

## **Advancing the Adoption of Medical Device "Plug-and-Play" Interoperability to Improve Patient Safety and Healthcare Efficiency**

Unlike the connected “plug-and-play” environment of networked computers and modern consumer electronics, medical devices – essential for the practice of modern medicine – have traditionally been designed to operate independently. 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.

The importance of applying modern systems engineering solutions, such as interoperability, to improve patient safety and reduce costs was addressed in a National Academy of Sciences report entitled *Building a Better Delivery System: A New Engineering/Health Care Partnership*<sup>1</sup>. However, standards and technology for medical device interoperability are not complete, and have not been widely adopted by medical device manufacturers. Currently, when cross-vendor medical device integration is required, customized device interfaces must be developed, with high cost and incomplete functionality.

Standards-based medical device interoperability can provide real-time comprehensive population of the electronic health record (EHR) and lay a foundation for the more comprehensive improvements in patient safety and quality that can arise from the integration of medical devices. Interoperability will enable the creation of integrated error-resistant medical systems to support advanced capabilities such as automated system readiness assessment; physiologic closed loop control of medication delivery, ventilation, and fluid delivery; decision support; safety interlocks; smart alarms; 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; comprehensive data collection (like a “flight data recorder”) for the analysis of near-misses and adverse events; enhanced disaster preparedness and response capabilities; and other innovations to improve patient safety, treatment efficacy, and workflow efficiency. These improvements in workflow will reduce medical errors and healthcare costs to the benefit of patients throughout the continuum of care – from the home, to out-of-hospital transport, and to clinical areas as diverse as the OR, ICU, and general hospital ward.

Barriers to the widespread adoption of interoperability have included the absence of proven standards for data communication and control, and a lack of reliable and safe system architectures. Moreover, there have been regulatory concerns, liability concerns, and a scarcity of well-defined use cases. These barriers underscore the need for an integrated clinical environment “ecosystem” that would enable system-level functions such as real-time clinical decision support algorithms, data logging, data security, device authorization, and connectivity to the hospital information system. These functions would provide a complete systems solution that meets regulatory, safety, and clinical requirements.

### **About the Medical Device “Plug-and-Play” (MD PnP) Interoperability Program**

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 (the 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 ASTM F2761-09 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 MD PnP program received CIMIT’s 2007 Edward M. Kennedy Award for Healthcare Innovation.

Since the program’s inception, more than 750 clinical and engineering experts, and representatives of more than 90 companies and institutions have participated in five plenary workshops/conferences, working group meetings, and focus groups to contribute to ongoing program activities and help shape the common goals. Our geographically dispersed, interdisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, FDA, NIST, university computer and information science groups at Pennsylvania, Illinois/Urbana-Champaign, Waterloo, New Hampshire, and Kansas State, Draeger Medical Systems, Philips Medical Systems, DocBox Inc., Moberg Research Inc., LiveData Inc., Mitre Corporation, IXXAT, Lockheed Martin Corp., NSF Cyber Physical Systems, Geisinger Health System, and the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women’s Hospital, and Partners HealthCare IS).

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 and test related network safety and security systems, and to support interoperability and standards conformance testing. In the Lab we are developing demonstrations of interoperability-based patient safety improvements, such as improving the safety and quality of portable x-rays, and patient-controlled analgesia systems that are used for pain management.

Healthcare Delivery Organizations (HDOs) are making it clear that they wish to adopt emerging interoperability standards for medical device connectivity. Kaiser Permanente in 2006 began to include limited requirements for medical device interoperability in vendor contracts. As a result of collaboration with the MD PnP program, in 2008 MGH/Partners HealthCare, Kaiser, and Johns Hopkins Medicine became actively engaged in this effort with the goal of expanding and strengthening the original language to make it clear that customers want interoperability and expect vendors to cooperate in making it happen. These institutions have issued a nationwide Call to Action to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. This collaboration has produced sample RFP and contracting language that is being shared with other institutions as well as device manufacturers (MD FIRE: Medical Device Free Interoperability Requirements for the Enterprise).

Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to “improvements in patient safety and clinical efficiency”. Since the first clinical society endorsement in March 2007, the need for medical device interoperability has been endorsed by seven societies, including the American Medical Association:

*Intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. We also recognize that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit.*

## Key MD PnP Program projects include:

- Eliciting clinical scenarios to inform interoperability solutions that are enabled by the integration of medical devices and IT systems
- Refining a clinical requirements acquisition and analysis methodology that enables use cases to be specified at the level of detail needed to derive engineering requirements, including both functional and quality requirements
- Compiling a database repository of interoperability use cases that can be shared
- Developing a new open standard for a patient-centric “Integrated Clinical Environment” (ICE) and informing changes to related existing standards – Part I of the ICE standard has been published as ASTM F2761-09; subsequent parts are in process
- Developing a prototype healthcare intranet with an open ICE platform and tools to ensure safe and effective connectivity of medical equipment and decision support for clinical care
- Defining a safe regulatory pathway for patient-centric networked medical devices, in partnership with the FDA (see January 2010 FDA Workshop content on our web site)
- Creating and refining interoperability contracting language for use by hospitals in their procurement of medical devices

## 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. Diversity of use cases increases the likelihood of effective and generalizable solutions.
- **Engineers** can analyze clinical use cases to generate functional specifications, assess current standards to perform “gap analyses”, and evaluate proposed technologies. Diverse engineering expertise is essential.
- **Healthcare delivery organizations** can specify performance requirements, and require adherence to medical device interoperability language in vendor contracts, adopting the sample language now available and continuing to refine it. Widespread adoption of interoperability will happen only when there is recognized consumer demand.
- **Regulatory agencies** can facilitate regulatory clearance of interoperable medical devices, creating new regulatory paradigms where needed.
- **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 and use case demonstration environment.
- **Interoperability promoting organizations** can support revision of 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.

Learn more at <http://www.mdnpn.org>, including links to MD FIRE and the ICE standard, or contact us using the information below.

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<sup>1</sup> National Academies Press, 2005, Recommendation 4-3