Reston, VA
March 25, 2015

The Medical IoT*: Challenges and Opportunities

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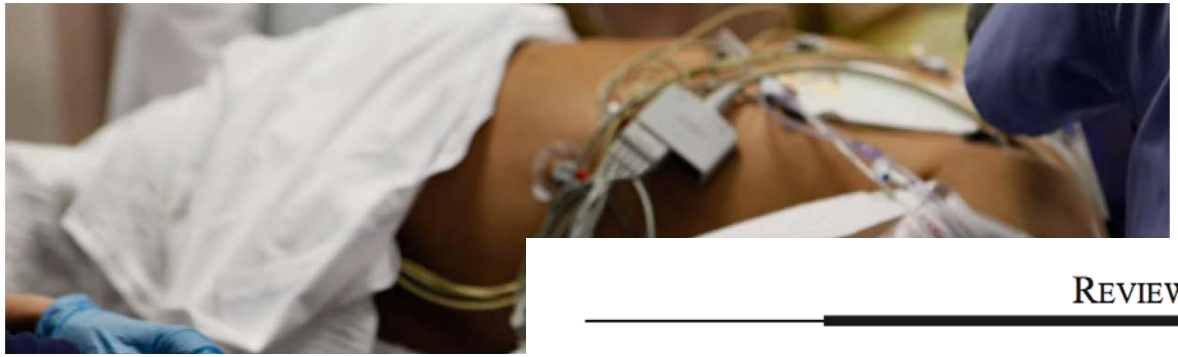
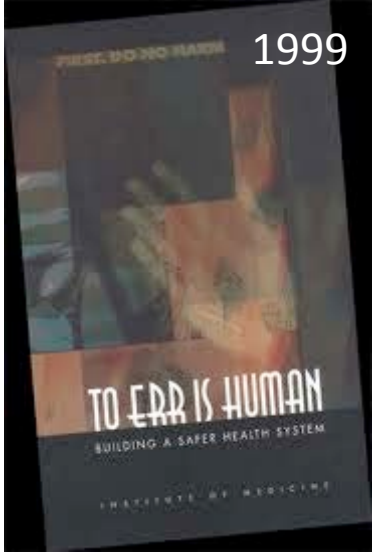
*Internet of Things

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

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





REVIEW ARTICLE

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. "

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

Devices, processes, non-integrated system → errors (home AND hospital)

Home ventilator

JM Goldman MD / MGH

OR scene – patient's life saved:
Clinicians need timely, accurate data to reduce error, treatment delays, injuries and deaths. *Is that how we practice today? Where are innovative solutions?*

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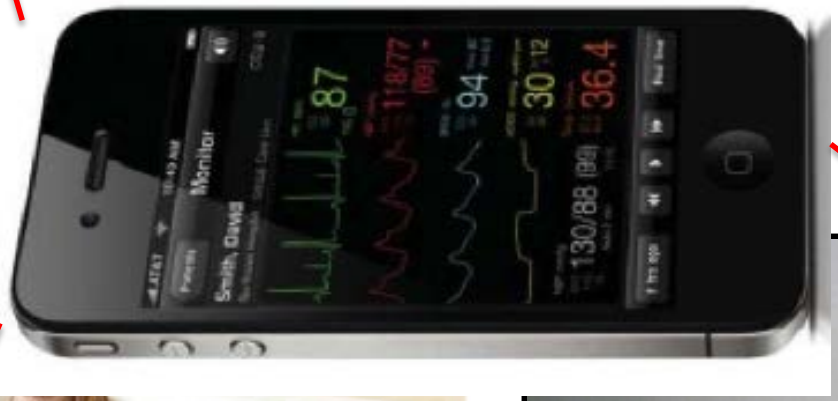
“Medical IoT”

Apps store for smart alarms; med safety



What if…

Asking a lot of the platform

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OPEN MEDICAL DEVICE AND DATA INTEGRATION PLATFORMS TO SUPPORT THE MANAGEMENT OF EBOLA ILLNESS

Oct - Nov 2014

Project Timeline: Oct – Nov 2014

Over 20 days, multiple organizations collaborated to demonstrate concepts of methods to improve Ebola care, inter-vendor data sharing, device integration, and remote and closed-loop control to provide capabilities beyond those available today to improve patient care and protect healthcare workers

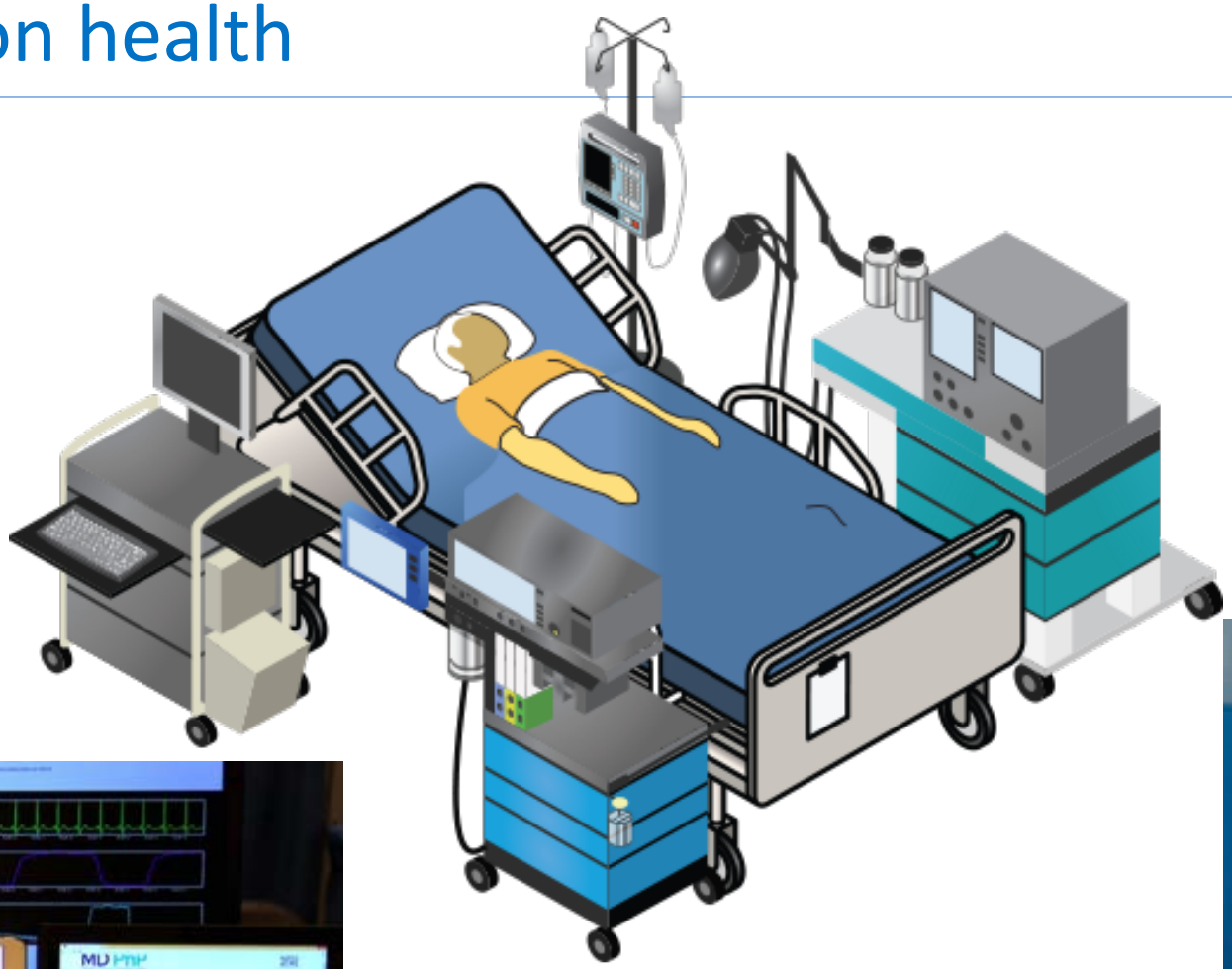
Several concepts, relationships, and methodologies were based on the **SmartAmerica** and **Global City Challenges**

http://www.wcvb.com/health/local-researchers-testing-remote-control-ebola-care/29586104

In Hospital

We need to move personnel away from patient areas

Remote data display, remote device control, auto-batched tasks and checklists, reduce exposure and improve monitoring of individuals as well as population health



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Robot Access Tunnel / Door

Contaminated

UV Decontamination

Clean

Medical supply robot is decontaminated in tunnel to isolation room (like a doggie door)

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Challenges in Management of IV Drug Infusions

ISOLATION BARRIER

CARRIER FLUID

DRUG

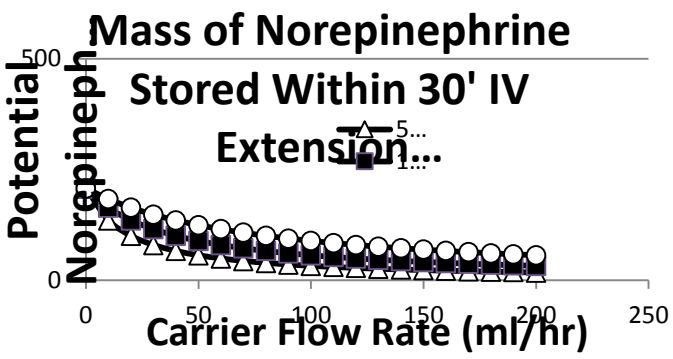
INFUSION PUMPS

JUNCTION

Example:
Carrier flow 100 ml/min
Intended dose Norepinephrine = 5 mcg/min
Target delivery achieved **20 min** after starting drug pump

∗ Distance along tubing between stars ∗

= 30 feet



Courtesy of R. Peterfreund, MD PhD, MGH

STOP THE SPREAD OF FLU

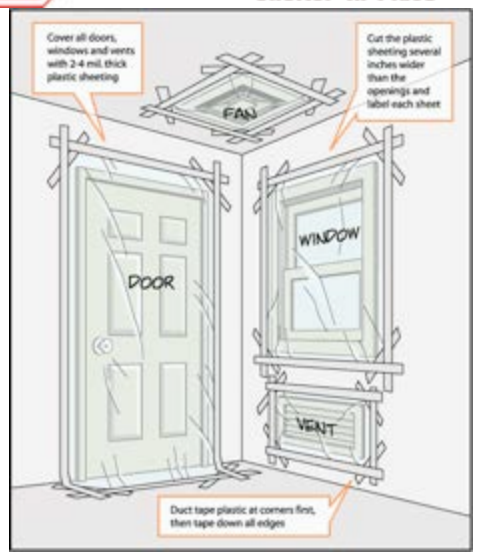
Pandemic – "epidemic of infectious disease that has spread through human populations across a large region". <u>All</u> resources are constrained during pandemic.

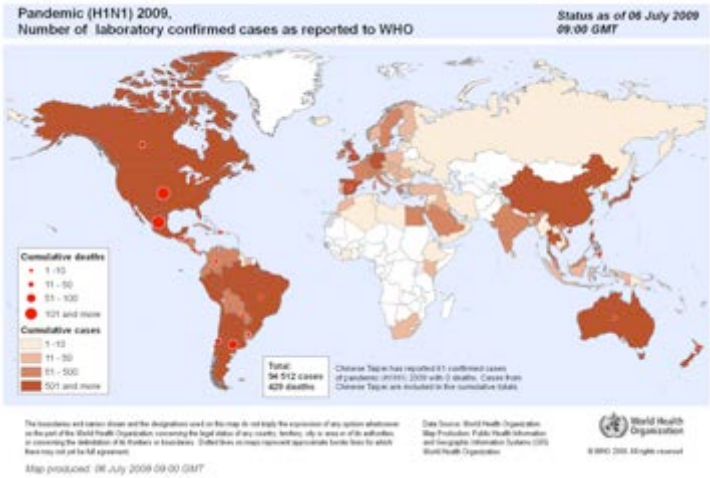
From NIST Global City Challenge

Opportunities:

- **Diagnose and treat those who can't travel**
- **Early dx; early tx through remote presence**
- **When go to ER?**
- **Reverse quarantine?**
- **Assess treatment**

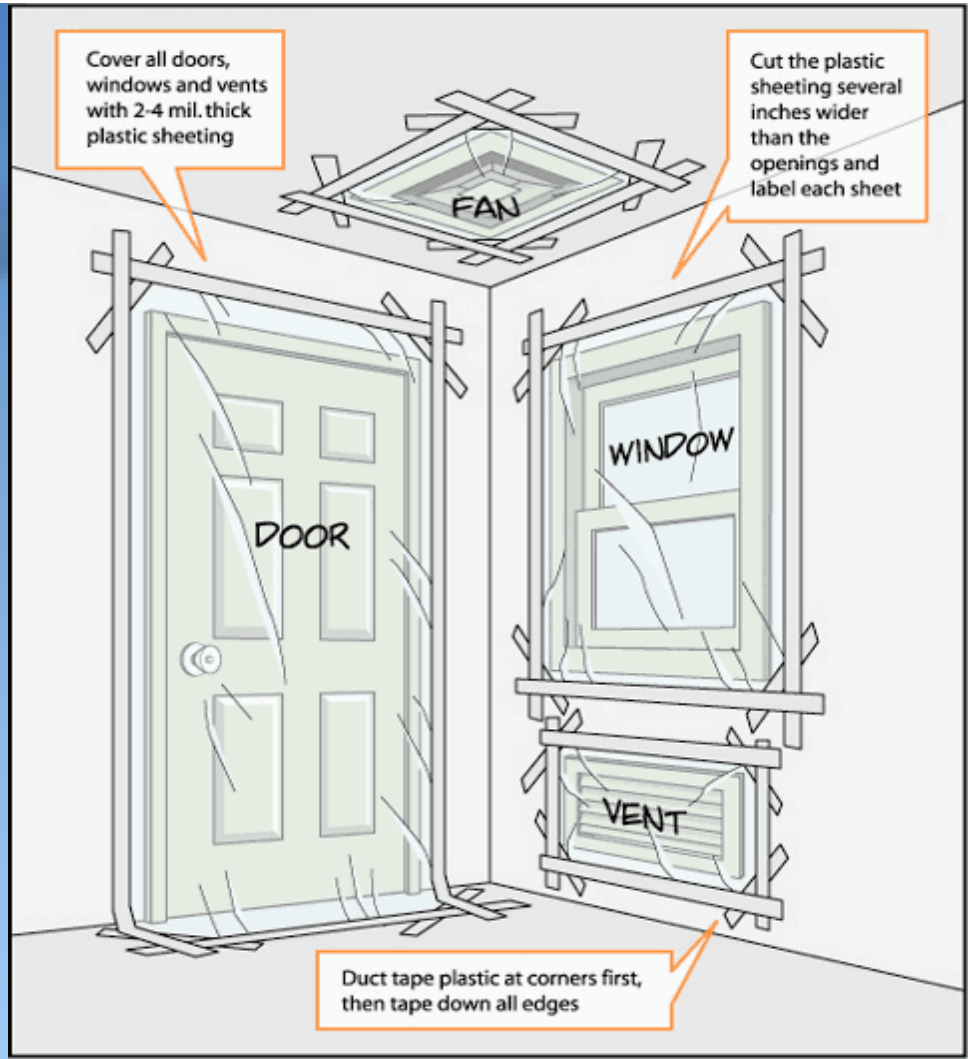
Or?





H1N1 2009

PRE-hospital – isolation, monitoring



Ebola Care Problem Statement

How can we support the safety of patients, and workers dealing with the care of Ebola-exposed persons in quarantine *or* under medical care in a hospital or similar facility?

1. Improve the monitoring of health status and clinical care of individuals as they progress from quarantine to medical care
2. Medical and environmental sensors sourced from manufacturers must be integrated to collect and converge the data for analysis
3. Exposure to Ebola-exposed or infected persons must be minimized during the delivery of healthcare
4. Provide capabilities beyond those available today to improve patient care and protect healthcare workers

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OpenICE MIoT Platform

- http://openice.info/
- http://openice.info/numerics.html

3-day “hackathon” for Ebola care technologies

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Open Medical Device and
Data Integration Platforms
MD PnP

- Demonstrations in the MD PnP lab at the Massachusetts General Hospital included remote control of ventilators, infusion pumps, and monitors, integration of multiple sensors for quarantine monitoring, remote monitoring, and sophisticated data processing and visualization.

http://www.wcvb.com/health/local-researchers-testing-remote-control-ebola-care/29586104

COLLABORATORS

FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

HARVARD MEDICAL SCHOOL

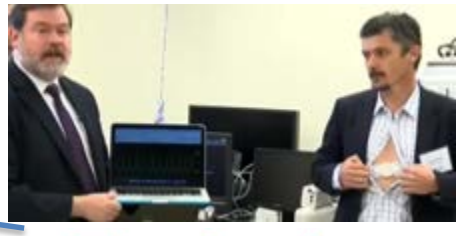
GE Healthcare

Lyntek INCORPORATED

MD PnP™

Dräger

PHILIPS



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RED INNOVATION

Zephyr™
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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.

Ebola Response Page

http://mdpnp.org/ebola.html

Global City Teams Challenge – SmartAmerica Round Two

ABOUT

FAQ

PARTNERS

SECTORS

SUBSCRIBE AND FOLLOW:

The Global City Teams Challenge (GCTC) is a collaborative network of project teams, or "action clusters," working on innovative applications of Internet of Things (IoT) technologies within a smart city / smart community environment. National Institute of Standards and Technology (NIST) and US Ignite have teamed-up with the Department of Transportation (DoT), National Science Foundation (NSF), International Trade Administration (ITA), Department of Health and Human Services (HHS) and Department of Energy (DoE) to create the Global City Teams Challenge to advance practical applications of the latest research in cyberphysical systems.

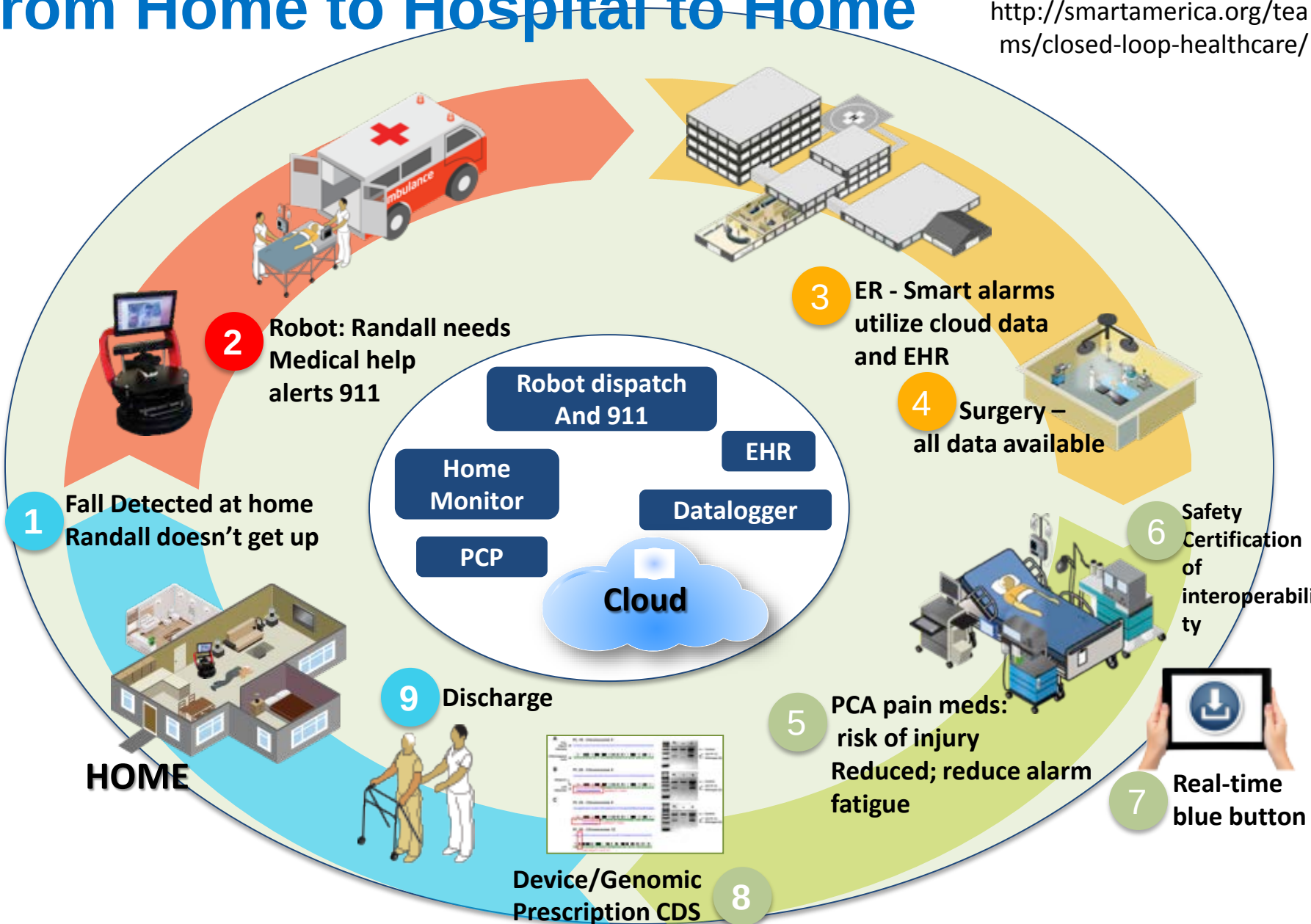
Why participate in a Global City Team "Action Cluster"?

The Challenge is an opportunity for forward-looking communities to partner with public and private organizations to accelerate the deployment of IoT technologies designed to address some of the most pressing challenges facing cities. The Challenge also benefits innovative companies and non-profits by giving them a chance to implement and/or assess their solutions in valuable municipal testbeds, and provides them with exposure to scores of potential new customers.

Closed Loop HealthCare:
From Home to Hospital to Home

SMART AMERICA

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



Closed Loop HealthCare Team: Home to Hospital to Home

Expo Participants

MD PnP
Getting Connected for Patient Safety
MGH · Partners HealthCare

*Julian Goldman
Jeff Plourde
Jeff Peterson
Sue Whitehead

Mizzou
University of Missouri

*Marge Skubic
Erik Stone

Penn Engineering

Oleg Sokolsky
Insup Lee

NIST

Lukas Diduch
Martial Michel
Antoine Fillinger
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Emory Fry
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Gary German

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WPI

Taskin Padir
Vinayak Jagtap

PRISMTECH

Steve Jennis

talend
open data solutions

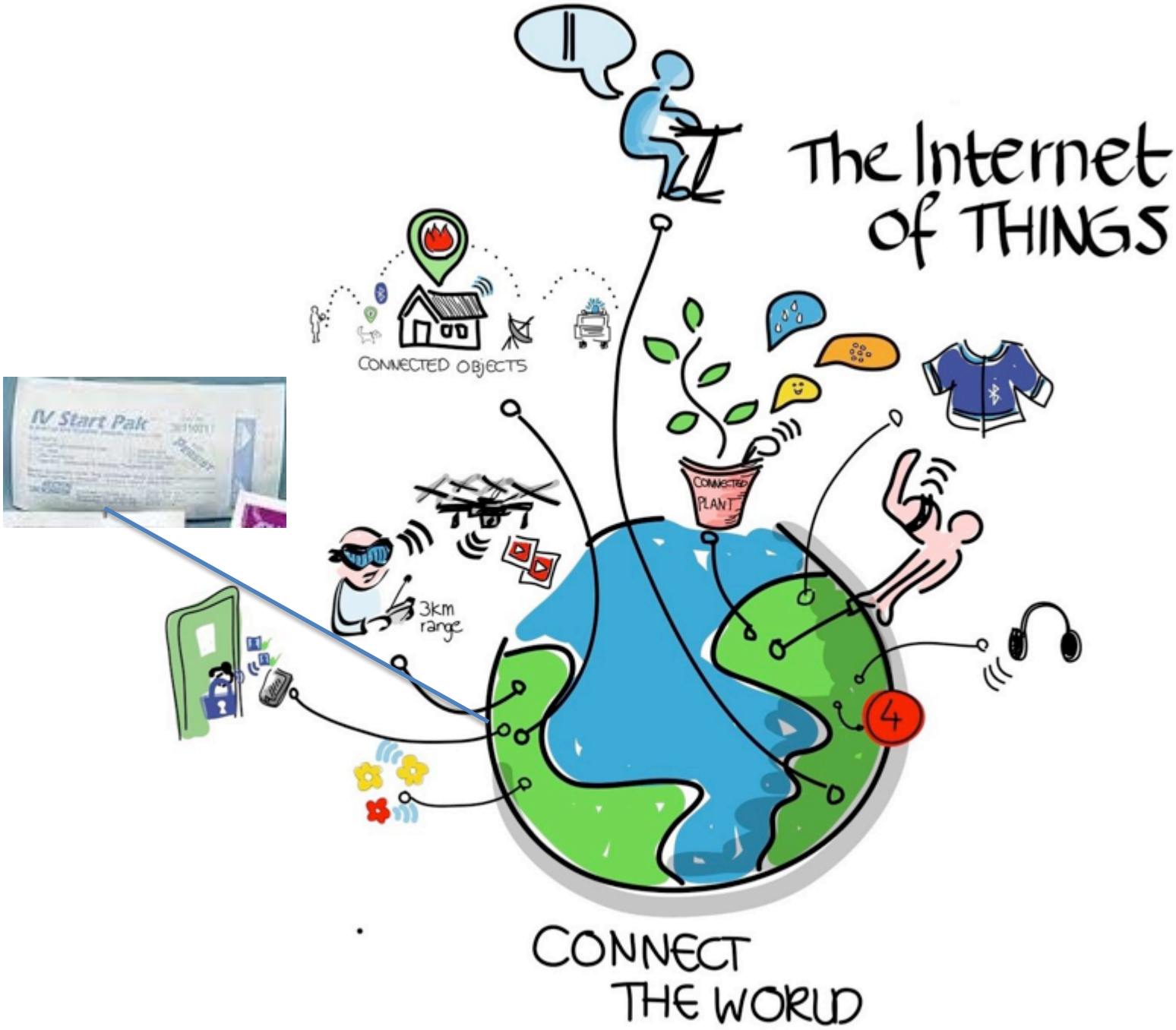
The Apache Software Foundation
http://www.apache.org/

Edward Ost
Hadrian Zbarcea

SMART AMERICA

*Co-leads

SmartAmerica Closed Loop Healthcare Team
Development & Demo at the MGH/MD PnP Lab, Cambridge, MA March 2014



http://en.wikipedia.org/wiki/Internet_of_Things#mediaviewer/File:Internet_of_Things.jpg

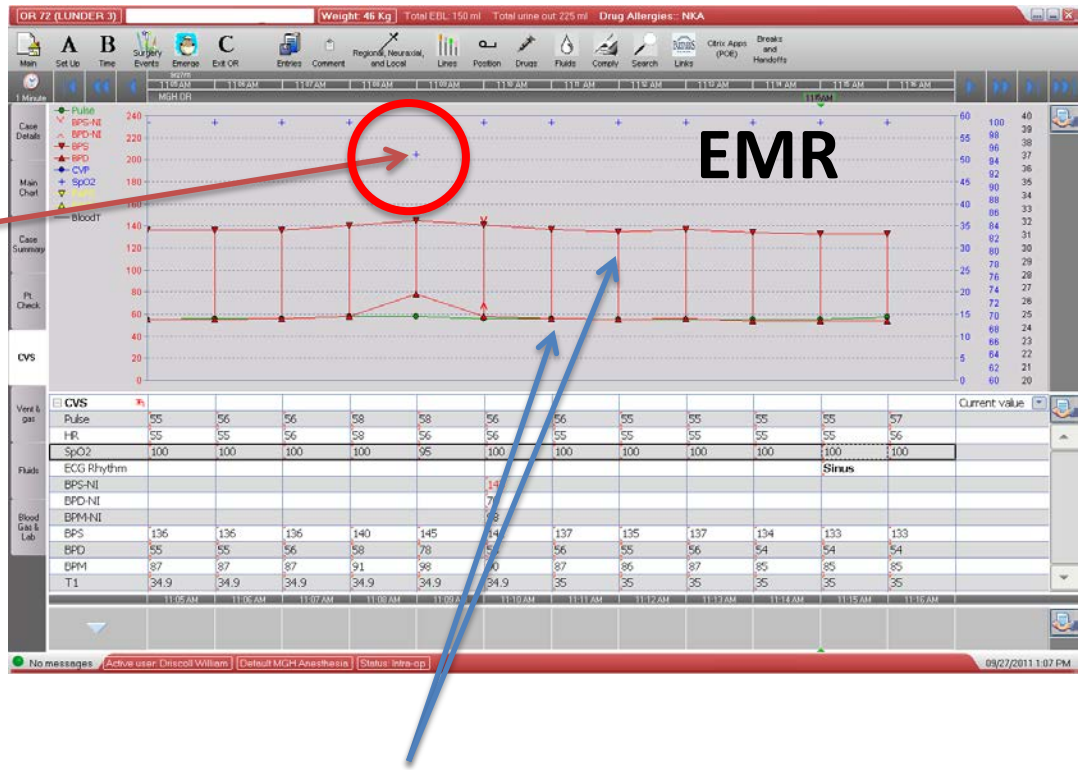
Does it matter how data gets from A to B?

Medical Devices generate "First Mile" of data (from patient)

Pulse Oximeters measure oxygen saturation – displayed as SpO_2 %

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

Bluetooth pulse oximeter



These infusion pumps are for use on ONE patient

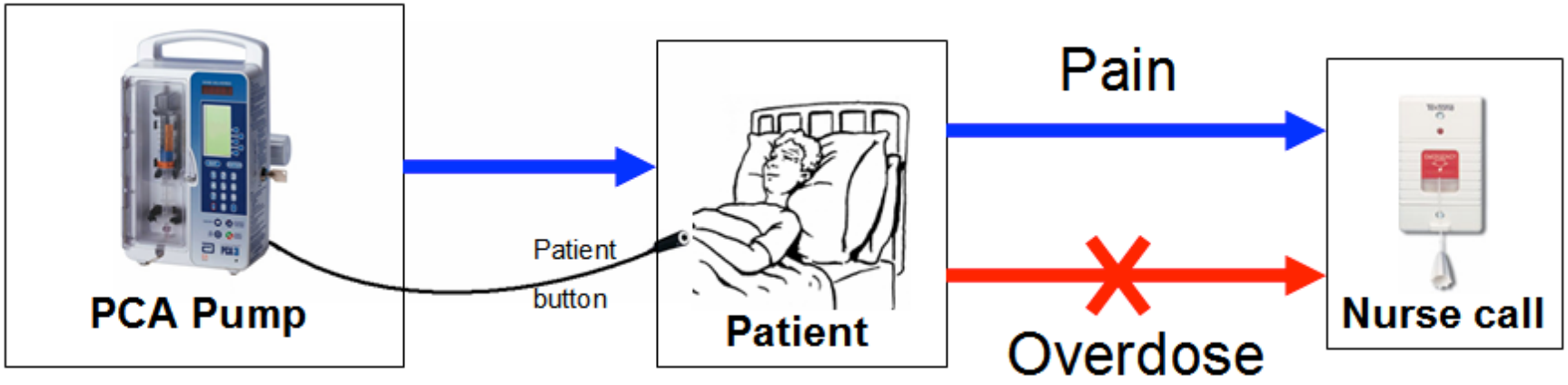
Medical Devices are also the "Last Mile"
(data back to devices)

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?

Patient Controlled Analgesia (PCA)

Typical Patient Controlled Analgesia System



1. *Up to 6,000 serious <u>preventable</u> PCA-related adverse events occur annually*
2. *Based on $13,803 per injured patient, economic impact is approximately $15-145M annually*
3. *PCA can be fixed! Digital platform of interoperable devices + apps -> safer medication administration*

- *WHY IS INTEGRATING SENSOR DATA SO CHALLENGING?*

PCA Safety Issues continue …

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."

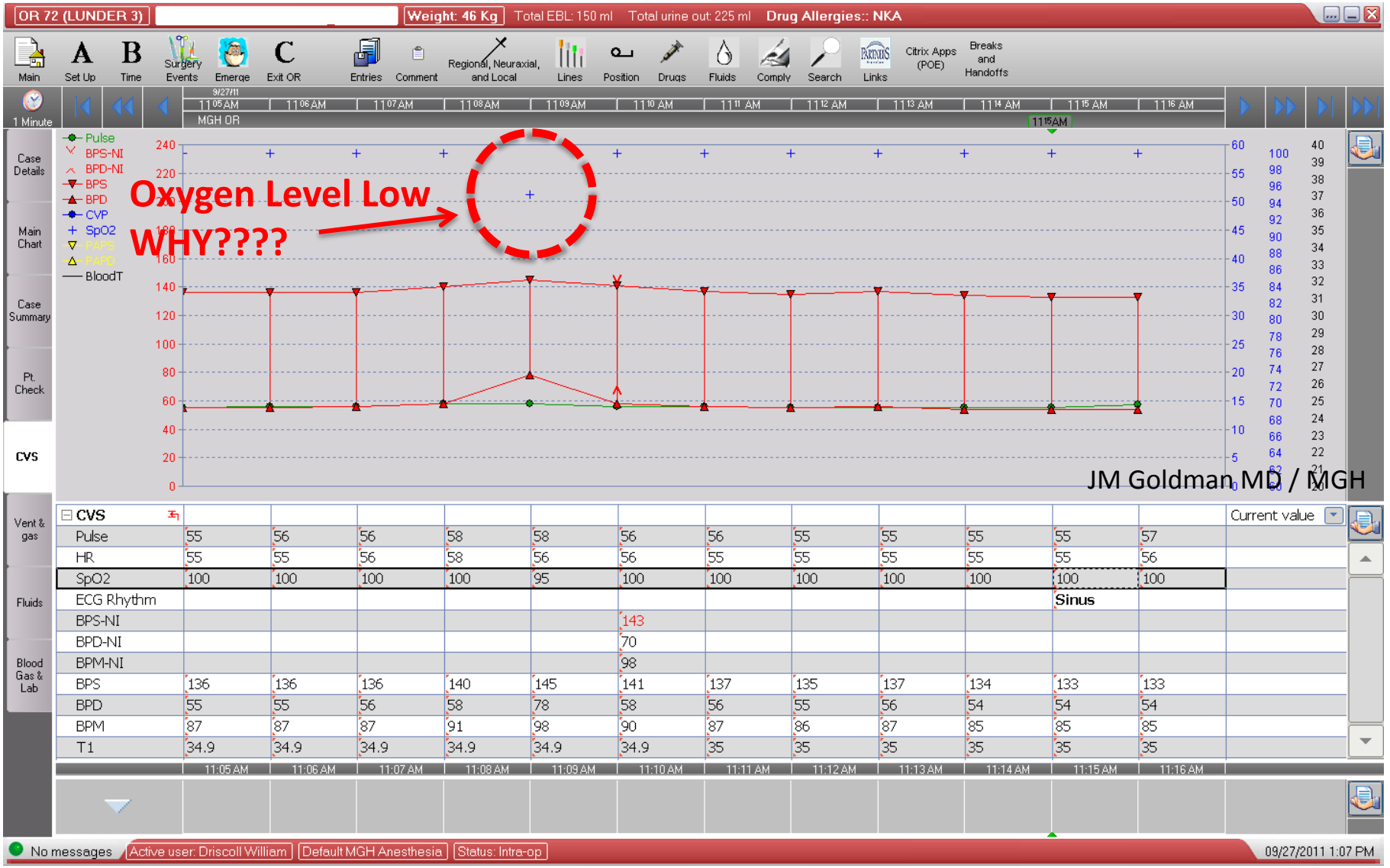
http://www.apsf.org/newsletters/html/2010/spring/12_coalition.htm
This is a statement from a multi-hospital coalition frustrated by ongoing adverse patient events:
"A closed-loop system, which stops or pauses opioid dosing if respiratory depression is detected, is desirable. Systems are most ideally centrally monitored. In any case, alarms should be audible or otherwise available to the primary caregiver, and a mechanism for prompt response should be in place."

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."

Can EHRs address these issues? E.g. with clinical decision support?

- EHRs do not contain fine-grained, complete, accurate data
- Not intended for real-time applications
- Waveforms not stored

Pulse Oximeter Data example



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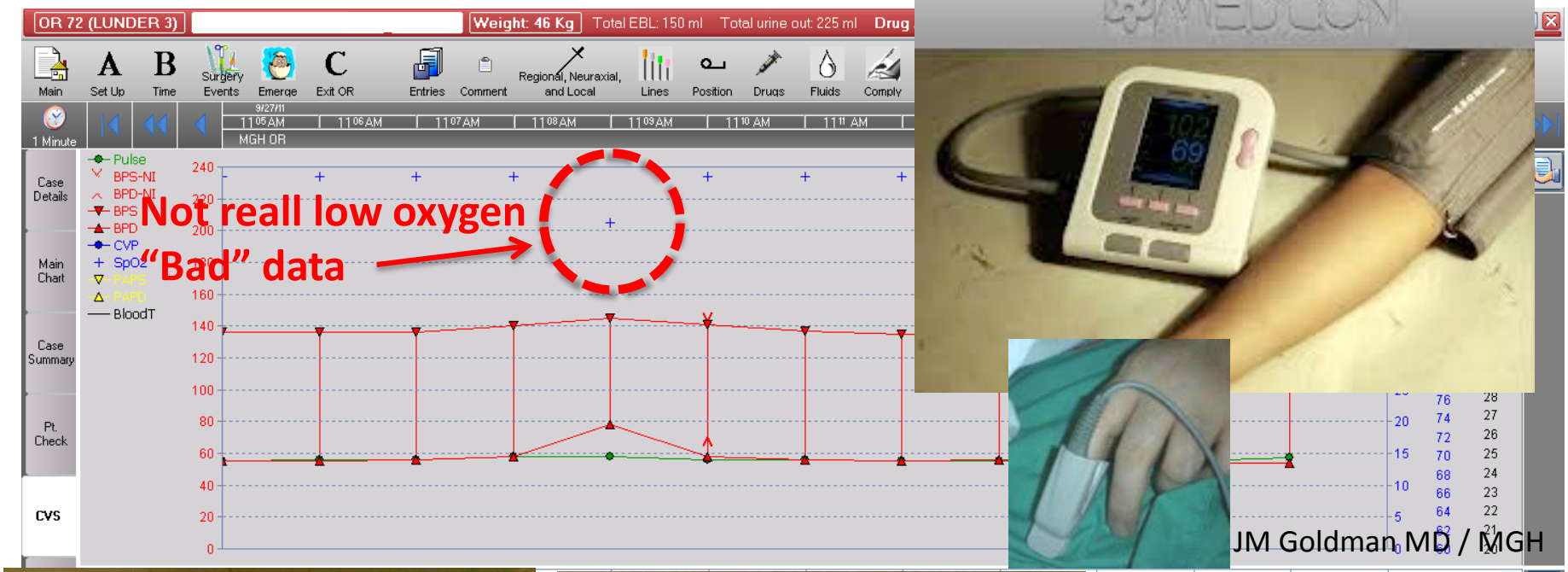
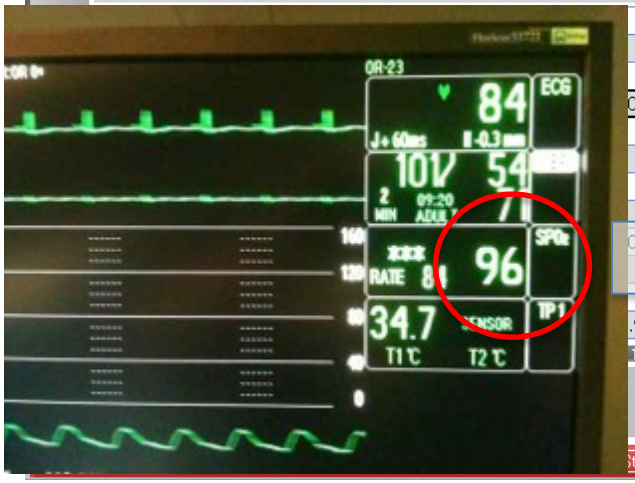
BP cuff - Pulse Oximeter Interaction

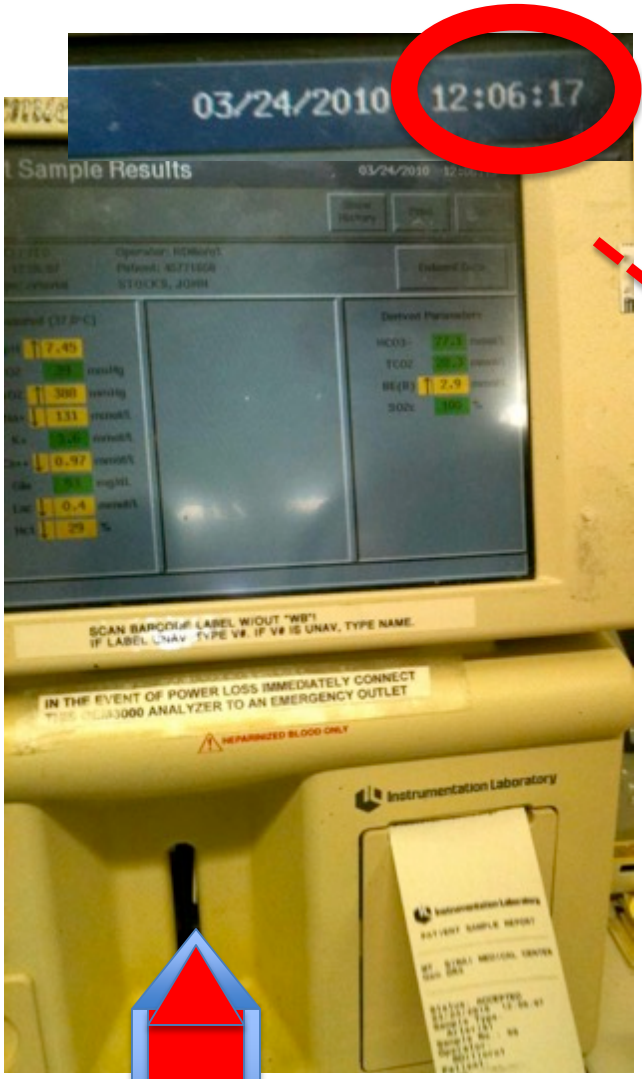




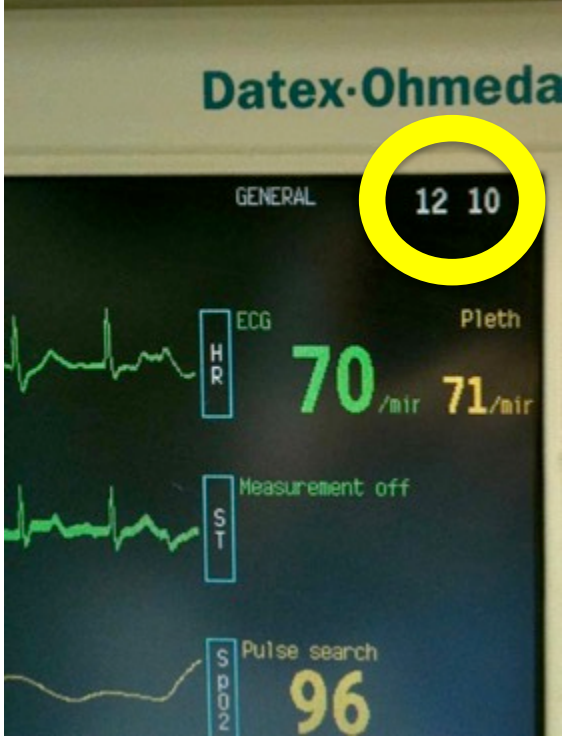
Baseline

Cuff inflates – loss of finger signal

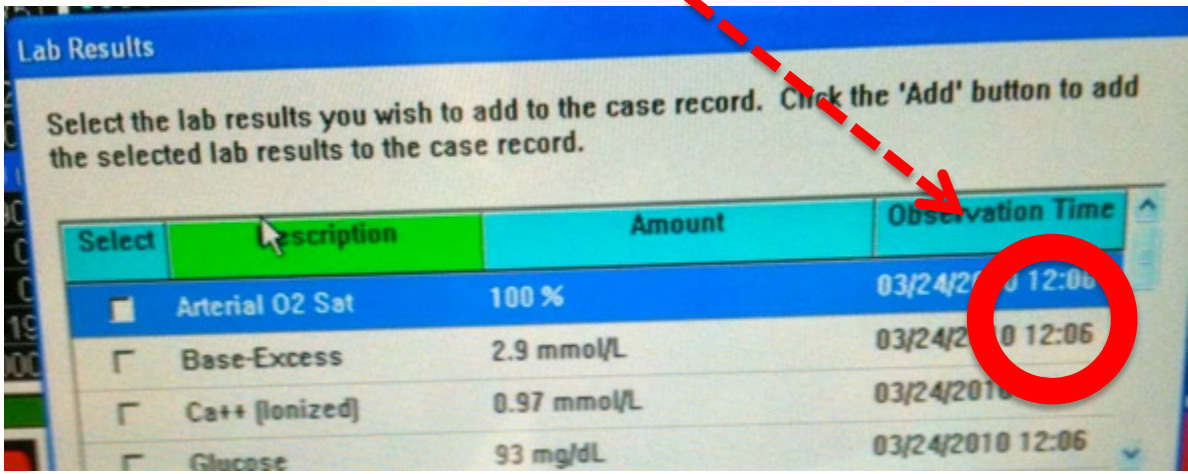
Blood returns to finger



Blood gas analyzer in OR



EMR time stamp error



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Medical devices

A ticking time-bomb

May 23rd 2012, 10:46 by M.H. | SEATTLE

The Economist

A MAN with one clock knows what time it is, goes the old saw, a man with two is never sure. Imagine the confusion, then, experienced by a doctor with dozens. Julian Goldman is an anaesthetist at Massachusetts General Hospital in Boston. Like many modern health care facilities, it has become increasingly digitised and networked, with hundreds of high-tech medical devices feeding data to a centralised electronic medical record (EMR), which acts as both a permanent repository for health information and a system that can be accessed instantly by doctors to assist with clinical decisions.

Consolidated 4 Hospital Summary (Draft)

Device Type	Count	StdDev Offset	Average Offset	Maximum Offset
Medical Devices (Excl. Workstations & Wall Clocks)	1324	1:32:34	0:33:26	16:42:10
All devices	1732	1:22:12	**0:25:58**	16:42:10
Networked Devices that Auto-Sync	291	0:02:16	0:00:53	0:31:16
Stand-alone Devices	950	1:46:38	0:46:06	16:42:10
Hospital A	52	0:31:11	0:30:25	1:52:00
Hospital B	495	1:41:23	0:32:55	16:42:10
Hospital C	468	0:47:12	0:17:10	13:39:28
Hospital D	717	1:27:24	0:26:35	13:18:47

Incorrect dates

Device Location	Device Location (Room)	Device Type	Manufacturer/ Model	Date Picture Taken	Date on Device	Device Offset (DAYS)
General Unit	Patient Tower	Bladder Scanner	BVI 3000	11/7/2011	1/8/2012	62D
Adult ER	Emergency Department	Bladder Scanner	Verathon Medical/ BVI 9400	11/22/2011	11/2/2011	-20D
Adult ER	Emergency Department	Bladder Scanner	Verathon Medical/ BVI 9400	11/22/2011	11/16/2011	-6D
OR	Hallway 1	Imaging System	Volcano S5 Cart Monitor	7/8/2011	7/7/2011	1D
Neuro Angio	Neuro Angio	Radiology Display	*N/A*	11/21/2011	11/18/2011	-3D
PACU	PACU	Ultrasound	Sonosite M-Turbo	11/29/2011	1/1/1970	42 years
NICU	NICU	Ventilator	Drager/ Evita XL	11/29/2011	11/1/2016	5 years

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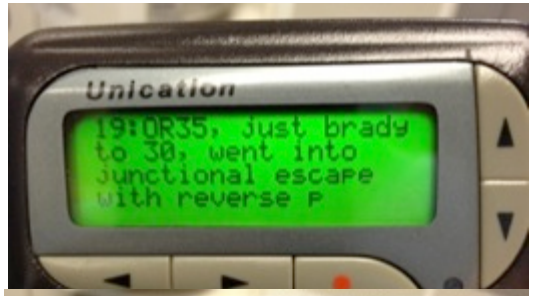
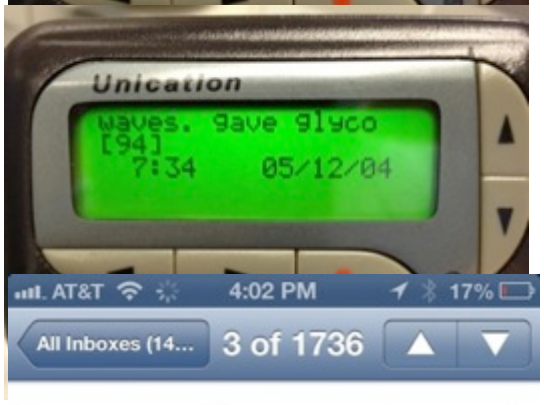
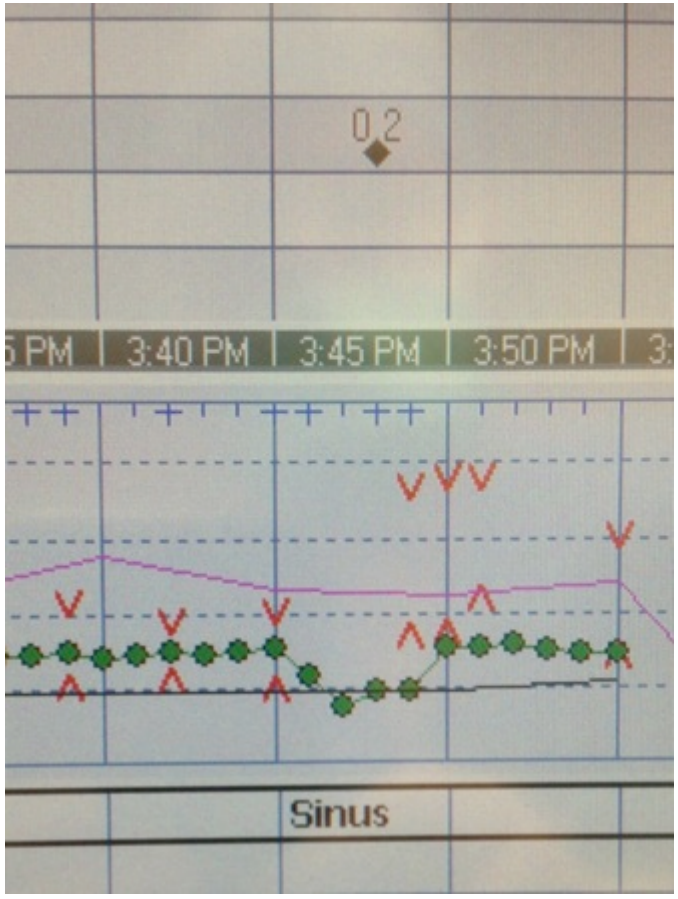




Date Sent	**11/20/2012 15:49:36**
Callback#	
Message	OR35, just brady to 30, went into junctional escape with reverse p waves. gave glyco



Data Gaps

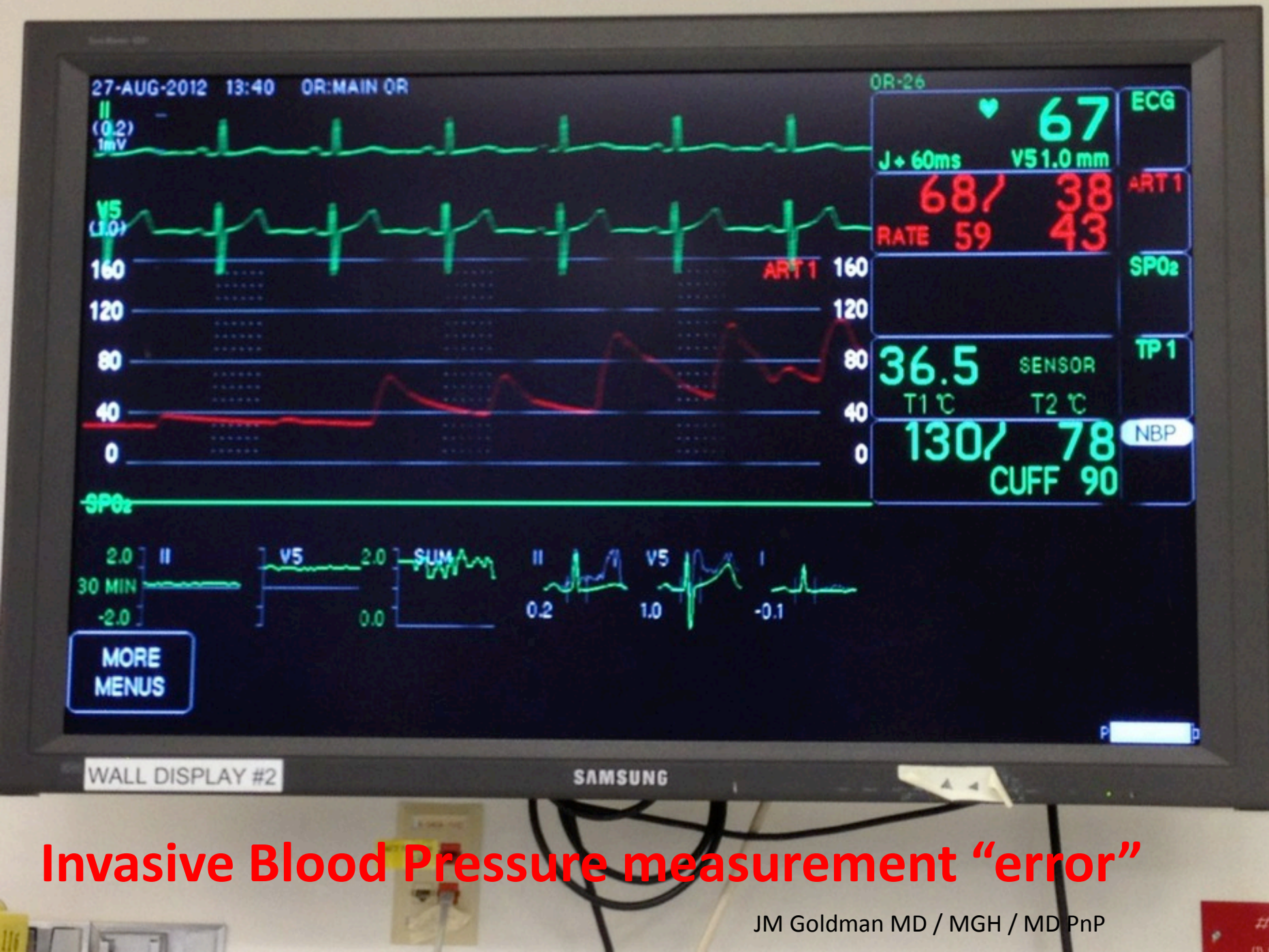
Example of data gaps today:

Complete physiological data is not recorded

The following are missing

- Minimum HR
- Reverse p waves
- BP

J Goldman
MGH, 2012



Invasive Blood Pressure measurement “error”

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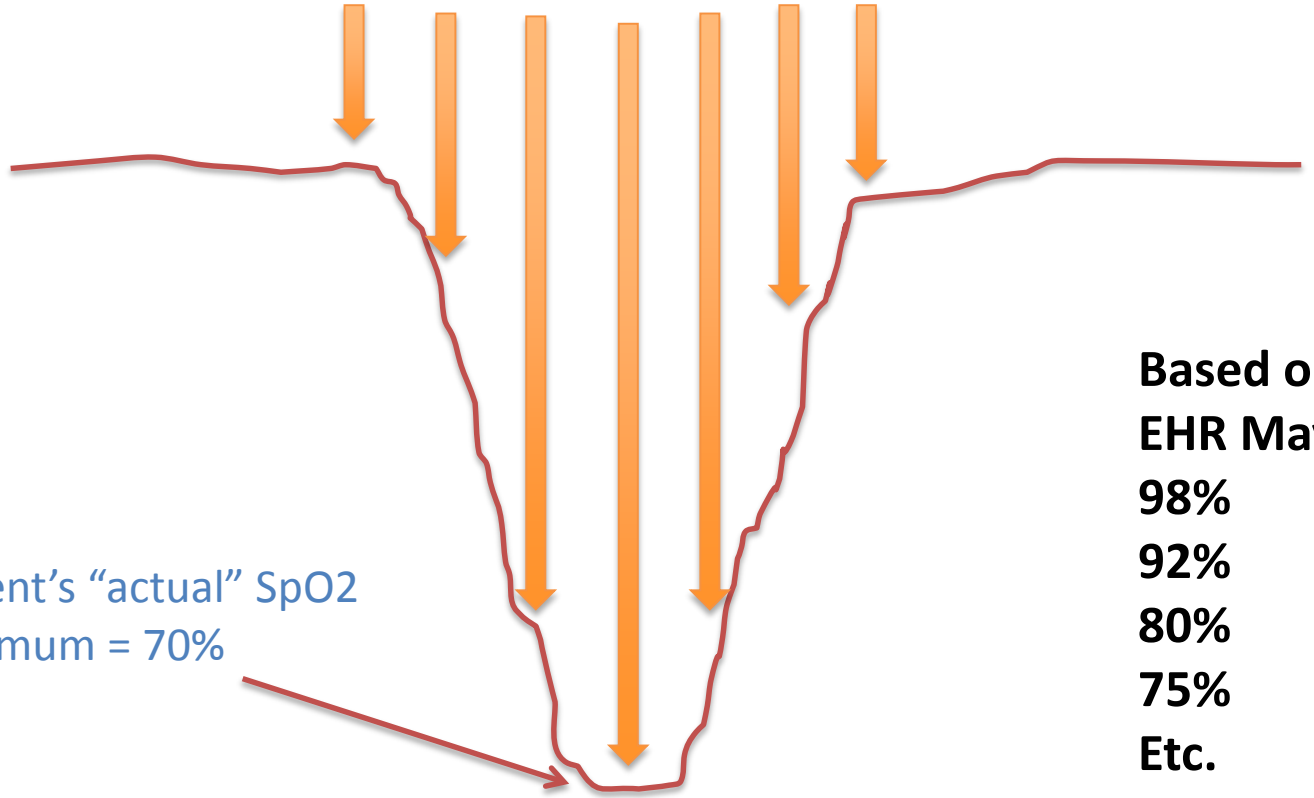
Sources of variation in EHR documentation due to Data Sampling

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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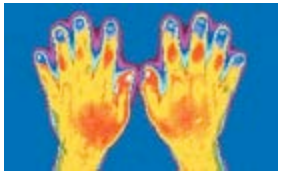
How will data from electronic medical devices be used in the larger data ecosystem?

ccurate interpretation of the sensor may require more sensor data + contextual info
Device interface capabilities relate to planned use

Signal integration with BP device to reduce artifacts

Fitness -
No waveform, no alarm, no signal quality data needed

Cold hands



May need signal strength and amplifier and LED drive current to diagnose

Child on home ventilator

Signal quality / accuracy metrics; motion artifact status

A Fib - May need “better” devices to measure accurately

May need heart rate + activity data to interpret health status

MD PnP™
Getting connected for patient safety™

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

Founded in 2004, the MD PnP research program is a multi-institutional community with Lab based at Massachusetts General Hospital (MGH), with grant support from NIH/NIBIB, NSF, DoD/TATRC, and NIST

Mission: lead the adoption of open standards and technologies for medical device interoperability to improve patient safety

MD PnP Lab at MGH/Partners

- Vender-neutral testbed for device interoperability solutions (standards technologies, products), system engineering, MIoT
- Contains devices – production and research
- Supports diverse collaborators

Standard for ICE
"Integrated Clinical Environment"
ASTM F2761-09

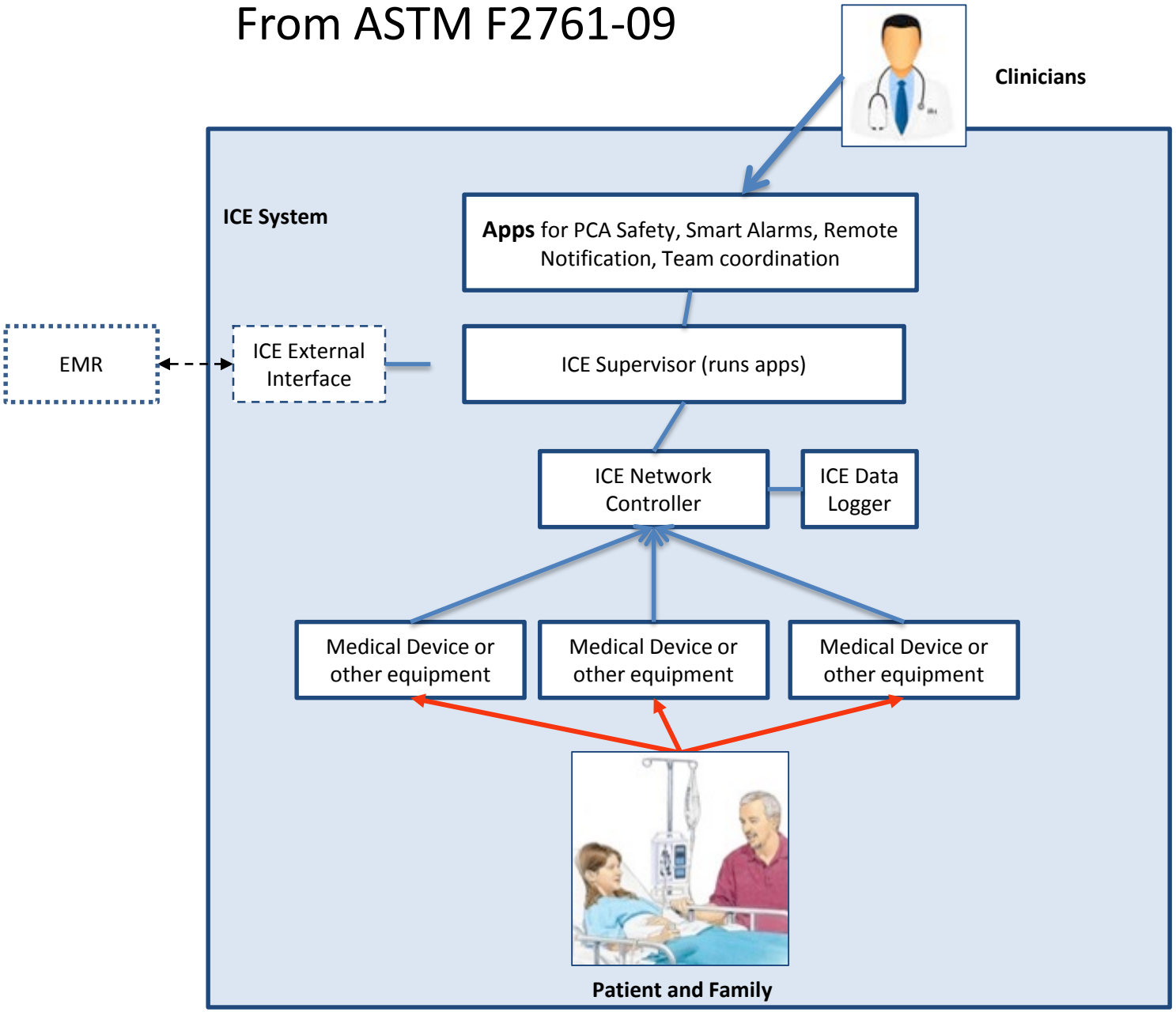
"Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model"

Provides a standards-based system architecture intended to support safe interoperable medical systems

Recognized by FDA 8/2013: http://www.gpo.gov/fdsys/pkg/FR-2013-08-06/pdf/2013-19020.pdf

Integrated Clinical Environment - Architecture

From ASTM F2761-09

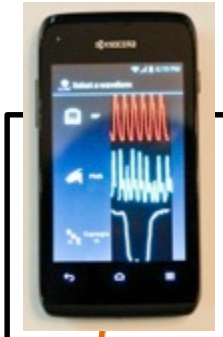


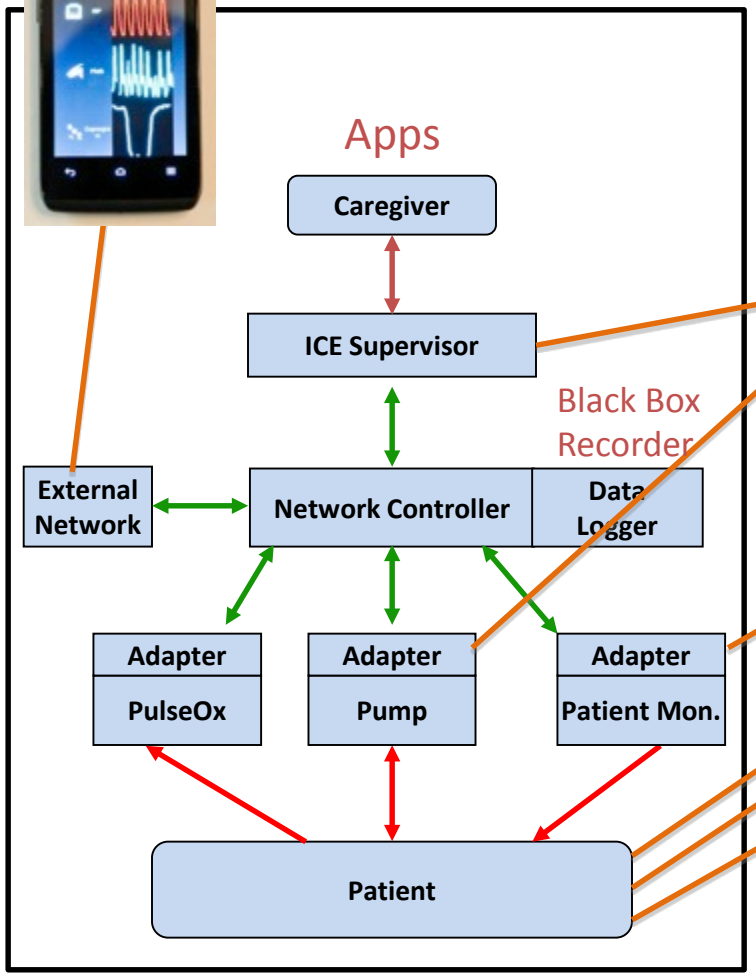
Standard recognized by FDA in August 2013

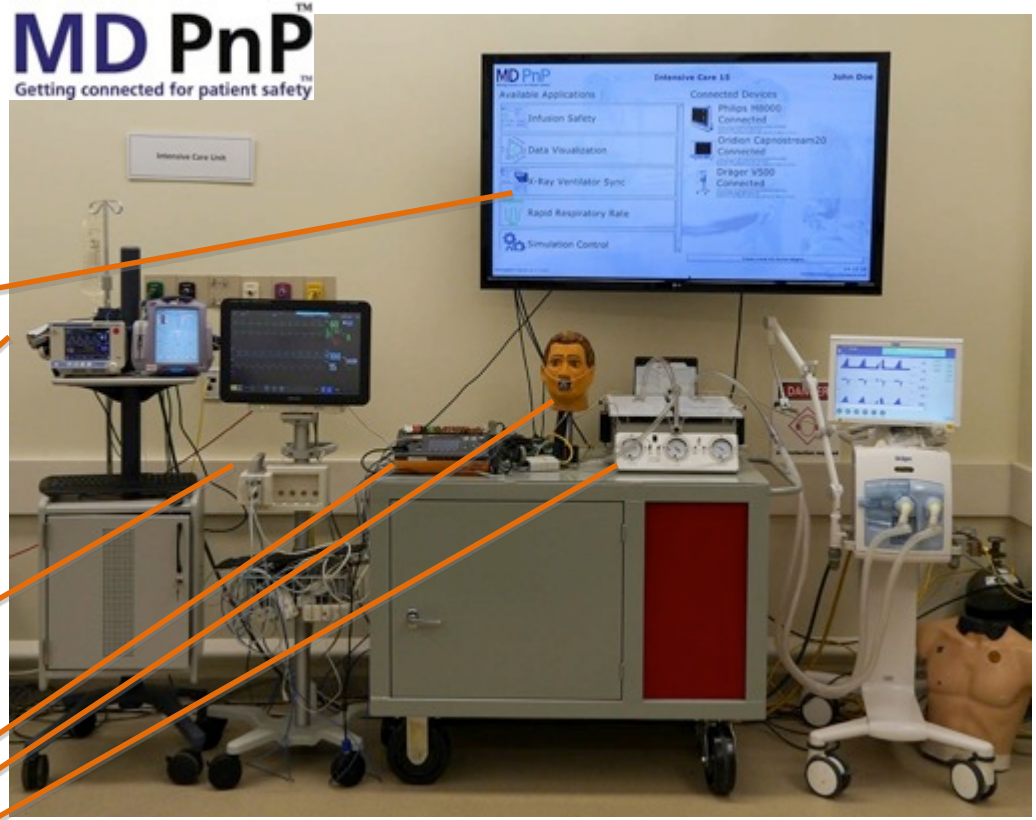
OpenICE Open-Source Digital Research Platform (MGH)

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 “Prototype Healthcare Intranet to Improve Health Outcomes”

The ICE Alliance

We are joining together to improve the safety and quality of healthcare by enabling Integrated Clinical Environments. It's a tall order, but the healthcare community is up to the challenge.

The ICE Alliance is a place for clinicians, engineers, computer scientists, manufacturers, regulators, standards developers, and big thinkers to to create a new way to approach safety and innovation in healthcare.

Stay tuned for more information about the IA and how you can get involved.

The ICE Alliance program of the IEEE-ISTO is a non-profit organization committed to establishing healthcare environments that are safe, secure, and interoperable. An Integrated Clinical Environment (ICE) will enable improved patient safety, diagnosis, treatment, and equipment management, and can facilitate more accurate data in electronic health records and communicated by the Medical Internet of Things (MIoT).

Note: The ICE Alliance is not a standards development organization, but provides requirements and implementations that can be used by organizations developing consensus standards.

www.icealliance.org

Recommendations

Develop open, interoperable, healthcare / MIoT platforms to unleash innovation of sensors, actuators, and analytics while enabling crowd-sourcing of solutions to current and future capability needs/hazards

- Shared testbeds with standards reference implementations
- Data Logging
- App development
- Suitable for “safety critical” applications
- Rich, contextual data for BIG DATA analytics

Key Considerations

- Identify MIoT System Requirements to ensure ecosystem will reliably support vision of intended use- no BSoD*
- Don’t be afraid to “boil the ocean” – the MIoT is NOT an incremental change – it is revolutionary

*Blue Screen of Death

E-card:
www.jgoldman.info

MD PnP Program:
www.mdpnp.org