Seminario Ejecutivo: Aplicaciones, retos y oportunidades de Internet de las Cosas
San Jose, CR
April 17, 2015

MD PnP
Getting connected for patient safety

Retos y Oportunidades del IoT Médico: Mejorar la Salud

The Medical IoT (MIoT): Opportunities and Challenge and for Improving Healthcare

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

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?

The Economist | World politics | Business & finance | Economics | Science & technology | Culture

Special report: Tech startups

Platforms

Something to stand on

Proposal: Can open digital health platforms add "error resistance" to healthcare delivery?

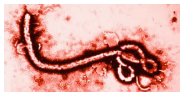
Proliferating digital platforms will be at the heart of tomorrow's economy, and even government

Jan 18th 2014 | From the print edition

Like 180 Tweet 364

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?*

Ebola Medical-Technology Response:



Oct - Nov 2014

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

Project Timeline: Oct – Nov 2014

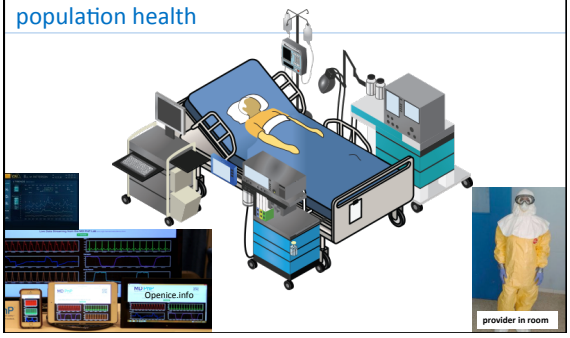
Over 20 days, multiple organizations collaborated to demonstrate concepts of methods to improve Ebola care, inter-vendor data sharing, device integration, and remote and closed-loop control to provide capabilities beyond those available today to improve patient care and protect healthcare workers

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



Ebola Care Problem Statement

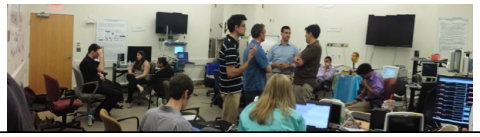
How can we support the safety of patients, and workers dealing with the care of Ebola-exposed persons in quarantine *or* under medical care in a hospital or similar facility?

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

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, with support from NIH, NSF, DoD/TATRC, and NIST
- Mission: lead the adoption of open standards and technologies for medical device interoperability to improve patient safety
- Vender-neutral testbed for experimenting with device interoperability solutions (standards technologies, products)



3-day "hackathon" for Ebola care technologies

- 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

OpenICE Platform

- http://openice.info/

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

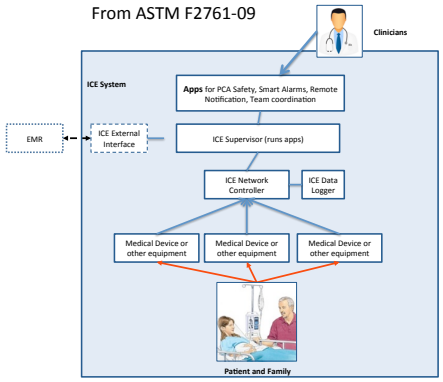
"Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model"

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

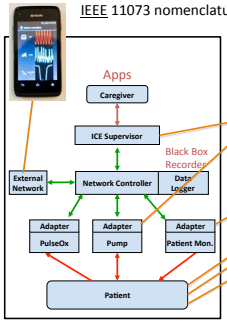


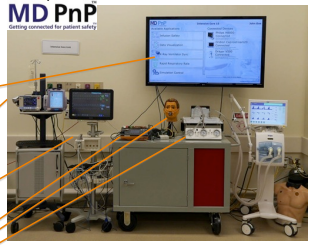
Standard recognized by FDA in August 2013

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"

ICE = Integrated Clinical Environments

An Integrated Clinical Environment (ICE) will accelerate innovation in the medical device and Health IT ecosystem by enabling the efficient development of software and hardware for improved safety, diagnosis, treatment, research, quality improvement, equipment management, and adverse event detection and reporting.

ICE systems can also facilitate more accurate and contextually rich data from medical and consumer devices to be included in electronic health records and other analytic environments

ICE is defined in standard ASTM F2761-09 (12):

"Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model". It provides a standards-based system architecture intended to support safe interoperable medical systems

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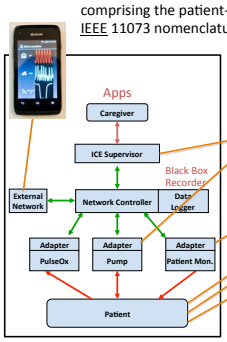
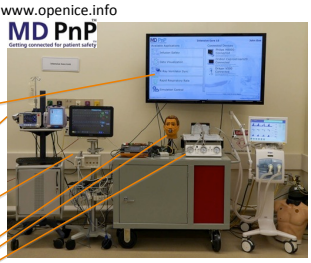




Testbed funded in part by grants from NIH, NSF, and DoD

COLLABORATORS

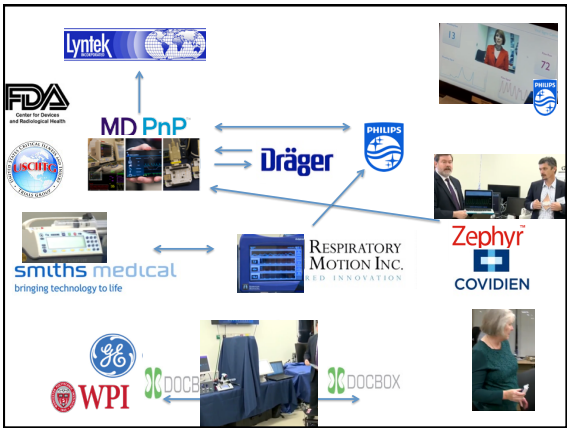
Dear Dr. Goldman,

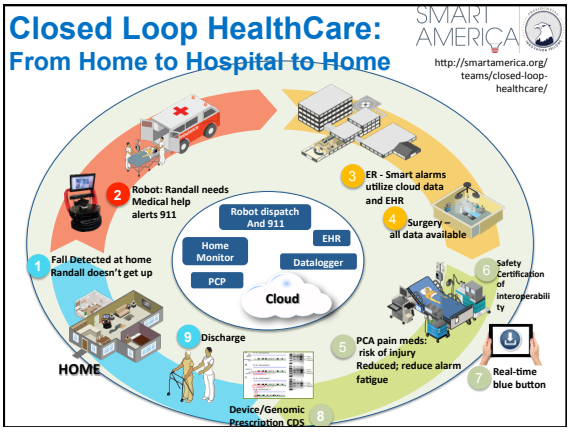
Thank you for reaching out to the Center for Devices and Radiological Health (CDRH) via our Emergency Preparedness/Operations and Medical Countermeasures (EMCM) Program.

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.

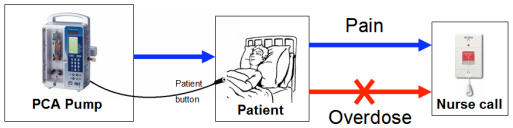
CDRH recognizes the importance of these efforts and is ready and willing to collaborate with you, the clinical community and your industry partners to demonstrate the potential of this technology in serving this particular public health emergency. We are eager to observe the demonstration taking place 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.





Patient Controlled Analgesia (PCA)

Typical Patient Controlled Analgesia System



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*
3. *PCA can be fixed! Digital platform of interoperable devices + apps -> safer medication administration*

- *WHY IS INTEGRATING SENSOR DATA SO CHALLENGING?*

Can the EHR/EMR be "the platform" for … everything?

Medical devices

A ticking time-bomb

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

The Economist

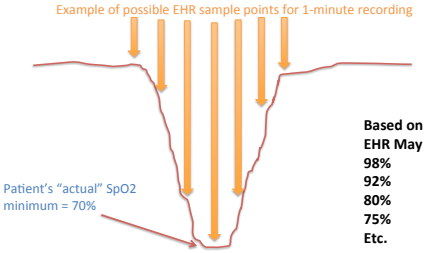
A MAN with one clock knows what time it is, goes the old saw, a man with two is never sure. Imagine the confusion, then, experienced by a doctor with dozens. Julian Goldman is an anaesthetist at Massachusetts General Hospital in Boston. Like many modern health care facilities, it has become increasingly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

Invasive Blood Pressure measurement "error"

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%

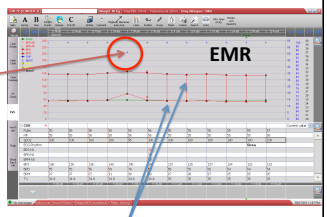
Based on this example, EHR May record SpO2 as:
98%
92%
80%
75%
Etc.

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

Pulse Oximeters measure oxygen saturation – displayed as SpO_2 %

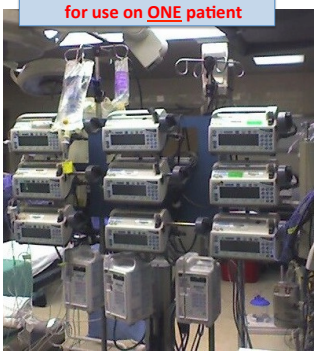
Pulse Oximeter oxygen saturation is 84% on instrument display and in EHR

Bluetooth pulse oximeter



Blood Pressure

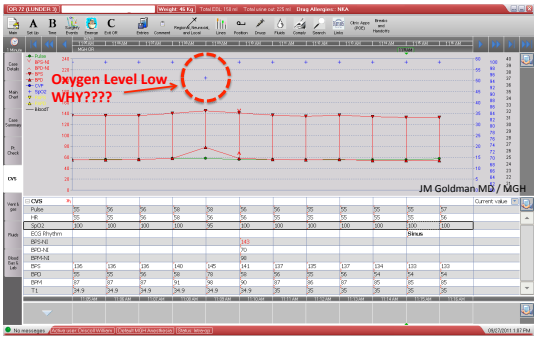
Julian M. Goldman, MD / MGH MD PnP



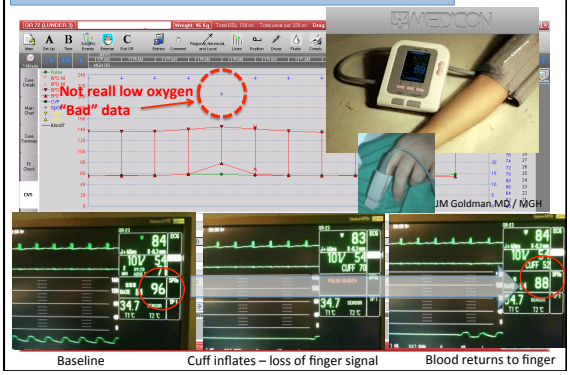
Medical Devices are also the "Last Mile"
(data back to devices)

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?

Pulse Oximeter Data example



BP cuff - Pulse Oximeter Interaction

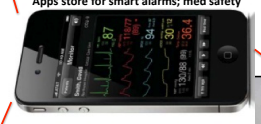


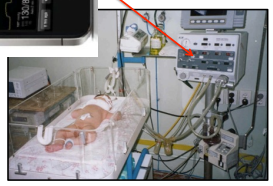
"Medical IoT"

Apps store for smart alarms; med safety

What if…

Asking a lot of the platform

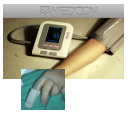




Accurate interpretation of the sensor may require more sensor data + contextual info

Device interface capabilities relate to planned use

Signal integration with BP device to reduce artifacts



Child on home ventilator

Signal quality / accuracy metrics; motion artifact status

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

Cold hands

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

A Fib - May need "better" devices to measure accurately

May need heart rate + activity data to interpret health status

Recommendation #1

Develop open, interoperable, medical device – HIT ecosystem Medical IoT 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

ICE Alliance

Integrating Clinical Environments

MD PnP
Getting Connected for Patient Safety

A non-profit program hosted by the IEEE-ISTO committed to establishing healthcare environments that are safe, secure, and interoperable

Note: The ICE Alliance, or "IA", is not a standards development organization (SDO). It provides use cases, requirements, and example implementations for use by SDOs for the development of consensus standards.

What can ICE platforms deliver?

ICE platforms can enable revolutionary improvements in

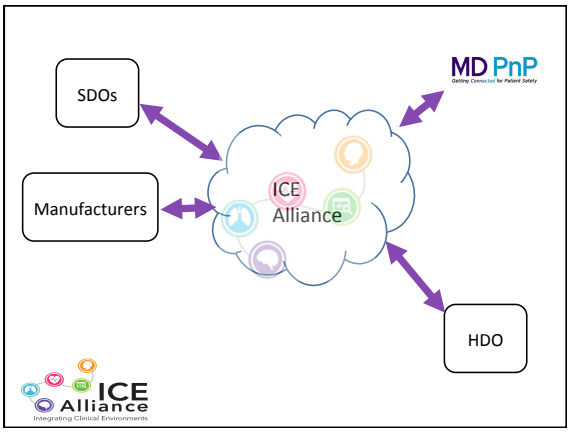
- Patient Safety
- Rich clinical data availability
- Innovation through interoperable apps, sensors, actuators
- Operations and Logistics
- Cybersecurity of medical devices and HIT

Foundation

MD PnP
Getting Connected for Patient Safety

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

Founding Members: HDOs, Industry, SDOs, Healthcare Safety Organizations



What Will the ICE Alliance Deliver?

ICE Alliance
Integrating Clinical Environments

Some IA Deliverables already in progress through MD PnP Program

- Medical and Health IT equipment procurement language for use by healthcare delivery organizations (MD FIRE http://mdpnp.org/mdfire.php)
- Clinical Needs Assessment and Descriptions – by HDOs
- System Requirements Specifications – elaborated by MD PnP program
- Use Case and Clinical Scenario Library – maintained by MD PnP
- ICE reference implementations, including safety and security requirements, and test tools – Started by MD PnP, see http://www.openice.info
- Feedback to Standards Development Organizations (SDOs) to help standards conform to ICE requirements – currently performed by MD PnP
- Regulatory science analysis related tosubmission http://mdpnp.org/MD_PnP_Program__MDISWG.html interoperable medical devices and systems (FDA Pre-submission bit.ly/mdiswg)
- Elaboration of requirements for EMR inclusion of device data

Example of deliverables

MD PnP