

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

Medical devices are essential for the practice of modern medicine. However, unlike the inter-connected "plug-and-play" world of modern computers and consumer electronics, most medical devices are designed to operate independently, and do not employ open networking standards for data communication or for device control. The integration of individual medical devices into patient-centric networked systems can provide real-time comprehensive data for the electronic medical record (EMR) and can support advanced patient safety and workflow improvements such as:

- Decision support
- Safety interlocks
- Physiologic closed-loop control of medication, fluid delivery, and ventilation
- Monitoring of device activity and performance
- Automated system readiness assessment (prior to starting invasive clinical procedures)
- Support of "e-ICU" implementations
- Safeguarding of protected patient information through real-time encryption
- "Plug-and-play" modularity to support "hot swapping" of "best of breed" devices
- Facilitation of disaster preparedness: real-time inventory of hospital equipment in-use and national stockpiles, and rapid deployment of devices in makeshift emergency care settings
- Avoidance of unnecessary redundancy by using shared resources
- Reduction of the cost and implementation barriers to technology dependent innovation

Networked medical device systems could support improvements in workflow and reductions in medical errors and healthcare costs to the benefit of patients throughout the continuum of care: from the home, to pre-hospital transport, and to clinical areas as diverse as the OR, ICU, and general hospital ward.

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 adopted cross-vendor standards-based interoperability for medical device communication. Therefore, when device integration is required, customized device interfaces must be developed, which, in addition to increased costs and development time, may not provide needed functionality. For example, Kaiser Permanente recently analyzed the costs associated with integrating medical devices with clinical information systems (including the EMR), both with and without standards-based interoperability. In this preliminary analysis, Kaiser projected that the cost of EMR integration adds 40% to the cost of medical device acquisition, and that adoption of medical device interoperability could reduce Kaiser's integration costs by 30% or approximately \$12M annually for the next 10 years².

About the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program

The MD PnP program was established in 2004 to lead the development and adoption of standards-based medical device integration solutions to support clinical innovation. Founded by Julian M. Goldman, MD, 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 and CIMIT, the MD PnP program remains clinically grounded. The program has been convening diverse stakeholder groups (clinicians, biomedical and clinical engineers, healthcare delivery systems, regulatory agencies, medical device vendors, standards development experts) to learn from past efforts to develop medical device interoperability solutions, to harmonize with current synergistic programs, and to elicit clinical scenarios of "better healthcare through interoperability". Since the program's inception, more than 500 clinical and engineering experts, and representatives of more than 65 institutions that share a vision of medical device interoperability have participated in ongoing convening activities.

Barriers and Solutions

We believe that key barriers to the adoption of interoperability are the absence of suitable standards for data communication and device control, a suitable “plug-and-play” system architecture, and the absence of specified requirements for an integrated clinical environment “ecosystem” that would include ancillary system functions such as data logging, data security, and device authorization. These ancillary functions would provide a complete systems solution that could meet clinical, technical, regulatory, and legal requirements.

To support these goals, 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, model clinical use cases (in a simulation environment), develop and test related network safety and security systems, and 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. Our geographically dispersed, multidisciplinary, multi-institutional team of collaborators includes participants from: Kaiser Permanente, Draper Laboratory, FDA, Univ. of Penn. Dept. of Computer Science, Drager Medical Systems, LiveData, Inc., Mitre, Univ. of New Hampshire, IXXAT, NIST, NSF, Geisinger Health System, as well as the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women’s Hospital, and PHS Information Systems).

Other active projects include:

- Eliciting clinical scenarios to inform interoperability solutions
- Developing methodologies to analyze clinical scenarios to derive engineering requirements
- Drafting an international standard to define the MD PnP “ecosystem” requirements
- Collaborating with the FDA and others to elaborate a regulatory pathway for patient-centric networked medical devices
- Planning a June 2007 joint conference with the NSF/NIST initiative on High Confidence Medical Devices, Software, & Systems (see <http://www.cis.upenn.edu/hcmdss07>)
- Developing shared contract language to support the preferential acquisition of standards-conformant systems by healthcare organizations (recently implemented by Kaiser Permanente)
- Refining a two-stage solution to support widespread adoption of standards-based interoperability. The first stage will provide affordable near-term means to transfer data from legacy medical devices to clinical information systems and EMRs, in preparation for a subsequent stage of comprehensive standards-based interoperability.

How You Can Participate

- *Clinicians* can contribute clinical scenarios to ensure that new interoperability standards and technology will enable meaningful clinical solutions.
- *Engineers* can analyze clinical use cases to generate functional specifications.
- *Healthcare delivery systems* can require adherence to medical device interoperability language in vendor contracts.
- *Regulatory agencies* can create new paradigms for regulatory clearance of interoperable medical devices.
- *Medical device manufacturers* can participate in the development and adoption of interoperability standards, contribute devices and engineering support to the MD PnP Program, and provide financial support to accelerate the program’s success.
- *Standards development organizations* can revise existing standards to meet MD PnP ecosystem requirements, and shepherd new standards through the adoption process.
- *Learn more at <http://www.mdnp.org>*

References:

1. National Academies Press, 2005, Recommendation 4-3
2. http://mdnp.org/uploads/Impact_HC_6.pdf