

Hospitals Issue Call for Action on Medical Device Interoperability

We highlighted the importance of medical device interoperability for patient safety in an article in *PSQH* in January/February 2007. Interoperability enables the integration of individual medical devices into a networked system for the care of a high-acuity patient, and will support an infrastructure for innovation in patient safety, treatment efficacy, and workflow efficiency. Such a system can reduce medical errors and healthcare costs to the benefit of patients throughout the continuum of care. In the past year, the primary potential users of such integrated systems—clinicians and healthcare delivery organizations (HDOs)—have begun to strengthen their demand for this vital capability.

Six clinical societies have now endorsed medical device interoperability as enabling improvements to patient safety and healthcare efficiency. These include the Anesthesia Patient Safety Foundation, American Society of Anesthesiologists (ASA), Society of American Gastrointestinal Endoscopic Surgeons, World Federation of Societies of Anaesthesiologists, Society for Technology in Anesthesia, and Massachusetts Medical Society. Similar endorsement language is under consideration by additional groups.

Three leading HDOs—Massachusetts General Hospital/Partners HealthCare System, Johns Hopkins Hospital, and Kaiser Permanente—collaboratively developed draft interoperability requirements that they have agreed to incorporate in their procurement contracts with medical device vendors. The collaborative team—including clinicians, procurement/materials managers, clinical and information systems engineers, and legal counsel from each of the institu-

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tions—was convened and led by the Medical Device Plug-and-Play (MD PnP) Interoperability Program and worked together over a 6-month period to develop a white paper and sample sharable contracting language. The resulting document—MD FIRE (Medical Device Free Interoperability Requirements for the Enterprise)—was announced and released at the annual meeting of the ASA in October 2008, and is available for download on the MD PnP web site (<http://mdpnp.org>). The document's release was followed by a press release from the ASA and a cover article in the December 2008 issue of *Anesthesiology News*.

The original collaborating institutions have issued a call to action for interoperability of medical devices and systems—they are encouraging other hospitals and HDOs to adopt MD FIRE or similar language for contracts and RFPs, in order to drive procurement changes that make it clear to medical device vendors what we need. This work is closely aligned with the U.S. FDA's position on interoperability. The document urges device manufacturers to adopt open electronic data interfaces once they are available, and to participate in the development of such interfaces. Additional large national HDOs are currently considering the MD FIRE language.

A set of interoperability standards called ICE—the Integrated Clinical Environment—is currently under development in ASTM International, one of the world's largest standards development organizations. The multi-part ICE standard defines the necessary characteristics of a patient-centric clinical environment that can safely support integrated networked medical devices, such as “flight data recorder” capture of network and user data (e.g.

EXCERPTS FROM MD FIRE (http://mdpnp.org/MD_FIRE.php)

We HDOs wish to adopt interoperability standards for medical device interconnectivity. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. ...Our goal is to document the clinical demand and to strongly encourage the development and adoption of medical device interoperability standards and related technologies.

...We believe that changing the way in which we procure medical devices to integrate requirements for interoperability will provide a way for us to ensure patient safety, improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information.

keystrokes), and authentication of devices coming onto and going off the network. Part I of ICE is out for ballot, and work is beginning on the drafting of subsequent parts (Device Models and Network Control).

MD FIRE reflects the recognition by HDOs of the need for medical device interoperability in the modern healthcare environment and their deep-felt desire to adopt interoperability standards when available. By releasing the MD FIRE document and encouraging ongoing discussion and improvement of interoperability requirements, HDOs seek to hasten the day when patients and providers can benefit from the same level of interoperability that we all enjoy as consumers of modern computers and consumer electronics that have these capabilities now. **IPSQH**

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communications, and projects for the multi-disciplinary, multi-institutional MD PnP program, which includes a growing network of more than 600 individuals and 85 institutions. Whitehead may be contacted at swhitehead@partners.org.

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Option 1: Complete Interoperability

1. Supplier shall list all external interfaces for each Product, including interface and communication standards and terminology definitions (referred to collectively herein as "interfaces"). This includes listing any interface standards for a Product which Supplier does not intend to implement or conform to....

2. During the Term of the Agreement and any subsequent period during which Customer is purchasing support and maintenance services from Supplier for Products, Supplier will implement federally ratified interoperability standards and interoperability specifications for all interfaces described in paragraph 1 above as follows:...

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