

Advancing the Adoption of Medical Device "Plug-and-Play" Interoperability to Improve Patient Safety and Healthcare Efficiency *- a white paper from the MD PnP Program -*

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 using proprietary electronic data interfaces for system integration. With the increasing complexity of the healthcare environment, stand-alone, proprietary devices and systems are no longer acceptable. Medical devices must easily integrate with other vendors’ equipment, software, and systems in order to improve healthcare quality, reduce healthcare costs, and provide for more accurate, 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*¹. However, medical device vendors have not widely adopted cross-vendor standards-based interoperability for medical device integration. Currently, when cross-vendor medical device integration is required, customized device interfaces must be developed, with high cost, long development time, 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 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 include system functions such as enabling 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, 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 to define engineering requirements for interoperability. The MD PnP program received CIMIT's 2007 Edward M. Kennedy Award for Healthcare Innovation.

Since the program's inception, more than 700 clinical and engineering experts, and representatives of more than 85 companies and institutions have participated in plenary workshops/conferences, working groups, and focus groups to contribute to ongoing program activities. Our multidisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, FDA, university computer and information science groups at Pennsylvania, Illinois/Urbana-Champaign, Waterloo, and New Hampshire, Draeger Medical Systems, DocBox Inc., Moberg Research Inc., LiveData Inc., Mitre Corporation, IXXAT, NSF/CPS, Geisinger Health System, as well as the Partners HealthCare System community (including clinical and biomedical engineering departments at Massachusetts General Hospital, and Brigham & Women's Hospital and Partners HealthCare Information Systems).

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.

Leading Healthcare Delivery Organizations (HDOs) wish to adopt emerging interoperability standards for medical device connectivity. As a result of collaboration with the MD PnP program, Kaiser Permanente in 2006 began to include limited requirements for medical device interoperability in vendor contracts. In 2008 MGH/Partners HealthCare and Johns Hopkins Medicine joined the collaboration to issue a nationwide Call to Action to improve patient safety by including medical device interoperability requirements as essential elements in vendor selection criteria and procurement processes. This collaboration has produced sample RFP and contracting language that is being widely shared with other institutions as well as device manufacturers. For additional information, see the white paper titled MD FIRE – "Medical Device Free Interoperability Requirements for the Enterprise" (available at our web site).

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, most recently the American Medical Association and the Massachusetts Medical Society:

"RESOLVED, That our American Medical Association (AMA) believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes 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 optimum patient safety, efficiency, and outcome benefit while preserving incentives to ensure continuing innovation."

Key MD PnP Program projects include:

- Eliciting clinical scenarios to inform interoperability solutions; this includes identifying adverse events and near misses that could have been avoided through the integration of medical devices and IT systems
- Compiling a repository of interoperability use cases that can be shared
- Developing a clinical requirements acquisition and analysis methodology that enables use case scenarios to be specified at the level of detail needed to derive engineering requirements, including both functional and quality requirements
- Developing a new open standard for a patient-centric “Integrated Clinical Environment” (ICE) and informing changes to related existing standards – the ICE standard is being advanced within ASTM International
- Preparing an open ICE research platform to deploy and evaluate reference implementations of proposed standards, technologies, and products
- Defining a safe, “least-burdensome” regulatory pathway for patient-centric networked medical devices, in partnership with the U.S. FDA

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 as 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.mdppnp.org>, including links to MD FIRE contract terms and the ASTM ICE standard, or contact us using the information below.

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¹ National Academies Press, 2005, Recommendation 4-3