

Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)

“Consumer” Empowerment: Hospitals Can Accelerate the Adoption of Medical Device Plug-and-Play Interoperability for Patient Safety

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Major healthcare delivery organizations – **Massachusetts General Hospital/Partners HealthCare, Johns Hopkins Medicine and Kaiser Permanente** – have agreed to use shared equipment acquisition contracting requirements to promote vendor compliance with emerging interoperability standards for medical device connectivity. These requirements will be used in procurement contracts for medical devices and related equipment. This collaboration reflects the mutual interest of these prestigious institutions in documenting the clinical demand and strongly encouraging the development and adoption of medical device interoperability standards and related technologies.

The initiative to foster the adoption of medical device interoperability standards in the nation’s medical centers is gaining traction as a result of the work of the Medical Device Plug-and-Play (MD PnP) Interoperability program, based at Massachusetts General Hospital and CIMIT¹. The adoption of medical device interoperability is expected to result in improved safety for patients, as well as better workflow efficiency for hospitals. The collaboration of these institutions through the MD PnP program over the last four years has led them to conclude that essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and systems.² Furthermore, clinical societies and the FDA now endorse the potential of medical device interoperability to lead to “improvements in patient safety and clinical efficiency”.^{3,4}

Background

Medical devices, essential for the practice of modern medicine, have traditionally been designed to operate independently using proprietary protocols and interfaces for system integration. With the increasing complexity of the healthcare environment, stand-alone, proprietary devices and systems no longer provide an acceptable solution. Medical devices and systems must easily integrate with other vendors’ equipment, software, and systems in order to improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information. Examples of clinical scenarios that could benefit from interoperability have been demonstrated in ASA scientific exhibits in 2006 (x-ray / ventilator synchronization to obtain clear images without stopping ventilation) and 2007 (PCA safety interlock to stop the flow from the infusion pump and call the nurse when a patient shows signs of respiratory distress).

Standards-based medical device interoperability can provide real-time comprehensive population of the electronic medical record (EMR), and in the future will permit the creation of integrated error-resistant medical systems that will support advanced capabilities such as automated system readiness assessment; physiologic closed loop control of medication delivery, ventilation, and fluid delivery; decision support; safety interlocks; monitoring of device performance; plug-and-play modularity to support “hot swapping” of replacement devices and selection of “best of breed” components from competitive sources; and other innovations to improve patient safety, treatment efficacy, and workflow efficiency. These capabilities have been described in a new standard for the Integrated Clinical Environment (ICE) developed by ASTM International.⁵

¹ Center for the Integration of Medicine and Innovative Technology, Boston, MA

² Getting Connected for Patient Safety: How Medical Device “Plug-and-Play” Interoperability Can Make a Difference. *Patient Safety & Quality Healthcare* 5:1, Jan-Feb 2008. (<http://mdpnp.org/Publications.html>)

³ http://mdpnp.org/Endorsements_of_Interop.html

⁴ “FDA Perspective,” 2007 Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS-MD PnP 2007), pp xii-xiii, 2007 (<http://tinyurl.com/mdpnpfda>)

⁵ ASTM F29.21 draft standard on the Integrated Clinical Environment, Annex B: “Clinical Context and Clinical Scenarios”

Healthcare Delivery Organizations (HDOs) are making it clear that they wish to adopt emerging interoperability standards for medical device interconnectivity. Other HDOs are eager to follow the lead of Massachusetts General Hospital/Partners HealthCare, Kaiser Permanente, and Johns Hopkins Medicine, and to adopt the shared contracting language. While recognizing that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors, HDOs believe that adoption of standards-compliant interoperable devices and systems will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency for patient care; will improve the quality of medical devices; will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; will release HDO resources now used to maintain customized interfaces; and will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual, institutional, and national goals for improved healthcare quality and outcomes.

As a result of collaboration with the MD PnP program, Kaiser Permanente in 2006 began to include general language about medical device interoperability in vendor contracts. Massachusetts General Hospital/Partners HealthCare and Johns Hopkins Medicine became actively engaged in this effort in 2008 with the goal of expanding and strengthening the original language to make it clear that customers want this capability and expect vendors to cooperate in making it happen. The general principles reflected in the contracting language include (1) disclosure of existing and planned standards compliance, (2) commitment to comply with emerging medical device interoperability standards when required, (3) independent testing for compliance if requested, and (4) interface specifications as needed by customers for connectivity with third-party systems that interoperate with the medical devices they use.

MD PnP Program Overview

The MD PnP program was established in 2004 to lead the evaluation and adoption of open standards and technology for medical device interoperability to support clinical innovation. The program is affiliated with Massachusetts General Hospital (MGH), CIMIT (Center for Integration of Medicine and Innovative Technology), and Partners HealthCare Information Systems, with additional support from TATRC (U.S. Army Telemedicine & Advanced Technology Research Center). Having evolved from the OR of the Future program at MGH, the MD PnP program remains clinically grounded. We have taken a multi-faceted approach to begin addressing key barriers to achieving interoperability, including the development and support of suitable open standards (e.g. the Integrated Clinical Environment, or ICE), and the elicitation, collection and modeling of clinical use cases and engineering requirements for the ICE platform and “ecosystem”. The CIMIT MD PnP Lab opened in May 2006 to provide a vendor-neutral “sandbox” to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop demonstrations of interoperability-based patient safety improvements, to develop and test related network safety and security systems, and to support interoperability and standards conformance testing.

How You Can Participate

- Clinicians can contribute clinical scenarios (or “use cases”) to ensure that new interoperability standards and technologies will enable meaningful clinical solutions.
- Engineers can analyze clinical use cases to generate functional specifications, assess current standards to perform gap analyses, and evaluate proposed technologies.
- **Healthcare delivery organizations can specify performance requirements, and require adherence to medical device interoperability language in vendor contracts** (see sample requirements language at www.mdpnp.org).
- Medical device manufacturers can participate in the development and adoption of interoperability standards, and partner with the MD PnP Program to develop a shared interoperability testing environment.
- Interoperability promoting organizations can support revising existing standards to meet clinical requirements, collaborate on clinical use-case implementations in the MD PnP Lab, and ensure that through collaboration we shepherd the adoption of medical device interoperability to empower innovation in the safety and efficiency of health care.