Open Health Platforms
to enable the next era of healthcare transformation

Opportunities ... and a Challenge

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First, the good news:

Anesthesia Mortality 1950-2004

~640 per Million Anesthetics → ~60/Million

Credit: Penn. Society of Anesthesiologists
Improved Survival

Decreased Infant Mortality

Improved Leukemia Survival

Credit: Wash Post, 2013

Napper and Watson, 2013
How Many Die From Medical Mistakes in U.S. Hospitals?

A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care 2013

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. “
Leading causes of death in the USA

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

http://www.cdc.gov/nchs/fastats/deaths.htm
Medical Errors - in Context

1. 597,689 Heart Disease
2. 574,743 Cancer
3. *Deaths Due to Medical Errors (220-440,000)*
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Equivalent to 1-3 747 airplane crashes every day!

Slide: Julian Goldman, MD / MGH MD PnP program
Patient’s life saved after automobile accident
Clinicians need timely, accurate data to reduce error, treatment delays, injuries and deaths.
Technologies to reduce error and improve efficiency are difficult to implement
Patient-Controlled Analgesia (PCA) system safety concerns

- Over-medication may be caused by pump programming error, PCA button press by proxy, other reasons
- Over-medication can cause respiratory and cardiac arrest
- Comprehensive monitoring is not typically used due to high false/nuisance alarm rate

Slide: Julian Goldman, MD / MGH MD PnP program
PCA Safety Issues are Longstanding ...

http://ppahs.wordpress.com/2012/02/01/guest-post-yes-real-time-monitoring-would-have-saved-leah-2/
This is the story of an 11 year old who died from narcotic-induced respiratory depression. "Ten years after my daughter's death, nothing has changed in the codes of monitoring post-op patients continuously, until they leave the hospital. Alive."

This is a statement from a multi-hospital coalition frustrated by ongoing adverse patient events: "A closed-loop system, which stops or pauses opioid dosing if respiratory depression is detected, is desirable."

http://ppahs.wordpress.com/about/
"Carly Ann Pritchard ... suffered an ankle injury and then underwent surgery to reduce lingering pain from her ankle injury. Unfortunately, although she survived surgery, she suffered brain damage because of an accidental overdose from a morphine-filled pain pump - after surgery. A California appeals court recently upheld a jury's award of about $9.9 million in damages."
PCA is an Archetypal Use Case: gaps are well-known. Limited solutions

Pennsylvania Patient Safety Authority analysis
- 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: Anesthesia Patient Safety Foundation 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** 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**” – safe systems to improve patient safety

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
Cardio-Pulmonary Bypass
(Heart-Lung bypass)

Normal routine: Switch from anesthesia machine ventilator to cardiopulmonary bypass machine, and back to ventilator (after heart repair)
Failure to Ventilate after Bypass

- Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.
- Anesthesiology. 87(4):741-748, October 1997
- “… In the second case, the anesthesiologist forgot to resume ventilation after separation from cardiopulmonary bypass. The delayed detection was attributed to the fact that the audible alarms for the pulse oximeter and capnograph had been disabled during bypass and had not been reactivated. Both patients sustained permanent brain damage.”

Every surgical team (that I surveyed) has experienced this error!
Cardio Pulmonary Bypass Alarm

No App for that

Smart system would provide warning if ventilator off and bypass pump flow = 0.

Slide: Julian Goldman, MD / MGH MD PnP program
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
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.

from January 2009-June 2012,
98 alarm related events reported* ➞ 80 resulted in death
13 resulted in permanent loss of function
5 resulted in unexpected additional care or extended stay

Recommendations/Solutions
1. Have a process for safe alarm management and response
2. Inventory alarm-equipped medical devices
3. Have guidelines for alarm settings
4. Have guidelines for tailoring alarm settings and limits for individual patients
5. Inspect, check, and maintain alarm-equipped devices
These actions correspond with recommendations from The Joint Commission, the Association for the Advancement of Medical Instrumentation (AAMI) and ECRI Institute.

For additional solutions view our Sentinel Event Alert at www.jointcommission.org/sea_issue_50/
Integration of devices and data in the clinical environment should enable improvements in 6/10 top hazards especially Alarms performance

**The List for 2015**

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Platforms

Something to stand on

Proliferating digital platforms will be at the heart of tomorrow’s economy, and even government

Jan 18th 2014 | From the print edition
Grand Challenge to IIC

Remove Medical Errors from 10 Ten List!

CDC, 2010

http://www.cdc.gov/nchs/fastats/deaths.htm

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11. REDUCE Deaths Due to Medical Errors

Will requires an order of magnitude decrease in deaths due to medical errors

Slide: Julian Goldman, MD / MGH MD PnP program
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 finger signal
Blood returns to finger
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 change)

Sampling error for transient events
Sources of variation in EHR documentation due to Data Sampling

Example of possible EHR sample points for 1-minute recording

Based on this example, EHR May record SpO2 as:
98%
92%
80%
75%
Etc.

Patient’s “actual” SpO2 minimum = 70%
Medical Device “Plug-and-Play” Interoperability Program (MD PnP)

- Program established 2004
- $18M funding primarily from NIH, NSF, DOD, NIST
- Vendor-neutral testbed for experimenting with device interoperability solutions (standards technologies, products)
- Contains > $1M devices/network technology – production and research
- Clinical, biomed, and computer science subject matter experts
- Develops OpenICE open-source software www.openice.info*

*3000 downloads in last 26 months
Integrated Clinical Environment Architecture (ICE)

Logical architecture to address:

- App platform
- Safety and performance of the system
- Security (sandboxing)
- Patient ID-data binding
- Correct time data time stamps
- Data logging for forensic, QA, and liability
- Builds on medical device interoperability

From ASTM F2761-09

Standard recognized by FDA in August 2013

Slide: Julian Goldman, MD / MGH MD PnP program
Implementation of standards and functions in MD PnP Lab

Many standards used: OMG DDS; IEEE 11073; HL7 FHIR
Challenge – incomplete standardized data representation / data and device models. Very broad scope of domain

Testbed funded in large part by NIH, NSF, and DoD
OpenICE Platform

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
Ebola Care Medical-Technology Response

Oct - Nov 2014

OPEN MEDICAL DEVICE AND DATA INTEGRATION PLATFORMS TO SUPPORT THE MANAGEMENT OF EBOLA VIRUS DISEASE
In Hospital/ICU

- Personnel must be protected from infection
- 20 minutes to don/doff PPE -> unsafe delays
Data roll-ups, remote device control, resource tracking, to enable more timely care, reduced exposure, and improve monitoring
Participation of the US FDA was a powerful incentive for medical device manufacturers to explore innovative medical technology solutions, especially those benefiting from interoperability between manufacturers.
Medical Device Interoperability Lab
Testbed used for Ebola Med-Tech Response

http://mdpnp.org/ebola.html
http://www.wcvb.com/health/local-researchers-testing-remote-control-ebola-care/29586104
Manual data validation is the norm – results in substantial data loss

“Automated Validation of Medical Device Data for EMRs”

OpenICE Exhibit at IIC – Dave Arney (Lead Engineer)
The ICE Alliance is a non-profit program committed to establishing healthcare environments that are **safe**, **secure**, and **interoperable**

Note: The ICE Alliance is hosted by the IEEE-ISTO. It is not a standards development organization (SDO).

www.icealliance.org
Foundation

Over 10 years and over $30M of government and privately funded research delivering foundational open, interoperable ICE platforms by MD PnP Interoperability Program and academic and industry collaborators

Founding Members include Healthcare Delivery Organizations, Medical Societies, Industry, SDOs, Healthcare Safety Organizations

www.icealliance.org
What can ICE platforms deliver?

ICE platforms can enable revolutionary improvements in

- Patient Safety
- Rich clinical data availability
- Innovation through interoperable apps, sensors, actuators
- Operations and Logistics
- Cyber-security of medical devices and HIT
Next Steps

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URLs:
www.mdpnp.org
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