

Ensuring Patient Safety: A Summary of the 2008 Intersociety Conference

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The Intersociety Conference was established in 1979 to promote collegiality, encourage communication among the national radiology societies, and make recommendations on areas of concern identified by the 53 member societies invited to participate in the Summer Conference. The 2008 meeting was held July 18 to 20 at the Resort at Squaw Creek in Olympic Valley, California. As in prior years, the conference consisted of a series of plenary talks and breakout sessions during which each of 3 groups deliberated on specific aspects of the radiology report and reported to the conference on Saturday morning.

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INTRODUCTION

The landmark publications by the Institute of Medicine *To Err Is Human: Building a Safer Health System* [1] and *Crossing the Quality Chasm: A New Health System for the 21st Century* [2] highlighted problems in American health care. The institute estimated that adverse health care events resulted in 44,000 to 98,000 preventable deaths each year. It further asserted that the quality deficiencies were due primarily to systems problems rather than poor providers.

Professional radiology organizations responded to the need to improve quality through education and specific quality initiatives. In 2002, the American Board of Radiology began offering only time-limited certification and initiated a maintenance-of-certification process [3]. In 2003, the ACR held its forum on quality [4]. In 2006, the presidential address at the convention of the Radiological Society of North America discussed quality initiatives in radiology [5]. In 2007, a new section in the journal *RadioGraphics* was created to address quality [6,7].

IONIZING RADIATION

The majority of diagnostic imaging is performed with ionizing radiation. The number of these medical imaging studies being performed, especially computed tomographic (CT) studies, is growing rapidly [8], which reflects the value of these studies in providing the diagnostic information needed to make treatment decisions. The challenge lies in weighing the risk of the exposure to the ionizing radiation needed to perform the imaging examination with the expected benefit to be derived from the diagnostic information.

The adverse effects of ionizing radiation are often seen many years after exposure. Ionizing radiation can ionize deoxyribonucleic acid directly or create hydroxyl radicals that interact with it to cause strand breaks [9]. Although much of this damage can be repaired within the cell, point mutations, chromosomal translocations, and gene fusions are linked with cancer induction.

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In trying to determine the risks associated with low doses of radiation, most investigators turn to studies of survivors of the atomic bombs used in Japan in 1945. There was a significant increase in the risk for cancer among those who received 5 to 150 mSv [10]. The risk to children is even greater because their tissues are more sensitive, and they have a longer time to develop malignancies. Thus, it is not surprising that the campaign to limit the radiation used in diagnostic examinations to doses "as low as reasonably achievable" first took hold among pediatric radiologists. The Image GentlySM campaign, which is aimed primarily at the imaging of children being treated in traditional "adult" hospitals, has 4 recommendations for CT examinations in children [11]: First, use examination protocols designed for children, not adults. Sample protocols are available on the Image Gently Web site (<http://www.imagegently.org>). Second, make sure the examination is really needed. Third, limit the examination to the anatomic area of interest. Fourth,

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use a protocol that requires only a single scan of the area. Multiphase scanning is seldom needed in children.

IMAGING IN PREGNANCY

Because of the risk for teratogenic effects on a fetus, a pregnant or potentially pregnant woman poses an even greater challenge. When faced with a request for imaging in such a patient, a radiologist must first determine that a study is needed and then work with the referring physician to select the examination(s) that will best answer the clinical question with the least risk to the patient and fetus. A urine pregnancy test may be obtained on women who are uncertain of whether they are pregnant. These tests have high accuracy and can be performed in a timely fashion.

In radiography and fluoroscopy, when the uterus is outside the field of view, the dose to a fetus is minimal. The radiation exposure is higher with CT imaging, and the dose to a fetus varies with the size of the patient, the location of the uterus in relation to the scanning field, and the technique factors. However, the dose to a fetus from a single-acquisition CT examination adds minimal risk from radiation [10].

When the anatomic area to be examined includes the fetus, other imaging modalities, such as ultrasound or magnetic resonance (MR) imaging, should be considered. Ultrasound is generally considered the examination of choice because of its widespread availability and relatively low cost.

IMPLANTED DEVICES

A number of reports of adverse events in patients with implanted electronic medical devices undergoing CT examinations have appeared [12], and experimental studies support the link between the x-rays used in CT scanning and device malfunction [13,14]. Those that are deemed likely to be caused by x-ray irradiation during scanning include

- unintended shocks from neurostimulation,
- malfunction in insulin infusion pumps, and
- rate changes in pacemakers.

Additional adverse events that may be caused by x-ray irradiation during scanning include

- interrogation problems with pacemakers and defibrillators,
- lack of output from pacemakers,
- premature battery depletion with defibrillators, and
- patient seizure after CT scanning of an implanted neurostimulator.

The response of a variety of implantable cardiac rhythm management devices to the radiation delivered

during CT imaging was prospectively studied by McColough et al [15]. They found oversensing in 20 of 21 devices at maximum doses and oversensing in 17 of 20 devices at typical doses. However, oversensing was transient and ceased as soon as the x-ray beam was turned off.

Until more information on these potential risks is available, it is prudent to move the electronic circuitry outside the scanning region or exclude the device from the scan field. Alternatively, if it is felt to be safe, the device could be turned off during CT scanning. If the device must be included in the scan field, the lowest possible dose consistent with a diagnostic examination should be used.

BALANCING RISK

Because the science of the risks of radiation exposure to human subjects in the doses used for diagnostic examinations is not clear, it is challenging to balance those risks with the potential gain from the diagnostic procedures. Nevertheless, the risks from ionizing radiation are only one reason that imaging studies must be appropriately used. Unnecessary examinations add cost to our health care system. They may expose patients to additional risks, such as intravenous contrast administration, and incidental findings may be detected that generate the need for additional testing [16].

The ACR Appropriateness Criteria[®] provide a guide to assist referring physicians in selecting the most appropriate examination for a given clinical setting [17]. The criteria have been developed not only by radiologists with a special interest in the examinations but also by other physicians specializing in the areas of study. Continued upgrading of these criteria and endorsement by the subspecialty societies could be an important method of improving the appropriateness of imaging examinations.

In reviewing the information available, Verdun et al [18] concluded that the risk associated with the exposure to ionizing radiation from a diagnostic radiologic examination is low compared with the natural risk. However, any added risk is unacceptable if it does not benefit the patient.

MAGNETIC RESONANCE IMAGING

Magnetic resonance imaging has become an essential imaging modality for the care of patients in a wide variety of clinical settings. Although it does not use ionizing radiation, the powerful magnets used have significant risks for patients and members of the health care team as well as support personnel, such as those providing environmental services.

The most dramatic of these hazards is when unrestrained ferromagnetic objects are drawn into the magnetic field. Serious injuries, including death, have been

reported from unsecured ferromagnetic materials within the MR suite, as well as ferromagnetic materials within human subjects [19-22].

Radiologists are also aware of the effect of the powerful magnetic field on some implanted devices or leads [23]. Such patients, especially those with pacemakers, are often excluded from MR imaging, but increasingly, manufacturers are developing devices compatible with MR imaging.

A third hazard of MR imaging is the radiofrequency power deposition and heating due to the MR excitation field [24]. Approximately 40 surface burns associated with MR imaging were reported in 2005 and 2006 [25]. Patients should be advised of this potential and be asked to avoid wearing metallic jewelry, clothing containing metallic threads or pigments, and cosmetics while being scanned.

The "ACR Guidance Document for Safe MR Practices: 2007" [26] is a useful reference for the full range of safety concerns, including practical recommendations for policies for MR imaging centers.

IODINATED CONTRAST MEDIA

Iodinated contrast media are used extensively for angiography, urography, and computed tomography. The non-ionic media in current use have proved much safer than the older ionic agents [27]. However, severe reactions, including death, may still occur, even with nonionic media. Adverse reactions are classified as either idiosyncratic or nonidiosyncratic [28].

Idiosyncratic reactions, which include erythema, hives, perioral edema, narrowing of the airway, and vascular collapse, are "allergy-type" responses and are referred to as "anaphylactoid" reactions. They are difficult to predict, but patients with asthma, histories of allergies, or prior reactions to iodinated contrast media administration are at increased risk. The incidence of an adverse reaction can be reduced by premedication with corticosteroids [29,30].

Nonidiosyncratic reactions result from direct toxic effects of the contrast material and include nausea, vomiting, cardiac arrhythmias, and pulmonary edema. Contrast-induced renal failure is seen more commonly among patients with preexisting renal failure, especially when the azotemia is due to diabetes mellitus. Because these reactions are more predictable, a study may be avoided or precautionary measures taken in high-risk patients.

GADOLINIUM-CONTAINING CONTRAST MEDIA

Acute allergy-type reactions to gadolinium-containing contrast media are rare. Dillman et al [31] reported an incidence of only 0.07% in their review of 78,353 contrast administrations. Although most of these reactions

were mild, moderate and severe reactions requiring treatment did occur.

Recently, a systemic disorder characterized by widespread tissue fibrosis has been associated with the administration of gadolinium-based contrast media, especially gadodiamide, in patients with renal disease, especially those requiring dialysis [32]. Although no effective therapy exists, rapid correction of renal function stops disease progression and may improve symptoms.

If requested to perform an imaging examination normally requiring a gadolinium-based contrast agent in a patient with renal failure, it is prudent to consider other imaging modalities. If consultation with the referring physician and informed consent by the patient determine that the study is needed, the lowest dose needed to answer the clinical question should be used. After completion of the examination, dialysis, preferably within the first 3 hours, is recommended [32]. Although peritoneal dialysis may be used, hemodialysis clears the gadolinium-based contrast agent more effectively [33].

QUALITY IMPROVEMENT EFFORTS

Many organizations, including the Joint Commission, the National Patient Safety Foundation, the Association of American Medical Colleges, the Leapfrog Group, the National Quality Forum, the American Medical Association, the Physician Insurers Association of America, and the federal government have developed efforts to improve the quality of health care in the United States [34].

Professional radiology organizations, especially the ACR, have provided education and developed specific programs designed to improve the quality of radiology service. Accreditation programs are designed to improve the quality of imaging facilities [35]. The ACR Appropriateness Criteria were developed by committees of experts to assess the relative usefulness of imaging examinations for patients with common clinical presentations [36]. The experts who developed the evidence-based recommendations included both radiologists and referring physicians. The Breast Imaging Reporting and Data System[®] was developed to standardize the language of mammography reports [37]. The ACR's practice guidelines and technical standards provide specific details on performing imaging examinations [38]. To provide a tool for radiologists to assess the accuracy of interpretation, the ACR developed the voluntary RADPEER[®] program [39]. This quality assessment tool uses the current imaging examination as "truth" to compare with a prior imaging study. Disagreements are scored and reviewed at a later time to identify outliers or common themes in interpretive errors that can be addressed in an education effort to improve interpretation accuracy. To help radiologists benchmark their practices, the ACR

has developed a series of national databases (the National Radiology Data Registry) in which data from practices across the country can be stored and mined for normative values [40].

APPROPRIATE UTILIZATION

All imaging studies have associated risks for patients. Those that involve intravascular contrast administration or require ionizing radiation have received the greatest attention. However, even ultrasound examinations performed without contrast agents risk the detection of incidental findings. Such findings may fortuitously identify potentially harmful lesions that could be treated before they harm patients. More often, however, these incidental findings are benign but put patients at risk for the additional studies needed for their evaluation. Thus, imaging studies that are not medically necessary have the potential to adversely affect patients and provide little, if any, benefit to them.

There are many causes of inappropriate medical imaging, including ignorance of what imaging study is needed, the expectation of patients that they will undergo imaging tests, a fear of liability for missed diagnoses, and self-referral [41]. The tendency of physicians to overutilize imaging tests when they have equity positions in imaging centers has been well documented in landmark papers by Hillman et al [42,43] and confirmed by the US General Accounting Office [44]. This tendency has been further documented in recent publications by Levin [45] and Levin and Rao [46]. Levin [45] further pointed out that imaging centers operated by untrained physicians are more likely to produce poor-quality images and that if untrained physicians interpret these images, they will be more likely to make avoidable errors.

It must be recognized that radiologists may also contribute to inappropriate utilization. When a radiology report recommends an additional imaging study to clarify an abnormality, this could be considered a form of self-referral, even though the referring physician must make the decision of whether to request the examination. Lee et al [47] reviewed 31,111 repeat examinations and found that 8% were recommended by the radiologist.

RECOMMENDATIONS

The 2008 Intersociety Conference concluded with a number of recommendations to improve the quality of radiology:

1. Improve the appropriateness of diagnostic imaging. The ACR Appropriateness Criteria are well done but will require periodic review and updating to reflect new information and changes in examination techniques. These should be endorsed by the pertinent

subspecialty societies and clearly communicated to our referring physicians.

2. Follow the principle of “as low as reasonably achievable” and the Image Gently guidelines to use the lowest possible dose of ionizing radiation to perform a diagnostic study that answers the clinical question. The principles of the Image Gently campaign should be applied to all patients, not only children or pregnant women.
3. Improve safety in MR imaging. A concise and nationally accepted patient screening form should be made available for online access to patients, referring physicians, and radiologists. Similarly, a centralized registry of implantable medical devices should be developed to provide an assessment of MR compatibility.
4. Radiologists, radiation oncologists, and radiologic physicists should be encouraged to develop and use national databases to provide benchmark information.
5. Structured reporting using a standard lexicon, such as RadLex, should be used to improve result communication with referring physicians and to allow report mining for utilization management and patient safety information.
6. Vendors must be encouraged to develop products that support quality and patient safety efforts. Much of this involves information technology, and those proprietary systems must be compatible with one another using Digital Imaging and Communications in Medicine standards. Integrated data transfer is needed to avoid repeated manual entry. Order entry products should include a list of recent prior examinations, an estimate of the relative radiation dose, and an assessment of examination appropriateness for the clinical setting. Imaging examinations must be transportable from one health care institution to another to avoid repeating examinations.

Although many of these recommendations will require significant and ongoing volunteer effort, they are likely to result in a reduction in inappropriate examinations, an improvement in patient safety, and more readily available information on which to base medical decisions. It is essential that radiology maintain intellectual leadership in this effort.

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