Testimony to the Subcommittee on Health of the United States House Committee on Energy and Commerce

Topic: Medical Radiation: An Overview of the Issues.

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Mr. Chairman and members of the committee,

My name is Eric Klein. I am a Professor of Radiation Oncology at Washington University, and have been a Clinical Medical Physicist for 28 years. Over this time period, I have seen dramatic changes in terms of our profession's capability to diagnose and treat cancer. I doubt if any other medical discipline has experienced technological advances to the degree Radiation Oncology has. Our ability to image patients with modalities, such as CT, MRI, and PET, allows us to visualize tumors and involved lymph nodes with millimeter accuracy. We can now customize how doses are delivered to tumors by performing sophisticated calculations, allowing physicians to escalate dose to increase cure rates. Simultaneously, we can reduce doses to critical organs, even those close to a tumor. This has resulted in reduced toxicity.

The delivery technique of intensity modulated radiotherapy (IMRT), which provides superior treatment delivery customization, comes with an increase in irradiation time by a factor of 2 to 10 compared with conventional radiation therapy. Thousands of hospitals and private treatment facilities all over the country have purchased IMRT machinery, often for competitive purposes, and far too often, without properly trained staff in place.

Hospitals need to ensure staffing levels are adequate, not only in number, but in expertise. There should be hands-on testing methods before therapists are allowed to treat patients, with re-testing on a frequent basis. The training for all staff involved, should include the consequence if something is incorrect. There can be as many as 100 steps for each process, and each step must be understood by everyone, especially those with greatest volatility. We do a good job teaching people what to do and what to watch for, but not the consequence if something is wrong.

Though the anecdotal *reported* rate of errors in radiation oncology is quoted as less than one in ten thousand, there are two problems with this rate. First, it may be inaccurate, as there is no depository, nor statewide mandate for reporting such errors. In most states, hospitals are not obligated to report errors occurring with their linear accelerator. <u>A national depository for anonymous error reporting should be instituted</u> in order for the community to learn from such errors (or 'near misses'). The second problem with the low anecdotal reported error rate, is that it is too high.

Hospitals also need to encourage scheduling patterns to allow for "time-outs" before each treatment begins to allow for cross-checking of all parameters by the therapists. Related to this, the time leading up to the patient's first treatment, should allow for careful review by the physicist of all parameters to be used.

In addition, the manufacturers' testing of radiotherapy equipment should include fault and interface testing.

In regards to Medical Physicists, we are the vital interface between the physician's orders and the eventual treatment. We are responsible for; the accuracy of the images used for planning, the validity of the calculations, the quality of a resultant patient treatment plan, the accuracy of the linear accelerator's delivery systems, and the overall end-to-end validation that each patient will be treated accurately. But, having the intuition and wisdom to detect a potential or underlying problem only occurs with rigorous residency training. Medical Physicists are educated in many important areas including quality assurance and radiation safety, and after proper training, ideally in an accredited residency program, may become certified by the American Board of Radiology (ABR).

Starting in 2014, the ABR will only allow physicists, who have completed a Residency Program, to sit for the Boards. This will 'raise the bar' for the exam, thereby raising the competency of medical physicists in the very near future. The ABR has to wait till 2014 is to allow growth in the number of accredited residency programs, which is hampered by lack of funding. There are some funding mechanisms, but the most assured and balanced method, would be for the Center for Medicare Services to provide reimbursement for training Physics Residents similar to the method in place for Physician Residents.

And finally there is an ironic situation regarding oversight of radiation treatment equipment. To operate a mammography unit, and be reimbursed for the procedure, a robust quality assurance program must be in place, with oversight by a qualified medical physicist, and most importantly programmatic overview by the FDA and the American College of Radiology. This model of requiring a quality program and qualified personnel to be in place, with review by an agency, in order to be reimbursed for providing treatments, should be strongly considered for radiotherapy.

In closing, approximately a million patients per year are safely and accurately treated with radiation therapy, receiving outstanding and vital treatment. But further steps to ensure patient safety, can and must be made.