "nature" or natural science. The study of matter and its motion through spacetime and all that derives from these, such as energy and force… the general analysis of nature, conducted in order to understand how the world and universe behave.*[2]

A "real" dictionary[3] defines science as "*a branch of study concerned with observation and classification of facts and especially with the establishment of verifiable general laws.*" I can end my argument here—Not one in ten medical physicists meets this definition of scientist, but I am supposed to write 500 words, so—If we are not scientists, maybe we are clinical scientists? Clinical science… *the practical*

study of medical principles or investigations using controlled procedures to evaluate results.[4] Other than occasionally participating in clinical trials, most of us (medical physicists) rarely do that, so we are not clinical scientists either.

By process of elimination then we must be technicians. Technician: *Someone in a technological field who has a relatively practical understanding of the general theoretical principles of that field… more versed in technique compared to the average layman… A midlevel of understanding of theory and a high level of technique is generally mastered by the technician… to become expert in a specific tool domain… a medical technician is an employee who provides technical support in the medical industry or to the medical profession*.[5] Webster's definition is similar: Technician: *A person who has acquired the technique of a specialized skill or subject*.[3] Is not that us?

Is not the current "anti-Ph.D./pro-residency" trend indicative of the shift toward training medical physicists for a "specific tool domain" rather than a "high level of understanding of theory?"

Do some medical physicists "engage in a systematic activity to acquire knowledge," or study "how the world and universe behave" as per any reasonable definition of scientist? Sure, but what about the other 95% of us who spend less than 5% of our time engaged in such endeavors and instead have only a "midlevel of understanding of theory" and are "employees who provide technical support… to the medical profession?"

Calibrating x-ray machines, running computer programs, designing and implementing a QA program, and evaluating new technology and making it work is all important stuff but it is not science. "Be happy in your work."[6] "To thine own self be true."[7]

AGAINST THE PROPOSITION: Frank Van den Heuvel, Ph.D.

Opening Statement

There is a lot of routine in what we do and a lot of the things we do can be done by people with other skills and background. This involves doing monthly QAs, calibrations, making and checking treatment plans, etc. All of this is straightforward and can be done by following recipes (TG51, TG142, etc.…), and making checklists.[8,9,10,11,12,13] It does not take someone who has passed quantum mechanics to do this. So why do we need someone like that?

There are several reasons. First, what happens if things on the checklists or recipes do not have the expected results? Now you need someone who really understands why the recipes are set up as they are. What is the theory behind it? What types of errors can generate the results? Why is it that you need to measure dose in an electron field at a given depth? What if you cannot use water for your measurement medium?

Second, what are the boundaries within which the given techniques and algorithms work? Remember the first IMRTs when we obtained strong skin reactions? That is right, most algorithms do not work at tissue interfaces. Which algorithm to use for which technique? Does everything work out when you install or upgrade a planning system? I have seen weird stuff in very expensive software by reputable companies.

Third, the technology in RT is evolving rapidly. New techniques (IMRT, VMAT, IGRT, protons, carbon ions, gating, nanotechnology, and mini x-ray sources) are introduced with increasing speed. Who has the background to understand these techniques rapidly? Get them working in a clinical environment with all the necessary checks and set them up so that some of the work can be delegated. It is part of the job of physicists to make themselves obsolete for the delivery of certain procedures. I remember introducing computerized planning into our practice (to be honest, George Sherouse wrote it[14] and we introduced a few if-then-else statements to make it work in our place), networking, record and verify, and electronic imaging. All of this using the knowledge we had of computer science, hardware, and mathematics,

including statistics. Now you buy a planning system with all the bells and whistles. Not all new technology introduced by these companies works in the way it is advertised. There is a lot of wishful thinking. You need these stubborn physicists with their models and calculations to tell you that the emperor has no clothes.

Finally, physicists are in an interesting position in that they have oversight of the complete chain of events that is needed to treat a patient adequately and safely. It is the physicists who have the best knowledge to understand why and how things can go wrong. And if they go wrong, they go wrong disastrously.

We should move away from the notion that all physicists do are chart checks and machine QA; they are the resident scientists and lubricant that makes a department tick. The education of physicists should reflect that they should be scientists with a thorough schooling in all the aforementioned areas. You can drive your car pretty far without lubricant but it will blow up in the end.

Rebuttal: Howard I. Amols, Ph.D.

I fear that my esteemed colleague's description of the work of medical physicists as being akin to that of other scientists or describing them as "resident scientists and problem solvers" is outdated. I think he is talking about Harold Johns, John Laughlin, John Cameron, and other dead people. Over recent years the AAPM has worked toward changing medical physics from a science into a profession, and has largely succeeded in this questionable goal. Most members of the AAPM now want to be medical professionals, not scientists. They do not want Ph.D. or even MS degrees—They want Doctorates in Medical Physics. They want to close the field to chemists, computer scientists, and the like, and accept only bona fide CAMPEP approved medical physicists. They do not want to do fellowships like other scientists, but rather residencies like other medical professionals. These are not just words, labels, or job titles. They represent genuine changes in philosophy and in the definition of our field. A university is composed of various schools. Scientists obtain degrees from Schools of Arts and Sciences as opposed to professionals who obtain their degrees from the professional schools within the university such as the Schools of Medicine, Law, Business, etc. In the School of Arts and Sciences you learn how to think, how to discover new knowledge, how to be a Renaissance man (or woman), and how to lubricate Dr. Van den Heuvel's car before it blows up. In the professional schools, you basically learn a trade and how to make a buck. Medical physics has become a trade.

When something breaks in the hospital, such as a linac or a scanner, most people call the manufacturer's service engineer rather than the medical physicist. When the treatment planning computer starts giving strange results they call the manufacturer's software help desk. The medical physicist used to be the "resident problem solver," but that is rapidly changing. I am afraid that Dr. Van den Heuvel has described yesterday's medical physicist, not today's, and certainly not tomorrow's.

Rebuttal: Frank Van den Heuvel, Ph.D.

It is always rewarding in a debate to see your opponent go the "semantics" route. This is usually an admission of weakness with regard to the real content of the proposition. Essentially, Dr. Amols is telling medical physicists that they never were and never will be scientists, and that they are at best aides to the physicians without their own minds.

Let us look at all of the definitions provided by Dr. Amols and pick the one that applies to a medical physicist, namely, scientist—One who uses the scientific method. I certainly hope that the medical physicists we train are well versed in the scientific method. By the scientific method I do not only mean the experimental validation and refutation of scientific facts, but also the use of physical models to describe reality, something our physician colleagues are not necessarily good at. By that definition I daresay medical physicists *are* scientists.

Of course if you want to be considered a scientist, *be* a scientist. It is easy to be caught up in the routine of day-to-day work. Clinical physicists should stay interested in changes in the scientific environment. This means to educate themselves constantly on new concepts, techniques, and advances in their field. In order to be a scientist you have to act like one. Be curious, ask questions, find answers, and look further than your current knowledge. Try to develop new technologies yourself and not wait for someone else to develop (or sell you) them. There is nothing stopping you from proposing new technologies to companies: They will be happy to use anything you can bring them. Examples are legion: VMAT,[15] RapidArc,[16] TomoTherapy, etc., not all of which have been introduced by large academic departments.

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7.10. The Chief Information Technology Officer in a Radiation Oncology department should be a medical physicist

R. Alfredo C. Siochi and Collin D. Brack
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OVERVIEW

The Chief Information Technology Officer (CITO) in a Radiation Oncology (RO) department needs to be familiar with not only all aspects of radiation oncology technology but also with the information technology (IT) field, which is ever increasing in complexity. Some would argue that the IT field has become so specialized that only an IT professional should be the CITO, but others might claim that only a medical physicist who understands all the intricacies of radiation oncology should assume this role. It is this latter premise that is the Proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is R. Alfredo C. Siochi, Ph.D. Dr. Siochi received his BS in Physics from Ateneo de Manila University in 1985, his M.S. and Ph.D. in Physics from Virginia Tech in 1988 and 1990, respectively, and his M.S. in Radiological Physics from the University of Cincinnati in 1995. He is currently an Assistant Professor and the Director of Medical Physics Education in the Radiation Oncology Department of the University of Iowa. He is also the Chair of the AAPM Working Group on Information Technology. His current research interests are in the areas of 4DRT verification and QA software development for paperless clinics. Dr. Siochi is certified in Therapeutic Radiologic Physics by the ABR.

Arguing against the Proposition is Collin D. Brack, MBA. Mr. Brack obtained his MBA from the University of Houston and is a certified professional in health information management systems. He is Manager of Software System Programming at the University of Texas Medical Branch, Department of Radiation Oncology where he specializes in medical imaging, oncology informatics, and high performance computing for medical physics research. He has published and presented on the topics of system design, stereoscopic imaging, and EMR disaster recovery. He is currently President of the Health Information Management Systems Society, Houston, TX.

FOR THE PROPOSITION: R. Alfredo C. Siochi, Ph.D.

Opening statement

The appropriate management of IT in RO is crucial to the safe, effective, and timely delivery of radiation therapy (RT). The medical physicist is in the best position to understand the propagation and transformation of data through imaging, planning, treatment, archiving, and retrieval of prior plans.[1] The management and nature of that data have been the subject of many AAPM task group reports[2,3,4] that further prepare the physicist to handle the nuances and clinical implications of these data intensive processes.

As physicists trained in every aspect of the RT clinical workflow, we have a profound appreciation of the effects of downtime, upgrades, and installations of imaging devices, treatment planning and linac control systems, and electronic medical records [especially the record and verify (R&V) portions] on our ability to deliver the radiation dose distributions the physicians prescribe. We are called upon to handle problems that prevent, delay, or interrupt treatment delivery. We are uniquely qualified to address the situation with clinically appropriate actions that also satisfy legal obligations to verify the transfer of dose-related parameters.[5,6]

With RO highly dependent on computer control systems, troubleshooting involves in-depth knowledge of the specialized applications and computers. While a person trained in IT may be familiar with the processes involved in the maintenance of such systems, the management of these systems requires an understanding of the impact of these processes on dosimetric and positioning accuracy. Appropriate timing and execution of these tasks are necessary to allow physicists to ensure that all the clinical data (e.g., treatment planning commissioning data, adaptive imaging data) as well as their interpretation by various systems have been preserved.

Historically, the RO medical physicist assumed IT-related responsibilities and has contributed much to healthcare IT.[7] Our IT education and skill set grew in the context of the RO clinical workflow. Hence, we have developed policies and procedures that make our IT activities consistent with the overall goal of safe and effective treatments. While the practice of medical physics has become more demanding and we require help from IT professionals, many of our IT colleagues lack the necessary depth of understanding of RO clinical operations.[8] We still must provide guidance to them. We are well prepared to make decisions about the required level of IT support and availability, the allocation of IT tasks, and the related QA activities that should accompany these IT processes. RO-related IT resources and activities must be managed by a professional who has the clinical experience to evaluate the impact of those management decisions on the care of patients. Therefore, a medical physicist should be the Chief IT Officer in RO.

AGAINST THE PROPOSITION: Collin D. Brack, MBA

Opening statement

The title CITO, as with most technical titles, including my own, suffers from ambiguity. A few definitions and assumptions are in order. The Chief Information Officer (CIO), a member of the executive committee, is involved in strategy decisions for enterprise information systems.[9] The Chief Medical Information Officer (CMIO), a clinical executive, leads the hospital's electronic medical record (EMR) initiative and manages the clinical IT department.[10] By extension, the CITO would operate at the departmental level and have final authority on IT selection and strategy.

Dr. Trueblood and Dr. Hogstrom discussed the physicist's role within the field of informatics in 2000 when the prevailing concerns included EMR, PACS, HIS/RIS, and networking.[11] The conversation is still relevant today as the list of informatics concerns continues to grow. Kagadis *et al.*[7] identified three key informatics-related issues in radiation therapy which have augmented the role of the medical physicist, namely, R&V QA needs, hospital and radiation oncology EMR integration, and PACS. Furthermore, the Center for Studying Health System Change found oncology's clinical IT adoption rate to be the highest among medical specialties.[12] A dedicated CITO position would address these and future informatics concerns in radiation oncology.

Enter human resources. I propose the following CITO job description: IT vendor selection authority, budgetary authority to set and manage a departmental IT budget, trend analysis, strategy formulation, and project leadership. The CITO would also serve as radiation therapy and oncology informatics advisor to the CIO and CMIO. For example, if a hospital is replacing an end-of-life PACS, the CITO would sit on the selection committee and argue for the inclusion of DICOM-RT as part of the vendor selection criteria. The hospital IT landscape is constantly changing, and a CITO must be cognizant of clinical informatics trends inside and outside the department. A sampling of informatics projects within the CITO's jurisdiction include radiation oncology information system (ROIS) interface engines (HL7) for code capture, laboratories, formularies, discharge summaries, cancer registries, and transcriptions. Disaster preparedness, data redundancy, and secure off-site access to PACS and ROIS also require CITO leadership and project oversight. Larger departments have costly and formidable IT projects in the form of multisite R&V infrastructure, teledosimetry, and clinical trial integration—all of which necessitate a CITO.

The ideal CITO candidate based on the above examples would be a master's level medical informaticist with at least 5 years of experience. My contention against a medical physicist assuming the role is not based on ability but is instead based on the full-time commitment required to fulfill the CITO role. In a similar fashion, physicists do not assume the role of PACS administrator but instead provide strategy and technical expertise to this individual.[13] The AAPM report on peer review in clinical radiation oncology physics[14] addresses IT as a peer review component but does so by listing software updates for major equipment within the context of patient safety and service continuity. In matters of patient safety, the medical physicist should clearly take a leadership role while the CITO lends assistance.

Rebuttal: R. Alfredo C. Siochi, Ph.D.

The day-to-day work of ensuring the security, integrity, communication, and redundancy of data does indeed require dedicated IT staff, especially in the era of image guided radiation therapy. A master's level medical informaticist, however, even with 5 years of experience, would not have had sufficient clinical exposure to the subtleties of data transformation within the IT workflow in RO. For example, IT personnel with experience in radiology may be aware of image quality issues, but they most likely do not have experience with RO databases and applications that control the delivery of potentially lethal doses of radiation.

RO medical physicists have the training to make clinical judgments about IT. They fully appreciate the implications of IT decisions on the care of patients. While they may not have the full-time commitment to handle daily IT operations and the implementation of new projects, they have the appropriate domain knowledge and sufficient time to manage RO IT processes and communicate with other hospital IT decision makers. Although dedicated nonmedical physicist RO IT professionals may come to appreciate the nuances of RO data operations, this may require many years of experience. During that time, who should make the decisions?

Individuals like my learned opponent are rare. For most clinics, their IT support will come from the hospital IT group. RO departments typically do not have dedicated IT support, even though it is increasingly important that they do. Hospitals should at least have their IT departments dedicate specific individuals to RO. In these situations, the only individuals with the clinical judgment to make IT decisions are the medical physicists. Hospital IT should recognize the importance of the medical physicist's IT leadership and RO departments should allocate time for these duties through proper human resource management. The final authority of RO IT decisions must rest with the medical physicist. Appointing medical physicists to be CITOs would give them the voice needed for the IT decision making part of their jobs. In the end, these decisions have an impact on patient care, and the CITO must be willing to accept this clinical responsibility.

Rebuttal: Collin D. Brack, MBA

Key aspects of the RT workflow are highlighted in Dr. Siochi's opening statement and I concur that the medical physicist has a profound technical understanding of these processes. And rightly so, as the medical physicist has been instrumental in every technical RO milestone long before linear accelerator computerized control. The physicist must be granted authority to create and enforce IT policy surrounding mission-critical processes outlined by Dr. Siochi in matters of planning, imaging management, commissioning, and quality assurance.

Outside the boundary of the physics operational core, however, lies an ever-expanding set of IT duties as described in my fictitious chief IT officer job description. For example, R&V systems, previously reserved for machine data, have evolved into full-fledged radiation oncology information systems populated with patient data, demographics, scheduling, vitals, Rx dose, laboratories, and notes—all of which are key to physician workflow. The ROIS is one such system which has increased in scope beyond the typical physics workflow and as such could be assigned to the chief IT officer for archival, data mining, security, integration, and curation efforts.

Granted, there are intimidating IT challenges within RO physics, and Dr. Siochi is correct to assume that an IT generalist would not be well suited to the specialized nature of RO. My contention is that the CITO must possess specialized informatics training with experience in EMR/RIS, PACS, HL7, and IT project management. The increased adoption of informatics standards (e.g., DICOM-RT) and initiatives such as integrating the healthcare enterprise in RO have removed barriers to entry for informatics professionals into RO. With an increased supply of graduates from healthcare informatics programs, the timing is right to establish the position of Chief IT Officer. As for the selection committee, one well stacked with medical physicists will yield the best candidate.

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7.11. Radiation departments should be certified to provide certain new technologies such as IGRT

Christopher F. Njeh and Abdul Rashid
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OVERVIEW

With new technologies for the radiation treatment of cancer being implemented at an alarming rate, it should be no surprise that some departments will adopt these new technologies without having the necessary staff to use them safely and effectively. In order to prevent this, it has been suggested that radiation departments should be certified before they put new technologies such as IGRT into clinical practice, and this is the Proposition debated in this month's Point/Counterpoint.

Arguing for the Proposition is Christopher Njeh, Ph.D. Dr. Njeh obtained his Ph.D. degree in Medical Physics from Sheffield Hallam University, U.K. and, after graduation, he worked at Addenbrooke's Hospital in Cambridge, U.K. and Queen Elizabeth's Hospital in Birmingham, U.K. He then came to the US as a Visiting Postdoctoral Fellow at the University of California, San Francisco, CA where he was subsequently appointed an Assistant Professor of Radiology. He later completed a Medical Physics residency at Johns Hopkins University, Baltimore, MD and is currently Chief Medical Physicist at Texas Oncology in Tyler, TX (a subsidiary of US Oncology) and holds an adjunct faculty position at the University of Texas at Tyler, TX. Dr. Njeh is certified in Therapeutic Radiologic Physics by the ABR and his major research interests are ultrasonography and bone densitometry.

Arguing against the Proposition is Abdul Rashid, Ph.D. Dr. Rashid obtained his Ph.D. degree in Atomic Physics from Quaid-i-Azam University, Islamabad, Pakistan in 1999. Subsequently, he completed a 2 year Medical Physics residency at Johns Hopkins University, Baltimore, MD in 2002 and is currently Director of Stereotactic Radiosurgery in the Department of Radiation Oncology, Georgetown University Hospital, Washington, DC. His major research interests include image guided radiotherapy and radiosurgery, breast and prostate radiosurgery, and magnetic nanoparticles for molecular imaging.

FOR THE PROPOSITION: Christopher F. Njeh, Ph.D.

Opening Statement

Recently radiation therapy has experienced an explosion in technological development, from 3DRT to IMRT, PET-CT, IGRT, and 4DCT. However, not every radiation therapy department is properly equipped with the infrastructure or personnel with the necessary expertise and training to provide these new modalities. It is my belief that radiation therapy departments should be certified to offer specific modalities. This certification process will provide assurance of sufficient knowledge and expertise of all personnel involved in the provision of radiation therapy. This includes, but is not limited to, radiation oncologists, medical physicists, medical dosimetrists, nurses, and radiation therapists. The main purpose of certification or accreditation is to foster healthcare safety and quality improvement. It also creates an atmosphere of self-regulation and self-assessment. Accreditation of radiation oncology practice has been implemented since 1996;[1] however, the proposed certification would take the process one step forward, where individual modalities are accorded certification just like PET or CT.

Effective radiation therapy depends on the accurate delivery of radiation. Its multifaceted process entails a high potential for error.[2] The accuracy of the final process is dependent on the weakest link in the radiation process. Poor patient simulation, for instance, would have an impact on the final treatment regardless of the scrupulousness of the treatment plan and accuracy of the linear accelerator calibration.

Evaluation and certification should not be limited to the radiation oncologists or medical physicists but should cut across the spectrum of all involved in the treatment process. Personnel should be aware that they are part of a chain; the stronger the rings the stronger the whole chain. Prostate localization using ultrasound presents a useful illustration of this chain metaphor. The radiation therapist greatly impacts the final outcome in localization but this is achieved through the interdependence of the various roles involved. Russell Ackoff's "system rule" points out that each part alone is insufficient for the system to function and each part depends on the behavior and properties of at least one other part of the system.[3]

In credentialing a department for participation in clinical trials, the Radiological Physics Center reported that 30% of institutions failed to deliver a dose distribution to a head and neck phantom that agreed with their own treatment plan to within 7% or 4 mm.[4] This is clear evidence that all departments with new technologies such as IMRT might not put it to optimal use.

We live in an era of evidence-based medicine, yet it would be unethical to carry out a controlled randomized trial to document the impact of certification. There is ample evidence, however, to support the fact that accreditation or certification does improve the quality of care.[5,6,7] For example, improved quality of mammograms in the US has been associated with American College of Radiology (ACR) mammography accreditation and MQSA. This has contributed to the early detection of breast cancer and consequently improved survival.[7]

The implementation of certification would generate discussion resulting in the establishment of guidelines and standards in the adoption of new technologies. These would in turn help in the identification of pitfalls and limitations of such new technology. These views are also echoed by the International Atomic Energy Agency (IAEA) 2006 international expert meeting entitled "Quality Assurance and New Techniques in Radiation Medicine."[8]

AGAINST THE PROPOSITION: Abdul Rashid, Ph.D.

Opening Statement

Every radiation therapy department should be ready to adopt new technologies that benefit patient treatment. How could anyone oppose measures taken to assure high quality patient care? The issue here is not to discuss whether such measures should be taken but to debate whether it is necessary for radiation departments to be certified whenever they acquire such new technologies.

The primary clinical responsibility of a qualified medical physicist (QMP) is "to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result as prescribed in patient care."[9] The patient is the ultimate beneficiary of a medical physicist's effort. The radiation therapy department can, and should, embrace recommendations and protocols advanced by the American Association of Physicists in Medicine (AAPM) and the ACR and conform to regulations established by appropriate regulatory agencies so as to assure that technology is safely and effectively used for patient treatments. It must be realized that when new technology is acquired, such as image guided radiation therapy, the technology itself may not be new, but the way it is used may be different. Certification does not, however, preclude the occurrence of mistakes: Recently the International Atomic Energy Agency published an analysis of accidental exposures in radiotherapy and suggested measures for the prevention of such incidents.[10]

Numerous AAPM Task Group reports address specific technologies and clinical procedures and many of these practice patterns have been endorsed by the ACR.[11,12,13,14] Recommendations are available to test and commission new technology and any QMP should be capable of performing these tests. Because of the high cost of some of these new technologies such as IGRT, departments should not be burdened by the extra cost of certification since the personnel who are involved are already adequately trained and certified to commission and use these technologies safely and effectively. If new technology is acquired

and we add certification to the requirements, this will unnecessarily add to the cost of treatment and these additional costs will ultimately have to be borne by patients.

Rebuttal: Christopher F. Njeh, Ph.D.

Dr. Rashid states that "every radiation department should be ready to adopt new technologies." The reality is, however, that not every department is ready to adopt new technologies because of factors such as fiscal constraints and dearth of qualified personnel. Those that can surmount these obstacles need some kind of certification or accreditation to set them out from the pack.

Dr. Rashid further advances two important points: Expectation and cost. The expectation is that radiation departments are staffed with appropriately trained personnel. Radiation therapy, however, is technologically driven and most are staffed by personnel whose initial training may not have included these technologies. This is why professional certification boards have adopted maintenance of certification requirements.

The cost of "certification" should be put in context. New technologies are always associated with higher reimbursements; hence, like every investment, the cost of certification for that technology could easily be recouped.

I beg to disagree with Dr. Rashid's assumption that certification will not preclude accidents. In reviewing radiotherapy incidents, Shafig *et al.* concluded that lack of appropriate training was one of the contributing factors to these incidents and that 45% of incidents were attributable to errors that occurred during the introduction of new systems.[15]

Dr. Rashid finds solace in ACR and AAPM protocols for the implementation of new technologies. These protocols, however, are just recommendations and their implementation remains voluntary. A recent paper by Das *et al.* showed that even *with* protocols, there is still significant variation from institution to institution.[16]

In conclusion the admonition "First, do no harm," paraphrased from the Hippocratic oath,[17] has long been a universal guiding principle for the delivery of healthcare services. The regulation and accountability that come with accreditation and certification would invariably check the incidence of "harm," thereby inching us closer to the strict observation of that sacred oath.

Rebuttal: Abdul Rashid, Ph.D.

Dr. Njeh has made some excellent points in his argument for the need for certification of departments whenever they acquire new technology. I agree with Dr. Njeh that excellence must continue to be a priority in our radiation oncology departments. It is quite reasonable to assume that the best interests of patients are tied to good facilities, qualified personnel, and good clinical practices.

I also agree with some of Dr. Njeh's arguments for the need for certification of personnel involved with new technologies. However, Dr. Njeh fails to acknowledge one point: Certification is voluntary. Experience shows that such voluntary activities are not widely adopted. Take the American College of Radiation Oncology practice accreditation, for example: Only 290 centers have become accredited, of which only 204 are currently active, and 30% (86) have not applied for reaccreditation after the expiration date.[18] Similarly, only about 50% of mammography units were accredited when it was a voluntary service.[19] It is also interesting to note that, when the mammography accreditation program was voluntary, for 31.3% of the units that did not pass accreditation, users chose to not correct the identified deficiencies in order to reapply for accreditation.[7] To make accreditation or certification effective, it should be made mandatory (by regulation) or linked to reimbursement.

I also feel that I must respectfully disagree with Dr. Njeh's arguments on the adoption of new technology. My esteemed colleague 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 with the trained personnel involved.

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7.12. The title “radiation oncology physicist” should be changed to “oncologic physicist”

William P. Kowalsky and Martin W. Fraser
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OVERVIEW

Some years ago, physicians who practiced radiotherapy changed their appellation from “radiation therapists” to “radiation oncologists.” This led radiotherapy technologists to seize the opportunity to change their name to “radiation therapists.” It has been suggested that maybe radiation oncology physicists are in need of a change of title, possibly to “oncologic physicists.” This is the proposition debated in this month’s Point/Counterpoint.

Arguing for the Proposition is William P. Kowalsky, Ph.D. Dr. Kowalsky received his Ph.D. in physics from New York University and is certified by the American Board of Radiology in therapeutic and medical nuclear physics. After spending 25 years at St. Vincent’s Hospital in New York City, he moved to Mississippi in 1994 where he is currently chief physicist at the Baptist Memorial Hospital in Columbus. While at St. Vincent’s his main interests were in hardware and software development in radiotherapy and nuclear medicine. In Mississippi his interests have been the history of mathematics and physics, and tramping around his farm with his dogs.

Arguing against the Proposition is Martin W. Fraser, M.S. Mr. Fraser has been a radiation oncology physicist for over 30 years, practicing mainly in the community setting at various clinics in Eastern Massachusetts. A graduate of Northeastern University (BS, Physics) and the University of Massachusetts Lowell Graduate program, he returned to academia in 2007, taking a position at Tufts Medical Center Radiation Oncology Department. Mr. Fraser is a Past President of the New England Chapter of the AAPM and has served the national AAPM in a number of capacities including as a member of the Board of Directors and, currently, as Chair of the Clinical Practice Committee. He is certified in therapeutic radiologic physics by the American Board of Radiology.

FOR THE PROPOSITION: William P. Kowalsky, Ph.D.

Opening Statement

Therapy physicists have never taken much of an interest in determining their professional title. Our colleagues, however, were wiser. Dr. J. Frank Wilson, a historian of radiotherapy, gives the following account of the development of the title “radiation oncologist:”[1] The original title for a radiotherapy physician was therapeutic radiologist. By 1970, this had been changed to radiotherapist. Pressure by radiotherapists for a second change came from their desire for recognition as cancer specialists equal in every respect to medical oncologists and for the disentanglement from similar sounding professional titles such as physical therapist and occupational therapist. The designation of radiation oncologist was the end result. Therapists at this time were known as radiotherapy technicians or technologists. When the physicians abandoned the therapist title, the technologists claimed it for their own and became radiation therapists.

Both of these professions gained substantially by a title change while we radiation oncology physicists sat smugly back thinking that no title could possibly be superior to that linked with Röentgen, Curie, etc.[2] We did not realize that we had already created a new clinical profession that deserved a well thought out clinical title. The problem with the designation radiation oncology physicist is subtle but important. Oncology is defined as the study or science of tumors or neoplasms.[3,4] In the hospital,

however, radiation oncology means, to most people, a department where cancer patients are treated. A radiation oncology physicist is therefore a physicist who works in radiation oncology. Similarly, a radiation oncology plumber would be one who fixes pipes in radiation oncology. Now we see the difference between our title and that of our colleagues. A radiation oncologist is a specialist in the clinical science of radiation oncology. A radiation therapist is a specialist who treats disease with radiation. Do we want our title to associate us with a place of work or a clinical specialty? I argue that it is the latter and therefore the title radiation oncology physicist should be retired.

The above argument also rules out radiotherapy physicist, therapy physicist, and oncology physicist. What is left? I submit that only three titles remain that are not overly long, are specific to our subfield, and still make sense: Oncologic physicist, oncological physicist, or physical oncologist. The first two have identical meanings[5] but oncological is longer and sounds rather singsong compared to oncologic. The last is a possibility but, although some definitions of oncologist simply indicate a specialist in oncology,[3] others indicate a physician specialist in oncology.[6] The title physical oncologist also breaks the last ties we have with our parent science. It has been stated by a past president of the AAPM that members want to be professionals not scientists.[7] If this is the case, we should call ourselves oncologic physicists today and physical oncologists at some point in the future when doctoral programs or residencies in physical oncology come into being. In any case we should claim the title oncologic physicist before the physicists in the newly formed Physical Sciences-Oncology Centers[8] appropriate it for themselves.

AGAINST THE PROPOSITION: Martin W. Fraser, M.S.

Opening Statement

It is incumbent upon any thriving profession to periodically engage in a bit of self-examination and ask if it has deviated from its once presumed province to the degree that some dearly held definitions and characterizations are no longer appropriate. In this spirit I am happy to examine the question at hand. Have we evolved to the degree that our established title has become antiquated? Inaccurate? Or, worse yet, was it always ill chosen? After all, our primary certification was called *X-Ray and Radium Physic*s up until 1961, and the improved *Roentgen Ray & Gamma Ray Physics* through 1975,[9] and now the American Board of Radiology (ABR) is considering another change under the theory that "Radiologic Physics" is passé. Is the title *Radiation Oncology Physicist* equally moribund? After due consideration, I am happy to report that to the questions framed above, the answer is clearly NO, on all points.

The proposal points to an unusual coinage: "Oncologic Physics" and the fact that your search engine will offer a dearth of citations on the phrase is not an adequate reason to reject it out of hand. After all, it has the ring of Radiologic Physics, the respected, if soon to be former, ABR certification. Indeed, there are cases to be made for numerous alternate professional titles. The logical flaw in the proposal here is, as any practitioner will quickly point out, that "Oncologic" (i.e., "of or relating to the study of cancer") hardly encompasses the breadth of radiotherapy physics. Books have been written on noncancerous conditions that are amenable to treatment with ionizing radiation[10] and so a logical step might be away from the *onco* prefix and toward a bigger-tent term like *Therapeutic Medical Physics*. Clearly, the rubric of "treatment" encompasses our routine endeavors, whether we are treating metastatic lung cancer or mycosis fungoides.

But that is not the question. The proposal, *Oncologic Physicist*, while it may ignore some common activities and research, will certainly include essentially all physicists who presently consider themselves to be Radiation Oncology Physicists and so would be adequate on that score. Perhaps the benefit intended by my opponent is derived from the ablation of the nasty term "radiation." Why? Well it is off-putting, a bit dangerous sounding even, and a good marketing person would surely nix it in a flash. And is not marketing important? Are not we all salespersons at some level?—only to a degree. Not to the degree, however, that we may ignore science, ignore our heritage, ignore the day-to-day

reality of our profession in favor of a cheerier title. There is not going to be a sitcom on NBC featuring the exploits of a trio of zany Medical Physicists, no matter how happy or sexy our job title!

We are encumbered with the weight of a professional ethic, which dictates that we embrace precision over euphemism, and in the process declare our conviction that "radiation" is neither to be feared nor ignored but embraced and respected. We strive to educate other professionals and the public as to the favorable risk/benefit of the judicious use of ionizing rays—to deny the term on our shingle would be hypocrisy indeed.

Rebuttal: William P. Kowalsky, Ph.D.

My opponent has two objections to the title oncologic physicist: (1) Noncancerous lesions are treated with radiotherapy and (2) the word radiation is missing from the title.

For the first objection, I must reiterate that oncology is the study of tumors or neoplasms[3,4] (many of which are benign) and not the study of cancer, as my opponent incorrectly states. Incidentally, mycosis fungoides is a malignant neoplasm, a lymphoma, in fact,[11] placing it squarely in the realm of oncology. Also with regard to this first objection, mention may be made of the title of one of the most successful specialists in radiotherapy: The radiation oncologist.

The second objection is more emotional. The word radiation tacked onto any title that also contains physicist (except radiation physicist, which is already taken and does not describe our profession) results in a long, multisyllabic title of at least three words. As my opponent says, a marketing person would nix such a title, but not for the reason given. Madison Avenue has always known that conciseness matters in choosing a name. Unlike the words oncology and therapy, Webster's definition of physics contains the word radiation: *Physics: "a science that deals with matter and energy and their interactions in the fields of …radiation…."*[5] There is, therefore, no need to include radiation in our title.

The title oncologic physicist has much going for it. I have already mentioned the Physical Sciences-Oncology Centers[8] where principles of physics will be applied to the treatment of cancer. These principles involve a much broader range of phenomena than just ionizing radiation. In the future, oncologic physicists may branch out into fields of cancer research and clinical practice which may not involve accelerators, Gamma Knives, and high dose rate afterloaders. The title oncologic physicist suits us well for the present and into the future.

Rebuttal: Martin W. Fraser, M.S.

We have heard many options presented in the quest to relabel our profession, and most are inoffensive and (with the possible exception of "physical oncologists") relatively unambiguous. The effort appears to be to embrace the "onco" prefix, while paring away the qualifying adjective "radiation." Some would consider this change to be progress and evidence that we, like our MD and RTT colleagues, can define our field as we wish and change our appellation on whim.

Some of us old enough to have worked with "technicians" only to be one day corrected in our salutation, once to "technologist" and later "therapist," met the retitling with a wry smile of amusement. A rose remains a rose (or perhaps a thorn, a thorn) and most readers will feel, I will wager, that our present title is not in need of editing.

Radiation Therapy Physicist is clear and correct. My opponent contends that Oncologic Physicist is more correct and he even resorts to parsing the expression and calling up the textbook definitions. This approach, however, illustrates the failure of the title.

Physicist we can agree with, but Oncologic? In what possible sense can we physicists be thought of as oncologists? Do we study tumors? Are we expert in the area of neoplastic cells? No. In fact, the knowledge of oncology is precisely the bright line that separates our responsibilities and skill sets from those of our physician colleagues. The term "radiation oncology" in the present title does, as my

opponent argues, modify “physicist” in such a way as to identify where we ply our trade. This is clear and correct. To describe ourselves as “oncologic(al) physicists” is to state that we are physicists who specialize in the study and nature of tumors—a claim that could not be further from the truth.

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7.13. The professions of Medical Physics and Clinical Engineering should be combined into a single profession "Clinical Science and Technology"

Wilhelm J. M. van der Putten and Chadd E. Smith
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OVERVIEW

In North America, Medical Physics and Clinical Engineering are two separate professions, represented by different professional and scientific organizations, and different departments in hospitals and universities. In other parts of the world, however, especially in Europe, these two professions are represented by combined professional and scientific organizations and single departments. It has been suggested that the professions of Medical Physics and Clinical Engineering should be combined into a single profession "Clinical Science and Technology," and this is the premise debated in this month's Point/Counterpoint.

Arguing for the Proposition is Wilhelm J. M. van der Putten, Ph.D. Dr. van der Putten was awarded an M.Sc.(Eng) degree in Applied Physics from Eindhoven University of Technology (The Netherlands) in 1980. After National Service, he subsequently moved to Ireland where he was awarded a Ph.D. from Trinity College Dublin in 1987. Since then, he has worked in all areas in medical physics in both Ireland and Canada. He has been in Galway since 1995, where he developed a department of medical physics and bioengineering from scratch. The department covers radiotherapy, medical imaging, radiation protection as well as clinical instrumentation. He is currently Chief Physicist in Galway University Hospitals and Adjunct Professor of Medical Physics in the National University of Ireland, Galway. He is currently Chair of the Professional Matters Committee of EFOMP. He is a Fellow of both the Institute of Physics and Engineering in Medicine (UK) and the Canadian College of Physicists in Medicine. He is a consultant to the IAEA.

Arguing against the Proposition is Chadd E. Smith, Ph.D. Dr. Smith received his Ph.D. in Physics from Johns Hopkins University in 2002 for his work in high-energy physics involving a search for supersymmetric particles at Fermilab. After four years of postdoctoral research at the University of Illinois at Chicago, he completed two years in the medical physics residency program at the University of Michigan in 2008. He is currently a Senior Associate Physicist and Associate Director of the newly CAMPEP-accredited Medical Physics Residency Program at the Henry Ford Health System in Detroit. He is the current President of the AAPM Great Lakes Chapter.

FOR THE PROPOSITION: Wilhelm J. M. van der Putten, Ph.D.

Opening statement

Medical Physics is a branch of Applied Physics which is the study of physics and physical methods in all branches of science, engineering, and technology. Medical physics is the application of physics and physical methods to problems in the field of medicine. Applied physics and *ipso facto* medical physics are thus closely related to engineering.

Engineering in turn is the discipline dealing with the art or science of applying scientific knowledge to the design, building, and use of machines.[1] As such, clinical engineering is the application of engineering principles and technology to medicine and medical devices.

It is clear that both applied physics and engineering do not exist in a separate environment but that there is a continuum in science and technology with "pure" engineering on one side and applied physics on the other. These two apparent extremes are linked through the use of equipment and technology. The "physics" side may concern itself with knowledge obtained through modeling and measurements using technology and instrumentation whereas, in contrast, engineering typically concerns itself with the actual technology in use.[2] In order to properly support the entire spectrum of medical technology in a hospital, it should be apparent that knowledge from the whole continuum ranging from medical physics to engineering is required.[3]

Having established that medical physics and clinical engineering are different only to a degree and that, in fact, most medical physicists and clinical engineers utilize principles from both areas in their everyday work, it is useful to consider where these two disciplines are applied in health care. Currently, medical physics appears to have limited itself almost exclusively to the use of ionizing radiation in medicine. For example, about 107 AAPM reports relate to the use of radiation in medicine, whereas only 19 are in topics such as MR and ultrasound and fewer still in other areas of medical physics. In practice, this means that medical physics is typically confined to radiology or radiotherapy departments. This implies that large areas of medicine are not supported by medical physics.

This arrangement of separate departments and narrow focus was considered adequate in the past. Rapid advances in health care technology, however, require now a broad scope of knowledge from other disciplines. Examples of this are biologically based radiotherapy treatment planning,[4] molecular imaging,[5] and an increasing pervasiveness of information technology with patient-connected devices.[6] Medical physics will in the future have to become involved in areas such as nanotechnology, molecular biology, and genetics,[7,8] if it is not to wither on the vine. This will increasingly require individuals with different education, knowledge, and skills compared that of the "traditional" medical physicist or clinical engineer. Boundaries between professions will disappear. Medical physics and clinical engineering should broaden their perspectives and be combined in a single profession, that of Clinical Scientist. If this does not happen, the profession of medical physics will be in trouble.

AGAINST THE PROPOSITION: Chadd E. Smith, Ph.D.

Opening statement

For medical physicists in the United States and Canada, the proposal to form a combined profession with Clinical Engineering may seem a foreign concept. In fact it is. Literally. In the United Kingdom and parts of Europe, the two disciplines often share academic departments, professional bodies (the Institute of Physics and Engineering in Medicine in the United Kingdom, for example), and coordinated training schemes such as the Moderinising Scientific Careers programs in the United Kingdom.[9,10] Even on this side of the pond, there exist commonalities between the two fields that could be leveraged. Yet an attempted merger would ignore fundamental differences in the roles each play in healthcare, dramatically reverse recent developments in training and certification, and create confusion for the public and practitioners.

Physicists are from Venus, engineers are from Mars

How clinical engineers and medical physicists self-identify provides insight into the subtle distinctions between them. "A clinical engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology," whereas the "essential responsibility of the Qualified Medical Physicist's clinical practice is to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result as prescribed in patient care."[11,12]

Both professions require similar skills and responsibilities for management of the technology utilized in patient treatment. The essential difference is that the physicist assumes additional responsibility in the actual care of the patient. Treatment planning and evaluation, quality assurance, and chart review have

no counterparts in clinical engineering. Subspecialization into “physicist” or “engineer” roles would likely continue even within a combined academic or clinical department.

Diverging pathways

The career pathway for medical physicists is asymptotically approaching that of our physician colleagues. The so-called “2014 Initiative” introduced changes to board certification eligibility that have driven CAMPEP accreditation of medical physics residency programs and altered the landscape of pathways into the field.[13] The AAPM Work Group on Coordination of Medical Physics Residency Programs has created the Common Application Program in order to ease the application process for both applicants and programs, as a first step toward a system similar to the National Resident Matching Program.[14] In the future, graduate degrees in medical physics could come to be viewed as the equivalent of medical school, thus completing the parallel with physician training.

What is in a name?

Adoption of the umbrella term “Clinical Science and Technology” would result in the equivalent of “brand dilution” for medical physics. The meaning of “medical physicist” is well-established in the public consciousness, while uncertainty over terms such as “biomedical engineer” and “clinical engineer” persists. In early 2011, the Association for the Advancement of Medical Instrumentation “Future Forum” recommended a new, official name for the field—“healthcare technology management”—yet this has introduced even greater confusion.[15]

Medical specialties are also grappling with issues of organization and subspecialization.[16] Proper recognition of specific training and skills must be balanced with perceived patient benefit, issues of professional image, clinical need, and market forces. Emerging cross-disciplinary subspecialties have employed bridges across specialties and avoided shoehorned integration. As Cassel and Reuben noted regarding proliferation of specialties in internal medicine, “a proliferation of specialties without adequate justification may simply confuse the public without creating a social good.”[16]

Rebuttal: Wilhelm J. M. van der Putten, Ph.D.

A physicist in my department plans procedures, calibrates his equipment, ensures quality assurance of devices and reviews charts and vital signs of patients during treatment. He is not a radiotherapy physicist but works in the intensive care unit. The activities mentioned by Dr. Smith are obviously not uniquely related to ionizing radiation. Some people call this clinical engineering. However, what is important is not what it is called but the level of professionalism applied to the task. The definition of a professional encompasses many things, but amongst the more important ones are an ability to deal with complex and uncertain situations’ and the requirement to reflect on ones actions and decisions.[17]

Dr. Smith contends that career paths are diverging because the education/training of medical physics is converging to that of physicians. The fact that medical physicists in the United States are certified by the Board of a specific medical specialty as well as economic factors may be the reason. In fact, this might actually not be a good thing as it can be argued that this will force medical physics into a scientific cul-de-sac! Medical Physicists should be first and foremost physicists and not physicians.[18]

If we accept that medical physics as a science is applicable in all areas of medicine and that there is considerable overlap with clinical engineering, then a name change is appropriate. Finally, no one is an expert in all areas of medical science and technology. It is now well recognized that even in radiotherapy a medical physicist will require significant knowledge of other areas of medical technology such as imaging, information technology and possibly others in the future. Dr. Smith mentions subspecialization and the existence of bridges between these. Such bridges will have to be built between all areas which apply physics and technology to health care. Medical physics and clinical engineering can be used to great effect in the whole spectrum of medicine. The current job demarcation is an artificial one which

does not benefit the professions and certainly does not benefit patients or the organizations for which these professionals work.

Rebuttal: Chadd E. Smith, Ph.D.

I concede that medical physics and clinical engineering are "different only to a degree." The fact remains, however, that they are not the same. Physics and Chemistry were classically intertwined but today are separate branches of science incorporating vastly different training and application. Similarly, Radiology and Radiation Oncology originated as a single discipline yet emerged as distinct specialties in the late 1960s and early 1970s as the scope of knowledge and clinical practice expanded.[19] Today, most physicians do not practice as both radiologists and radiation oncologists, nor do many physicists practice in both diagnostic and therapeutic medical physics.

Medical physics may have "limited" itself to the therapeutic and diagnostic use of ionizing and nonionizing radiation, but it has also carved out a distinct and important role in patient care. Clinical engineering has done the same. These roles must be allowed to develop organically and should not be artificially manipulated.

Medical physics is continually expanding its horizons. This has been achieved through cross-collaboration with other disciplines (such as molecular biology, gene therapy, etc.) rather than mergers or assimilations. While large areas of medicine may remain untapped by medical physics, these are already supported by clinical engineers, vendor service engineers, biologists, or existing medical staff with completely different backgrounds and training. The fact that medical physics and clinical engineering developed independently is a strong indication that combining the two is neither desirable nor advantageous to those in either profession.

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7.14. Physicists who are responsible for high-tech radiotherapy procedures should have to be specially credentialed

Brian D. Kavanagh and Geoffrey S. Ibbott
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OVERVIEW

The past decade-or-so has seen the introduction of numerous high-tech procedures in radiotherapy, such as stereotactic radiosurgery, IMRT, IGRT, SBRT, proton therapy, and many others. Physicists working with these new technologies need to be highly knowledgeable about them, since it is their responsibility to make sure that they are introduced and used safely and effectively. It has been suggested that such physicists should have to be specially credentialed in these procedures, and this is the claim debated in this month's Point/Counterpoint.

Arguing for the Proposition is Brian D. Kavanagh, MD, MPH. Dr. Kavanagh earned his MPH and MD degrees from Tulane University in 1988 and completed his Radiation Oncology Residency at the Duke University Medical Center. He subsequently worked in the Radiation Oncology Department at the Medical College of Virginia, Virginia Commonwealth University from 1993–2001, and then moved to the University of Colorado Denver, Department of Radiation Oncology, where he is currently Professor, Vice-Chair, and Clinical Practice Director. Dr. Kavanagh is certified in Radiation Oncology by the American Board of Radiology (ABR), and has served on many ASTRO committees, including as Chairman of the Regulatory Committee and a member of the Board of Directors. He is also a member of Task Group 101 of the AAPM, Stereotactic Body Radiation Therapy. Dr. Kavanagh's major interests include stereotactic body radiation therapy, radiobiological aspects of stereotactic radiotherapy, and professional values and legal considerations in radiation oncology.

Arguing for the Proposition is Brian D. Kavanagh, MD, MPH. Dr. Kavanagh earned his MPH and MD degrees from Tulane University in 1988 and completed his Radiation Oncology Residency at the Duke University Medical Center. He subsequently worked in the Radiation Oncology Department at the Medical College of Virginia, Virginia Commonwealth University from 1993–2001, and then moved to the University of Colorado Denver, Department of Radiation Oncology, where he is currently Professor, Vice-Chair, and Clinical Practice Director. Dr. Kavanagh is certified in Radiation Oncology by the American Board of Radiology (ABR), and has served on many ASTRO committees, including as Chairman of the Regulatory Committee and a member of the Board of Directors. He is also a member of Task Group 101 of the AAPM, Stereotactic Body Radiation Therapy. Dr. Kavanagh's major interests include stereotactic body radiation therapy, radiobiological aspects of stereotactic radiotherapy, and professional values and legal considerations in radiation oncology.

Arguing against the Proposition is Geoffrey S. Ibbott, PhD. Dr. Ibbott earned his MS in Medical Physics in 1981 at the University of Colorado Health Sciences Center, Denver and his Ph.D. in Radiation Biology at Colorado State University, Fort Collins. He started his career in medical physics at the University of Colorado and subsequently held faculty appointments at the Yale-New Haven Hospital, the University of Kentucky Medical Center, and the M. D. Anderson Cancer Center, where he is currently Professor and Chairman of the Department of Radiation Physics. During his first ten years at M. D. Anderson he was Director of the Radiological Physics Center. Dr. Ibbott is certified by the ABR in Therapeutic Radiological Physics and Diagnostic and Medical Nuclear Physics, and serves as a member of the ABR Board of Trustees. He has been very active in many organizations, especially the AAPM, where he has served as President, Chair of the Professional Council, and a member of numerous

other committees and councils including the Editorial Board of *Medical Physics*. When not engaged in medical physics, he can be found ballroom dancing with his wife, Diane, or racing his sailboat.

FOR THE PROPOSITION: Brian D. Kavanagh, MD, MPH

Opening Statement

Why invite mayhem? The AAPM should certify medical physicists in specialized radiotherapy procedures.

Hmmm, on second thought, no. The AAPM is too narrow-minded and could not possibly figure out how to recognize expertise in complex procedures. The task of certifying medical physics subspecialists is best handled by bureaucrats in government agencies. Alternatively, we can defer to insurance companies. Or maybe some mail-order company would just print and frame bogus certificates for a few hundred bucks.

So, are you ready to unleash your inner Tyler Durden yet? *Because I am trying to start a fight*. Because I am worried about all of us becoming enslaved by the professional equivalent of an Ikea nesting instinct[1]—that stultifying amalgam of complacency and passive acceptance of externally imposed standards.

Before any of you start throwing a roundhouse at me, let me be clear:

1. That medical physicists are conscientious, law-abiding citizens is not open to debate. We all agree on that.
2. Medical physicists are highly intelligent. They would ace standardized tests, if that is what certification entails…and *there's the rub*…

Oh, sure, the mechanics of quality assurance and technology implementation is need-to-know information. For example, Benedict[2] and Solberg[3] compiled legitimate test fodder for an SBRT qualification exam. But subspecialty certification should not involve just raising your right hand, placing the left on a stack of Task Group reports, and reciting a White Paper. On the contrary, the process should be dynamic and self-renewing.

The blueprint has already been laid out in an action item identified during the AAPM-sponsored "Safety in Radiation Therapy: A Call to Action" meeting:[4]

"… Professional associations (AAPM and ASTRO) should sponsor "user groups" of individuals who use complex treatment machines …User groups should provide a forum for open discussion … about operational issues, including safety concerns…"

These proposed vendor-centric groups would morph into modality-centric mini-societies focused on issues of safety, proper documentation, and quality assurance for a given specialized treatment procedure (brachytherapy, SRS, SBRT, etc). The price of admission, for which maintenance of certification is the reward, is willingness to undergo case-based peer review in a webinar format on a periodic basis and to participate in the review process of others in an open, nonjudgmental forum. That latter part is borrowed from what Patti Hardenbergh has already done in the *Chartrounds.com* project,[5] where radiation oncologists receive credit toward maintenance of certification via peer review of a very similar nature. No need to reinvent any wheels here—just call Patti—I am sure she would help the AAPM figure out how to set this up.

Although I suggest a modality-centric rather than vendor-centric approach, I am confident that vendors would help support a program like this. After all, the likes of Specialized Quark Interstitial Delivery (SQUID) brachytherapy systems and intensity-Selective Organic Radiosurgical Equipment (iSORE) do not want their users making mistakes that injure patients and result in high profile newspaper articles dragging their names (SQUID Brachytherapy and iSORE are not actual companies. But if anyone ever

wants to use those names, I hereby claim copyright and expect to receive stock options) through the mud…because none of us want to see that happen again, ever.

AGAINST THE PROPOSITION: Geoffrey S. Ibbott, Ph.D.

Opening Statement

The proposition suggests that physicists who take responsibility for advanced technology procedures cannot be assumed to have obtained the necessary skills. Instead, they presumably must undergo an evaluation specific to the technology to demonstrate their competence. The following is a rejection of this proposition on the grounds that certification by the ABR constitutes sufficient demonstration of skills and that no further credentialing is required.

The complexity of radiation therapy equipment and procedures has increased significantly in recent decades. The increased complexity is credited with leading to improvements in patient care but, at the same time, the complexity is believed to have increased the risk of errors.[6,7] While many of the treatment errors result from mistakes made by other staff, physicists are identified as responsible for a significant fraction.[6] Unfamiliarity with a procedure could cause physicists to make errors, but certification is intended to demonstrate that a physicist possesses the fundamental knowledge, technical skills, and also the professional judgment to recognize and rectify any deficiencies before participating in the provision of advanced technology procedures.

In the US, certification by the ABR is the most common criterion by which a physicist's competence is judged. Certification by the ABR requires candidates to demonstrate a broad and comprehensive set of skills. Three separate examinations must be passed. Part 1 consists of a general medical physics exam and a clinical exam; Part 2 is a focused examination on core material specific to one of the three subfields of medical physics; and Part 3 is an oral exam that evaluates the candidate's knowledge in five general areas. The exams test candidates in a variety of ways as characterized by Bloom's taxonomy.[8] The Part 1 and Part 2 exams require candidates to remember information, demonstrate their understanding of concepts, and apply their knowledge. The oral exam is an opportunity to evaluate candidates at the top of Bloom's taxonomy, demonstrating that they can analyze the information given and justify a decision or course of action. Oral exams are effective in assessing a candidate's clinical decision-making ability and interpersonal skills, as well as intrapersonal qualities such as confidence and self-awareness.[9]

As a member of the American Board of Medical Specialties, the ABR has implemented a program of Maintenance of Certification, now called Continuous Certification (CC).[10] Beginning in 2002, physicists have been required to participate in CC to retain this credential. In addition, a number of physicists with lifetime certificates (including the ABR trustees and the current and past Associate Executive Directors) voluntarily participate in CC. Participating in CC allows one to demonstrate the six essential competencies on a continuous basis: medical knowledge, patient care and procedural skills, interpersonal and communication skills, professionalism, practice-based learning and improvement, and systems-based practice. A physicist demonstrates competence through certification and CC and should not be required to submit to further credentialing.

Rebuttal: Brian D. Kavanagh, MD, MPH

Well, sorry, but I tried to pick a fight, because people want to see Manny Pacquiao try to knock out Floyd Mayweather and not just do another speedbag workout. Unfortunately, Dr. Ibbott and I actually have too much common ground of agreement to face off in the ring. For example, we both applaud the ABR certification program, which has provided a great service to the radiation oncology community. Thus, what we are doing here in this post-Olympic year resembles not so much boxing but something more like synchronized diving.

Diving, however, into a pool of sharks. It is risky to assume that there is no appreciable lag time between the clinical implementation of new ideas and technology and the conversion of acquired practical knowledge about them into multiple choice test questions. What concerns me is that time in between, when things happen that lead later to courtroom questions like this:

“Dr. Whatsyourname, were you really unaware of the work of Dr. Who, at Wossamata U., who had already noticed that the Spacely Space Sprockets sprocket does not interface safely with the Humperdinck Hermunculator, when you treated someone with this potentially explosive combination?”

I will spell it out: what I am suggesting is that the certification process should embrace an official WikiPhysics forum of sorts for specialized technologies, obliging diplomates to log in frequently. The infinite expanse of cyberspace at its worst can be dangerously polluted by vast amounts of unfiltered misinformation, but at its best the internet and other electronic media provide real-time dissemination of important news. What I want to know is that the medical physicist responsible for my family member's specialized treatment is hyperlinked into up-to-the-minute safety and performance information about the system they are using and the modality of treatment in general. Whatever it takes to guarantee that is OK with me.

Rebuttal: Geoffrey S. Ibbott, PhD

Sure, I am ready for a fight! But it does not seem that we disagree on much. My opponent and I have agreed that physicists must take the responsibility for understanding complex equipment and procedures. The risk is that, in becoming proficient in high-tech procedures, we overlook fundamental activities such as routine QA.

Through the ABR's Continuous Certification program, physicists are encouraged to educate themselves about new techniques, equipment, and procedures. Two components of CC facilitate such educational activities:[10]

- Component 2, Lifelong Learning and Self-Assessment: this includes traditional educational credits for attending presentations at the AAPM Annual Meeting, for example, but also allows for Self-Directed Educational Projects (SDEPs). Up to 15 CE credits can be awarded for each SDEP. An SDEP can be conducted on any topic on which a physicist needs professional improvement and/or educational augmentation. Clearly, learning a new treatment technique such as radiosurgery would qualify. There are straightforward requirements that, when followed, allow a physicist to claim these educational credits.
- Component 4, Practice Quality Improvement (PQI): this is an important mechanism by which physicists and physicians can ensure they maintain their proficiency on advanced and complex procedures in addition to the routine, but extremely important fundamental practices such as basic calibration. The AAPM does, in fact, have a template for PQI that addresses routine clinical procedures.[11]

Could manufacturers help? Absolutely! Several manufacturers already require specific training for physicists who will provide QA and technical support for their equipment. This training can, and should, be described in terms of an SDEP, and physicists enrolled in CC should receive CE credit for learning a new technology or procedure. There are opportunities for manufacturers to contribute to PQI projects as well, and the ABR continues to encourage such programs.

Given the opportunities for physicists to maintain their competence through the CC program, there clearly is no need for a special credential and the added layer of bureaucracy it would bring.

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7.15. The *h* index is the best measure of a scientist's research productivity

Clive Baldock and Ruimin Ma
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OVERVIEW

It is sometimes necessary to evaluate the research output of a scientist when, for example, making decisions on recruitment or advancement of faculty, or considering a candidate for an award. The quantity of a scientist's publications is easy to evaluate, but not the quality. Hirsch[1] proposed a single number, the *h* index, for the characterization of both the quantity and significance of a scientist's research publications. Some, however, have questioned the "accuracy" of this index for a variety of reasons. The premise that the *h* index is the best measure of the research productivity of a scientist is the topic of this month's Point/Counterpoint.

Arguing for the Proposition is Clive Baldock, Ph.D. Dr. Baldock obtained his M.S. in Radiation Physics from St. Bartholomew's Medical College, University of London and his Ph.D. from Kings College, University of London. His Ph.D. research was on the development of MRI of radiation sensitive gels for three-dimensional radiotherapy dosimetry. In 1997 he moved to Australia where he initially worked at the Centre for Medical, Health and Environmental Physics, School of Physical Sciences, Queensland University of Technology in Brisbane. In 2003, he was appointed to his current position in the School of Physics at the University of Sydney where he is Professor of Medical Physics. At the University of Sydney he is also the Director of the Institute of Medical Physics and Associate Dean and Director of Postgraduate Coursework in the Faculty of Science. His research interests include most aspects of radiation physics, radiotherapy physics and dosimetry, and medical imaging.

Arguing against the Proposition is Ruimin Ma, M.S. Mr. Ma obtained his B.S. from Shanxi University in 2000 and his M.S. from Wuhan University, Wuhan, People's Republic of China, in 2004. He is currently completing research for his Ph.D. in Informatrics at Wuhan University, where he is an assistant researcher in the Research Centre for Chinese Scientific Evaluation. His major research interest is scientometrics, especially domain analysis, visualization, and evaluation of research competitiveness. He has participated as one of the research leaders in several evaluation projects for Chinese and other universities, and Chinese academic journals, and has prepared consultant reports commissioned by the Ministry of Education of the People's Republic of China and several universities. He has published over 20 papers on research evaluation in both international and domestic journals.

FOR THE PROPOSITION: Clive Baldock, Ph.D.

Opening Statement

The *h index* has been devised by Hirsch[1] as a research performance indicator intended to be an improved measure of the impact and quality of the work of an individual researcher. The *h* index is that value where N_p of their papers has at least *h* citations each and the other (N_p–*h*) papers have $\leq$ *h* citations each. Researchers with an *h* index of 30 have, when their papers are ordered by the number of citations received from highest to lowest, their 30th paper having been cited at least 30 times and papers 1–30 having greater than or equal to 30 citations. The *h* index reflects both the number of publications and the number of citations per publication. It is designed to improve upon simpler measures such as the total number of citations or publications. The *h* index works properly only for comparing scientists from the same discipline because citation conventions differ for different disciplines. It has rapidly become an

alternative to the more traditional metric of journal impact factor in the evaluation of the impact of the work of a particular researcher.[2] Numerous papers published in the literature explore the role of the *h* index further,[3,4,5] including in the discipline of medical physics.[6]

As only the most highly cited articles contribute to the *h* index, its determination is a relatively simple process. The *h* index can be determined using databases such as Web of Science®, Scopus®, or Google Scholar®. Different databases used to calculate the *h* index for the same researcher, however, often produce a slightly different result, with Google Scholar® having more citations than Scopus® and Web of Science®, with the latter citation collections tending to be more accurate than the former.[6]

Hirsch calculated the highest *h* value among physicists to be that of Witten from the Princeton Institute for Advanced Study, for whom it is 110, with Hawking having an *h* index of 62.[1] Hirsch subsequently demonstrated that the *h* index is highly predictive as to whether a scientist will be elected to a fellowship of a national academy or even awarded a Nobel Prize.[7] For physicists, Hirsch suggested that a value for *h* of about 10–12 might be a useful guideline for making a decision regarding tenure at major research universities. A value of 18 might be a useful guideline for a full professorship, 15–20 for fellowship in the American Physical Society, and 45 or higher for membership in the National Academy of Sciences. As a numerical value it can be used to quantify both the *productivity* and *impact* of a scientific researcher and is becoming the metric of choice in academic circles for assessment when considering grant allocation, and making offers of employment, tenure, promotion, and fellowship in learned societies.[8]

AGAINST THE PROPOSITION: Ruimin Ma, M.S.

Opening Statement

The *h* index, which measures the quality and quantity of an author's research papers,[1] has become an accepted indicator for evaluation of the research productivity of scientists. However, because of several drawbacks, it is not the best measurement, as I will demonstrate.

First, ingenious though the *h* index is, it neglects the dynamicity of citations. The *h* index is significantly influenced by highly cited papers which, once selected, have no influence whatsoever on the computation of the author's *h* index in subsequent years, no matter how their citations increase.[9] The *g*, *R*, and *AR* indices[9,10] have been developed to correct this deficiency. In addition, the *h* index has been shown to be easily influenced by subterfuges such as excessive self-citation.

Second, the relevance of the *h* index varies considerably between specialties. It is more logical to apply it to the measurement of research productivity in the natural sciences than humanities and social sciences, for which researchers publish significantly more in monographs rather than journals: These are not included in *h*-index computations. However, even *within* the natural sciences, citing patterns vary considerably between subjects. For example, the average *h* index for the top ten scientists is 147.1 for the life sciences but only 63.7 in computer science.[11] Several methods have had to be developed to address this problem of noncomparability.[12,13,14]

Third, the *h* index is highly dependent on the length of time scientists have devoted to research work. The *h* index is biased toward older scientists because younger scientists have had less time to generate sufficient numbers of papers and subsequent citations. It is possible for a scholar who has hardly published any papers for several years to have a high *h* index. Therefore, the *h* index puts newcomers at a disadvantage, potentially hampering the recognition of young but excellent scientists.[13]

Fourth, the *h* index overvalues the quantity of papers published and undervalues the quality. A researcher with a large number of poorly cited papers will have a higher *h* index than one with half as many very highly cited papers,[15] which means it is impossible for a scientist with a limited number of excellent papers to obtain a high *h* index.[16]

Lastly, the *h* index alone cannot substitute for indicators from traditional bibliometrics. After so many years of application, the combined use of bibliometric indicators, such as number of papers, citations, average citations, and impact factor, is recommended rather than a single *h* index.[15] The *h* index alone relies too heavily on the number of papers and total citations.[15] It is significant that the standard adopted by the Institute for Scientific Information (ISI) and the Essential Science Indicators (ESI) databases for selection of the most highly cited and "hot" papers considers both the time period of publication and the subject field of a paper and reduces the impact of the total number of citations, in contrast to the *h* index.

In summary, it is a complicated process to evaluate a scientist's research productivity. The *h* index should be considered as a supplement to traditional bibliometric indicators but definitely not an omnipotent indicator. The *h* index is neither perfect nor the best.

Rebuttal: Clive Baldock, Ph.D.

The introduction by Hirsch of the *h* index generated much interest in the academic community and discussion in the literature as to whether the *h* index is the "best" metric to measure how "good" a scientist is.[17] In this context, and in order to investigate whether there are better comparative indices than the *h* index, a study was undertaken of nine different Hirsch-type variants on the *h* index, which had been suggested in the literature.[18] These variants were the *m* quotient, *g* index, *h*(2) index, *a* index, *r* index, *ar* index, and h_w index. The authors found from factor analysis that there are two types of indices: Some describe the most productive "core" of a scientist's output and give the number of papers in that core, and the others describe the impact of the papers in the core. The use of pairs of indices was suggested as a meaningful indicator for comparing scientists, where one index relates to the number of papers in the researcher's productive core (either the *h* or *g* index) and the other relates to the impact of the papers in the researcher's productive core (either the *a* or *m* index). It is noted however that a number of the proposed Hirsch-type indices are actually derived variants of the *h* index, thereby perhaps reinforcing the premise that the fundamental metric, the *h* index, or a variant of, is the best "measure" of a scientist's research productivity.

It will perhaps be only after more studies have been published in this area, particularly by those working in the information sciences and researching into evaluative bibliometrics, that the true value of the *h* index will become evident. However, since the *h* index is automatically calculated in the "citation report" function of Web of Science®, it is likely to be used by researchers in the foreseeable future as it does indicate the broad impact of a scientist's cumulative research contributions.

Rebuttal: Ruimin Ma, M.S.

Indeed, the *h* index is quite remarkable for its ingenuity and ease of use, and it does measure the quantity and quality of the papers of an author. However, these advantages do not guarantee that it is the best measurement.

Dr. Baldock, in citing Ball's paper,[2] stated that the *h* index has become an alternative to the impact factor, which is ambiguous. The impact factor evaluates the quality of journals and is not capable of measuring the impact of the work of any specific researcher directly. It is possible that the *h* index might eventually gain stature equal to that of the impact factor, but they have completely different functions.

Also, Dr. Baldock, by citing Hirsh,[1] demonstrated that the *h* index may be a useful guideline to classify researchers and make decisions on promotion, fellowship, and so on. However I have to indicate that some drawbacks exist in the *h* index's algorithm. For example, author A has published six papers which, respectively, have 20, 15, 9, 7, 6, and 4 citations. In contrast, author B has also published six papers but with citations of 100, 25, 8, 7, 6, and 4, respectively. Obviously, both authors have the same *h* value (viz., 5). The total citations of author B are, however, much higher than those of author A, which means that the *h* index has ignored some significant aspects of the outputs of these researchers. It is not sufficient to apply the *h* index, therefore, without combining it with traditional metric indicators.

In addition, Dr. Baldock considered that the *h* index should only be used to compare the outputs of researchers within specific disciplines, which is a major drawback. Some suggestions have been made to address this deficiency.[12,13,14]

In summary, whether the *h* index should be widely used to measure the outputs of researchers has still to be adequately tested. It is certainly an interesting and attractive index, but definitely not the best indicator of the impact of a researcher's work.

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CHAPTER 8

General Topics

8.1. Despite widespread use there is no convincing evidence that static magnets are effective for the relief of pain

Max H. Pittler and Tim Harlow
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OVERVIEW

Magnets have been used to relieve pain for over 4000 years. The use of magnets for pain relief in Chinese medicine dates back to about 2000 B.C., Aristotle and Plato both talked of the benefits of lodestone for pain relief, and the great physicist Michael Faraday published extensively about the healing effects of magnetic fields. Currently, millions of people worldwide (and probably hundreds of medical physicists!) use static magnetic fields in some form or other for pain relief. However, many experts believe that there are no physical or biological mechanisms to explain any value of these devices for the relief of pain and no clinical evidence to support their use. This is the topic discussed in this month's Point/Counterpoint.

Arguing for the Proposition is Max H. Pittler, M.D., Ph.D. Dr. Pittler earned his M.D. (Applied Physiology) from the University of Freiburg, Germany, and his Ph.D. (Medical Sciences) from the Universities of Exeter and Plymouth, United Kingdom. Currently he is Deputy Director and Senior Research Fellow, Complementary Medicine, Peninsular Medical School, Universities of Exeter and Plymouth. His main research interests relate to complementary medicine: studies of effectiveness and safety, the design and conduct of clinical trials, meta-analyses, and systematic reviews. He is the author or coauthor of several books and over 100 papers in peer-reviewed journals.

Arguing against the Proposition is Tim Harlow, MB ChB. Dr. Harlow studied Zoology before Medicine and, until 2002, practiced as a family doctor in Cullompton, a market town in Devon, England. For the last 5 years he has worked in Palliative Care. He has been interested in complementary therapies and has published research in this area. He helped establish the Master's Degree Program in Integrated Healthcare at the Peninsula Postgraduate Health Institute, Universities of Exeter and Plymouth, and has led the module on Different Paradigms of Healthcare. He was elected to the Ethics Committee of the Association of Palliative Medicine in 2004.

FOR THE PROPOSITION: Max H. Pittler, M.D., Ph.D.

Opening Statement

I base my case in support of the proposition on the results of a review my colleagues and I conducted in which we systematically searched the literature in numerous data sources and demonstrated that there is no convincing evidence to support the use of static magnets for the relief of pain.[1] All randomized clinical trials of static magnets for treating pain from any cause were considered. Trials were included only if they involved a placebo or a weak magnet as the control, with pain as an outcome measure. Twenty-nine potentially relevant trials were identified. For a subset of these trials, pain was assessed on a 100-mm visual analog scale. For these nine trials a meta-analysis was performed.

Meta-analysis of the nine trials that assessed pain indicated no significant difference in pain reduction between the magnet and placebo groups (weighted mean difference 2.1 mm, 95% CI −1.8−5.9 mm, p=0.29). The χ^2 test for heterogeneity indicated that the observed differences between trial results were unlikely to have been caused by chance (χ^2=9.03, degrees of freedom=8, p=0.34; I^2=11.4%). For peripheral joint osteoarthritis the evidence is insufficient to exclude a clinically important benefit that creates an opportunity for further investigation. For all other conditions, there was no convincing evidence to suggest that static magnets might be effective for pain relief. Given the possibility of small effects, if any, that cannot be excluded on the basis of the evidence, further study is warranted.

Across all trials there was no convincing indication that high-strength magnets performed any better than low-strength magnets. Positive and negative studies were spread across magnet strengths, and the results reveal neither an optimal magnet strength nor a "window of time" when magnet therapy is effective for treating pain.

The strengths of our systematic review pertain to its rigor in terms of searching the literature, inclusion and exclusion criteria, and data assessment. Our analyses of data from randomized controlled trials have yielded a relatively robust indication of the effects of magnets on pain outcomes, although further trials are still required. We searched databases with a focus on the U.S. and European literature, as well as specialist data sources, and included hand searches in relevant journals, with no restriction in terms of publication language.

In conclusion, the evidence does not support the use of static magnets for pain relief, and such magnets therefore cannot be recommended as an effective treatment. For osteoarthritis, the evidence is insufficient to exclude a clinically important benefit, which creates an opportunity for further investigation.

AGAINST THE PROPOSITION: Tim Harlow, MB ChB.

Opening Statement

There are two related but separate points implicit in this title that can, unfortunately for doctors and their patients, be conflated. First are the fascinating questions about underlying physiological mechanisms, our understanding of these, the validity of placebos in trials, and expectation effects. The second point, the pragmatic usefulness or otherwise of static magnets in alleviating pain, whatever our understanding of the underlying model, is also very important.

There is disagreement in both of these areas. A view exists that the lack of consistent evidence from randomized trials and the lack of a plausible physiological mechanism are enough to discourage the use of static magnets as an effective treatment for pain relief.[1,2] This conclusion has shades of "guilty until proved innocent." But there is evidence to provide support for those who might recommend static magnets.[3,4]

There is no widely accepted model of how static magnets might work at a physiological level, and some investigators go so far as to suggest theoretically that "magnet therapy seems unrealistic."[2] However, there are two considerations before we rush to accept that assertion. First, the idea that an electrically conducting solution (blood) filled with many different ions moving through a magnetic field might experience physiological effects does not seem inherently implausible. Interestingly, the evidence for electromagnetic fields (not static magnets) being useful in bone healing seems compelling.[5] Second, we always know less than we think we do and there may be other mechanisms we do not yet know. The sun glowed quite satisfactorily and natural selection proceeded apace for a long time before we understood anything of the mechanisms underlying either. To consider something impossible simply because we do not yet understand it is hubris.

The pragmatic argument is strong—patients using static magnets for relief of pain have been shown to report significantly less pain than those with dummy magnets.[6] This pragmatic approach can be

criticized as merely a placebo effect, as if the real pain relief experienced somehow does not count, as if it is cheating! We know the placebo effect is strong.[7] Yet, even if it were entirely a placebo effect, static magnets would still be an effective treatment for the relief of pain and certainly would be far safer than conventional drugs.

I know practicing physicians who are unable to produce a rationale for static magnet use but still will not part with their own magnetic bracelet because they find it helps. How then should we advise patients? I believe we should give them the information to choose:

• in the absence of a pacemaker or insulin pump, magnet therapy may be a safe although poorly understood mechanism,

• there is certainly considerable activation of placebo and expectation response, and

• beyond that–uncertain.

The clinical equipoise is to advise patients that if they use adequate strength static magnets ($\geq$ 180 mT) they are likely to experience less pain than if they do not. And if they choose a reputable vendor with a money back guarantee then they have nothing to lose but their pain.

Rebuttal: Max H. Pittler, M.D., Ph.D.

Practicing evidence-based medicine requires integrating individual health care expertise, the patient's circumstances, and the best available clinical evidence from systematic research.[8] The best available, most current evidence from a systematic review and meta-analysis suggests that there are no significant effects of static magnets for pain relief relative to a placebo. Therefore, the evidence does not support the use of static magnets for pain relief.[1] All previous reviews become irrelevant in the face of new and more rigorous systematic reviews, and selective quotations of single, handpicked trials are not helpful when it comes to questions on how to advise patients. Clearly, placebo effects are beneficial but they are not specific to magnets and do not require magnets. In fact, they come with every medical intervention and they are usually free of cost. Promoting placebo treatment is counterproductive. It is expensive; costs the patients and, in some countries, the taxpayer; undermines rational thinking; and opens the door to a plethora of quack treatments. Patients should be advised that magnets are not more effective than placebos and that they should save their money. Perhaps general practitioners should spend more time with their patients and be more empathetic rather than recommending magnets.

Rebuttal: Tim Harlow, MB ChB.

Dr. Pittler has admirably paraphrased his excellent paper[1] reviewing the evidence in this matter. He clearly sets out one, narrow, way of looking at the issue. Those who have been closely involved in research in this area are fully aware of the great difficulties inherent in trying to perform definitive studies in this field. However, the evidence still suggests that those who use strong static magnets report significantly less pain in some real-life situations than those who do not use them—whatever the mechanism.[6]

Many conventional treatments, such as nonsteroidal anti-inflammatory drugs, cause serious side effects and will kill some patients. We realize that there are very few and relatively minor side effects associated with static magnets. Some patients do find them effective for the relief of pain and frequently tell their doctors so. I cannot agree with Dr. Pittler's assertion that such magnets cannot be recommended as an effective treatment: they are effective and we should recommend them to our patients.

The arguments I outlined in the opening statement and now emphasize still seem to me compelling despite Dr. Pittler and colleagues' review of the evidence. Infinitely more compelling is the fact that, after we had both agreed to take part in this debate and I had written my opening statement, Dr. Pittler requested a change in the title he was to defend. Out went the pragmatic original Proposition: “Despite widespread use static magnets are not effective for the relief of pain” and in came a much more cautious

"Despite widespread use there is no convincing evidence that static magnets are effective for the relief of pain." Obviously Dr. Pittler realized that his meta-analysis does not prove beyond question that magnets do not relieve pain, only that the evidence for relief of pain is not "convincing." Patients who experience pain relief with magnets would not be so convinced.

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8.2. There is currently enough evidence and technology available to warrant taking immediate steps to reduce exposure of consumers to cell-phone-related electromagnetic radiation

Vini G. Khurana and John E. Moulder
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OVERVIEW

In the May 27, 2008 Larry King Live show, Dr. Vini Khurana asserted that the danger of cell phones could have far broader health ramifications than asbestos and smoking.[1] He stated that risks included brain and salivary gland tumors, behavioral abnormalities, electrohypersensitivity, and male infertility. Subsequently, in September 2008, the European Parliament voted 522 to 16 to impose tighter limits on exposure to electromagnetic fields citing as evidence a report that implicated cell phone use with brain tumors.[2] In sharp contrast, a National Cancer Institute study found that cell phone use posed no increased risk of brain cancers.[3] Whether or not the evidence that cell phones pose a health risk is compelling enough to warrant taking steps to reduce exposure of consumers is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Vini G. Khurana, M.B.B.S. Ph.D. Dr. Khurana obtained his M.B.B.S. in 1995 from the University of Sydney, Australia, and his Ph.D. in Molecular Pharmacology and Experimental Therapeutics in 2001 from the Mayo Clinic, Rochester, MN. He is currently a staff specialist neurosurgeon at the Canberra Hospital and Associate Professor of Neurosurgery at the Australian National University, Canberra, Australia. His major research interests include the risks of brain cancer from cell phone use, and diagnosis and treatment of cerebrovascular diseases. He uses a cell phone occupationally, but never holds it to his ear.

Arguing against the Proposition is John E. Moulder, Ph.D. Dr. Moulder obtained his Ph.D. in Biology in 1972 from Yale University. Since 1978, he has served on the faculty of the Medical College of Wisconsin, where he directs the NIH-funded Center for Medical Countermeasures Against Radiological Terrorism. His major research interests include the biological basis for carcinogenesis and cancer therapy, biological aspects of human exposure to non-ionizing radiation, and the prevention and treatment of radiation-induced normal tissue injuries. He has served on a number of national advisory groups concerned with environmental health, non-ionizing radiation, and radiological terrorism; and he currently serves as a radiation biology consultant to NASA.

FOR THE PROPOSITION: Vini G. Khurana, M.B.B.S. Ph.D.

Opening Statement

"*The weight of the published scientific evidence, in addition to the opinion of global health organizations, shows that there is no link between wireless usage and adverse health effects…It's important to look at studies that are peer-reviewed and published in leading journals and to listen to the experts.*" [CTIA mantra].[4]

No link? Really? We recently examined all of the epidemiologic evidence testing an association between long-term ($\geq$ 10-year) cell phone use and the development of brain tumors.[5] To be incorporated in the meta-analysis, cell phone-brain tumor epidemiology studies had to be peer-reviewed publications and include statistical reporting of participants using cell phones for $\geq$ 10 years. There are 11 studies that meet these criteria. Brain tumors studied were gliomas, acoustic neuromas, and meningiomas. The

publications fall into two distinct data streams, namely: Hardell's Swedish studies (n=2),[6,7] which first reported an association between the use of cellular and cordless phones and brain tumors, and the multinational studies (n=9) of the INTERPHONE consortium (see Refs. 8,9,10, for examples). INTERPHONE is substantially industry-funded, although administered by the World Health Organization. Using a fixed-effects model, meta-analysis of these 11 studies with appropriate handling of pooled analyses to avoid data redundancy gives the following odds ratios [OR (95% confidence intervals; CI)] for "ipsilateral" cell phone use ≥ 10 years: glioma OR=1.9 (CI=1.4–2.4), acoustic neuroma OR=1.6 (CI 1.1–2.5), and meningioma OR=1.3 (CI 0.9–1.9).[5] That is, there is a statistically significant elevated odds (about twofold) of developing a glioma or acoustic neuroma on the same side of the head preferred for cell phone use over a duration of exposure ≥ 10 years.

Still not convinced? Read the BioInitiative Report written by an international working group of scientists, researchers, and public health policy professionals (BioInitiative Group) concerned with electromagnetic radiation (EMR) and health.[2] The authors assessed more than 2000 clinical and laboratory studies and reviews and concluded that (i) the existing public safety limits for EMR exposure set by the FCC and International Commission for Non-Ionizing Radiation Protection (ICNIRP) in Europe are inadequate to protect public health, and (ii) from a public health policy standpoint, new safety limits and regulation of further deployment of risky technologies such as power lines, cellular telephones and masts, and WiFi systems are warranted based on the total weight of evidence.

Safer technology? How difficult can it be to adopt an evidence-based precautionary attitude when the technology we need to make our lives safer in this context is already available? Use a conventional landline. When you can't, then remember that EMR-exposure respects the "inverse-square law," so use the speakerphone mode of your cellular and cordless phones, or a hands-free car kit. If you prefer a wired earpiece, buy one that is EMR-shielded. Furthermore, support regulation of the relatively unchecked proliferation of cell phone masts (would you want one next to your child's daycare center?) If you don't feel like heeding any of the above, please encourage children to do so, for there are reasonable grounds to suspect a looming public health tragedy.

AGAINST THE PROPOSITION: John E. Moulder, Ph.D.

Opening Statement

In 2005, I, along with three colleagues (a biomedical engineer, an epidemiologist, and a genetic toxicologist) reviewed over 1700 publications that were relevant to the issue of whether mobile phones are a plausible cause of cancer.[11] We concluded that "*…a weight-of-evidence evaluation shows that the current evidence for a causal association between cancer and exposure to radiofrequency (RF) energy is weak and unconvincing*."

What scientific discoveries have been made since then to justify the alarmist headlines we see about mobile phones and brain cancer? The short answer is that nothing new has been discovered that suggests a causal link, and several new studies have made the existence of a causal link even less likely.

Biophysical considerations continue to indicate that there is no theoretical basis for anticipating that RF energy would have significant biological effects at the power levels used by modern mobile phones.[12] This does not mean that such effects are impossible; it means that experimental and epidemiological studies must be very scientifically convincing to overcome this barrier.

Recently, some European studies suggested that RF energy might have genotoxic potential, but the validity of these studies is now questionable.[13] Other *in vitro* studies continue to find no reproducible evidence that RF energy has genotoxic or epigenetic potential at the power levels used by mobile phones.[11,12,14]

Extensive animal studies continue to find no reproducible evidence that exposure to RF energy at nonthermal intensities causes or promotes cancer.[11,12] The only recent peer-reviewed study which did

suggest that RF energy might have carcinogenic potential (a 1997 Australian study of lymphoma-prone mice) has now failed a second replication attempt.[15]

The epidemiologic evidence for a causal association between cancer and RF energy remains weak and limited.[11,12,16,17] At least 17 studies have been published that report data for cancer and duration of mobile phone use. In early 2008, Kan *et al.*[17] published a meta-analysis of nine such studies and found odds ratios (relative risks) for brain cancer and regular use of mobile phones that varied from 0.64 to 1.25, depending on which types of brain cancer were analyzed and on how "exposure" was defined. An even more recent meta-analysis of 17 studies was presented at the 2008 Bioelectomagnetics Society Annual Meeting;[16] this study found relative risks for brain cancer and regular use of mobile phones that ranged from 0.78 to 1.07.

Some commentators have reported elevated rates of brain cancer on the side of the head where the participants recalled using their mobile phones, but in the absence of overall increases in brain cancer in regular users, recall bias[18] is a stronger explanation for the ipsilateral increase than is carcinogenesis.

Weak epidemiological evidence of an association of mobile phone use with brain cancer incidence, when combined with the biophysical implausibility of a causal link and the strongly unsupportive animal studies, does not support the case that regulation of mobile phone use is urgently needed.

Rebuttal: Vini G. Khurana, M.B.B.S. Ph.D.

Respectfully, my opponent's 2005 literature review's "weight-of-evidence" conclusion is superseded by contemporary long-term (≥ 10-year exposure) epidemiologic data. In fact, nine (82%) of the 11 long-term cell phone-brain tumor studies are not quoted in his review, understandably because these were published in the same or subsequent year(s). Even Kan's "meta-analysis" of 2008 quoted by my opponent[17] is diminished by omitting all of Hardell's seminal long-term cell phone-brain tumor study data and by analyzing only one-half of the currently available long-term studies (compare this to Hardell's meta-analysis[19]). Despite such shortfalls, Kan still found significantly elevated odds of developing a brain tumor in the pooled long-term group. Attributing worrisome findings to "recall bias" is convenient but contested, *ergo* INTERPHONE's procrastination.[8,9,10] My opponent asks: "What scientific discoveries have been made since then [2005] to justify the alarmist headlines…?" Here's one (for scores more read the BioInitiative Report[2]): In 2008, researchers at my opponent's Medical College of Wisconsin[20] reported that in rats chronically exposed to cell phone radiation, significant upregulation occurred of mRNA associated with proteins linked to cellular injury. They postulated that such radiation "*may result in cumulative injuries that could eventually lead to clinically significant neurological damage*."[20] Surely the unproven allegations glamorized in an article quoted by my opponent regarding one laboratory[13] do not pertain to the many scientists who have recently reported DNA damage or modulation by cell phone radiation.[21] "No known mechanism" does not equate to "no mechanism;" after all, the accepted tobacco-lung cancer linkage rests on epidemiology, not definitive pathophysiology.

In conclusion: (1) don't ignore emerging long-term epidemiologic data; (2) conflicting laboratory results can be due to genomic, proteomic, and experimental variations; (3) monitor future brain tumor incidence, and (4) there is technology and compelling evidence for intervention now—10 years hence may be too late.

Rebuttal: John E. Moulder, Ph.D.

To support his position that people need to be protected from mobile phone RF energy, Dr. Khurana cites two sources: his own unpublished meta-analysis and a non-peer-reviewed Internet document. The biological implausibility of the link he claims[12] and the existence of strongly unsupportive animal studies[11,12,15,22,23] are not mentioned.

Since Dr. Khurana's meta-analysis is not published, I can say only that others who have done similar analyses have reached different conclusions.[16,17] I note that Dr. Khurana does not address the issue of

recall bias,[18] that is, does his analysis show an increased overall risk of brain cancer in heavy users of mobile phones, or is the increase he finds in ipsilateral risk counter-balanced by a decrease in contralateral risk, as has been found in other studies (e.g., Hepworth *et al.*[24]).

The Internet summary Dr. Khurana cites[2] is not a source that I regard as either accurate or balanced. Among the weakness of that summary are its internal inconsistencies, its neglect of nonconcurring views, and the lack of a weight-of-evidence approach (e.g., it takes into account only 2 of the 35+ published animal carcinogenesis studies). The Internet report also reaches much more alarmist conclusions than those reached by established health agencies and by expert panels from across the world.

Dr. Khurana presents no peer-reviewed studies that dispute the statement that epidemiological evidence of an association of mobile phone and brain cancer is weak. He also presents nothing to dispute the statement that such a link is biophysically implausibile[12] and strongly unsupported by extensive animal studies.[11,12,15,22,23]

Calls for regulation against speculative hazards should not be issued lightly.[25] Such measures can have unintended consequence for safety (e.g., reducing the effectiveness of mobile phones could have serious impacts on communications in time of need). If individuals are concerned about unproven health risks from their mobile phones, by use of hands-free kits they can take inexpensive and effective measures to reduce their exposure.

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8.3. Preparation for a terrorism-related radiation event should be no different from that for a biological or chemical event

Dean W. Broga and Richard J. Vetter
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OVERVIEW

It is fortunate that, so far, few terrorism-related events have been executed using radiation-emitting, chemical, or biological agents, but the threat of such events is real, and to be unprepared could be devastating. Emergency response must be quick, so response plans should be as straightforward as possible so as not to slow down the process or, worse, cause confusion, yet they must be effective. A single, all-encompassing, emergency response plan that would cover any type of agent would be efficient, but would it be effective? Or might it not be better to have different plans for each specific agent, especially radiation, which has many features distinct from those of chemical and biological agents? This is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is Dean W. Broga, Ph.D. Dr. Broga obtained his Ph.D. in Nuclear Engineering (Radiation Protection) from the University of Virginia, Charlottesville, in 1983. He has spent his entire career at the Medical College of Virginia/Virginia Commonwealth University, Richmond, where he is currently Associate Professor of Radiology and Director of the Office of Environmental Health and Safety. Dr. Broga is certified by the American Board of Health Physics, the American Board of Medical Physics (in Nuclear Medicine Physics), and the American Board of Radiology (in Diagnostic Radiological Physics). He serves on many National and State boards and committees and is currently Chair of the Central Virginia Hospital Disaster Preparedness Committee.

Arguing against the Proposition is Richard J. Vetter, Ph.D. Dr. Vetter obtained his Ph.D. in Health Physics from Purdue University in 1970 and is certified by the American Board of Health Physics and the American Board of Medical Physics (in Medical Health Physics). He is currently Radiation Safety Officer and Medical Director for Safety, and Professor of Biophysics, at the Mayo Clinic, Rochester, Minnesota. Throughout his career he has been active in numerous societies and organizations such as the NCRP, USNRC, and the Society of Nuclear Medicine, and has been a member of the Boards of Directors of the American Boards of Health Physics and Medical Physics and the Health Physics Society (he was President 1996–1997), and he is the current President of the American Academy of Health Physics. He is past Editor-in-Chief of the *Health Physics* journal.

FOR THE PROPOSITION: Dean W. Broga, Ph.D.

Opening Statement

NCRP 138 (Ref. 1) states: "*Many of the characteristics of terrorism involving radioactive materials are also present in terrorism involving other weapons of mass destruction such as chemical and biological materials*." REAC/TS indicates that "*serious medical problems always have priority over radiological concerns, and immediate attention is directed to life-threatening problems*."[2] Further, risks to caregivers from contamination on the patient's skin are small, and universal precautions provide staff with protection.

When it comes to disaster readiness, the primary goal should be "keep-it-simple." OSHA's Best Practices for Hospital-Based First Receivers of Victims[3] does not differentiate preparedness to any major degree. In addressing personal protective equipment (PPE), the overall goal is to provide a base line for protection of emergency department (ED) personnel from radiological, chemical, and biological agents.

This is practical considering that, in most cases, hospitals will not have any clear advance notice of what agents may have been deployed in a terrorism event. For the majority of medical personnel the major concern is proper use of the PPE and maintaining containment, followed by patient care. Evaluation of the scope and degree of a hazard is going to fall to a few select individuals. Here we gain an advantage in that most radiation tends to be easily detected and identified with the instruments already at most hospitals, instruments that personnel use routinely. Evaluation of chemical and biological exposures is not as easy or as routinely performed.

Thanks to abundant federal funds, most hospitals are equipment rich; but they are operationally bankrupt. Excessively complex plans detailing operational variances at a level only a specialist in the field can appreciate tend to confuse personnel whose focus needs to be decontamination and control. The less probable the event the simpler the plan needs to be. People's recall is limited, training time is almost nonexistent, and there is no time to refer to a complex protocol in the heat of the moment.

In a recent survey, the major concern of ED physicians and nurses[4] was their being overwhelmed by patients. Boom; it is 10:00 p.m. and a dispersion device was just detonated at a local venue. There are dozens of self-referred patients on their way to your ED in their cars. EMS is right behind them with the nonambulatory. First responders cannot identify the agent. You have 5 min. Radiological, biological, chemical? Your facility needs to react before it is overrun and shut down. The front-end decontamination, containment, and management for all three is basically the same. The facility that has an integrated and simple approach will deploy and survive. The facility that has individualized its plans, over educated and confused its staff, and created an unnecessarily complex and bureaucratic deployment, will most likely be overrun and shut down before it gets to treat anyone.

"Keep it simple" and "less is more" reinforce the fact that simplicity is important. Approaching terrorism planning on an agent-by-agent basis defeats this philosophy and undermines real preparedness.

AGAINST THE PROPOSITION: Richard J. Vetter, Ph.D.

Opening Statement

Responses to radiological, chemical, and, to some extent, biological events have a number of similarities and will often be carried out based on secondary indicators such as labels, signs, or placards that indicate the presence of a hazardous material. The level of response to radiological or chemical events may be based on readings from specialized instruments. Because of these similarities and to be prepared for any type of event, first responder organizations and hospitals develop all-hazards response plans that usually include a mass decontamination procedure for chemical or radioactive contamination. But responses to these three events have several important differences.[5] Unlike chemicals or biological agents, radiation sources can cause exposure even when people are not in contact with them. Whereas many responders and receivers have experience responding to chemical emergencies such as industrial, transportation, or agricultural events or to disease outbreaks such as influenza or pertussis, they do not have any experience with radiation emergencies. Chemical or biological response is often based on the appearance of medical symptoms in exposed individuals whereas radiological response will most likely depend on secondary indicators. Depending on the radionuclide, even very low levels of radioactive contamination can be detected rapidly with simple portable instruments. Consequently, even though basic emergency response plans should be based on an all-hazards approach, they should include a customized process for radiological incidents.[6]

Most first responders and first receivers who have minimal training on radiation tend to overestimate its effects,[7] and the public, media, and responders often have an exaggerated fear of radiation.[5] Radiation is often equated with the hazards of chemical warfare agents that can cause injury or death even in small amounts. This may lead to an inappropriate response to a nuclear or radiological incident such as delay in victim rescue or transport or denial of treatment.[6] The type, duration, and frequency of training for all-hazards should be based on the duties and functions to be performed and must include training in the

hazards of specific hazardous substances.[8] Approximately one-fourth of that training time should be spent on training for nuclear and radiological incidents. "*Optimally, most first responders and first receivers should have competency in the nuclear and radiological aspects of operations-level training.*"[7] How well a community responds to a radiological incident may depend largely on how well the public health, medical, and first responder communities understand the basics of radiation.[9] Consequently, preparation for a terrorism related radiation event should include specific radiological classroom and tabletop training supplemented with emergency exercises that include radiation monitoring and decontamination.

Rebuttal: Dean W. Broga, Ph.D.

I do not think my opponent is necessarily disagreeing with me. Even JCAHO advocates an all-hazard approach to allow organizations to be flexible enough to respond to emergencies of all types.[10] I become concerned when I see hospitals that have separate and detailed plans for radiation, chemical, and biological events. It has been my experience that these are just not functional and are more to satisfy JCAHO requirements than to present a plan that is quickly implemented.

The Sarin gas attack on the Tokyo subway in 1995 is probably the best example of what can go wrong. Hospitals can anticipate a large number of self-referred victims (as many as 80% of the total number of victims) and should assume victims will not have been decontaminated prior to arriving at the hospital.[3] In a metropolitan area these people will be at your Emergency Department in minutes. Managing dozens, if not hundreds, of panicked victims in a quick and organized fashion is critical. The hospital must have a simple unambiguous response in order not to be overrun.

As I pointed out in my opening statement, REAC/TS recommends that serious medical problems should take priority over radiological concerns.[2] Contrary to what my opponent has stated, individuals contaminated with biological agents like anthrax will not be symptomatic. Individuals contaminated with the chemical warfare agent Vx may be asymptomatic for hours.[11]

Yes, radiation is generally easily detected and it will be easier to deal with than agents that are not. But if a hospital is going to be prepared to rapidly respond to a major terrorist event, its plan needs to be simple. The management and decontamination processes at the front end are basically the same regardless of the agent. An integrated approach ensures simple and effective deployment.

Rebuttal: Richard J. Vetter, Ph.D

Dr. Broga points out that NCRP 138 (Ref. 1) relates similarities between terrorism involving radioactive materials and chemical or biological materials. But hospitals must be prepared to deal with each agent and with events other than terrorism. Whenever hospitals have developed emergency response plans which include how to deal with (or avoid) communication failures, potential impact on resources and assets, threat to safety and security of patients, ability of staff to adapt to new demands of an emergency, interruption of utilities, and clinical needs of patients during an emergency, they have developed an "all-hazards" approach that will address a range of emergencies.[2] But this is not the same as a single plan for radiological, biological, and chemical events. The Joint Commission still requires hospitals to develop emergency operations plans for specific events based on a hospital's hazard vulnerability analysis (HVA).[10]

As noted by Dr. Broga, proper donning of PPE is critical to the protection of healthcare personnel before they begin patient care activities. Subsequently, patient care is dependent on the agent. For example, decorporation agents would not be administered to patients who were exposed to a biological agent, and antibiotics would not be administered to patients exposed to a radioactive material except to treat physical injuries.

Dr. Broga states that "The less probable the event, the simpler the plan needs to be." Most hospital HVAs probably rank the likelihood of pandemic flu higher than a radiological event and the probability

of a chemical event (industrial or farm accident) higher than either. However, the competency of the staff to respond to any one of the three must be maintained regardless of the likelihood. If the hospital HVA determined that all three events have some likelihood of occurrence, staff must maintain their competency in all three areas. Preparedness activities for each will not be the same.

My colleague points out that the front-end decontamination and containment for all three agents are similar, but he suggests that individualized plans are unnecessarily complex and bureaucratic. First, plans do not need to be complex. Second, determination of decontamination effectiveness and the treatment options are agent dependent. Thus, except for decontamination and containment, the plans for specific agents must differ to accommodate for their differences.

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8.4. Medical Physics should adopt double-blind peer review of all manuscripts

A. Kyle Jones and Hugo Palmans
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OVERVIEW

The potential for reviewer bias exists whenever a research paper is sent to referees for peer review prior to publication. For most journals, including *Medical Physics*, the authors are "blinded" to the identities of the referees and it has been suggested that one way to reduce the risk of bias is to "blind" referees to the identities of authors and their institutions. The proposition that such "double-blind" review be adopted for articles submitted to Medical Physics is the topic debated in this month's Point/Counterpoint.

Arguing for the Proposition is A. Kyle Jones, Ph.D. Dr. Jones received his Ph.D. in Medical Physics from University of Florida, Gainesville and is currently Assistant Professor, Department of Imaging Physics, U.T. M. D. Anderson Cancer Center, Houston. Dr. Jones serves on several AAPM committees and Task Groups and is Co-Chair of TG 151 and Co-Director of the Educational Program-Imaging, for the 2010 Annual Meeting. He is certified in Diagnostic Radiologic Physics by the American Board of Radiology.

Arguing against the Proposition is Hugo Palmans, Ph.D. Dr. Palmans received his Ph.D. in Applied Physics from the University of Ghent, Belgium and is presently employed as Principle Research Scientist at the National Physical Laboratory, and is Honorary Senior Research Fellow at the University of Birmingham, England. His research activities include calorimetry, ionometry, and other dosimetry techniques applied to radiotherapeutic proton, carbon ion, photon and electrons beams, small and composite fields, and brachytherapy. He is active or has participated in numerous national and international working groups producing recommendations for dosimetry, including several AAPM Task Groups, and is a member of the *Medical Physics* Editorial Board.

FOR THE PROPOSITION: A. Kyle Jones, Ph.D.

Opening Statement

Malcolm Gladwell, in his bestselling book *Blink*,[1] relates a story that is a strong selling point for double-blind review of manuscripts. Specifically, over the past 30 years, the number of women in the top US orchestras has increased fivefold. This increase coincided with a small but significant change in the manner in which orchestra auditions were held: The insertion of a screen between the auditioning musician and the judges. This anecdote exposes the power of the human subconscious, demonstrating that everyone, regardless of how much we struggle against it, is subject to the influence of the subconscious in the form of reviewer bias. Whereas we all would vehemently deny any bias, a better approach is to accept it and investigate ways in which we can reduce the influence of our subconscious bias.

A double-blind review process serves exactly this purpose. By removing identifying information about the authors of a manuscript, referee bias can be eliminated. Studies have demonstrated that reviewers show bias against female authors,[2] against authors from institutions that are not highly prestigious,[3] and for authors from institutions similar to their own.[4] The cases of a reviewer with an axe to grind, or that of a junior reviewer who is intimated enough by the big names of the authors on a manuscript to refrain from pointing out serious deficiencies or perhaps duplication of previous work, are further examples of

reviewer bias. Eliminating any chance of reviewer bias should be reason enough for *Medical Physics* to adopt double-blind review of all manuscripts.

A double-blind review process has other benefits. First and foremost is the mere *perception* of increased fairness, which encourages authors to submit manuscripts to a journal. Convincing oneself that a double-blind review process is perceived as fairer than a single-blind review process is easy. Second, a study of articles in journals, controlled for article length and journal quality, showed that papers in journals that used a double-blind review process received more citations than did those for which single-blind review was used.[5]

The case for better quality manuscripts is further supported by the fact that according to editors, the quality of peer reviews using a double-blind process is higher than that of peer reviews using a single-blind process.[6] Also, manuscripts by prestigious authors have scored higher under double-blind review than under single-blind review,[7] demonstrating that double-blind review is more likely to result in the identification and acceptance of high quality, high impact manuscripts. Increased manuscript quality and numbers of citations, both proven benefits of a double-blind review process, would increase the impact factor of *Medical Physics*.

An increased perception of fairness, elimination of reviewer bias, and an increased impact factor make a compelling case for shifting *Medical Physics* to a double-blind review process. If you still are not convinced, contact the editorial staff of *Radiology*, one of the strongest competitors for manuscripts with Medical Physics, and ask them what type of review process they use. I double dare you.

AGAINST THE PROPOSITION: Hugo Palmans, Ph.D.

Opening Statement

Double-blind peer review (DBPR) and single-blind peer review (SBPR) both have pros and cons excellently reviewed by Snodgrass.[8] I will argue that the benefits of DBPR are not worth the added cost and time required for effectively implementing it and will be unlikely to improve the quality of the Medical Physics peer review process.

First of all, in spite of extra efforts required, DBPR will largely fail in guaranteeing anonymity.[9] Indeed, as an expert, the referee will often be able to identify authors or their institutions since, due to increased specialization, the pool of potential authors is limited and can be narrowed down by searching the internet for related papers. Furthermore, authors who have published before have a recognizable style and much research submitted for journal publication has already been presented at conferences that have been attended by these expert referees.

Second, DBPR will contribute little to the prevention of possible bias, the main argument used to promote it. It does not protect against bias when referees successfully guess the author's identity but also when referees might favor their own research by rejecting papers from others or delaying their publication. Bias based on gender or nationality, often quoted in favor of DBPR, has in several suspected cases been proven not to exist.[10] The generally perceived (but unproven) positive bias toward well-known, highly respected, and prolific authors in the field will also not be solved by DBPR since it is exactly these authors who are most easily identified.[11]

Last but not least, a substantial randomized trial involving multiple journals[12] found no difference in review quality or recommendations compared to SBPR, consistent with many similar examples in the literature. In fact, the present system employed by Medical Physics[13] fends well against bias. The Associate Editor (AE) knows the other players in the field, their relations and existing rivalries, can spot conflicts of interest or unfair reviews, and can act, if necessary, as a third referee, reducing the risk of an overall biased opinion. On the other hand, AEs who have a biased view themselves may choose referees who adhere to the same opinion, an issue not counteracted by DBPR but rather by adequate monitoring by the Editor.

DBPR also places an extra burden on referees in tracing relevant literature since knowing what the authors have published before is of great help in understanding the context of the work, evaluating its novelty, asking the right questions, and spotting potential conflicts of interest.[14] DBPR could thus result in more refusals to review, unwelcome at a time when referees are already overloaded and difficult to secure. Plagiarism is another serious issue and, as a referee, I have been confronted with cases of attempted self-plagiarism which would have gone undetected had I not known the authors' names. DBPR may thus reduce the quality of reviews and increase the risk of non-novel and self-plagiarized papers getting accepted.

In summary, there is no clear evidence that DBPR increases fairness or quality of review and the literature is generally inconclusive.[15] If there is an advantage, it must be small, not justifying the additional costs and risks for Medical Physics.

Rebuttal: A. Kyle Jones, Ph.D.

A very good baseball player is successful in getting a base hit only 33% of the time, so why bother even batting at all? Reported success rates for blinding referees to authors vary between 68% and 90%,[6,12,16,17] with the higher rates typical of journals that routinely use double-blind review. Success rates are difficult to generalize owing to dependence on size of the research field and the number and experience of referees. Further, the only authors' identities likely to be guessed by a reviewer are those who are prestigious and well-respected in the field, but these authors receive higher reviews in a double-blind process *anyway*,[7] owing to the higher quality of their manuscripts. Referees who demonstrate bias for their own research to the extreme of rejecting or delaying others' submissions would be problematic under either type of review system.

Trials based on subjective surveys have found both support for and against double-blind review.[6,12,16,17] Basing judgments on objective data such as citations[5] is a more tenable position than basing them on subjective data such as authors' opinions. Also, my opponent makes the assertion that a migration to double-blind review would result in a higher rate of refusal to review and thus would make it more difficult to recruit referees, while providing no evidence to support this assertion. As for the rightful concern regarding plagiarism, a simple Google search and at most a search of a small subset of academic journals for keywords will turn up most, if not all, similar prior work, whether it be plagiarism or self-plagiarism.

My opponent concludes with the assertion that the "additional costs and risks" of double-blind review do not justify any small advantage that might be gained, a common argument against double-blind review. The onus should be placed on the author to ensure that the manuscript is appropriately blinded and papers that are not blinded should be returned to the author. McNutt et al.[6] reported that after some experience, the time required for blinding manuscripts was only 5 min, which hardly seems a high price to pay for the benefits of double-blind review.

Rebuttal: Hugo Palmans, Ph.D.

My opponent appears to believe that DBPR has only advantages, whereas I pointed out several disadvantages and risks besides its economic cost. The cases he uses to demonstrate that DBPR reduces reviewer bias come predominantly from the Arts, Psychology, or Economy literature, and are not necessarily relevant to Medical Physics. Interesting to note is that DBPR is widely used in Social Sciences and Humanities but rarely in the Physical and Mathematical Sciences.[18] This may indicate a lesser need of it in scientific journals, where a larger level of objectivity can be assumed in judging a paper's quality, and I count Medical Physics among these.

An example from the life sciences where gender bias was reportedly demonstrated by increased female representation after introducing DBPR (Ref. 19) turned out to reflect rather the increased number of female researchers in the field.[20] Laband's results[5] are not very convincing either, since they actually

show that papers which underwent SBPR received more citations over five years than those that underwent DBPR. Only a complex (and debatable) metric involving article length and "journal quality" resulted in better results for DBPR. Also, the examples from the Medical Sciences[6,7] are small studies indicating possible reviewer bias, while other studies for similar journals contradict this, showing no evidence of bias.[12]

Of course there are reported cases of disadvantage suffered by researchers from certain groups, but it is not clear if this arises from the peer review process itself or from elsewhere in the arrangements for supporting, appointing, promoting, funding, and rewarding researchers.[15] It has also been argued that a much larger problem than bias in peer review is a lack of critical assessment skills, suggesting that training in peer review, or even a formal curriculum and credentialing process for referees, is more needed than anything else to improve the quality of reviews.[21]

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