

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 health record (EHR) and can create integrated clinical environments to support innovation in patient safety and workflow improvements such as:

- Clinical decision support
- Medical device safety interlocks to produce error-resistant systems
- 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, cross-vendor standards-based interoperability has not been widely adopted 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.

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 (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. 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 for “improving 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 to the adoption of interoperability have included the absence of suitable standards for data communication and device control, an appropriate “plug-and-play” system architecture, and elaborated requirements for an integrated clinical environment “ecosystem” that would include system functions such as data logging, data security, device authorization, and connectivity to the hospital information system. These functions would contribute to 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 and Information Science, Drager Medical Systems, LiveData Inc., Mitre, DocBox Inc., Univ. of New Hampshire, IXXAT, NIST, NSF, Geisinger Health System, as well as the Partners HealthCare System community (Massachusetts General Hospital Anesthesia, Biomedical Engineering at MGH and Brigham & Women’s Hospital, and PHS Information Systems).

As a result of collaboration with this program, Kaiser Permanente has since 2006 included the following language in vendor contracts:

“Supplier agrees to participate with Kaiser in the development of a medical device plug and play integration standard (the ‘Integration Standard’), and ... will make reasonable efforts to conform to the Integration Standard when approved and formulated by the parties in writing. Until the Integration Standard is approved, Supplier intends to continue ... to provide open interfacing protocols ...”

In March 2007 the Anesthesia Patient Safety Foundation issued the following endorsement of interoperability:

"APSF believes that intercommunication and interoperability of devices could lead to important advances in patient safety, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind....”

Other active projects include:

- Eliciting clinical scenarios to inform interoperability solutions
- Developing methodologies to analyze clinical scenarios to derive engineering requirements
- Supporting the development of the draft international standard to define the “ecosystem” requirements of a patient-centric “Integrated Clinical Environment” (ICE)
- Collaborating with the FDA and others to elaborate a regulatory pathway for patient-centric networked medical devices

- Developing shared contract language to support the preferential acquisition of standards-conformant systems by healthcare organizations (as implemented by Kaiser Permanente)
- Refining a staged implementation plan to support widespread adoption of standards-based interoperability.

How You Can Participate

- Clinicians can contribute clinical scenarios (or “use cases”) to ensure that new interoperability standards and technology will enable meaningful clinical solutions.
- Engineers can analyze clinical use cases to generate functional specifications, assess current standards to perform requirements gap-analyses, and evaluate proposed interoperability technologies.
- Healthcare delivery systems can specify performance requirements, and 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, and partner with the MD PnP Program to develop a shared interoperability-testing environment.
- Standards development organizations can revise existing standards as needed to support interoperable patient-centric networked medical device system requirements.

Learn more at <http://www.mdnp.org>.

(Follow the link above for streaming video coverage of the entire June 25-27, 2007 conference on MD PnP and HCMDSS.)

References:

1. National Academies Press, 2005, Recommendation 4-3

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