“Procuring Safety” Through Medical Device Interoperability to Transform Healthcare Delivery

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MGH Medical Device “Plug-and-Play” Interoperability Research Program (MD PnP)

Health environments need integrated technologies and rich data to improve patient safety and enable learning and transformational care delivery models.

- Program established 2004 at Mass General Hospital/Partners Healthcare
- Clinical, biomed, computer science, and IT subject matter experts
- Publish research to enable safe interoperability
- Develops OpenICE open-source interoperability research platform [www.openice.info](http://www.openice.info)
- $22M research funding primarily from DOD, NIH, NSF, DHS
- Multiple collaborative lab prototyping and public demonstrations with industry, academia, and government
- Developed foundational content for standard ASTM F2761 on the Integrated Clinical Environment ("ICE") , AAMI-UL 2800, and other standards
- FDA “pre-submission” on safe platform-based interoperability, publicly shared
- All above being leveraged for commercial products

Example of collaborators
PCA safety-interlock is an Archetypal Use Case:
Gaps are longstanding. Solutions are broadly applicable to other scenarios

Pennsylvania Patient Safety Authority analysis¹
- 4,230 events involving Patient Controlled Analgesia (PCA) pumps (from FDA MAUDE database, 2011)
- 19.5% of those events resulted in injury or death
- **2006**: APSF called for safety interlock of monitors and PCA pumps!

- Archetypal Patient Safety Example²: known problem, calls to action for solutions, but archaic ecosystem inhibits safety innovations, while injuries and deaths continue

What is required:²

1. **Apps** to integrate data for early detection of respiratory depression prior to patient harm, minimize false alarms, stop the pump, and summon help
2. **Devices** that can provide necessary data interfaces and be controlled
3. **Open platforms**, to allow safe integration of interoperable components from different manufacturers to enable the community to develop, evaluate, and improve PCA safety algorithms to optimize analgesia and safety
4. **“Safe Interoperability”³**— safe systems to improve patient safety

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¹. [http://patientsafetyauthority.org/PATIENTSCONSUMERS/PatientConsumerTips/Pages/PCA_Pump_Consumer_Tips.aspx](http://patientsafetyauthority.org/PATIENTSCONSUMERS/PatientConsumerTips/Pages/PCA_Pump_Consumer_Tips.aspx)
Monitor Displays Low SpO\textsubscript{2} Event in EMR

Falsely low SpO\textsubscript{2} data in EMR

SpO\textsubscript{2} Level Low
Artifact caused by BP Cuff inflation

Spurious SpO\textsubscript{2} data would interfere with PCA safety algorithm
• Solution: include NIBP metadata about cuff inflation status

No evidence of 84% SpO\textsubscript{2} in EHR (Blue ticks represent SpO\textsubscript{2} values)

The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems (NIHMSID 775190; Publ.ID: AAJ-D-16-01257)
Integrated Clinical Environment Architecture (ICE)

The PCA and other clinical scenarios identified a need for a platform-based medical device interoperability architecture.

ASTM F2761 "Essential safety requirements for equipment comprising the patient-centric Integrated Clinical Environment "(ICE)

ICE provides an architecture to help address:

- **App platform** for clinical care and device management
- **Safety and performance** of the system
- **Security** (sandboxing)
- **Patient ID-data binding**
- **Correct time stamp-data binding**
- **Data logging** for forensic, QA, and liability
- **Builds on medical device interoperability**
- **ICE systems are using applicable existing standards**

From ASTM F2761-09

https://www.astm.org/Standards/F2761.htm
http://mdpnp.mgh.harvard.edu/projects/ice-standard/
MD FIRE – Medical Device Interoperability Procurement Language

- Focused on providing capabilities to improve patient safety
- Requirements are based on clinical scenarios from providers
- Procurement concept based on Kaiser’s approach
- Endorsed by VA and American Society of Anesthesiologists
- Version 1 was developed by a collaboration of 5 groups from Partners, Kaiser, and Hopkins:
  - Clinicians
  - Purchasing/Procurement
  - IS/IT
  - Biomed
  - Legal
- Currently adding adoption pathway and Cybersecurity content.

http://mdpnp.mgh.harvard.edu/projects/md-fire/

Original version of MD FIRE
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