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

A geographically distributed, interdisciplinary, multi-institutional program

Currently Collaborating Organizations

Anakena Solutions Inc.
DocBox Inc.
FDA
Johns Hopkins Medicine
Kaiser Permanente
Kansas State University
Massachusetts General Hospital
Moberg Research Inc.
NIST
NSF
Partners HealthCare System
TATRC/USAMRMC
University of Pennsylvania
University of Illinois at Urbana-Champaign
Veterans Health Administration

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Based at CIMIT:
A non-profit consortium of Boston's premier teaching hospitals, universities and labs, CIMIT fosters interdisciplinary collaboration among world-class experts in medicine, science and engineering, in concert with industry and government, to rapidly improve patient care

CIMIT® Center for Integration of Medicine & Innovative Technology

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

The absence of an intranet-like ecosystem for interconnecting medical devices and clinical information systems is a fundamental impediment to realizing the national vision of using comprehensive, accurate, electronic medical records and HIT systems to improve the quality and efficiency of healthcare. Interoperability of devices and IT systems in clinical environments will permit mixed-vendor ("heterogeneous") data transfer, comprehensive secure data acquisition, and safety-enhancing capabilities such as safety interlocks and closed-loop device control. This functionality has been recognized by HITSP as an important part of the roadmap for common device connectivity requirements (as part of the Common Device Connectivity AHIC Extension/Gap, December 2008, and in TN 905 in January 2010). Medical device interoperability will enable innovations to improve patient safety, treatment efficacy, and workflow efficiency, reducing 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. Moreover, this will facilitate regulatory and Meaningful Use compliance.

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

The MD PnP program, established in 2004, has become a recognized leader in the development of the concepts and capabilities for integrated clinical environments of the future. We have been working to accelerate the adoption of medical device interoperability by providing interoperability building blocks (use cases, standards, a neutral lab environment, and open research tools) and by changing clinical and market expectations of what can be achieved.

The program is affiliated with Massachusetts General Hospital (MGH), CIMIT (Center for Integration of Medicine and Innovative Technology), and Partners HealthCare System, 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".

Our interdisciplinary, multi-institutional program team collaborates with diverse stakeholders (clinicians, biomedical and clinical engineers, academic engineering programs, healthcare delivery systems, regulatory agencies, medical device vendors, standards development organizations). Since the program's inception, more than 800 clinical and engineering experts, and representatives of more than 100 companies and institutions have participated in plenary workshops/conferences, working group meetings, and focus groups to help shape the common goals and contribute their expertise.

The CIMIT MD PnP Lab provides 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.

Key MD PnP Program projects

Support for MD PnP program work has come from DoD/TATRC, NSF, NIST, CIMIT, and NIH/NIBIB, which awarded a $10M Quantum grant in October 2010 to develop a healthcare intranet based on integrated medical device systems. Program work to date has achieved significant milestones in several interdependent and synergistic areas, pursued in parallel since 2004.

- Developing a new **open standard** for a patient-centric "Integrated Clinical Environment" (**ICE**) to define the conditions under which interoperability can enable device integration to create new medical device systems with greater safety and performance capabilities than any individual device – Part I of the ICE standard was published as ASTM F2761-09, and is providing a valuable framework for

Learn more at http://www.mdpnp.org, including links to MD FIRE and the ICE standard, or contact us:

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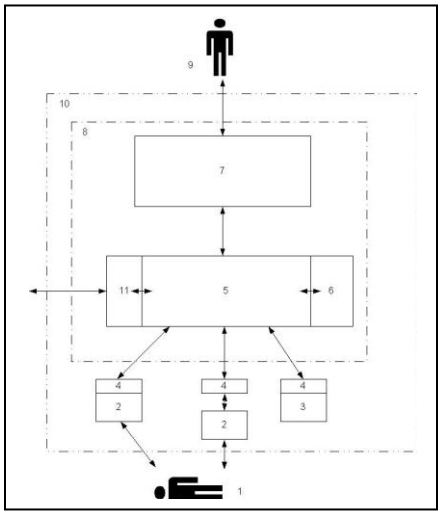
further defining the vision and clinical content for other standards (e.g. it was cited in HITSP Technical Note 905)



- Defining a **safe regulatory pathway** for patient-centric networked medical devices, in partnership with the FDA; progress includes co-sponsoring a workshop held by FDA in January 2010 on medical device interoperability, followed by a working group of companies, academics, and hospitals that have developed and submitted a pre-IDE regulatory submission to help refine the FDA clearance process (see FDA workshop content on our web site)
- Creating and refining **interoperability contracting language** for use by hospitals in their procurement of medical devices (**MD FIRE**: Medical Device Free Interoperability Requirements for the Enterprise) – signed by the VA in 2012.
- Eliciting and analyzing **clinical scenarios** at the level of detail needed to inform interoperability solutions and to derive engineering requirements
- Performing detailed **workflow analysis** of these use cases with a team of MD PnP collaborators (including multiple device companies) and analyzing the ability of existing standards (e.g. IEEE 11073) to meet these requirements (**gap analysis**), yielding important understanding of the capabilities and limitations of existing interface standards
- Developing **demonstration implementations** of clinical use cases in which integrating the clinical environment will improve patient safety (e.g. x-ray/ventilator synchronization and safety interlocks for patient-controlled analgesia medication delivery), and showing these at major clinical and health IT conferences

Through our Quantum grant, we are 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. This open prototype research platform could support evaluations by the FDA of interoperable medical device systems and serve as a generic model that could be shared with other organizations developing, for example, open device software adapters and an ICE Part I reference architecture.

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, work with the FDA on the regulatory pathway, 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.

We are interested in collaborating with researchers who are working on medical device architecture, communication, network security, and health IT infrastructure.

Learn more at http://www.mdpnp.org