HealthManagement
Promoting Management and Leadership

Volume 15 - Issue 2, 2015 - Cover Story

# Creating a Safety Network for Use in a Clinical Environment

**Harshal Sawant**
******@***mdpnp.org

Biomedical Engineer -
Massachusetts General Hospital -
MD PnP Program

**Developing Medical Device Plug-and-Play Interoperabllity to Improve Patient Safety and Healthcare Efficiency**

**Need For Interoperable Devices**

Medical devices are essential for the practice of modern medicine. However, unlike the interconnected “plug and play” world of modern computers and consumer electronics, most medical devices used for the care of high-acuity patients are designed to operate independently, and do not employ open networking standards for data communication or for device control. For years we have benefited from integrated systems to enhance the safety of potentially hazardous activities. For example, safety interlocks that require stepping on the brake before putting your car in gear, or having a clear alarm sound in the cockpit, if the landing gears are not deployed when a plane descends for landing, add “error resistance” to potentially hazardous equipment. This solution is not yet easily achievable in a crossvendor device integration scenario to implement error resistance in operating rooms (ORs) and other clinical environments today.

The absence of an intranet-like ecosystem for interconnecting medical devices and clinical information systems is a fundamental impediment to realising the use of comprehensive, accurate, electronic medical records and healthcare information technology (HIT) systems to improve the quality and efficiency of healthcare. Interoperability of devices and IT systems in clinical environments will permit mixed-vendor data transfer, comprehensive secure data acquisition and safety-enhancing capabilities, such as safety interlocks and closed-loop device control. 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, intensive care unit (ICU) and general hospital ward. Moreover this will facilitate regulatory compliance.

**Medical Device Interoperability Examples**

Below are some examples of how medical device interoperability would aid in a clinical setting.

**Patient-Controlled Analgaesia (PCA) Pump**

While on the PCA infusion pump, the patient is monitored with a respiration rate monitor and a pulse oximeter. If physiological parameters move outside the pre-determined range, the infusion can be stopped, and an alarm sent to notify the clinical staff and restart the infusion if appropriate. The use of two independent physiological measurements of respiratory function (oxygen saturation and respiratory rate) enables a smart monitor to optimise sensitivity to detecting respiratory compromise while reducing false alarms.

**X-Ray Capture During Lung Ventilation**

The x-ray and anaesthesia machine ventilator are synchronised, so that the x-ray is taken at the desired phase of ventilation, such as end-inspiration or end-expiration. When the technician pushes the exposure button, the image is taken at a synchronised point, triggered by the respiratory waveform. If necessary, the ventilator is instructed to supply a brief breath hold. The ventilator was not stopped for the x-ray, so the patient was never in danger from hypoventilation.

**Home and Remote Monitoring for Elderly Patients**

For patients with chronic illnesses a doctor may prescribe wearable and monitoring devices for disease management at home. In an emergency the patient’s body worn devices (eg ECg, blood pressure monitor, and continuous glucose monitor) are connected to the ambulance monitoring system for en route management. The devices can also be queried to obtain patient ID and recent data history. This information is transmitted to the managing emergency physician en route, and the data provenance is included in the EMR. Additional data from the remote disease monitoring service is made available to the physician.

**Continuum of Care – Workflow Support**

In order to improve the handoff process for a patient being transferred between an operating room (OR) and an intensive care unit (ICU), it is necessary to automatically push patient data and device settings from the OR to the ICU. This proposed state would enable a system in the OR to communicate with a system in the ICU in order to assist with setting up devices, and to enable a system readiness checklist. This is a dynamic and interactive checklist that maintains near real-time updates of the patient's status, required devices, physicians' orders and necessary supplies, depending on the patient's history, current status and physician's orders. It would also provide the OR with a continuous assessment of the state of the ICU.

**Quarantine Environment For Infectious Disease Care and Monitoring**

Interoperability can be used for sensor integration and data acquisition to improve disease screening, monitoring and diagnosis. Remote control, closed loop control, and remote data access could improve patient care and reduce the exposure of hospital personnel to infected patients by limiting the number of times caregivers enter the patient's intensive care environment to change device settings.

**Our Programme**

The Medical Device Plug-and-Play (MD PnP) programme, established in 2004, is accelerating the adoption of medical device interoperability to enable the creation of complete and accurate electronic health records and the cost-effective development of innovative third-party medical apps for diagnosis, treatment, research, safety and quality improvements, equipment management, and adverse event detection and reporting when using networked medical devices for clinical care.

The programme is affiliated with the 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 programme remains clinically grounded.

Our team has been developing shareable databases, tools and applications that will enable a broader community of researchers and manufacturers to implement medical device interoperability. We have taken a multi-faceted approach to begin addressing key barriers to achieving interoperability, including the development and support of suitable open standards and the elicitation, collection and modelling of clinical use cases and engineering requirements for the Integrated Clinical Environment (ICE) platform and "ecosystem".

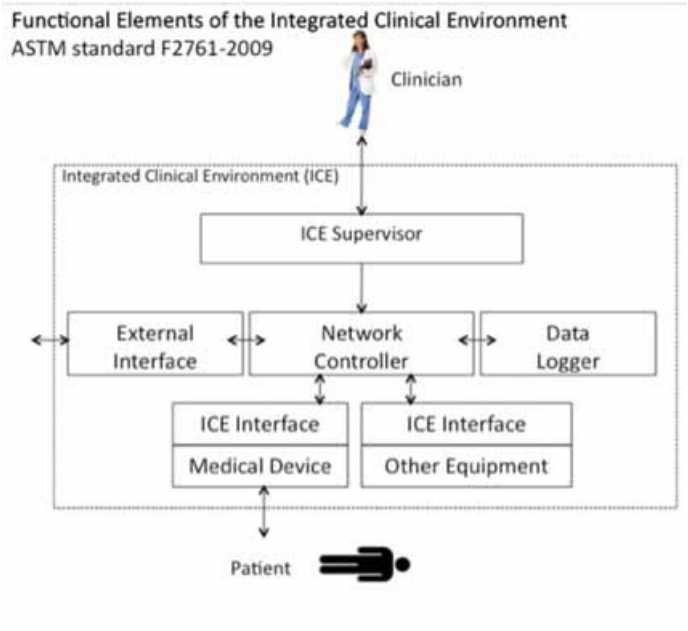


**Figure 1.** ICE Functional Model, redrawn from ICE Part I ( ASTM F2761-2009)

Our interdisciplinary, multi-institutional programme team collaborates with diverse stakeholders (clinicians, biomedical and clinical engineers, academic engineering programmes, healthcare delivery systems, regulatory agencies, medical device vendors, standard development organisations).

The CIMIT MD PnP Lab provides 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.

## Our Key Work

**Establishment of Engineering Requirements Needed to Overcome Current Barriers to Interoperability**

Using our Clinical Scenario Repository we have elicited and analysed clinical scenarios at the level of detail needed to inform interoperability solutions and to derive engineering requirements. We have performed detailed workflow analysis o f use cases with a team o f collaborators (including multiple device companies), and analysed the ability of existing standards (ISO/IEEE 11073- 1048:2014) to meet these requirements (gap analysis), yielding important understanding of the capabilities and limitations of existing interface standards. Our team is developing detailed requirements (ie clinical, functional, non-functional, safety) for safe and effective networking of heterogeneous (multi-vendor) medical devices to implement our use cases.

**Medical Device Interoperability and Integration Software and Architecture**

Using the requirements mentioned above, we are developing architecture and software to implement our use cases to enable improvements in patient care through the safe, reliable integration of medical devices and information technology.

We have developed 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 U.S. Food and Drug Administration (FDA) of interoperable medical device systems, and serve as a generic model that could be shared with other organisations developing open device software adapters and reference architecture.

Open ICE is an initiative to create a community implementation of the ASTM F-2761 standard for the ICE (ASTM International 2013). T he initiative encompasses not only software implementation of those functionalities described in the standard, but also architecture for a wider clinical ecosystem that incorporates seamless connectivity to increase patient safety.

We have also created demonstration implementations of clinical use cases, in which integrating the clinical environment will improve patient safety. We have created data visualisation apps and apps that reduce alarm fatigue or use intelligent algorithms to produce smart alarms (eg x-ray/ventilator synchronisation and safety interlocks for patient-controlled analgaesia medication delivery).

**Development of Suitable Open Standards For Integrated Clinical Environment (ICE)**

We have created 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 w as published a s A STM F2761-09, and is providing a valuable framework for further defining the vision and clinical content for other standards. The figure below shows the functional model o f ICE as described in t he ASTM F2761.

**Test and Validation Tools**

We are also developing a suite of software tools to test and validate that system interface software meets requirements for functionality, accuracy, timeliness, security, safety, consistency and completeness. Test tools are used both for component development and for validating compliance to design guidelines.

**Accelerating the Adoption of Medical Device Interoperability**

We have created a Medical Device “Free Interoperability Requirements for the Enterprise” (MD FIRE) whitepaper, which includes a sample request for proposals and contracting language (MD FIRE Contracting Language Medical Device Free Interoperability Requirements for the Enterprise 2012). Healthcare delivery organisations can use relevant sections to procure interoperable devices, convey the importance of interoperability to manufacturers and learn more about manufacturers’ involvement with interoperability efforts.

The simplest path to interoperability is through the manufacturer. If a product has been built to be interoperable, the manufacturer has addressed regulatory issues. If a hospital needs to write an integration program for a medical device, it may need to handle FDA regulatory issues. The more hospitals and clinical organisations get involved and clarify the potential benefits of Medical Device Interoperability (MDI), the easier it will be for manufacturers to understand the opportunities and provide these products.

We are also working to define a safe regulatory pathway for patient-centric networked medical devices, in partnership with the FDA.

**The Path Forward**

The barriers for widespread use of interoperability today are:

• Low market need for interoperable platforms and medical devices due to lack of awareness by healthcare professionals;

• Unclear regulatory path;

• Proprietary nature of currently available medical devices.

We believe that, given the right cause and motivation, we can bring medical device manufacturers on board to jointly explore the possibilities of interoperability. This would mean improvements for both patients and caregivers with easier to use apps and visualisation tools, improved quality of monitoring and detection, and easier access to data and diagnostics. Open sourced interoperability allows use to create collaborative technology, which no single manufacturer could do on their own. We believe the power of the community is greater than the power of a single product.

The MD PnP programme aims to create knowledge that will spark in the healthcare industry the creation and adoption of innovative healthcare applications, systems, and medical devices, which enable safer and more effective care through medical device interoperability. Success will not be achieved solely by our project, but in conjunction, partnership, and cooperation with the healthcare and related industries and the extensive activities of project collaborators.

**Key Points**

- Medical device plug-and-play interoperability can enable many improvements in safety and workflow surrounding patient care.
- the MD PnP programme for the last 10 years has taken a leadership role in the academic and industrial environment, to drive forward development and deployment of this technology.
- We have developed open source software to enable crossvendor device integration and interoperability, and created open standards to accelerate adoption.

Published on : Mon, 11 May 2015