

**Statement of E. Stephen Amis, Jr., M.D., FACR  
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To the  
House Energy and Commerce Health Subcommittee’s  
Hearing on  
“Medical Radiation: An Overview of the Issues”**

**February 26, 2010**

Chairman Pallone and Distinguished Members of the Subcommittee:

On behalf of the American College of Radiology (ACR)—a professional organization representing more than 36,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—I appreciate the opportunity to discuss the importance of quality and safety in the medical use of radiation. The ACR is deeply committed to ensuring the appropriate use of medical radiation in all modalities and clinical settings, and we believe this can best be achieved through robust mandatory accreditation of medical imaging and radiation therapy. In addition to expressing our support for mandatory accreditation, ACR would also like to share with the Health Subcommittee some of ACR’s efforts to improve medical imaging and radiation therapy services through our quality and safety programs, education and public awareness campaigns, and related projects.

First and foremost, it should be emphasized that medical imaging and radiation therapy procedures irrefutably save lives and improve patient care. Advances in medical imaging over the past few decades have rendered exploratory surgery virtually obsolete. Disease processes can be discovered and characterized earlier, and treatments can be monitored more readily to allow for optimal patient care. Image-guided medical procedures have replaced more invasive surgical options for many patients while improving outcomes and reducing hospitalization and recovery times. Furthermore, clinical trials and experience have demonstrated the benefits of radiation therapy in curing cancer, extending life, and alleviating pain and suffering for over one million patients each year.

However, the series of New York Times articles that gave rise to this hearing was a heart-wrenching reminder that the benefits received from medical radiation are not without risk. As a profession, we can and must do a better job of preventing such errors – not only to ensure all patients get the best quality of care we can provide, but also to maintain the confidence of the public who rely on our care. The ACR believes that the best way to address this is through expansion of existing federally mandated medical imaging accreditation requirements to encompass all clinical settings and radiation therapy modalities, enacting new minimum standards for technologists such as H.R. 3652, the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009 or CARE Act, using experienced accrediting bodies to run the program and requiring a CT dose index registry.

Accreditation

The ACR is the nation’s oldest and most recognized medical imaging and radiation oncology accrediting body with a long history of developing and administering accreditation programs that assess the quality of imaging facilities. Designed to be educational in nature, ACR accreditation is an efficient process of both self-assessment

and independent external expert audit, based on the ACR practice guidelines and technical standards, which assesses the qualifications of personnel, policies and procedures, equipment specifications, quality assurance (QA) activities, patient safety, and ultimately the quality of patient care.

ACR accreditation began in 1987, with the then-voluntary mammography and radiation oncology accreditation programs. Due to ACR's success with the voluntary mammography program, Congress passed the Mammography Quality Standards Act (MQSA) in 1992 to mandate accreditation of all mammography facilities. In 1994, the ACR became the only national accrediting body for mammography to be approved by the Food and Drug Administration (FDA) under MQSA.

Mandatory mammography accreditation has been credited with saving tens of thousands of women's lives and vastly improving the quality of patient care since the implementation of MQSA. Much of the success of MQSA can be attributed to the fact that FDA did not attempt to recreate the wheel when establishing the standards it would adopt. Instead it built upon standards and processes that were already being successfully implemented on a voluntary basis within the profession. Further, rather than relegating the quality review to federal employees who may not have had practical experience in the field, MQSA relies upon accrediting bodies, named and reviewed by FDA, to serve these functions.<sup>1</sup>

In addition to the mammography and the now joint ACR and American Society of Therapeutic Radiology and Oncology (ASTRO) radiation oncology programs, the College developed accreditation programs for ultrasound (1995), stereotactic breast biopsy (1996), magnetic resonance imaging (1996), breast ultrasound (1998), nuclear medicine (1999), computed tomography (2002) and radiography/fluoroscopy (2002). Like the radiation oncology program, these other accreditation programs were not mandatory. However, Congress adopted accreditation requirements as a requisite to Centers for Medicare and Medicare Services (CMS) payment for advanced diagnostic imaging services as part of the Medicare Improvements for Patients and Providers Act (MIPPA) in 2008. The MIPPA requirements represented a paradigm shift in which Congress made the decision to tie payment to quality and safety in medical imaging.

During implementation of the MIPPA provisions, CMS recognized the ACR, the Intersocietal Accreditation Commission (IAC), and the Joint Commission in January 2010 as deemed accrediting organizations. However, not all accreditation programs are robust enough to sufficiently improve quality and safety. Accreditation can only be successful if the accrediting bodies can clearly demonstrate their experience, expertise, and a track record in evaluating quality and phantom review in the overseen modalities. These elements are the foundation of any valid accreditation program and were specifically included in the medical imaging provisions contained in MIPPA.

While previously voluntary accreditation programs for certain medical imaging modalities will become mandatory in ambulatory settings in 2012 due to MIPPA, radiation oncology accreditation remains voluntary and participation is not as extensive as is clearly needed. This is made evident by the fact that the radiation oncology accreditation program is utilized by less than 10% of radiation therapy practices in the country. Congress must step in and mandate accreditation for radiation therapy per the lessons learned by MQSA and MIPPA.

### ACR Appropriateness Criteria

In addition to its respected accreditation programs, the ACR offers other important quality and safety resources to the radiology and referring physician communities, not the least of which being the ACR Appropriateness Criteria (AC). The ACR Task Force on Appropriateness Criteria was created in 1993 to develop nationally

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<sup>1</sup> Destouet JM, Bassett LW, Yaffe MJ, Butler PF, Wilcox PA. The ACR's Mammography Accreditation Program: ten years of experience since MQSA. J Am Coll Radiol. 2005 Jul;2(7):585-94.

accepted, scientifically-based guidelines to assist referring physicians in making appropriate imaging decisions for given patient clinical conditions. Currently, the ACR AC are the most comprehensive, evidence based guidelines for diagnostic imaging selection, radiation therapy protocols, and image-guided interventional procedures. There are 167 topics with over 800 variants as of the September 2009 iteration. ACR has also worked with software vendors to include ACR AC in computerized radiology order entry systems to address appropriateness of imaging orders by referring physicians.<sup>2</sup> By using these guidelines in making decisions regarding radiologic imaging and treatment, physicians enhance quality of care and contribute to the most efficacious use of radiology services.<sup>3</sup>

With regard to radiation dose, the ACR AC is guided by the principle that the overall risk of cancer induction from a diagnostic imaging procedure involving ionizing radiation is small, but it is not zero. Therefore, ACR AC recognizes the importance of minimizing patient radiation exposure and avoiding the ordering of unnecessary examinations. ACR AC advises referring physicians who are planning to order an imaging exam for their patient to consider the patient's previous imaging examinations. Above all, any exposure that accompanies an imaging examination should be justified based on the benefit to the patient.

In 2008, Congress recognized the potential for better patient care and reducing imaging utilization by including a demonstration project for AC in MIPPA. Future data from this demonstration project may indicate the value of expanding the use of AC to all physicians throughout the country, which the ACR strongly supports. Currently, despite the benefits in terms of quality, safety, and cost-effectiveness, the voluntary utilization of AC by referring physicians who order medical imaging studies is relatively low.<sup>4</sup>

#### “Image Gently” and “Image Wisely” Awareness Campaigns

ACR helped launch the Image Gently campaign in January 2008 as a founding member of The Alliance for Radiation Safety in Pediatric Imaging—a coalition of 41 organizations dedicated to raising awareness and promoting education about radiation protection for children undergoing medical imaging examinations. The Image Gently campaign is an effort to help ensure that medical protocols for the imaging of children keep pace with advancing technology. The goal of the campaign is to educate radiologic technologists, medical physicists, radiologists, pediatricians and parents about radiation dose used during the more than 4 million pediatric computed tomography (CT) examinations performed on children in the U.S. each year. The program has been recently expanded to include pediatric interventional radiology procedures as well.

The Image Gently website includes protocols that can be used to optimize pediatric technique used during CT imaging of children based on weight. The campaign emphasizes the need to differentiate these methods for children compared to adults. To date, 3,973 providers have taken the pledge on the Web site to “image gently” when performing pediatric imaging exams.

Due to the success of the campaign for pediatric CT, ACR and the Radiological Society of North America (RSNA) began the Image Wisely campaign to expand the principles and educational resources of the Image Gently campaign to CT imaging of adult patients. Image Wisely's partners have grown to include the American Association of Physicists in Medicine (AAPM) and the American Society of Radiological Technologists

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<sup>2</sup> Siström CS, Dang PA, Weilburg JB, Dreyer KJ, Rosenthal DI, and Thrall JH. Effect of Computerized Order Entry with Integrated Decision Support on the Growth of Outpatient Procedure Volumes: Seven-year Time Series Analysis. *Radiol* 251: 147-155; 2009.

<sup>3</sup> Hadley JL, Agola J, Wong P. Potential impact of the American College of Radiology appropriateness criteria on CT for trauma. *AJR Am J Roentgenol*. 2006 Apr;186(4):937-42.

<sup>4</sup> Bautista AB, Burgos A, Nickel BJ, Yoon JJ, Tilara AA, Amorosa JK; American College of Radiology Appropriateness. Do clinicians use the American College of Radiology Appropriateness criteria in the management of their patients? *AJR Am J Roentgenol*. 2009 Jun;192(6):1581-5.

(ASRT). When rolled out in 2010, the Image Wisely Campaign will feature educational resources for radiologists, medical physicists, and technologists, and will eventually work on increasing awareness in the referring physician and patient communities.

#### ACR National Radiology Data Registry: Dose Index Registry

Another pertinent ACR program is the Dose Index Registry (DIR), which will collect and provide feedback on radiation dose estimate information from various modalities. A pilot program focusing on CT that allows participants to compare average volume CT dose index (CTDI<sub>vol</sub>) and the dose length product (DLP) values across facilities is currently in progress, and there are plans to expand the pilot in 2010.

DIR is part of the ACR's larger National Radiology Data Registry (NRDR) program, which is a data warehouse for the DIR, General Radiology Improvement Database (GRID), National Mammography Database (NMD), CT Colonography (CTC), National Oncologic Positron Emission Tomography (NOPR), and IV Contrast Extravasation (ICE) data registries. The primary purpose of NRDR is to aid facilities with their quality improvement programs and efforts to improve patient care by comparing facility data to that of their region and the nation. Participating facilities may choose to share data with any or all registries as appropriate for their practice, and ultimately use NRDR to compare their own performance to that of other participants.

#### Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009

The ACR strongly supports H.R. 3652, the Consistency, Accuracy, Responsibility, and Excellence in Medical Imaging and Radiation Therapy Act of 2009 or CARE Act, which would require personnel performing the technical components of medical imaging and radiation therapy to meet federal education and credentialing standards in order to participate in federal health programs. The ACR encourages passage of the CARE Act in concert with mandated accreditation, dose index registry requirement, and the other aforementioned programs.

#### Conclusion

Although the use of radiation in medicine saves lives and improves patient care, the recent New York Times articles remind us that the use of medical radiation has certain risks. The ACR recognizes that even the most strenuous accreditation programs will never eliminate all medical errors in the respective services being accredited; however, the success of MQSA is proof that mandatory accreditation helps to significantly reduce these risks and ultimately improve quality.

The ACR believes Congress should expand the current MIPPA accreditation requirements for advanced imaging to include radiation therapy. In addition, the accreditation mandate should apply to all facilities, including hospital settings. Furthermore, the accrediting of these imaging and radiation therapy procedures should only be conducted by those accrediting bodies with experience and expertise in the area for which they are accrediting. Lastly, a required dose index registry would be a critical new component that could measure ongoing performance of the accreditation baseline. Such a dose registry index may have helped identify many of the problems covered in media reports far sooner. ACR has been working with industry to develop such a registry but a congressional mandate would aid this process.

As always, the College is ready to assist the Subcommittee and Congress in accomplishing these goals so that we can improve the treatment, safety and quality of care for our patients.