Safe Medical Device Interoperability to Enable Healthcare Transformation

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Has this clinical scenario changed in the last 20 years?

Technologies to reduce error and improve efficiency are difficult to implement.

Great ideas to improve safety and efficiency are not implemented.

Contextually rich data is difficult to acquire – No clinical BLACK BOX RECORDER.

Photo: J. Goldman, MD MGH
1. 597,689 Heart Disease
2. 574,743 Cancer
3. **Deaths Due to Medical Errors (210-440,000)**
4. 138,080 Chronic lower respiratory diseases
5. 129,476 Stroke
6. 120,859 Accidents
7. 83,494 Alzheimer’s disease
8. 69,071 Diabetes
9. 56,979 Influenza & Pneumonia
10. 47,112 Kidney diseases
11. 41,149 Suicide

Equivalent to filling one Arlington Cemetery every year!
Example - Patient-Controlled Analgesia (PCA) system safety concerns

- Overdose may be caused by pump programming error, button press by proxy, drug errors, etc.
- Can cause respiratory and cardiac arrest
- Comprehensive monitoring is not typically used due to high false/nuisance alarm rate
- Improving alarms very difficult due to limited data access and barriers to data-fusion based smart(er) alarms

Clinical scenario animations: [http://mdpnp.org/MD_PnP_Program___Clinical_S.html](http://mdpnp.org/MD_PnP_Program___Clinical_S.html)
10,000s of alarms / hospital / day
85-99% don’t require intervention ➔ dangerous “alarm fatigue”

Medical device alarm safety

Scope of problem
100s → 1,000s → 10,000s
85-99% of alarm signals don’t require clinical intervention

Alarm Fatigue
Clinicians become desensitized, overwhelmed or immune to the sound of an alarm.

Fatigued clinicians may:
• Turn down alarm volume
• Turn off alarm
• Adjust alarm settings
These actions can have serious or fatal consequences.

Photo: JM Goldman, MD / MGH

PCA is an Archetypal Use Case: gaps are well-known. Limited solutions

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 Example:** known problem, calls to action for solutions, but archaic ecosystem inhibits safety innovations, while injuries and deaths continue

What is required:

1. **Apps** that can connect to sensors and actuators, to deploy novel algorithms
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 clinical algorithms to optimize care
4. **Safe Interoperability**² – 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)
2. J Goldman, MD PnP Program
Babel in the ICU

Machines in an ICU can’t speak to one another—but what if they could?

Preventable medical errors may account for more than 100,000 deaths per year. These errors are primarily caused by failures of communication—a chart misread, or the wrong data passed along to a machine or a colleague.

Part of the problem could be solved if the machines could just speak to one another. Devices in hospital wards, which monitor everything from oxygen intake to the tilt of the hospital bed, are made by many manufacturers, which have little incentive to make their proprietary code—the language that makes the machines run—easy to process by their competitors’ machines. So that task of middleman falls to harried hospital staff.
SEDATION
ICU patients are sometimes put under sedation. To monitor their progress, a sensor strip (1) that measures the electrical activity in the brain is often attached to a patient's forehead. This sensor could communicate with the infusion pump (7) to determine the proper balance of medication, sedation and blood pressure, and to record the response to sedatives.
CHEST IMAGING

When chest X-rays must be taken multiple times during a patient’s stay, the images should capture the same stage of breath, so they’re easy to compare. This can be difficult to time. But a ventilator (2) could deliver precise information about the stage of breath to an X-ray machine (5) if these devices communicated directly. That automation would eliminate the cause of another dangerous source of error—when a technician turns off a ventilator to take the X-ray and then forgets to turn it back on.
CONCUSSION CARE

When a patient has a concussion, doctors monitor whether pressure is building inside the skull. Pressure can be measured with a catheter in the brain (3) or by taking ultrasound measurements of the velocity of blood flow through the brain. If such devices communicate with the device that measures bed tilt (4), the nurse can be notified if the tilt of the bed is putting too much pressure on the brain. The bed might someday automatically adjust itself to relieve pressure in the skull.
Integrate the Clinical Environment with:

- Platforms
- Devices
- Apps

What if...

Apps store for smart alarms; med safety
Integrating Devices and Data in the Clinical Environment (ICE) should improve 6/10 hazards

**The List for 2015**

2. Data Integrity: Incorrect or Missing Data in EHRs and Other Health IT Systems
3. Mix-Up of IV Lines Leading to Misadministration of Drugs and Solutions
4. Inadequate Reprocessing of Endoscopes and Surgical Instruments
5. Ventilator Disconnections Not Caught because of Mis-set or Missed Alarms
6. Patient-Handling Device Use Errors and Device Failures
7. “Dose Creep”: Unnoticed Variations in Diagnostic Radiation Exposures
8. Robotic Surgery: Complications due to Insufficient Training
9. Cybersecurity: Insufficient Protections for Medical Devices and Systems
10. Overwhelmed Recall and Safety-Alert Management Programs
If device data only resides in the EHR, is this sufficient to support the needed innovations?

- Is EMR data quality, meta-data, and granularity sufficient for robust diagnosis, personalized treatment, and effective adverse event analysis?
- Is medical device-based data from different hospitals comparable? Implications for Big Data analytics?
- Can the EMR be used to host real-time clinical decision support applications?
- How can we deliver more effective med-tech system-based care without the geographical limitations of EHR availability?
- How can we easily add new sensors and actuators?
Medical Devices generate “First Mile” of data (from patient)

Pulse Oximeters measure oxygen saturation – displayed as \( \text{SpO}_2 \) %

Pulse Oximeter oxygen saturation is 84% on instrument display and in EHR

Bluetooth pulse oximeter
Pulse Oximeter Data example

Oxygen Level Low
WHY????

JM Goldman MD / MGH
BP cuff - Pulse Oximeter Interaction

Not really low oxygen
“Bad” data

Baseline
Cuff inflates – loss of SpO₂ signal
Blood returns to finger
Invasive Blood Pressure measurement “error”
Inflation metadata could identify BP artifact
Monitor Displays Low Oxygen Level (SpO₂) Alarm Event “84%” at 2:07

No evidence of 84% SpO₂ in EHR (Blue ticks representing SpO₂ values Don’t decrease)

Sampling error for transient events
These infusion pumps are for use on **ONE** patient.

Medical Devices are also the “**Last Mile**” (data back to devices)

Examples:
1. Research protocol adherence
2. Decision support
3. Prevent contra-indicated infusion
4. “Artificial pancreas” Capabilities (closed loop)
5. Consolidate all data for adverse event analysis
Medical Device “Plug-and-Play” Interoperability Program (MD PnP)

- Program established 2004 at Mass General Hospital/Partners/CIMIT
- Vendor-neutral Lab for experimenting with safe interoperability (regulatory science, standards, technologies, products, workflow)
- Contains > $1M devices/network technology – production and research
- Clinical, biomed, and computer science subject matter experts
- Develops OpenICE open-source software www.openice.info
- >$18M funding from DOD, NIH, NSF, NIST, private
Chronology from
http://www.mdpnp.org/Plenary_Meetings.html

• May 2004 – Kickoff Plenary meeting hosted by CIMIT, Cambridge, MA
• November 2004 – 2nd Plenary held at FDA/CDRH, Rockville, MD
• June 2005 – 3rd Plenary meeting, at CIMIT
• 2007 – First Joint Workshop On High Confidence Medical Devices, Software, and Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability, Cambridge, MA
• 2009 – Publication of IEC 60601-1-10 on Physiologic Closed Loop Controllers; set a foundation for distributed system of sensors/actuators
• 2009 – Second Joint Workshop On HCMDSS and MD PnP Interoperability, San Francisco, CA (in conjunction with CPS Week)
• January 2010 – FDA Workshop on Medical Device Interoperability co-sponsored by FDA/CDRH, Continua Health Alliance, and CIMIT
  – Slides located http://mdpnp.org/MD_PnP_Program___FDA_Worksh.html
Advocacy

“Our American Medical Association believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes 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 optimum patient safety, efficiency, and outcome benefit while preserving incentives to ensure continuing innovation. (res. 519, A-09)”

Interoperability Endorsements 2007-2009*

1. American Medical Association
2. Massachusetts Medical Society
3. American Society of Anesthesiologists
4. Society for Technology in Anesthesia
5. The World Federation of Societies of Anaesthesiologists
7. Anesthesia Patient Safety Foundation

*From http://mdpnp.org/interopendorsements_.html
The MD PnP Program has had ongoing projects to clarify the regulatory pathway for integrated medical device and HIT systems.

**Project: FDA Pre-IDE (now called a "presubmission") for Interoperable Medical Devices**

As follow-up to the FDA workshop on Medical Device Interoperability held in January 2010, the Prototype Regulatory Submission Working Group formed (with approximately 20 participants from industry, clinicians, standards development organizations, and the FDA), and met via weekly teleconferences from 2010 through 2011 to develop a detailed risk model for a conceptual integrated medical device system, intended to allow the FDA and interoperability stakeholders to identify and address regulatory science issues related to interoperability.

In the Spring of 2012, the group provided the analysis to date to the FDA, and continued to meet as a sub-group without the FDA, re-named as as the Medical Device Interoperability Safety (MDIS) Working Group to create a Pre-IDE submission (now called a Pre-Submission). The MDIS Working Group meetings resulted in industry consensus on the architecture contained in the ASTM ICE standard as desirable for the Pre-submission, which was submitted to the FDA in February 2012, and discussed in a productive face-to-face meeting in April 2012.

With preliminary agreement from the FDA on the core approach of this submission, it was further refined and a Supplement was submitted in March 2014. The MDISWG expects to continue researching safety issues for systems of integrated medical devices and HIT.

MD FIRE

Medical Device “Free Interoperability Requirements for the Enterprise”

- Interoperable device procurement RFI/RFP language
- Conveys healthcare needs to industry, and simplify purchasing specifications

5 Stakeholder groups from each organization: Purchasing/materials management, BME, IS, Clinical, Legal

Download MD FIRE from www.mdppnp.org
OpenICE Open-Source Research Platform (MGH)

Driven by clinical requirements. Developed with expertise from computer scientists, biomedical engineers, clinicians, regulators, industry, and standards developers.
OpenICE Platform

https://www.openice.info/
This is what you would see on your computer:

OpenICE Screen

https://www.openice.info/
Devices Connected to OpenICE

- Philips Intellivue Series Monitors
  - Serial (RS-232) and Ethernet
- GE Solar 8000x / Dash 4/5000
- Dräger Apollo / EvitaXL / V500
- Nonin Bluetooth OnyxII 9650 / WristOx 3150
- Oridion Capnostream20
- Ivy 450C
- Nellcor N-595
- Masimo Radical-7
- Fluke Prosim6/8 Patient Simulator

www.openice.info
Demonstration from the American Society of Anesthesiologists meeting Oct 2015:
Safety System to Automatically Detect Cardiac Arrest (Pulseless Electrical Activity) and Display a Cognitive Aid using OpenICE

OpenICE App automatically displays correct Page from Stanford Emergency Manual to treat PEA


Note – this demonstrates CDS Without using the EHR
The Clinical Scenario Repository project:

- Provide a **new approach to reporting** tools that will enable researchers, engineers, patients and clinicians the means to describe, needs and challenges
- Collect “Good Ideas for Patient Safety” (**GIPS**)
- Capture important event information that could be impossible or difficult to document using other existing reporting tools or forms.
Scenario Title

PCA Safety Interlock

Scenario Unique ID: 72001

Guidelines

- Do not include protected health information
- Omit actual names of individuals or institutions
- No fields are mandatory. Complete the information in the tabs that is relevant for the case
- Keep information relevant and avoid redundant scenarios

Describe what happened (Current State):

A 49-year-old woman underwent an uneventful total abdominal hysterectomy and bilateral salpingo-oophorectomy. Postoperatively, the patient complained of severe pain and received intravenous morphine sulfate in small increments. She began receiving a continuous infusion of morphine via a patient controlled analgesia (PCA) pump. A few hours after leaving the PACU [post anesthesia care unit] and arriving on the floor [hospital ward], she was found pale with shallow breathing, a faint pulse, and pinpoint pupils.

The nursing staff called a "code," and the patient was resuscitated and transferred to the intensive care unit on a respirator [ventilator]. Based on family wishes, life support was withdrawn and the patient died. Review of the case by providers implicated a PCA overdose. Delayed detection of respiratory compromise in PATIENTS undergoing PCA therapy

Describe your possible solution (Proposed State):

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 is stopped and clinical staff is notified to examine the PATIENT and restart the infusion if appropriate. The use of two independent physiological measurements of respiratory function (oxygen saturation and respiratory rate) enables a smart algorithm to optimize sensitivity, thereby enhancing the detection of respiratory compromise while reducing nuisance alarm conditions.
Remotely Caring for Vulnerable Populations during a Pandemic

Our GCTC project demonstrates the transformational power of open, integrated, medical device and HIT platforms to automate detection, triage, and treatment of individuals affected by a pandemic, as applied to an Ebola Virus Disease (EVD) use case.

See [http://mdpnp.org/ebola.html](http://mdpnp.org/ebola.html) for more information
Dear Dr. Goldman,

Thank you for reaching out to the Center for Devices and Radiological Health (CDRH) via our Emergency Preparedness/Operations and Medical Countermeasures (EMCM) Program.

We understand that The Medical Device "Plug-and-Play" (MD PnP) Interoperability Program, under your coordination, has been asked by the White House Office of Science and Technology Program to mobilize resources among medical device manufacturers and the clinical community, so as to design and demonstrate proof of concept for an interoperable platform that would enable critical care of Ebola-infected patients in an isolation environment with reduced exposure to health care workers.

FDA recognizes the importance of implementing strategies that minimize direct exposure of clinical personnel to patients infected with Ebola virus. We understand that MDPNP, along with its collaborators, are developing potential approaches that would include comprehensive data access and potential remote control of medical devices in the isolation environment, thereby reducing the risk of healthcare worker exposure to the virus.

CDRH recognizes the importance of these efforts and is ready and willing to collaborate with you, the clinical community and your industry partners to demonstrate the potential of this technology in serving this particular public health emergency. We are eager to observe the demonstration taking place Friday November 7th for OSTP, and we look forward to participating in the development of next steps with MDPNP and your medical device partners so as to do our part in enabling advancement of technology that can protect our healthcare workers who put themselves on the front line to promote the public health mission.

Sincerely,
The ICE Alliance is a non-profit organization committed to establishing healthcare environments that are safe, secure, and interoperable.

Note: The ICE Alliance is hosted by the IEEE-ISTO
Proposed Deliverables are already underway in the MD PnP program + collaborators  [www.mdpnp.org](http://www.mdpnp.org) )
Example ICE Alliance Project: Pulse Oximetry MDIDS

www.icealliance.org

Virtuous Cycle of Stakeholders

Healthcare Delivery Organizations - Define Clinical needs (e.g. data elements needed for EHR)

Manufacturers – can inform MDIDS content. And implement requested functionality per users and SDOs

Researchers – define additional research needs for pulse oximetry

Example Project: MDIDS – Medical Device Interface Data Sheets For Pulse Oximetry.
Example (partial) listing of desired Outputs, Inputs, format, and links to applicable standards:

- Pulse Rate beats / min
- SpO₂ %
- Plethysmogram
- Signal strength %
- LED power?
- Signal averaging time
- Software and firmware revisions
- Last clock time update
- Last malware s/w update (date and version)
- Clinical measurements shall conform to IEEE 11073.xx
Our Shared Challenge: 
Remove Medical Errors from 10 Ten List!

CDC, 2010
http://www.cdc.gov/nchs/fastats/deaths.htm

1. 597,689 Heart Disease
2. 574,743 Cancer
3. 138,080 Chronic lower respiratory diseases
4. 129,476 Stroke
5. 120,859 Accidents
6. 83,494 Alzheimer’s disease
7. 69,071 Diabetes
8. 56,979 Influenza &Pneumonia
9. 47,112 Kidney diseases
10. 41,149 Suicide
11. REDUCE Deaths Due to Medical Errors

**GOAL: Decrease Medical Errors by an Order of Magnitude**