Summer Conference
Niskayuna, New York – July 16, 2015

Open Health Platforms to enable the next era of healthcare transformation

Opportunities … and a Challenge

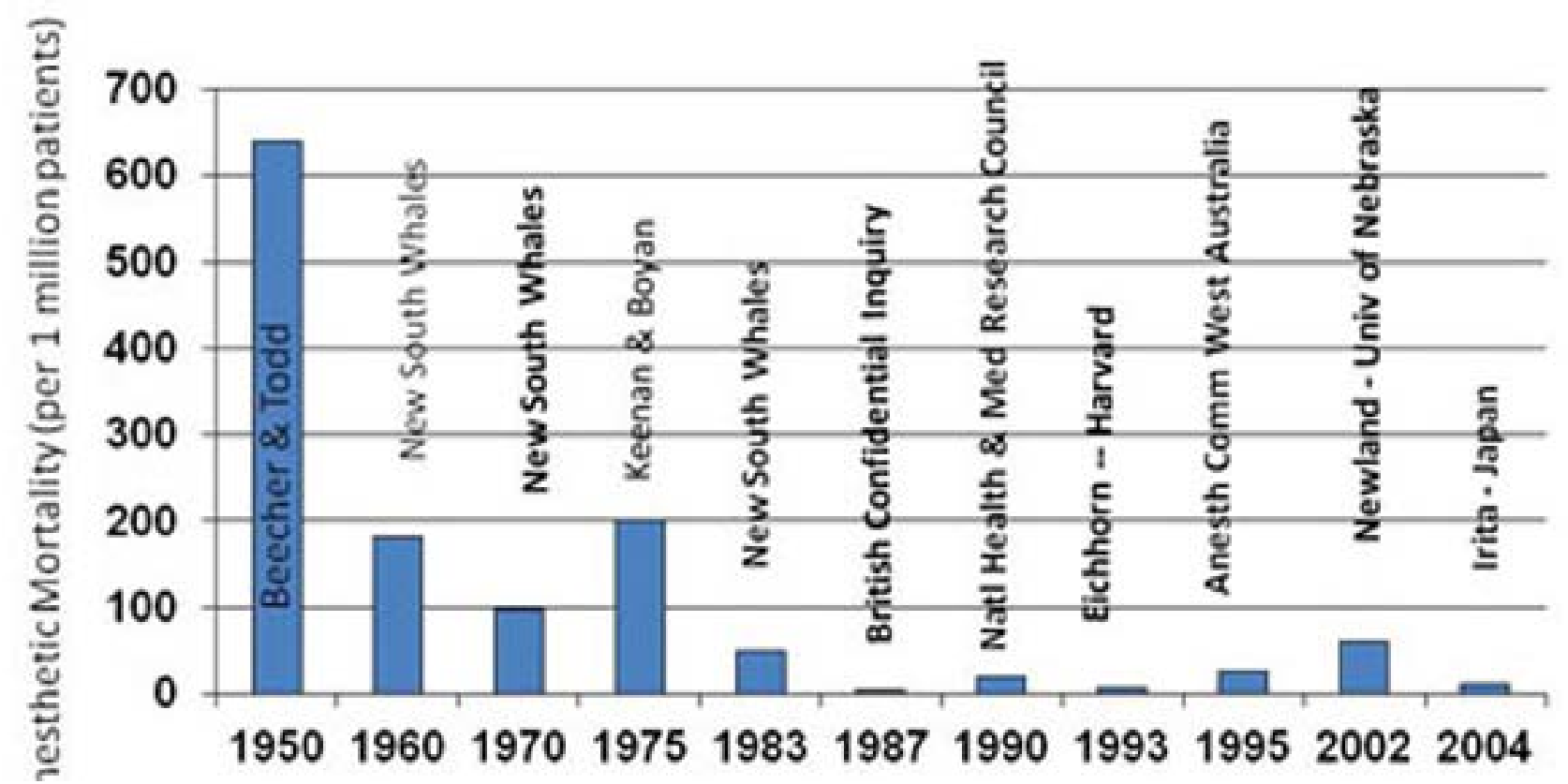
Julian M. Goldman, MD
Director, Program on Interoperability (MD PnP), Mass General Hospital / Partners
Medical Director, Partners HealthCare Biomedical Engineering
Anesthesiologist, MGH/Harvard Medical School
Chair, ISO TC 121

Contact information: www.jgoldman.info

First, the good news:

Anesthesia Mortality 1950-2004

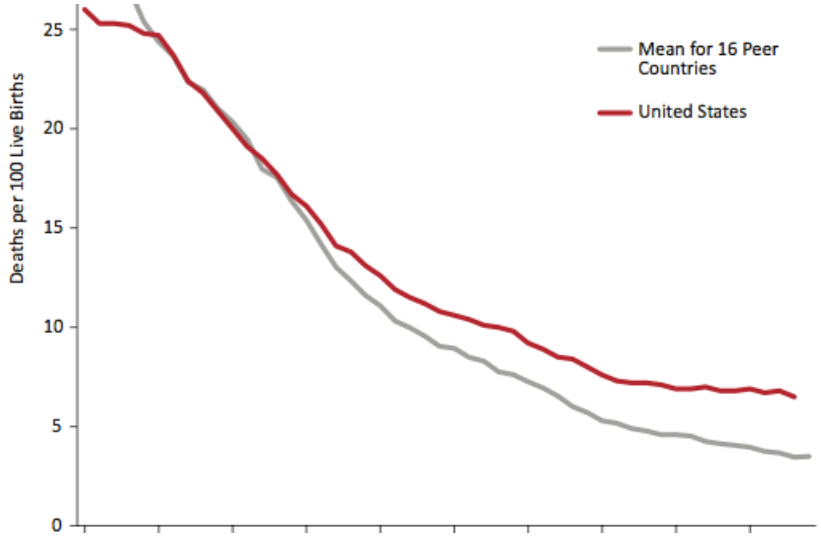
~640 per Million Anesthetics -→ ~60/Million



Credit: Penn. Society of Anesthesiologists

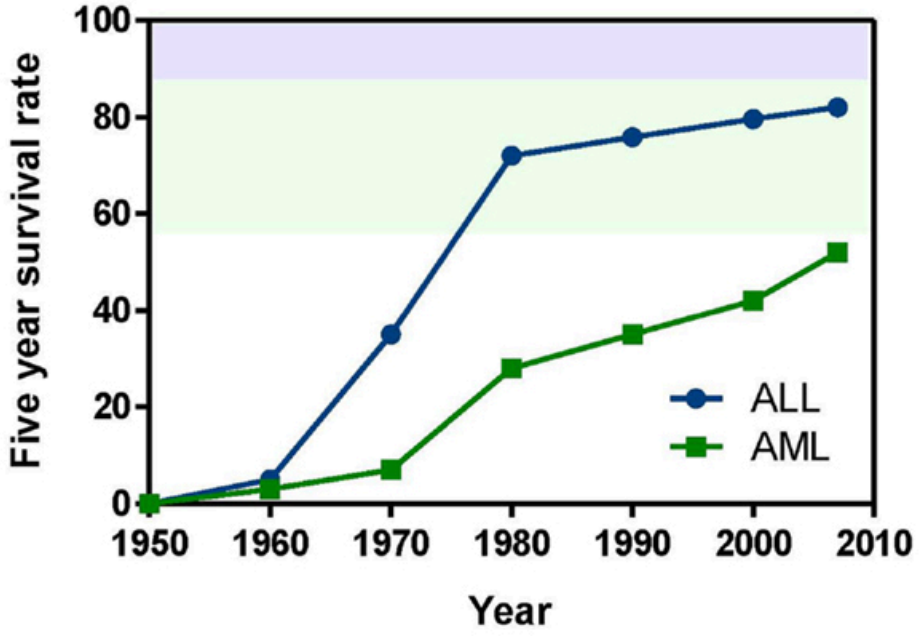
Improved Survival

Decreased Infant Mortality



Credit: Wash Post, 2013

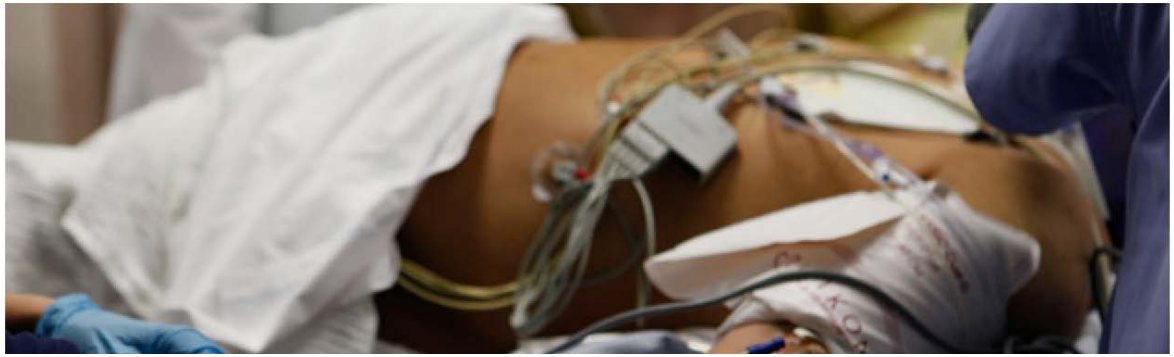
Improved Leukemia Survival



Napper and Watson, 2013

Patient Safety
Exploring Quality of Care in the U.S.

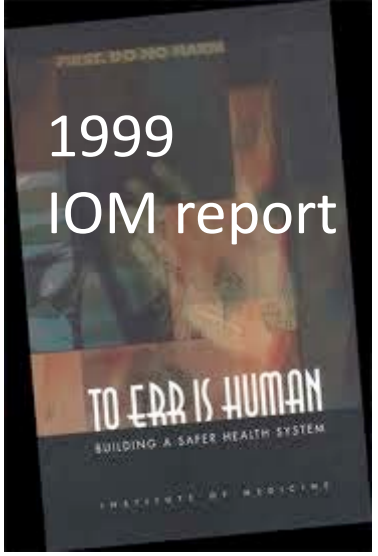
How Many Die From Medical Mistakes in U.S. Hospitals?



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

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

Medical Errors - in Context

1. 597,689 Heart Disease
2. 574,743 Cancer
3. *Deaths Due to Medical Errors (220-440,000)*
4. 138,080 Chronic lower respiratory diseases
5. 129,476 Stroke
6. 120,859 Accidents
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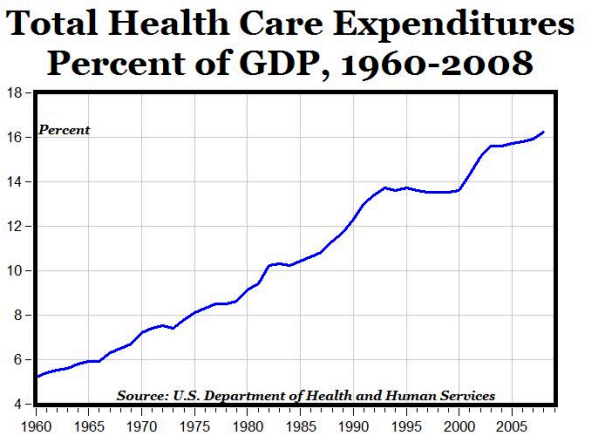

Equivalent to 1-3 747 airplane crashes every day!

Slide: Julian Goldman, MD / MGH MD PnP program

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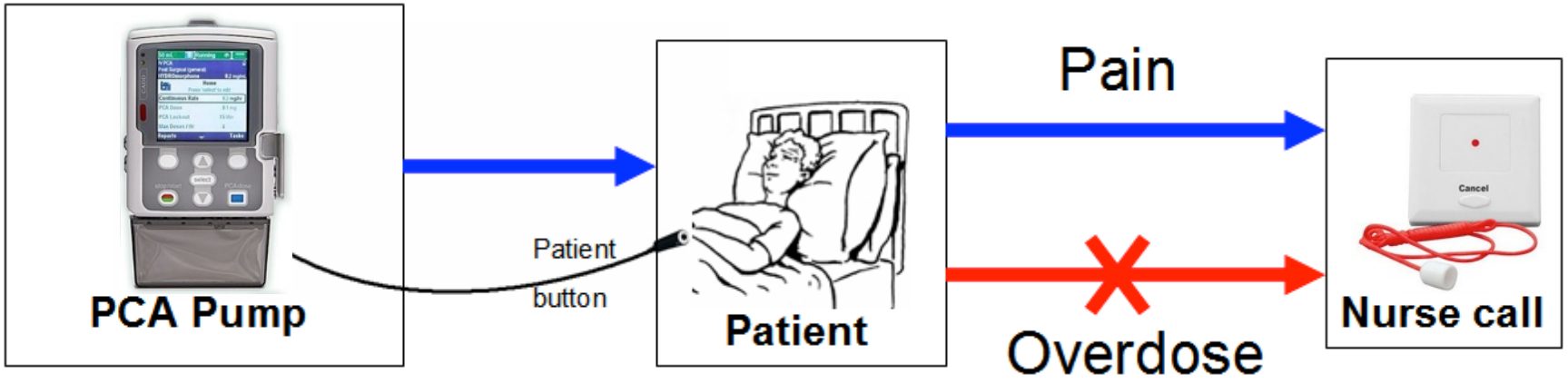
Patient's life saved after automobile accident
Clinicians need timely, accurate data to reduce error, treatment delays, injuries and deaths.
Technologies to reduce error and improve efficiency are difficult to implement

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

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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."

http://www.apsf.org/newsletters/html/2010/spring/12_coalition.htm
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

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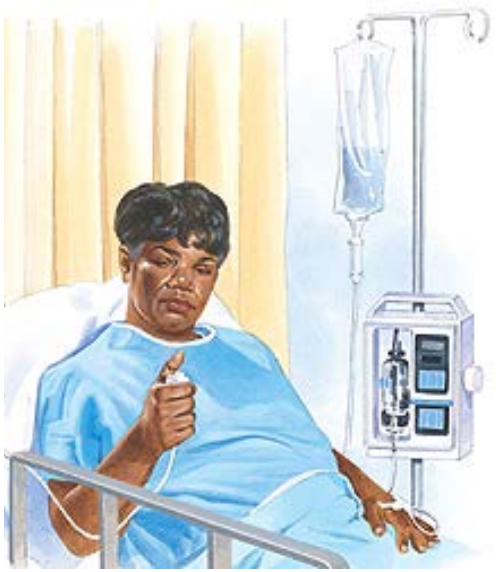

Pennsylvania Patient Safety Authority analysis[1]

- 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[2]

1. http://patientsafetyauthority.org/PATIENTSCONSUMERS/PatientConsumerTips/Pages/PCA_Pump_Consumer_Tips.aspx
2. J Goldman, MD PnP Program

Cardio-Pulmonary Bypass
(Heart-Lung bypass)

← or →

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

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Failure to Ventilate after Bypass

- Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.
- Anesthesiology. 87(4):741-748, October 1997 18 years
- "… 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

and

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

Slide: Julian Goldman, MD / MGH MD PnP program

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ECRI Institute

Top 10 Health Technology Hazards for 2015

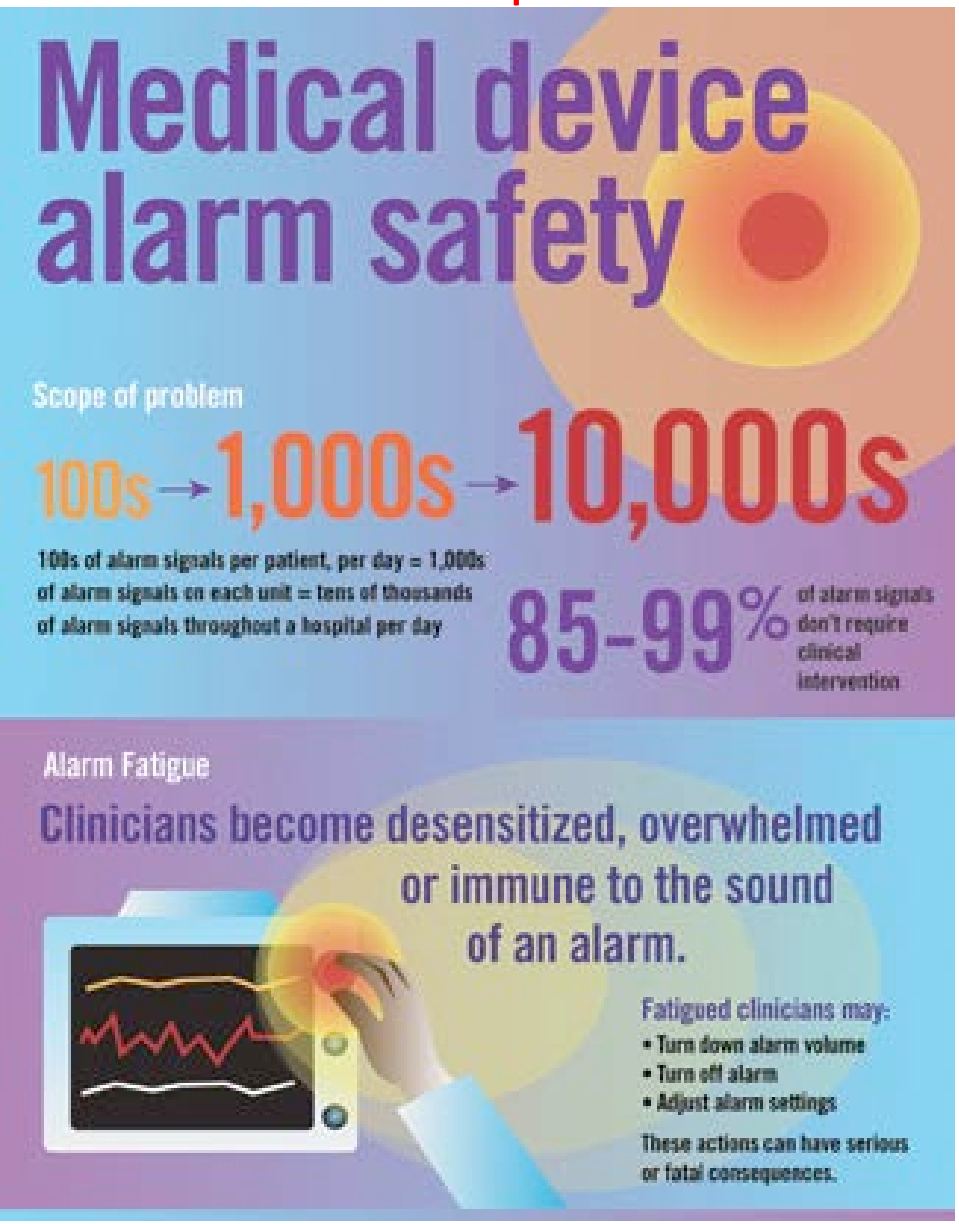
A Report from *Health Devices*

The List for 2015

1. Alarm Hazards: Inadequate Alarm Configuration Policies and Practices
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"



http://www.theamericannurse.org/wp-content/uploads/2013/10/medical_device_alarm_safety_infographic.jpg

ECRI Institute

Top 10 Health Technology Hazards for 2015

A Report from *Health Devices*

Integration of devices and data in the clinical environment should enable improvements in 6/10 top hazards especially Alarms performance

The List for 2015

1. Alarm Hazards: Inadequate Alarm Configuration Policies and Practices
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10. Overwhelmed Recall and Safety-Alert Management Programs

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

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industrial internet CONSORTIUM

Grand Challenge to IIC

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

~~*Deaths Due to Medical Errors (220-440,000 estimated)*~~

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

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

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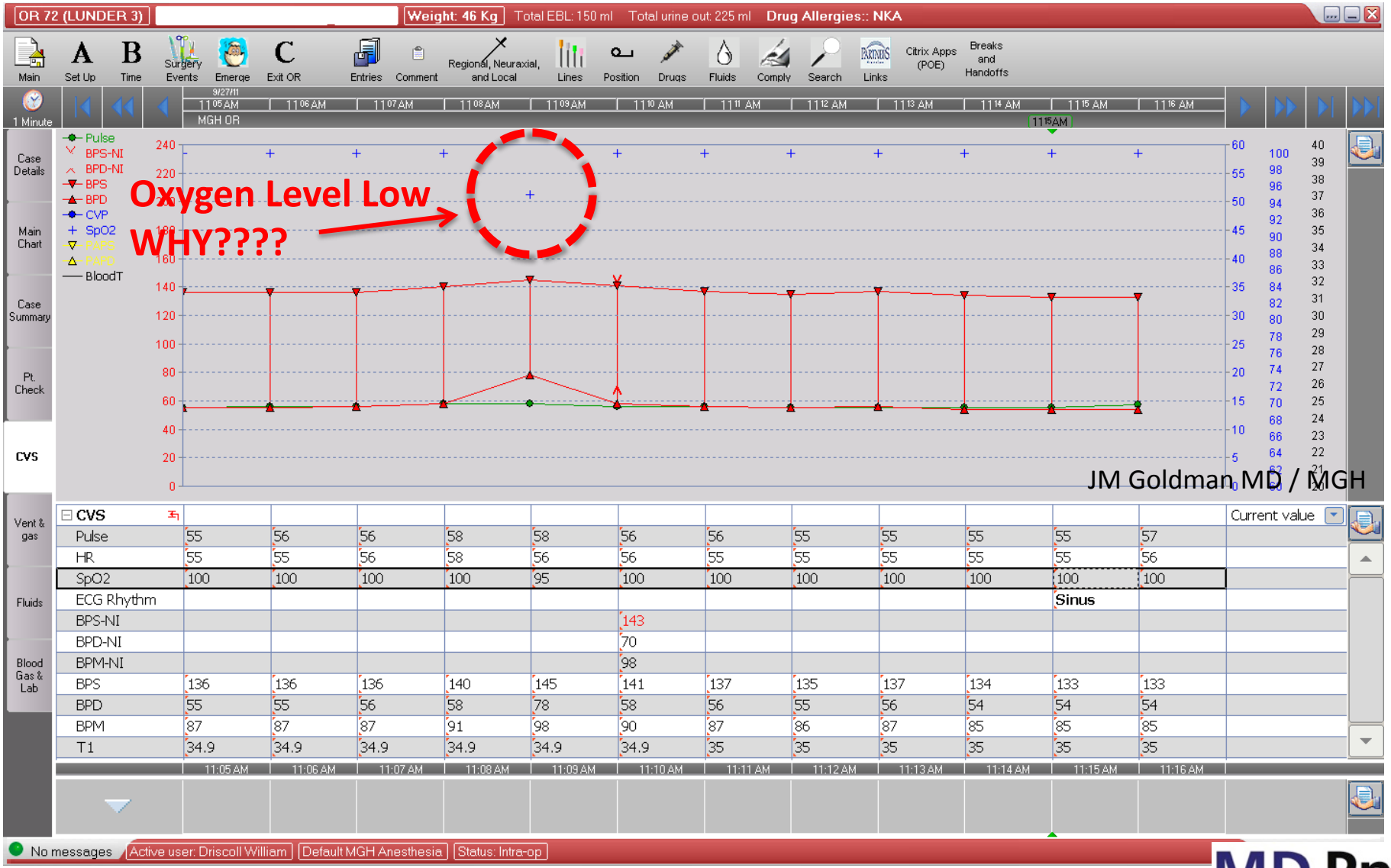
Pulse Oximeter Data example



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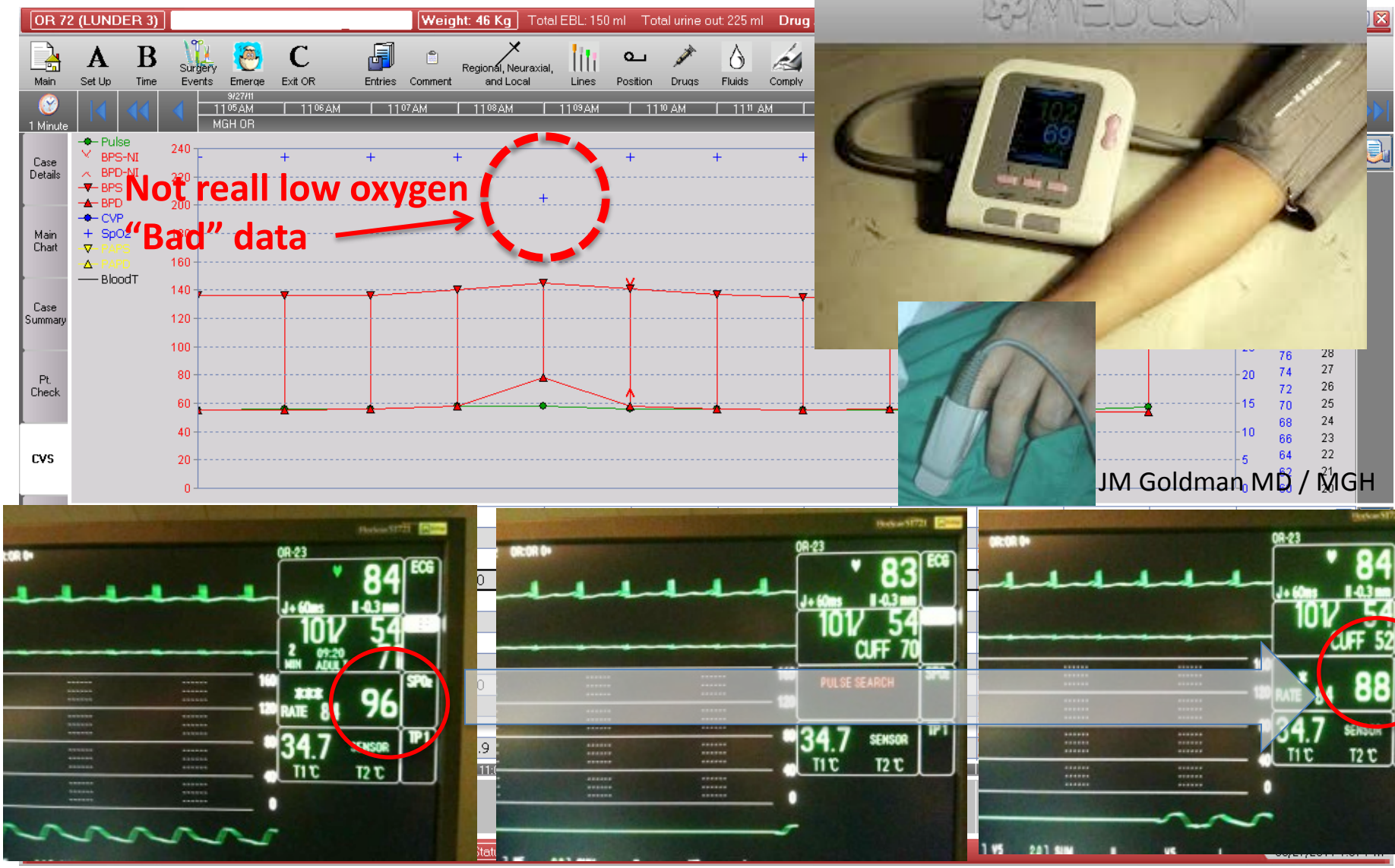
BP cuff - Pulse Oximeter Interaction



Baseline

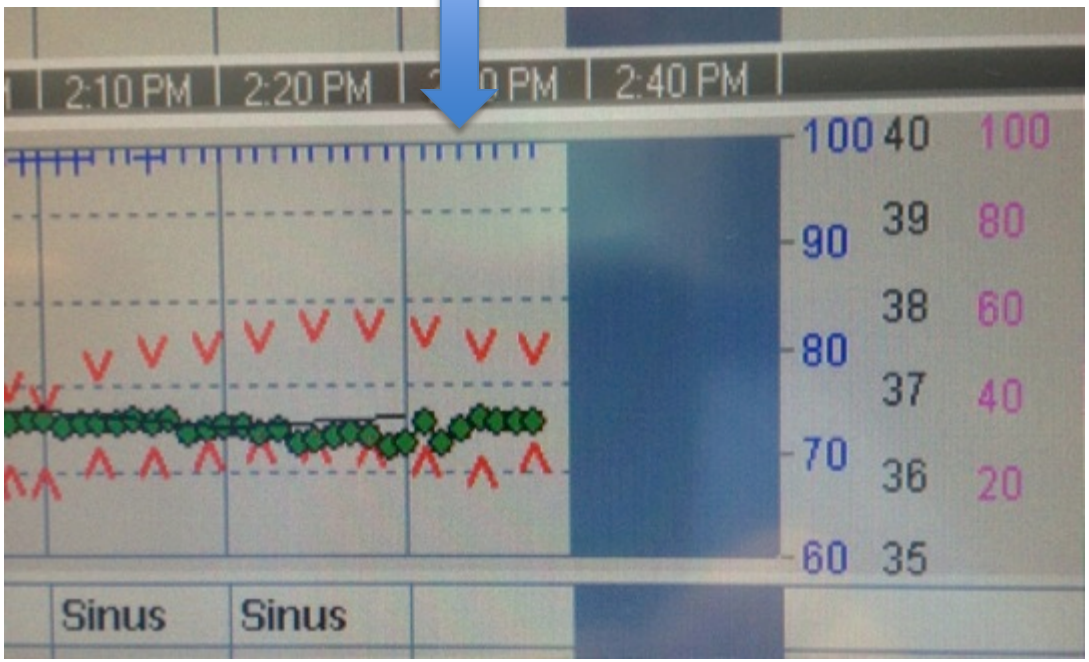
Cuff inflates – loss of finger signal

Blood returns to finger

Sampling error for transient events

Monitor Displays Low Oxygen Level ($SpO_{2)}$ Alarm Event "84%" at 2:07

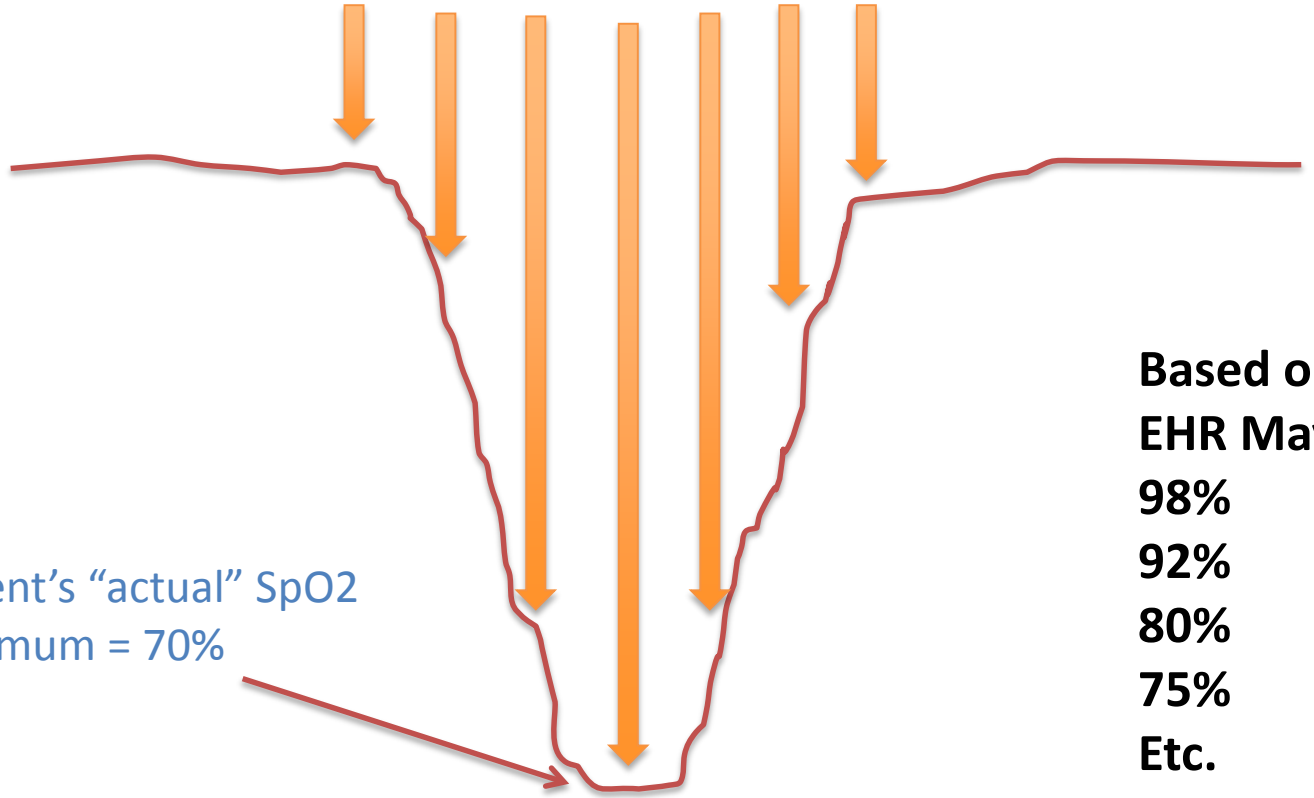
No evidence of 84% SpO_2 in EHR (Blue ticks representing SpO_2 values Don't change)



Sources of variation in EHR documentation due to Data Sampling

60 Seconds

Example of possible EHR sample points for 1-minute recording



Patient's "actual" SpO2 minimum = 70%

Based on this example, EHR May record SpO2 as:

98%

92%

80%

75%

Etc.

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Medical Device "Plug-and-Play" Interoperability Program (MD PnP)

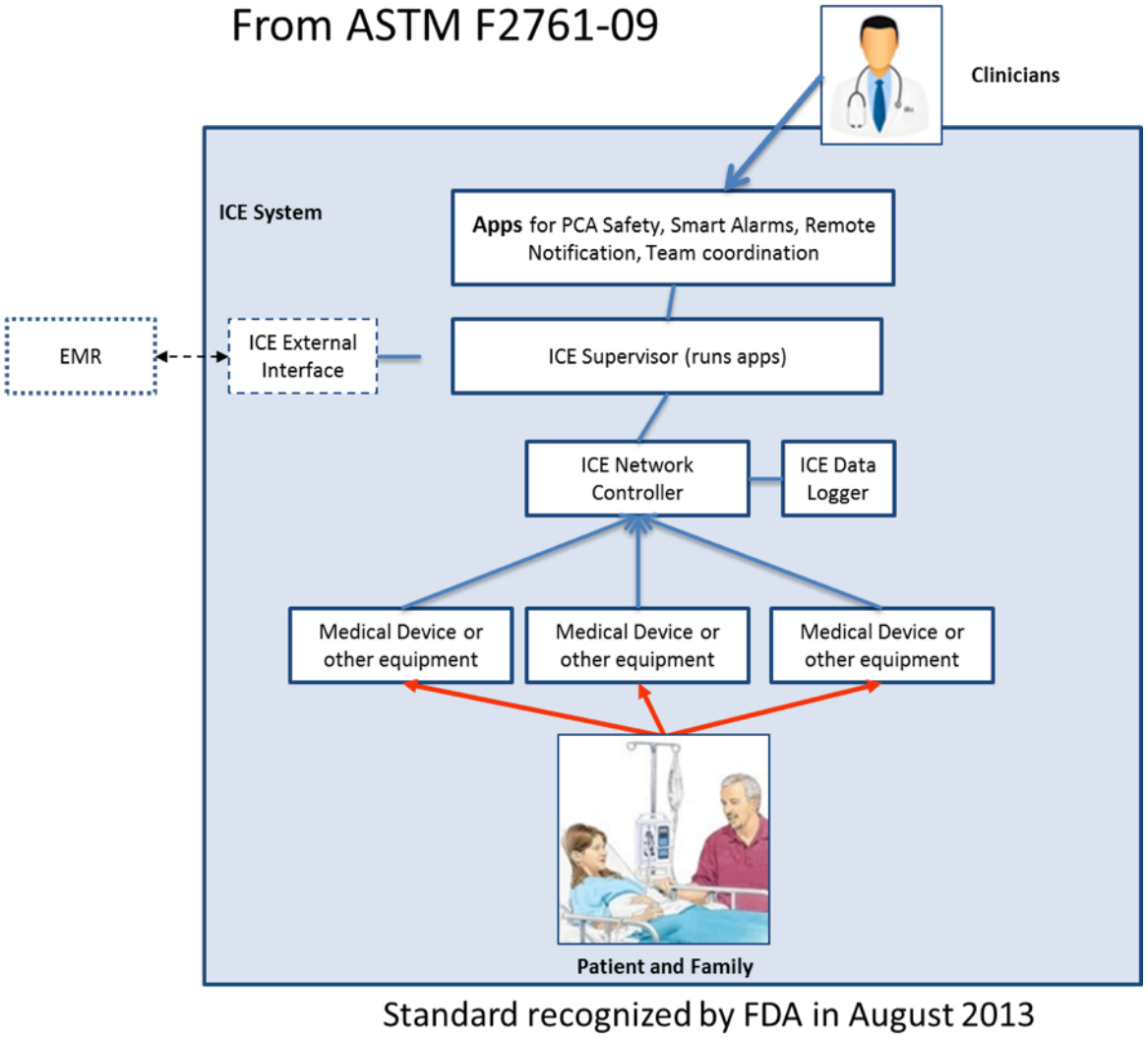
- Program established 2004
- $18M funding primarily from NIH, NSF, DOD, NIST
- Vender-neutral testbed for experimenting with device interoperability solutions (standards technologies, products)
- Contains > $1M devices/network technology – production and research
- Clinical, biomed, and computer science 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



Standard recognized by FDA in August 2013

Slide: Julian Goldman, MD / MGH MD PnP program

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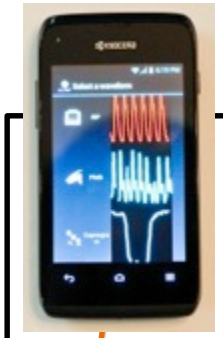
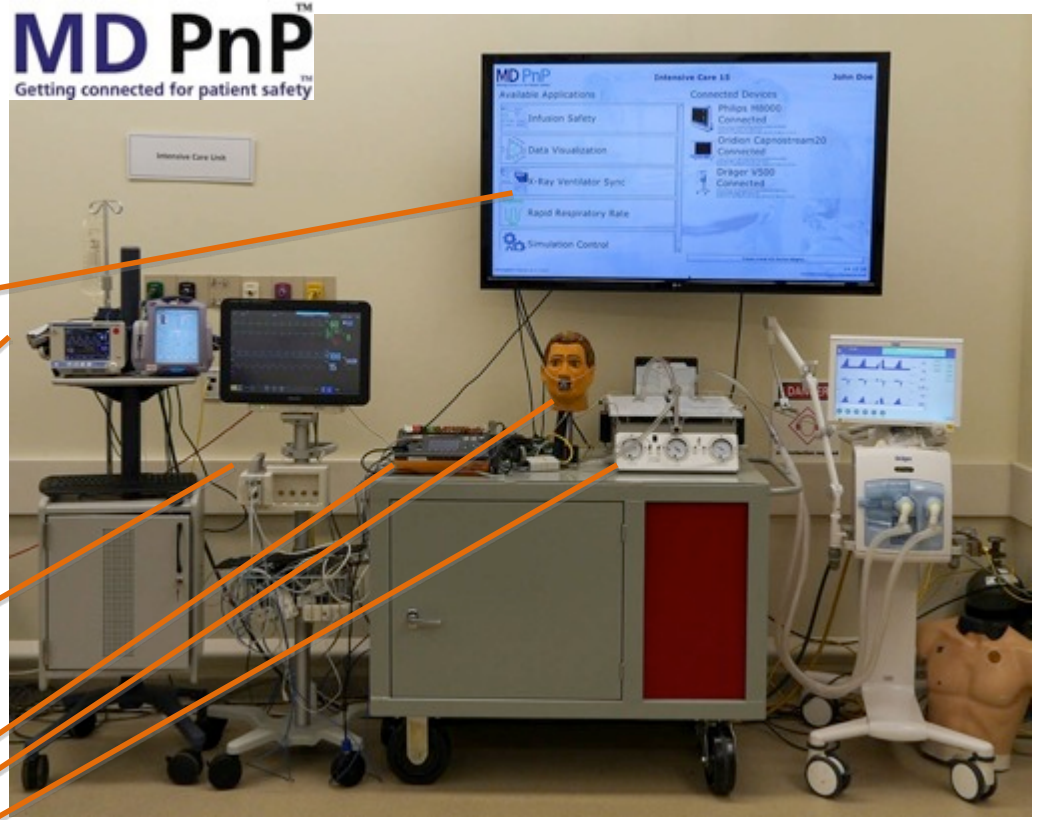
Implementation of standards and functions in MD PnP Lab

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

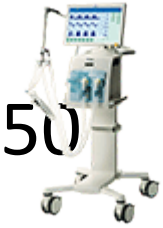
OpenICE Platform

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





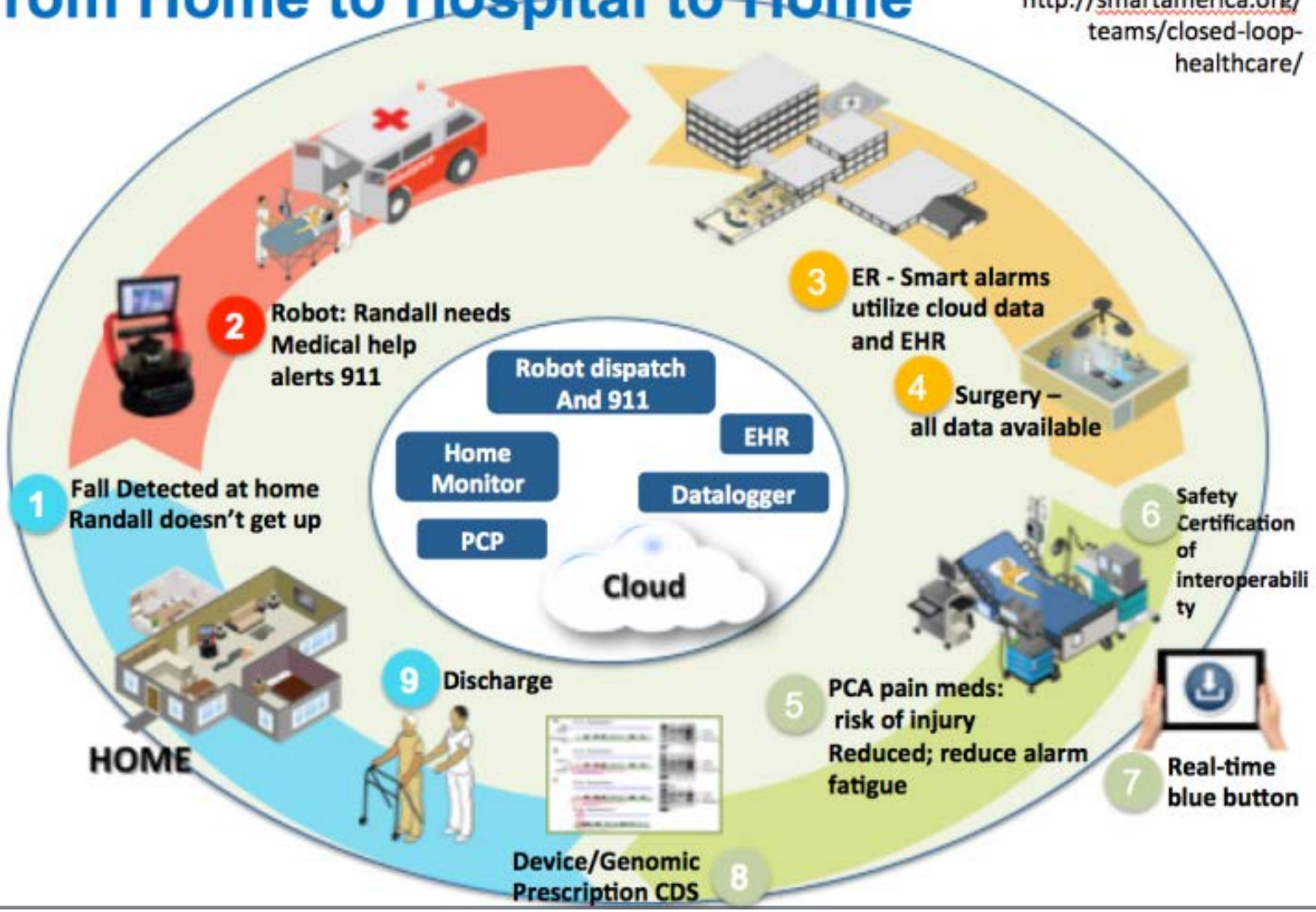




Closed Loop HealthCare:
From Home to Hospital to Home

SMART AMERICA

http://smartamerica.org/teams/closed-loop-healthcare/



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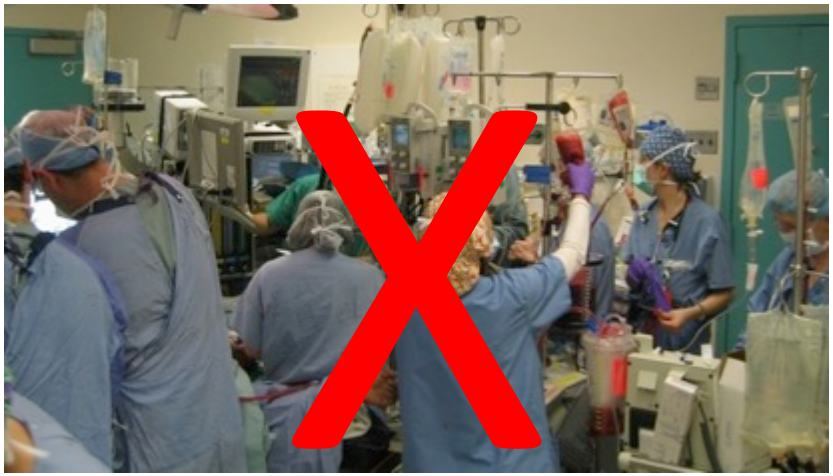
Ebola Care Medical-Technology Response

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

Slide: Julian Goldman, MD / MGH MD PnP program

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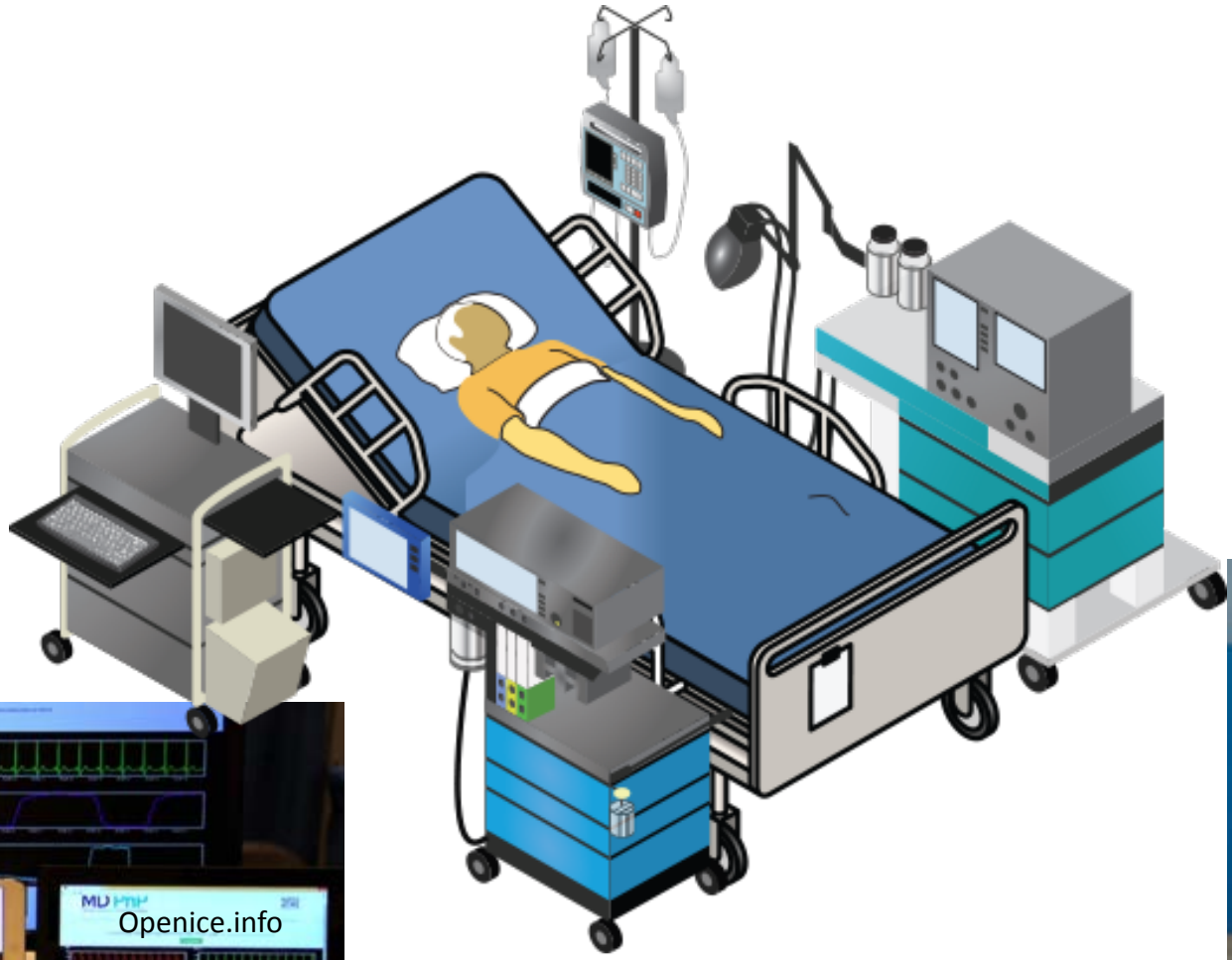
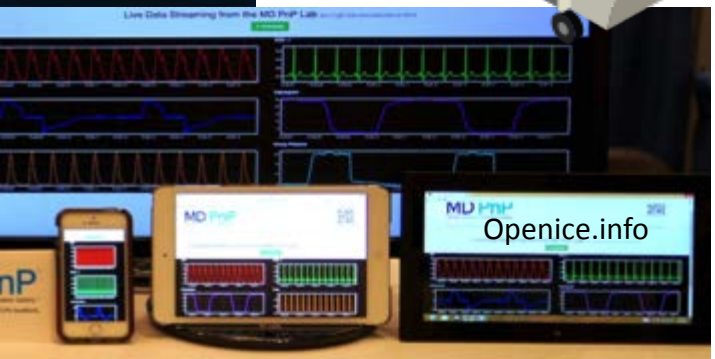
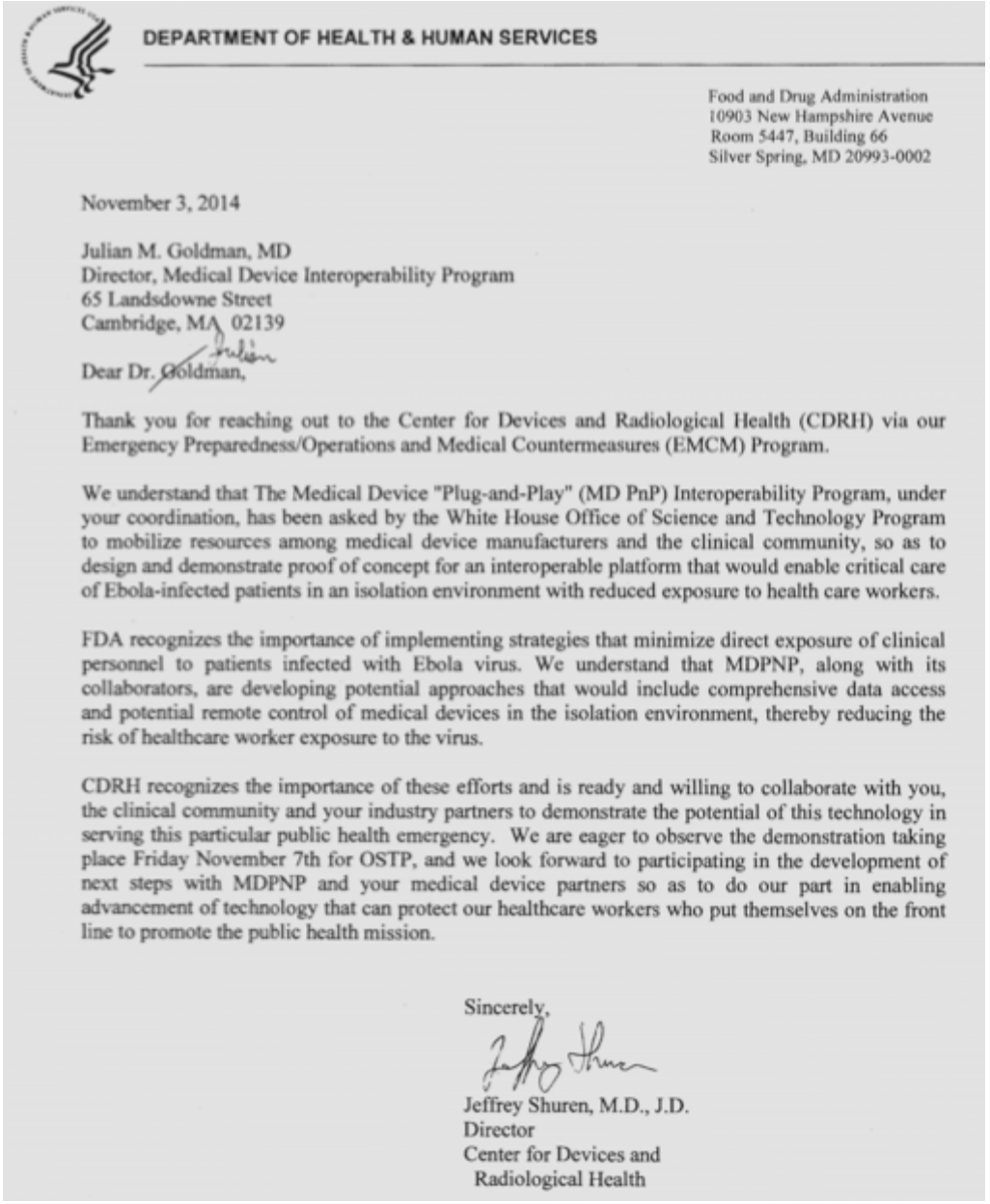
Data roll-ups, remote device control, resource tracking, to enable more timely care, reduced exposure, and improve monitoring





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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Room 5447, Building 66
Silver Spring, MD 20993-0002

November 3, 2014

Julian M. Goldman, MD
Director, Medical Device Interoperability Program
65 Landsdowne Street
Cambridge, MA 02139

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,

Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and
Radiological Health

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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).

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

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

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Next Steps

Contact me
or

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Research Affiliate, MIT
Senior Vice President, IIC
shoumen@mit.edu

URLs:
www.mdpnp.org
www.OpenICE.info
www.ICEAllianceorg