Medical Device Interoperability
Needs, Challenges, and Solutions

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How Many Die From Medical Mistakes in U.S. Hospitals?

A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

John T. James, PhD

- 1999 IOM published “To Err Is Human” up to 98,000 people a year die because of mistakes in hospitals.
- 2010 the Office of Inspector General for Health and Human Services said that bad hospital care contributed to the deaths of 180,000 patients in Medicare alone in a given year.
- 2013 Journal of Patient Safety: between 210,000 and 440,000 patients each year who go to the hospital for care suffer some type of preventable harm that contributes to their death.
- “That would make medical errors the third-leading cause of death in America, behind heart disease, which is the first, and cancer, which is second. “

Who is responsible for fixing these problems? Who is empowered? What is the solution pathway?
Safety Culture

Based on Reason, Managing the Risks of Organisational Accidents, 1977

http://www.coloradofirecamp.com/just-culture/definitions-principles.htm
Devices, processes, non-integrated system → errors

Home ventilator
Proposal: Can Medical CPS platforms add “error resistance” to healthcare delivery?
Apps store for smart alarms; med safety

“What if...”

“Medical IoT”
Based on CPS principles

Asking a lot of the platform
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

Blood Pressure
Example - Infusion technology:
1. Decision support?
2. Prevent contra-indicated infusion?
3. “Artificial pancreas” Capabilities? (closed loop)
4. Consolidate all data for adverse event analysis?
5. Check device status, software version? Recall?

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

These infusion pumps are for use on **ONE** patient
Patient Controlled Analgesia (PCA)

1. Up to 6,875 serious preventable PCA-related adverse events occur annually
2. Based on $13,803 per injured patient, economic impact is approximately $15-145M annually
Patient Controlled Analgesia (PCA)

Typical Patient Controlled Analgesia System

PCA injuries can be avoided! Sensor fusion to detect onset of problem + interoperable devices + apps -> safer medication administration

- **WHY IS INTEGRATING SENSOR DATA SO CHALLENGING?**
Monitor Displays
Low Oxygen Level
(\(\text{SpO}_2\)) Alarm Event
“84%” at 2:07

Notion of integrating sensors and actuators for PCA Safety seems simple
But point-of-care composition of heterogeneous devices is challenging
problem, in CPS problem space

**No** evidence of 84% \(\text{SpO}_2\) in EHR
(Blue ticks representing \(\text{SpO}_2\) values
Don’t change)
Data point sent to EHR

Example of possible EHR sample point

SpO₂ = 70%
Sources of Data Uncertainty due to system interactions

Patient’s “actual” SpO2 minimum = 70%

Example of possible EHR sample points for 1-minute recording

Based on this example, EHR May record SpO2 as:
98%
92%
80%
75%
Etc.
Experiment: Simulator is set to create transient desaturation 99%->70%->99%

Pulse Ox is set to: 16 sec averaging time

Effect of averaging time:
What is the real O₂ saturation?

8 sec averaging time

Only device set to 2 sec averaging time accurately captures the lowest sat created by the simulator.
Example demonstrates importance of knowing averaging time when interpreting data.
Integrated Clinical Environment - Architecture
From ASTM F2761-09

ICE System

Apps for PCA Safety, Smart Alarms, Remote Notification, Team coordination

ICE Supervisor (runs apps)

ICE Network Controller

ICE Data Logger

Medical Device or other equipment

Patient and Family

Standard recognized by FDA in August 2013
OpenICE Open-Source Digital Research Platform (MGH)

Based on ASTM F2761 “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE), IEEE 11073 nomenclature; OMG DDS pub/sub messaging middleware

www.openice.info

Testbed funded in large part by NIH, NSF, and DoD
SmartAmerica Closed Loop Healthcare Team
Development & Demo at the MGH/MD PnP Lab, Cambridge, MA March 2014
Closed Loop HealthCare: From Home to Hospital to Home

1. Fall Detected at home
   Randall doesn’t get up

2. Robot: Randall needs
   Medical help
   alerts 911

3. ER - Smart alarms
   utilize cloud data
   and EHR

4. Surgery – all data available

5. PCA pain meds:
   risk of injury
   Reduced; reduce alarm
   fatigue

6. Safety Certification
   of interoperability

7. Real-time
   blue button

8. Device/Genomic
   Prescription CDS

9. Discharge

http://smartamerica.org/teams/closed-loop-healthcare/
Closed Loop HealthCare Team: Home to Hospital to Home

Expo Participants

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ICU: 21,000 Alarms/day
The Ultimate Smart Surgical Algorithm?

Actual screen capture from intra-operative EMR during surgery

Julian M. Goldman, MD / MGH
OpenICE MIoT CPS Platform

• http://openice.info/
• http://openice.info/numerics.html
MDPnP Interoperability Lab
Getting Connected for Patient Safety

OpenICE Web Demo
Explore Our Software
Learn About Our Technology
Interoperability 101

www.openice.info
Devices Connected to OpenICE

- Philips Intellivue Series Monitors
  - Serial (RS-232) and Ethernet
- GE Solar 8000x / Dash 4/5000
  - Under development
- 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
Can our nation deliver these capabilities? There are many S&T Gaps ... 

- Security of networked medical things
  - Balance security and usability
- Composability - Healthcare delivery organizations and other system integrators must be able to compose reliable systems of devices from diverse manufacturers (hardware and apps)
- Standards gaps/lack of reference implementations
- Interoperability chasm
- Cost and use of COTS
- Software reliability and life-cycle management
- Etc.
It all began with a new way of thinking.
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