

Panel IV: Challenges: The Digital Health Platform (System of Systems)

Moderator: *Julian M. Goldman, MD, Harvard Medical School, MGH, Partners HealthCare*

Regulatory Ambiguity and Requirements for 'New Devices'
Bakul Patel, FDA

Medical Device Supply Chain Challenges
Ken Herold, Windriver

Security Design Implications: Safety and Privacy
Steven Abrahamson, GE Healthcare



The National Academies Innovation Policy Forum
Medical Devices Innovation:
Opportunities, Threats, and Challenges
Sept 10, 2014 Washington, DC



Panel IV: Challenges: The Digital Health Platform (System of Systems)

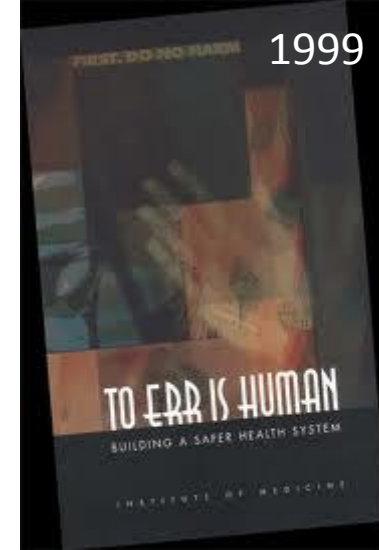
Aligning National Science & Technology Resources
to deliver a platform for healthcare innovation
to improve patient safety

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Medical Director, Partners HealthCare Biomedical Engineering
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How Many Die From Medical Mistakes in U.S. Hospitals?



REVIEW ARTICLE

2013

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?

Proposal: Can digital health platforms add “error resistance” to healthcare delivery?

Special report: Tech startups ▾

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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180

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364





Devices, processes, non-integrated system → errors

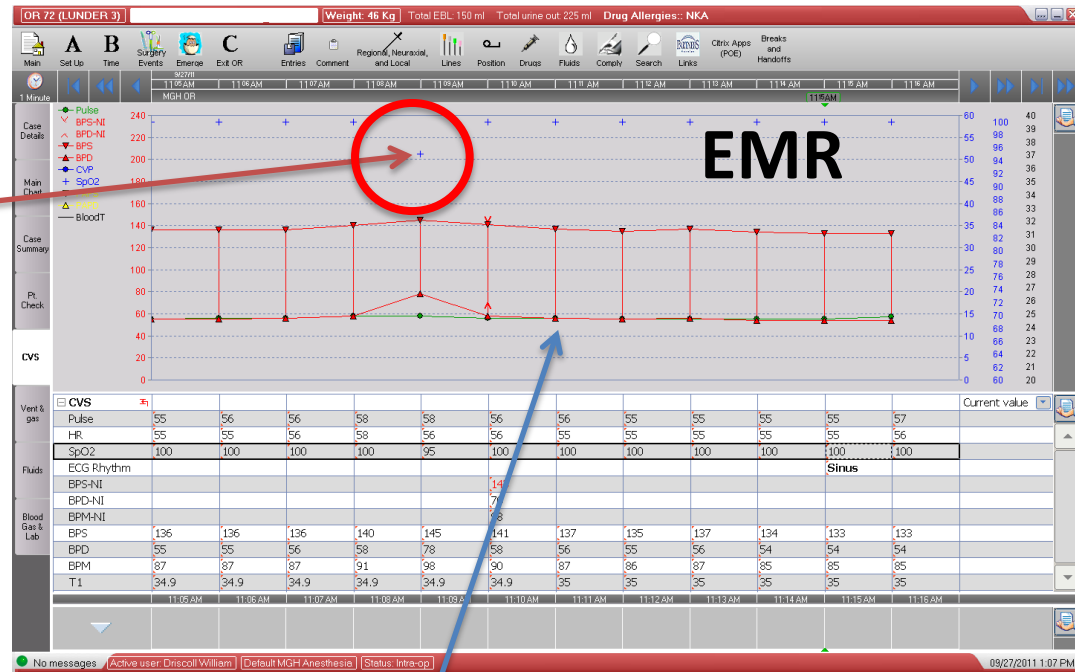
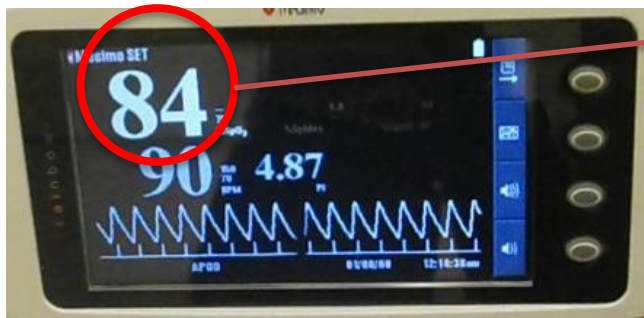


Clinicians need timely, accurate data.
Business process automation could help reduce error, treatment
delays, injuries and deaths.
Is that how we practice today? Where are innovative solutions?



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

Pulse Oximeters measure oxygen saturation – displayed as SpO₂ %



Pulse Oximeter and EMR show oxygen saturation of 84% and pulse rate

Blood Pressure



Infusion pumps for use on ONE patient

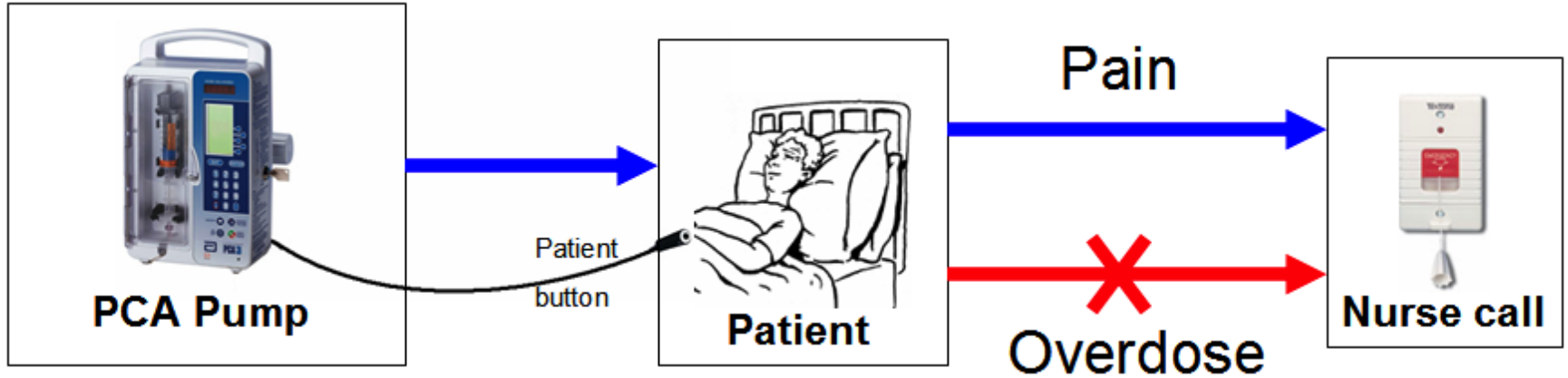
Medical Devices:
Also the “Last Mile”
(data back to devices)

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?

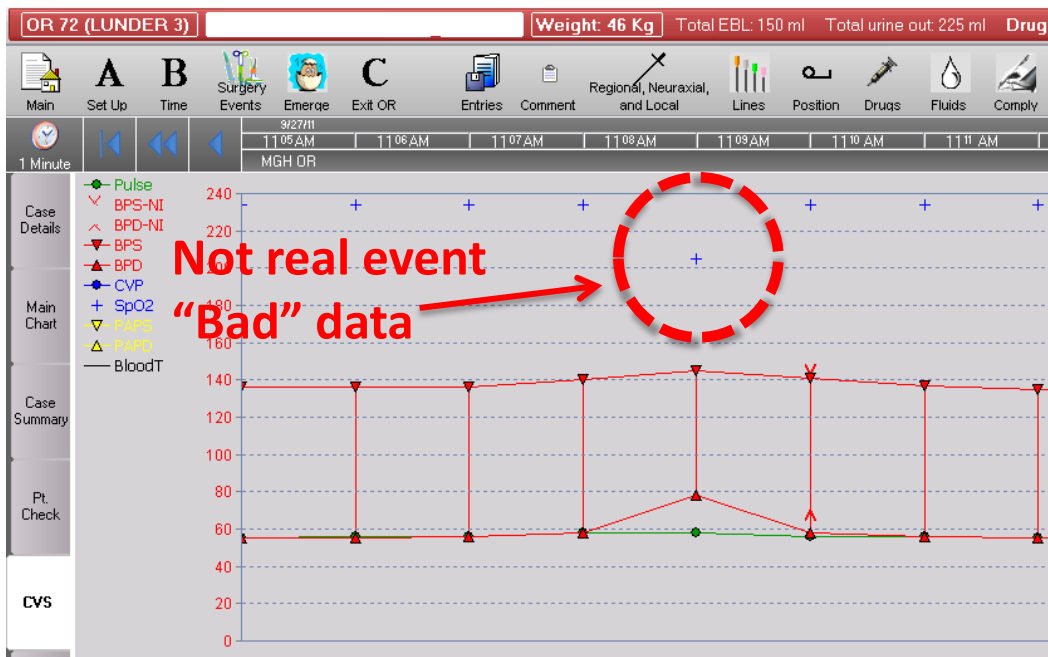
Patient Controlled Analgesia (PCA)

Typical Patient Controlled Analgesia System



1. *6.5% of 2009 events in FDA MAUDE voluntary reporting database over two-year period = 65 harmed patients/year.*
2. *Actual number of events: Up to 6,875 serious preventable PCA-related adverse events occur annually*
3. *Based on \$13,803 per injured patient, economic impact is approximately \$15-145M annually*
4. *Can be fixed! Digital platform of interoperable devices + apps -
> safer*

BP cuff - Pulse Oximeter Interaction



Baseline

Cuff inflates – loss of finger signal

Blood returns to finger

A ticking time-bomb

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

The
Economist



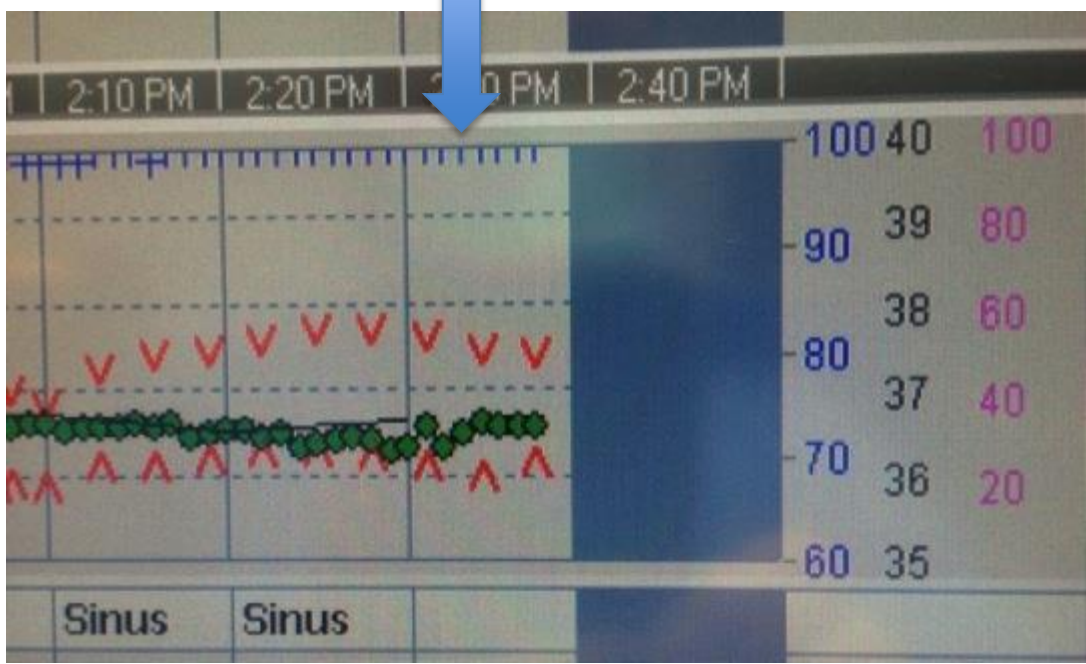
A MAN with one clock knows what time it is, goes the old saw, a man with two is never sure. Imagine the confusion, then, experienced by a doctor with dozens. Julian Goldman is an anaesthetist at Massachusetts General Hospital in Boston. Like many modern health care facilities, it has become increasingly 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.



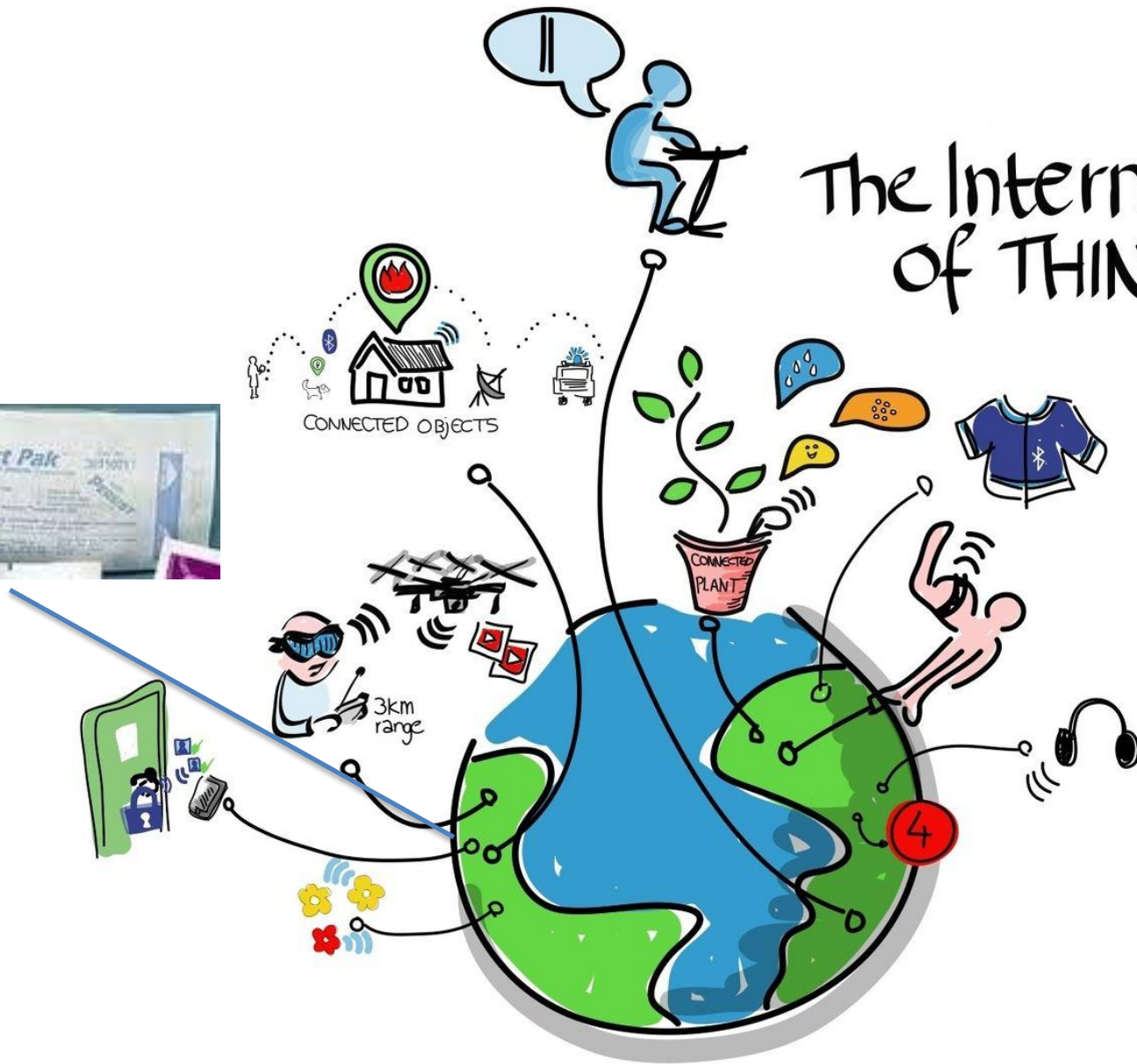
All clinical data is not necessarily transmitted to EHR

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

Monitor Displays Low Oxygen Level (SpO₂) Alarm Event "84%" at 2:07



The Internet of THINGS



CONNECT
THE WORLD

“Internet of Things *for Health Care*”



Apps store for smart alarms; med safety



Asking a lot of the platform

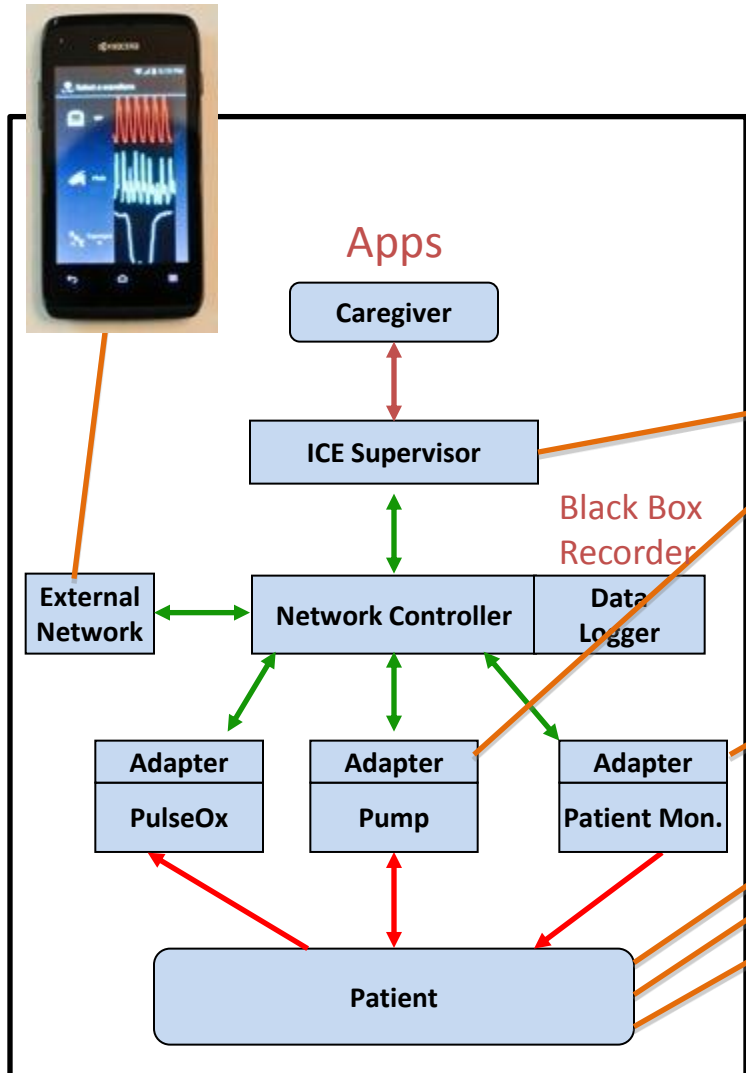
What if...



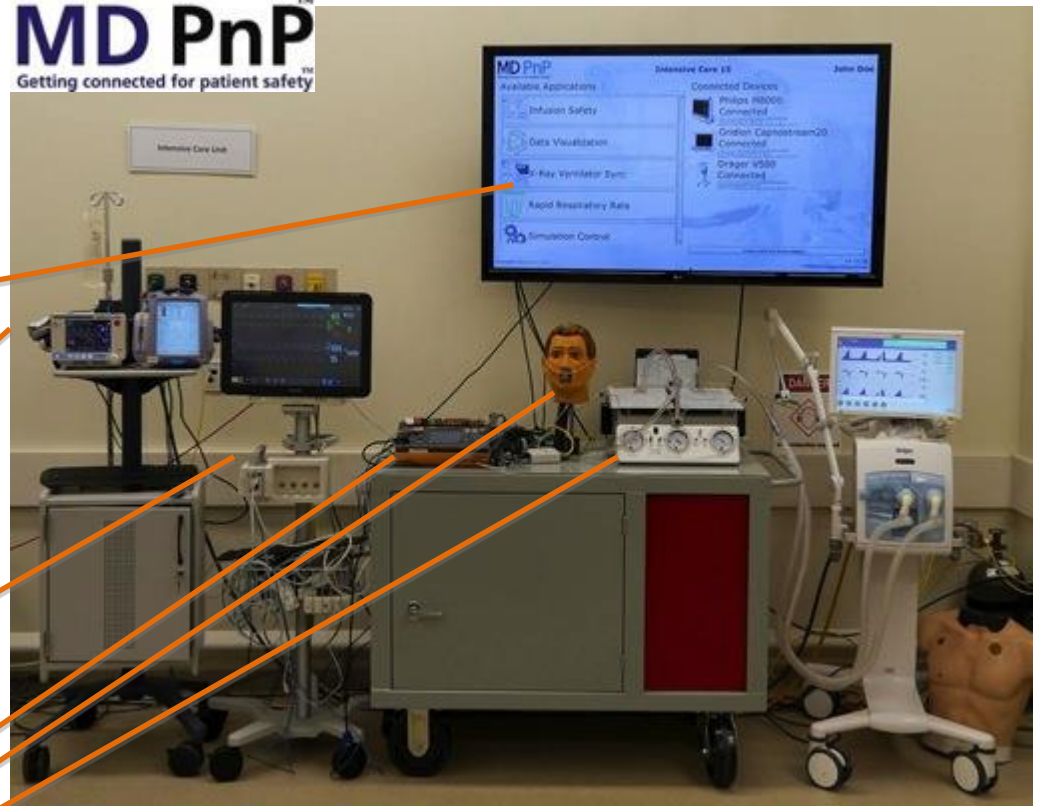
OpenICE Open-Source Digital Research Platform (MGH)

Based on ASTM F2761 “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)”

www.openice.info

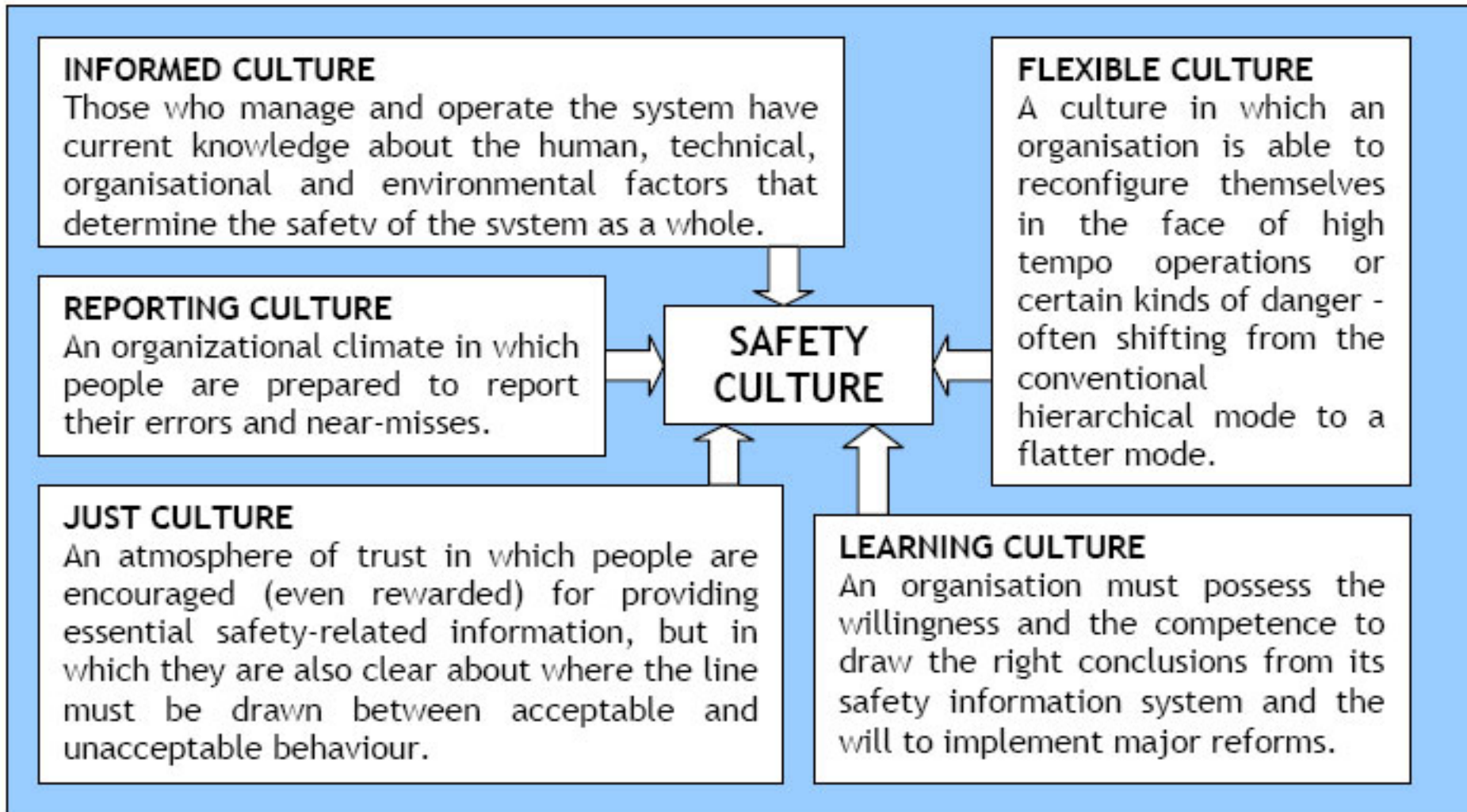


MD PnP
Getting connected for patient safety™



Testbed funded in large part by NIH, NSF, and DoD
“Prototype Healthcare Intranet to Improve Health Outcomes”

Safety Culture



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

Recommendation #1

Develop open, interoperable, medical device – HIT ecosystem 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

Recommendation #2

Alignment of national science & technology resources to develop, deploy, iterate IoT* for Health Care (build on CPS initiative)

- Use rich, contextual data to measure, baseline, create solutions
 - Planes, trains, automobiles have data loggers – essential for safety critical environments
- Require data for CMS reimbursement – pay for never events (only if data is provided)

* = Internet of Things

Can our nation deliver these capabilities? there are many S&T Gaps ...

- Security of networked medical devices
 - Cost
 - Balance security and usability
- Composability - Healthcare delivery organizations and other system integrators must be able to compose reliable systems of devices from diverse manufactures (hardware and apps)
- Standards gaps/lack of reference implementations
- Interoperability chasm
- Software reliability and life-cycle management
- Etc.



If this was a medical moonshot,
Who would benefit?
Who would contribute?



Medical Device Industry



AMC; Universities



Is NITRD the right “home”
OSTP?



A banner for NITRD (National Institute of Standards and Technology) featuring the NITRD logo and logos of various partner agencies. The background is dark blue with a glowing digital grid and binary code.

NITRD

The Office of the National Coordinator for Health Information Technology

NIST **DARPA** **Homeland Security** **U.S. DEPARTMENT OF ENERGY**

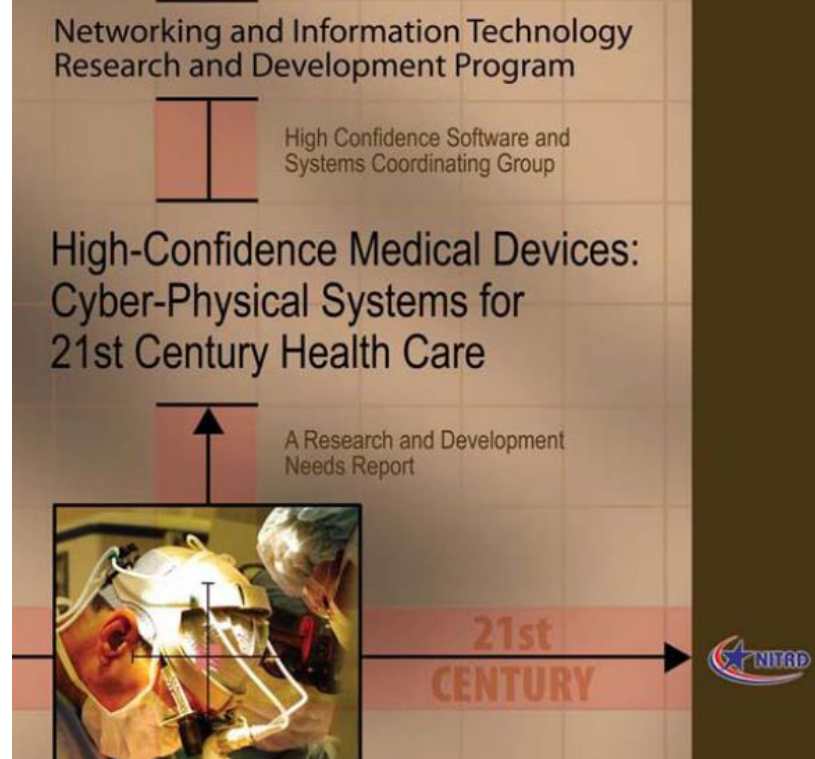
AHRQ **U.S. DEPARTMENT OF ENERGY** **NATIONAL ARCHIVES** **NASA** **NATIONAL INSTITUTES OF HEALTH**

NOAA **U.S. DEPARTMENT OF ENERGY** **NASA** **U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES** **NSI**

Office of Electricity Delivery and Energy Reliability **Office of Science** **National Nuclear Security Administration**

TRANSFORMING THE WORLD. DRIVING THE NATION'S COMPETITIVENESS. LEADING INTO THE FUTURE.

NITRD Cyber-Physical Systems (CPS) report February 2009



NITRD Report:

Plug-and-Play Network Devices

Another enabling technology for the aforementioned vision is the development of plug-and-play networking technology for medical devices. Plug-and-play capability is needed to ease the setup of integrated point-of-care and extramural arrays of medical devices that communicate with a patient's electronic health record.

Devising the technology would require addressing concerns about privacy, security, safety, regulations, and technology. In hospital settings, for example, networks would form and reform frequently, as patients are admitted and discharged. Technology for the rapid formation of ad hoc networks needs developing. At the same time, authentication mechanisms would be needed to



Funding



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Cyber-Physical Systems (CPS)

NSF-FHWA Joint Efforts

NSF and the Federal Highway Administration (FHWA) have a shared interest in advancing basic and applied research in Cyber Physical Systems (CPS), which are systems in which physical processes are tightly intertwined with networked computing. For those applying to this year's CPS solicitation, please see a recent NSF-FHWA Dear Colleague Letter...[More](#)

“The December 2010 report of the President's Council of Advisors on Science and Technology (PCAST) titled Designing a Digital Future: Federally Funded Research and Development in Networking and Information Technology calls for continued investment in CPS research because of its scientific and technological importance as well as its potential impact on grand challenges in a number of sectors critical to U.S. security and competitiveness such as the ones noted above. These challenges and technology gaps are further described in a CPS Vision Statement published in 2012 by the Federal Networking and Information Technology Research and Development (NITRD) Program's CPS Senior Steering Group.”

Wikipedia: The US National Science Foundation (NSF) has identified cyber-physical systems as a key area of research. Starting in late 2006, the NSF and other United States federal agencies sponsored several workshops on cyber-physical systems...



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Yesterday, the **National Science Foundation (NSF)** announced a new partnership with the **U.S. Department of Homeland Security Science and Technology Directorate (DHS S&T)** and **U.S. Department of Transportation (DOT) Federal Highway Administration (FHWA)**, issuing a **first-ever interagency solicitation for Cyber-Physical Systems (CPS)**. Leveraging years of investment in CPS science, engineering, and technology by NSF's **Directorates for Computer and Information Science and Engineering (CISE)** and **Engineering (ENG)**, the new solicitation establishes collaborations between NSF and mission agencies to "identify basic research needs in CPS common across multiple application domains."




Welcome to the home page of the Cyber-Physical Systems Virtual Organization

Join the CPS-VO

-  PUBLICIZE EVENTS & MAKE ANNOUNCEMENTS
-  SHARE DOCUMENTS & COLLABORATE
-  FORM & MANAGE COMMUNITIES OF INTEREST

In the Spotlight



CPS Week 2015

Cyber-physical systems (CPS) are complex engineering systems that rely on the integration of physical, computation, and communication processes to function. Examples include smart transportations, power grids, smart buildings, smart homes, data centers, health care and wellbeing support systems. Such systems must be...

It all began with a new way of thinking.



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