MD PnP Program Updates: Standards, Policy, and Collaborations

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The absence of open standards and related technologies for cross-vendor medical device integration is impeding national efforts to improve patient safety and healthcare efficiency [1]. 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 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 patient safety implications of the unmet needs for medical device interoperability are many. The landmark 1999 IOM publication, "To Err is Human", reported the disturbing number of preventable in-hospital deaths – 98,000 annually [2]. Of great concern is that according to the HealthGrades "Patient Safety in American Hospitals" study, the IOM report markedly underestimated the severity of the problem, and in the three-year period of 2000-2002 there were 195,000 annual deaths – nearly double the number reported by the IOM [3]. Eighty-six percent of alarms in the ICU are false alarms [4], and 78% of clinicians studied say that they disable clinical alarms because of the high percentage of false alarms [5].

The increasing deployment of medical devices in multi-vendor, multi-modality networking environments in hospitals has led to unanticipated emergent behaviors, resulting in additional network-device integration challenges for Biomed and IT organizations. Wireless networks only increase the potential problems because networks can't be physically segregated.

Standards-based medical device interoperability can provide real-time comprehensive population of the electronic medical record (EMR) and enable the creation of integrated error-resistant medical systems to support advanced capabilities such as physiologic closed loop control of medication delivery, ventilation, and fluid delivery; decision support; safety interlocks; smart alarms; 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 [6].

Since 2004 the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program has been working to accelerate the adoption of medical device interoperability by providing interoperability building blocks (use cases, standards, a neutral lab environment, and technology tools) and by changing clinical and market expectations of what can be achieved [7]. Our multi-faceted approach has included the development of a new open standard for a patient-centric "Integrated Clinical Environment" (ICE), the elicitation, collection and modeling of clinical use cases and engineering requirements for the ICE platform, the development of healthcare provider equipment procurement language to purchase interoperable products, and multiple collaborative projects to implement ICE components and assure the safety of such integrated systems.

Notable achievements from the past two years include:

- **Standards – ICE**: The ICE standard is being advanced within ASTM International, and is a new medical device standard that describes requirements for safe and effective "plug-and-play" integration of devices in high-acuity environments. Part I is in press as ASTM F2761-2009 "Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model" [8], and work has begun on subsequent parts. Annex B of the ICE standard, "Clinical context and clinical scenarios", includes clinical use cases derived from the MD PnP program's extensive collaborative projects on clinical requirements. Through ongoing gap analysis of related existing standards, ICE development is informing changes that are required to support these use cases.
- **Shared interoperability contracting language – MD FIRE**: Healthcare provider organizations are making it clear that they wish to adopt emerging interoperability standards for medical device connectivity. In October 2008 Massachusetts General Hospital / Partners HealthCare, Kaiser Permanente, and Johns Hopkins Medicine issued a nationwide Call to Action to improve patient safety by recommending that medical device

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interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. This document (Medical Device Free Interoperability Requirements for the Enterprise) includes sample RFP and contracting language that is being shared with other institutions as well as device manufacturers [9], [10].

- **Endorsements**: Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency" [11], [12]. 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:

  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.

- **Collaborations**: Supported through NSF grants and DoD SBIRs and STTRs, multiple companies and academic institutions are engaged in active collaborative projects with the MD PnP program to develop an open ICE research platform and, eventually, ICE-compliant products. The open platform will enable deployment and evaluation of reference implementations of proposed standards, technologies, and products, and other projects are investigating how to assure safe operation of integrated systems.

Information on the activities above has been provided in briefings to several federal agencies through invited presentations at meetings at NSF, NIST, and the White House Homeland Security Council Biodefense Directorate. The MD PnP program's work on standards, clinical requirements, procurement language, and platform development, and the endorsements from medical societies, are moving us ever closer to the tipping point for achieving medical device interoperability. We continue to communicate the MD PnP vision of improving patient safety and healthcare efficiency by

- changing expectations, which enables
- changing technology, which will lead to
- changing healthcare.

REFERENCES

[1] Whitehead, S. F., Goldman, J. M. 2008. Getting Connected for Patient Safety: How Medical Device "Plug-and-Play" Interoperability Can Make a Difference. Patient Safety & Quality Healthcare 5:1, Jan-Feb 2008. http://mdpnp.org/Publications.html#PSQ

[2] Kohn LT, Corrigan JM, and Donaldson MS, (eds.). 2000. To Err Is Human: Building a Safer Health System. The National Academies Press, 2000.

[3] In Hospital Deaths from Medical Errors at 195,000 per Year USA. Medical News Today. August 9, 2004. http://www.medicalnewstoday.com/articles/11856.php

[4] Tsien, C. L., Fackler, J.C. 1997. An Annotated Data Collection System to Support Intelligent Analysis of Intensive Care Unit Data. In Advances in Intelligent Data Analysis, X. Liu, P. Cohen, and M. Berthold (eds.); 111-121. Springer-Verlag, 1997.

[5] American College of Clinical Engineering (ACCE) Healthcare Technology Foundation. Impact of clinical alarms on patient safety. http://www.acce-htf.org/White%20Paper.pdf .

[6] Chiao, J. C., Goldman, J. M., Heck, D. A. , Kazanzides, P., Peine, W. J., Stiehl, J. B., Yen, D., Dagalakis, N. G. 2008. Metrology and Standards Needs for Some Categories of Medical Devices. J of Research of the National Institute of Standards and Technology 113:2, March-April 2008.

[7] MD PnP - Medical Device "Plug-and-Play" Interoperability Program. http://mdpnp.org

[8] ICE - Integrated Clinical Environment. http://www.mdpnp.org/ICE.html

[9] MD FIRE - Medical Device "Free Interoperability Requirements for the Enterprise". http://mdpnp.org/MD_FIRE.php

[10] Whitehead, S. F., Goldman, J. M. 2009. Hospitals Issue Call for Action on Medical Device Interoperability. Patient Safety & Quality Healthcare 6:1, Jan-Feb 2009.

[11] Interoperability Endorsement. http://mdpnp.org/Endorsements_of_Interop.html

[12] Tillman, D.-B., Kessler, L. 2007. Position Letter. http://mdpnp.org/uploads/FDA_Kessler-Tillman_position_letter.pdf