Quantifying Radiation Safety and Quality in Medical Imaging, Part 1: Creating the Infrastructure

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An integral part of cost-benefit analysis within medicine is the comparative assessment of the clinical gains introduced by a service or application compared with the patient costs, which can be measured in economic or clinical terms. When analyzing medical imaging, a number of factors must be included, the most important of which include issues pertaining to patient safety, image quality, and clinical outcomes. Although ionizing radiation has long been recognized as a potential carcinogen capable of introducing harm to patients, the long-term derived benefits have been accepted because of the diagnostic and therapeutic benefits derived from its use. With the increased utilization of high-dose ionizing radiation examinations (such as multidetector computed tomography), it is essential that the medical community create data-driven methodologies to quantify risk in objective terms, develop community-wide radiation standards and "best practice" guidelines (evidence-based medicine), develop new technologies and applications to proactively minimize radiation dose while maintaining quality, and create accountability measures for all pertinent stakeholders.

Key Words: Radiation, safety, quality, data mining

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INTRODUCTION

A number of high-profile publications issued by the Institute of Medicine (IOM) have called for accelerated efforts to improve patient safety, reduce medical errors, and improve the quality of health care delivery [1-3]. Included in these recommendations for major health care reform, the IOM has issued a number of proactive, patient-oriented recommendations, including the following:

- Provide guidance to consumers, providers, payers, and other key stakeholders on priority strategies to achieve short-term and long-term safety goals.
- Assess opportunities and key impediments to the nationwide implementation of medical error reductions and provide guidance to governmental agencies on promoting a national agenda for medical error reduction.
- Develop an applied research agenda to evaluate health and cost impacts of alternative interventions, through the Agency for Healthcare Research and Quality and other governmental agencies.

A consistent theme throughout these publications is patient empowerment, with a deliberate shift from the current provider-centric practice model to a patient-centric model of medical practice. In the creation of such a patient-centric model of health care, a patient's bill of rights has been advocated [4-6] (Table 1), which would serve as the foundation for the safe and ethical delivery of health care, irrespective of the individual medical discipline.

One of the important outcomes of this patient-centric model of medical practice would be the creation of objective accountability measures, which could provide patients the ability to make well-informed, data-driven decisions relating to selection of their health care providers, treatment regimens, and diagnostic testing. In the case of medical imaging, these accountability measures would provide a transparent means of assessing institutional, departmental, individual, and technology performance in the delivery of medical imaging services. The accountability components would need to include all steps within the medical imaging chain, all participating stakeholders, and all technologies being utilized.

DEFINING THE ACCOUNTABILITY MEASURES

Tables 2, 3, and 4 outline the individual steps within the medical imaging chain, the various stakeholders in-

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Table 1. Patient's bill of rights

1. Self-determination: the ability of each patient to control all clinical management decisions affecting the patient.
2. Informed consent: patients provided with all available medical options and alternatives.
3. Consultation: multidirectional communication between health care consumers (patients or designated surrogates) and health care providers.
4. Notification: the timely notification of all pertinent data, including clinically significant errors or adverse outcomes.
5. Designation: the ability to designate a surrogate to assist in decision making and communication.

volved, and the technologies utilized. These steps include examination ordering, scheduling, data access, protocol selection, image acquisition and processing, quality assurance, archival and transmission, interpretation, and reporting and communication.

Although the obvious stakeholders would include those health care professionals performing these designated tasks (clinicians, clerical staff members, technologists, and radiologists), a number of other stakeholders are actively involved in a less obvious fashion (administrators, physicists, vendors, patients, and payers).

Administrators are often responsible for establishing and ensuring compliance with departmental policies, which can include patient safety and confidentiality, image quality, staff education and training, and technology performance. Information technology specialists are relatively new stakeholders within the medical imaging chain and must maintain the integrity and accessibility of the digital data, along with integration of the electronic databases and compliance with community-wide information technology standards. Medical physicists are tasked with the dual responsibilities of maintaining equipment quality control and compliance with regulations and standards relating to radiation safety.

Table 2. Individual events within the imaging chain

1. Ordering
2. Scheduling
3. Data access
4. Protocol selection
5. Image acquisition and processing
6. Quality assurance
7. Archival and transmission
8. Interpretation
9. Reporting and communication

Table 3. Stakeholders within the imaging chain

1. Radiologist
2. Clinician
3. Technologist
4. Clerical staff
5. Administrator
6. Information technology specialist
7. Physicist
8. Vendor
9. Patient
10. Third-party payer

Vendors produce, sell, and service the various technologies being utilized within the imaging chain; ensure compliance with federal regulations; and make recommendations as to how the equipment should be properly implemented, calibrated, and maintained. At the same time, vendors are often asked to facilitate end users' education and training, technology integration, and clinical decision support.

Patients, who are commonly overlooked, should also bear some responsibility, for it is their very own health and well-being at stake. Patients should be responsible for providing accurate data relative to their medical histories, be compliant with mutually agreed on clinical management, and actively participate in the decision-making process.

Third-party payers also bear responsibility in the process by ensuring that payments issued are commensurate with services provided, that community-wide quality standards are being maintained, and that patients' well-being and individual rights are being accounted for.

The only realistic way of enforcing accountability in the chain of events, individual stakeholders, and technology providers would be to create an objective, data-driven process (ie, scorecard) that adheres to universal standards, quantitatively measures individual and col-

Table 4. Technologies within the imaging chain

1. Computerized physician order entry
2. Radiology information system
3. Hospital information system
4. Picture archival and communication system
5. Modality/acquisition device
6. Quality assurance workstation
7. Electronic medical record
8. Decision support

lective performance, and creates accessible (and understandable) data output that can be used for service and technology selection, reimbursement, research, and education and training. The ultimate goal is to eliminate the guesswork that currently permeates the medical decision-making process, create transparency, and create an incentive to those health care providers offering the highest (and reproducible) levels of quality, safety, and clinical outcomes. The creation of such a system would most certainly be challenging and complex and require the oversight of neutral, third-party entities, which could ensure data integrity and accuracy.

DATA PURVEYORS

A governmental infrastructure currently exists to assist in the creation, analysis, and reporting of objective quality and safety metrics within medicine. Within the medical imaging domain, these agencies include

- the Agency for Healthcare Research and Quality,
- the Centers for Medicare & Medicaid Services,
- the US Food and Drug Administration,
- the National Library of Medicine, and
- the Nuclear Regulatory Commission.

Each governmental agency would bring a different perspective and experiential knowledge to the endeavor. The Agency for Healthcare Research and Quality, for example, has an established mandate of overseeing safety-oriented research and could also serve as a repository of educational resources relating to patient safety. The Centers for Medicare & Medicaid Services is the largest payer of medical services within the Unites States and the overseer of existing pay-for-performance programs aimed at tying a portion of professional reimbursements to quality indicators. A logical extension of pay for performance would be the creation of quality metrics throughout the entire imaging chain, which could in effect create a comprehensive mechanism for introducing accountability measures tied to quality, while rewarding those providers with the highest performance measures.

The Food and Drug Administration is the chief federal agency responsible for ensuring that manufacturing safety standards are maintained and that technology vendors are in compliance with federal regulations. This agency could assist in the establishment of technology standards and the associated metrics that quantify technology performance, as it relates to safety and quality. The Nuclear Regulatory Commission performs a critical function within medical imaging in the creation of standards and measures of radiation safety. The National Library of Medicine could assist in the dissemination of health information on the Internet, as well as the creation of a national telephone helpline for health care consumers.

In addition to these governmental agencies, a number of nonprofit health care organizations exist with proven track records in the areas of patient safety, health care quality, medical research, and resource utilization. These include

- the Leapfrog Group (http://www.leapfroggroup.org),
- the Howard Hughes Medical Institute (http:/www/hhmi.org),
- the Robert Wood Johnson Foundation (http://www.rwjf.org), and
- Bridges to Excellence (http://www.bridgestoexcellence.org).

The combined efforts of these governmental and private agencies could be used to achieve the desired endpoint of creating quantitative accountability throughout medical care delivery. The governmental agencies, in conjunction with the IOM, could draft requests for proposals outlining the quality and safety goals and objectives, requisite standards, and reporting mechanisms. The goal of this public-private partnership would be the formulation of a national quality and safety health care initiative, through the standardization and objectification of medical data, the creation of national databases for research and meta-analysis, and the public dissemination of these quality and safety data to health care consumers, in understandable terms. Although all medical disciplines can benefit from such an endeavor, radiology is particularly sensitive because commoditization threatens the long-term viability of the medical imaging community [7].

CONCLUSION

Although medical imaging services are currently provided by a large number of medical practitioners, radiologists arguably offer superior expertise in their ability to provide clinical acumen, mastery of technology, and dedication to safety and quality [8]. If the radiologist community is to maintain its dominance over the delivery of medical imaging services, it is critical that the focus of service delivery be centered on the safety and quality concerns of patients who will achieve greater empowerment as recently issued IOM mandates are realized throughout health care delivery. The creation of data-driven quality and safety standards throughout each step of the medical imaging chain creates the infrastructure to create objective accountability measures for all stakeholders and technology providers. This initiative could simultaneously empower health care consumers, facili-

tate safety and quality-centric research and education, create financial incentives for those providers with the highest levels of proficiency, drive new technology development, and foster the creation of evidence-based medicine guidelines.

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