REPORT OF THE BOARD OF TRUSTEES

B of T Report 30 - A-07

Subject: Development of Standards for MRI Equipment and Interpretation to Improve Patient Safety

Presented by: Cecil B. Wilson, MD, Chair

Referred to: Reference Committee E
(Paul C. Matson, MD, Chair)

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Resolution 539, introduced by the American Association of Neurological Surgeons and the Congress of Neurological Surgeons and adopted at the 2006 Annual Meeting, asked that our American Medical Association (AMA) convene a meeting(s) with representatives from magnetic resonance imaging (MRI) manufacturers, radiology and other interested medical specialties, and imaging facilities, with the goals of: (1) agreeing to standards in electronic imaging formats (e.g., left to right, axial, coronal, sagittal); (2) developing standards of data manipulation and localization consistent throughout all units for best interpretation of the data; (3) ensuring that each electronic format is equipped with the capability of loading and launching its contained images on the physician's computer; and that a report of the meeting(s) be issued to the House of Delegates at the 2006 Interim Meeting.

This report summarizes the results and makes recommendations stemming from a meeting, convened by the AMA, of representatives from relevant physician organizations and MRI manufacturers to discuss the safety and quality issues associated with nonstandardized MRI systems.

Background

In accordance with Resolution 539-A-06, the AMA convened a meeting of physicians representing the American Association of Neurological Surgeons, American Congress of Neurosurgery, American Academy of Neurology, American College of Radiology, American Academy of Orthopaedic Surgeons, and American College of Cardiology as well as industry representatives from General Electric, Siemens, Philips, and Accuray to discuss the consequences arising from lack of MRI industry standards.

Electronic imaging, storage, and transmission in medical care has expanded exponentially. With the added utility of electronic imaging, more rapid dissemination, use, and communication about patients and health care decision-making may be greatly facilitated. However, the rapid growth of electronic technology, and particularly the competitive, proprietary forces inherent in its development, has had a significant negative impact on clinical care. In particular, manufacturers and vendors of MRIs, and their data and information transfer software, have adopted competing standards and methods to create, read, and transmit these clinical images. Problems that have arisen include:

- Unique manufacturer sequencing of images and data manipulation;

- Imagery that is reduced in quality when transmitted;

- Images that are not transferable for storage and/or to archive specific purposes across providers and systems;

- CD-ROM formats that are not compatible across computers and software platforms;

- Image presentation without standardized master key, legends, or localizing images;

- Differing quality of images provided, and presence or absence of related interpretation and/or reports associated with those images;

- Competing software that arranges images in opposite planes of view;

- Failure to design for the specific needs of specialists (e.g., CDs with enough data and flexibility to examine dynamic cine images, a critical cardiac diagnostic function); and

- Other nonstandardized approaches to capturing, transmitting, and viewing clinical images.

The emerging problems associated with these developments have had a tremendous impact on the effectiveness and efficiency of medical care and on patient safety.

Discussion

Nonstandard imaging systems create confusion, waste time that could be devoted to clinical care, and are a threat to safe, high quality, and medically appropriate care delivery. Furthermore, they create significant system inefficiencies, such as duplicating efforts and repeating MRIs, which result in greater costs for the medical system at large.

Patient safety is critically affected by the problems of nonstandardized imaging systems. Errors are inherent in proprietary systems that use different axes as reference (if any are denoted at all), different required viewers, and varying toolbars and navigation systems. This confusion requires physicians to be knowledgeable about, and have the software to read, the various systems—while concurrently organizing and sorting the particular functions of these multiple systems. The situation creates confusion and distraction that impede appropriate and timely access to important clinical information. In addition, this confusing and distracting process is exacerbated when physicians are simultaneously trying to interpret the MRI scans, diagnose the disease state, identify next steps, identify relevant surgical sites, and explain their clinical results to patients. In combination, MRI nonstandardization is a potential recipe for error and clinical disaster for a single physician addressing the needs of a single patient. Adding multiple sites of care and consultation with other similarly situated physicians magnifies the inherent systems issues that may exist in and across organizations. These factors represent direct risks to the patient's well being.

The tremendous downtime required to review MRI standards, readers, and other related concerns are also directly related to safety concerns. Physicians, as responsible professionals, are attempting to take reasonable and, indeed, extraordinary care when trying to assess and read nonstandardized

MRI information. At the same time, as the medical dollar becomes increasingly squeezed, the time devoted to navigating serpentine systems to emerge with the right information from the right readers assessing the appropriate data in the right form is time-consuming and daunting at best. Such circumstances are grave in any clinical setting. But the pressure of immediate clinical needs in emergent and other high intensity care settings may result in tragic patient care outcomes because of this nonstandard MRI system,. Hence, the processes associated with nonstandard MRI information take valuable time away from patients and substantive patient care assessment and are a threat to patient safety in some of the most sensitive times for the patient and the physician. Further, other important activities, such as research and dissemination of important findings relevant to improved clinical care, are also limited by the inefficiencies and the remedial care and activities necessary to address the limitations and outcomes associated with nonstandard MRI systems.

Additionally, nonstandardized clinical information, including limited quality images proffered by some vendors (versus others), creates ethical issues and impacts patient self-determination through ineffective informed consent. If physicians do not have the full information that would be provided by a high resolution MRI, or receive inadequate or unknown quality MRI scans, they cannot—ethically—make decisions on these data when relevant, higher quality information is available elsewhere. Informed consent requires that diagnosis and treatment assessments must be made on the basis of full data and information reviewed by the physician and then communicated to the patient in a manner he or she can understand. At present, the physician's obligation may be compromised, and hence the patient's consent rendered ineffective, by the nonstandard status of MRI data and information.

Other aspects of patient self-determination are also affected by the current nonstandard MRI system. Shared decision-making with regard to clinical treatment is an important ethical and legal mandate. However, patients cannot participate fully in their care if the very physicians in which they have placed their trust to provide them with accurate, timely, and complete information in fact cannot do so because of the barriers they themselves face in obtaining that information. Patients cannot be fully engaged in their care when physicians may not be able to access the complete information relevant to the patient to discuss it with him or her.

Finally, significant legal issues arise from the current situation. Errors that result from nonstandardized, inefficient MRI data, information, readers, and other related circumstances that result in patient injury are a tremendous liability concern. It is no defense that a physician confused an image, which then resulted in error because of the fact that he or she did not have an appropriate reader or was unfamiliar with the MRI CD-ROM format provided. The liability stemming from this issue may also extend to hospitals and other institutional providers if they can be shown to have had a duty to provide the relevant systems and did not. Additionally, liability may extend to hospital or community-based physicians communicating with other physicians in consultation who knew or should have known of the varying standards associated with MRI imaging but failed to ensure (somehow) that the consulting physician had information, hardware, and software to appropriately assess the patient's images to render an appropriate recommendation on care.

<u>Current AMA Policy</u>

Although current AMA policy does not specifically address MRI standardization, existing policy does encourage the setting of standards for health care information technology whereby the

different products will be interoperable and able to retrieve and share data for the identified important functions while allowing the software companies to develop competitive systems (D-478.996, AMA Policy Database). Additionally, existing AMA policy related to patient safety underscores the need to work collaboratively with a broad range of public and private organizations to advance efforts to improve patient safety and promote "best practices" in the delivery of health care services (Policy H-335.965, AMA Policy Database).

Conclusion

The lack of standardization of MRI information has important patient safety, ethical, and liability implications for physicians in a wide array of specialties and practice settings. Although the AMA has existing policy that generally supports standards setting for health information technology, the use of nonstandardized imaging systems is a current threat to high quality, medically appropriate, efficient, and safe care. Although the AMA-convened meeting of stakeholders was productive, it was not conclusive. Meeting attendees identified additional issues that must be addressed in order to expedite standards setting for MRIs. Attendees also identified other relevant stakeholders that should be a part of future discussions.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted and that the remainder of this report be filed:

That our American Medical Association:

1. Convene a meeting of medical stakeholders to identify optimal approaches for magnetic resonance imaging (MRI) standardization that would serve clinical needs. Invitees would include representatives from the following medical specialty societies: American Association of Neurological Surgeons; American Congress of Neurosurgery; American Academy of Neurology; American College of Radiology; American Academy of Orthopaedic Surgeons; American College of Cardiology; American Academy of Ophthalmology; American Academy of Otolaryngology – Head and Neck Surgery Foundation. (Directive To Take Action)

2. Once optimal approaches that serve clinical needs have been identified, convene a joint meeting of medical and other stakeholders, e.g., payers, vendor standardization organizations, accreditators, and major MRI manufacturers that would be impacted by MRI standardization. Invitees would include representatives from the following organizations: Centers for Medicare and Medicaid Services/other payers; National Electrical Manufacturers Association (NEMA); Digital Imaging and Communications in Medicine Standards Committee of NEMA; Intersocietal Commission for the Accreditation of MRI Laboratories; Intersocietal Accreditation Commission; Institute for Magnetic Resonance Safety, Education, and Research; GE; Siemens; Philips; Toshiba; Hitachi; and FONAR. (Directive to Take Action)

3. Recommend that stakeholders agree to a voluntary system of MRI standardization and accreditation, and focus on developing solutions across professional, payer, and industry partners that promote interoperability and use of MRI data and presentation and urge the

development of a timetable that would result in 50% interoperatibility within one year. (Directive to Take Action)

4. If voluntary efforts fail and/or vendors and others are reticent to act, advocate for mandated change through legislative channels. (Directive to Take Action)

Fiscal Note: $33,904