MD PnP™
Getting connected for patient safety™

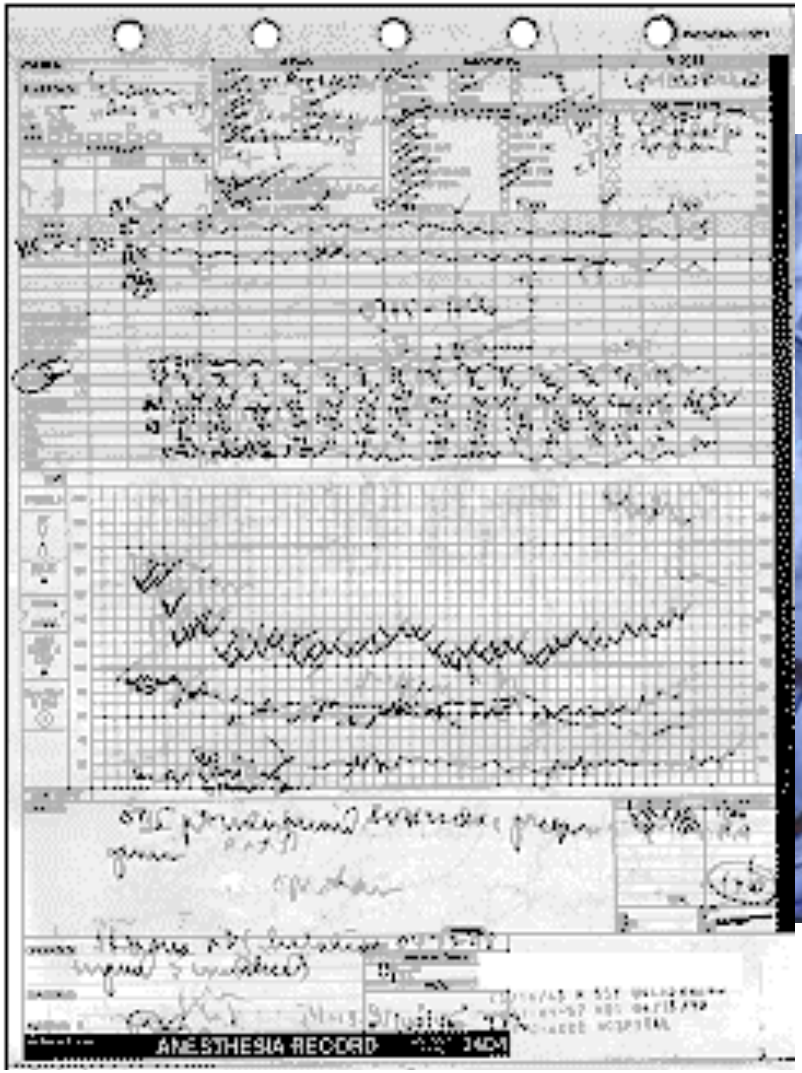
INTERNATIONAL FEDERATION FOR INFORMATION PROCESSING
WG 10.4 on DEPENDABLE COMPUTING AND FAULT TOLERANCE
June 29, 2012, MA, USA

Transforming Healthcare Through Medical System Integration: *from architecture to apps*

Julian M. Goldman, MD
Medical Director, Partners HealthCare Biomedical Engineering
Anesthesiologist, Mass Gen Hospital
Director, Medical Device Interoperability Program, CIMIT

www.jgoldman.info

We have come a long way …



We should collect, document, and process these events automatically to decrease errors and improve efficiency

Need:

- Real-time Allergy/drug checking
- Transfusion support
- Fluid balance management
- ACLS protocol adherence

Devices, processes, non-integrated system → errors

The Problem

- There are intractable barriers to improving the safety and efficiency of delivering clinical care
- Many reports confirming that there is significant “room for improvement”

Medication Errors in ICU

Source: Review of 1168 articles --- Medication errors in critical care: risk factors, prevention and disclosure; Eric Camiré MD, Eric Moyen MD, Henry Thomas Stelfox MD PhD Apr. 28, 2009, issue of *CMAJ*

- 1.7 error per patient per day in ICU
- 29% of these errors if uncorrected, had the potential to cause significant morbidity or even death.
- 70% of patients experience potentially life-threatening error during their stay
- Providing 1 critically ill patient with a single dose of a single medication requires correctly executing 80–200 steps.

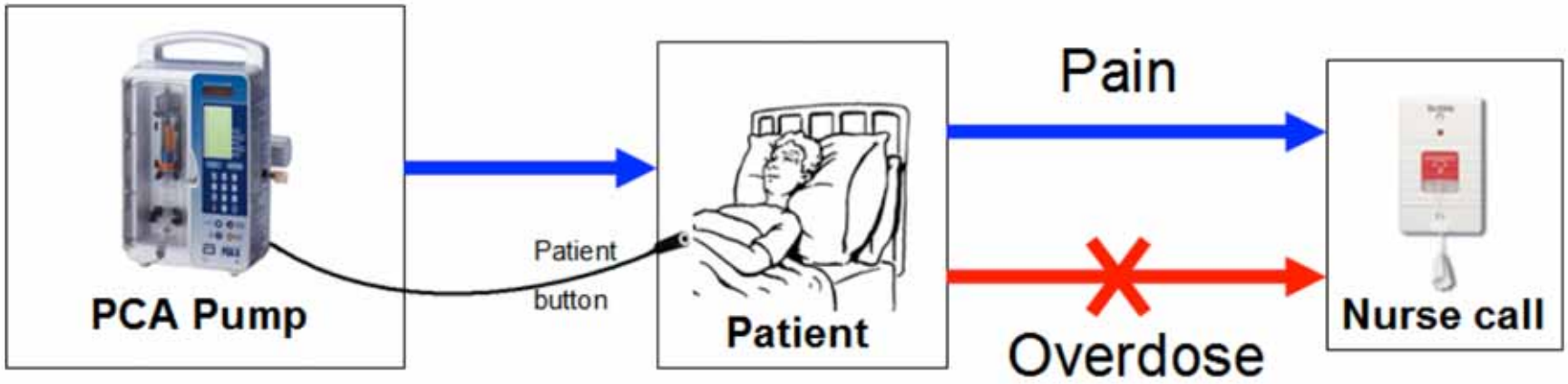
Clinical Scenarios

- Clinical Scenarios help convey the clinical needs and gaps at a high level.
- We will look at several examples ->

Example 1

Patient Controlled Analgesia

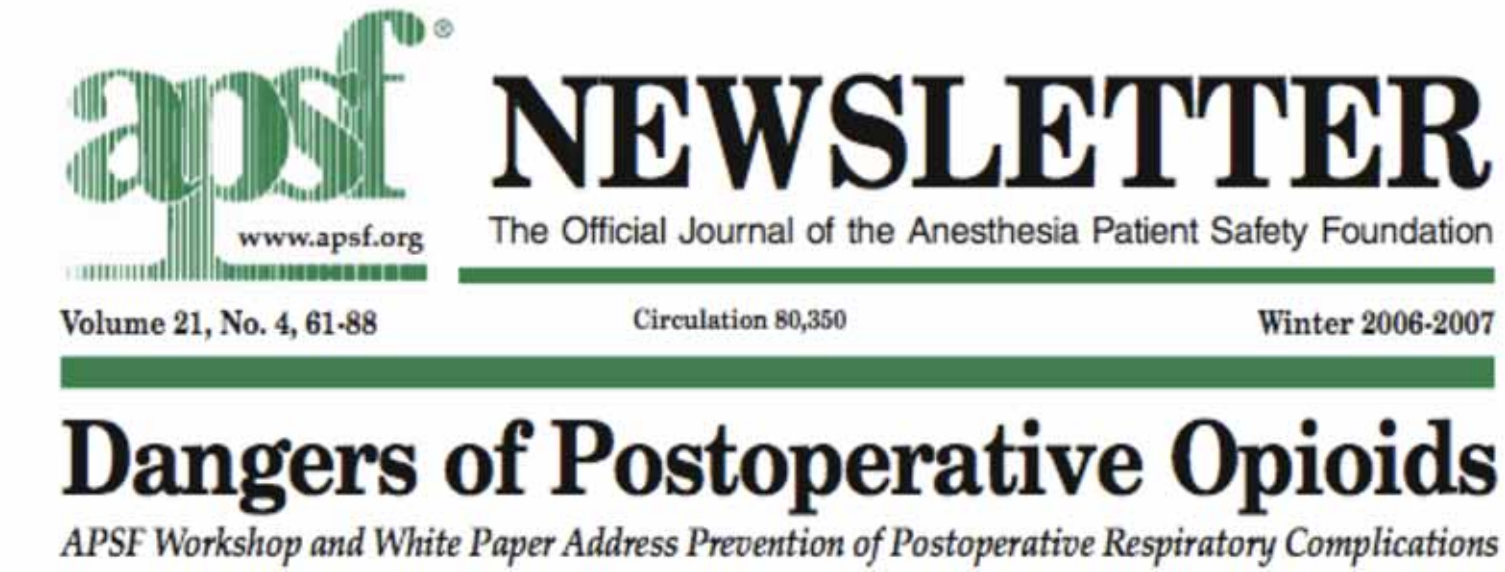
Typical Patient Controlled Analgesia System



Patient can call to request more analgesia, but, cannot call for help when over-medicated.

Why not monitor every patient? False and nuisance alarms -> alarm fatigue

Solution: Smarter alarms with sensor fusion + capability to stop medication infusion prior to injury



- "A particularly attractive feature may be the ability to automatically terminate or reduce PCA (or PCEA) infusions when monitoring technology suggests the presence of opioid-induced respiratory depression. To facilitate such capabilities, we strongly endorse the efforts to develop international standards for device interoperability and device-device communication.
- It is critical that any monitoring system be linked to a reliable process to summon a competent health care professional to the patient's bedside in a timely manner."

Problem was revisited at June 2011 workshop!

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."

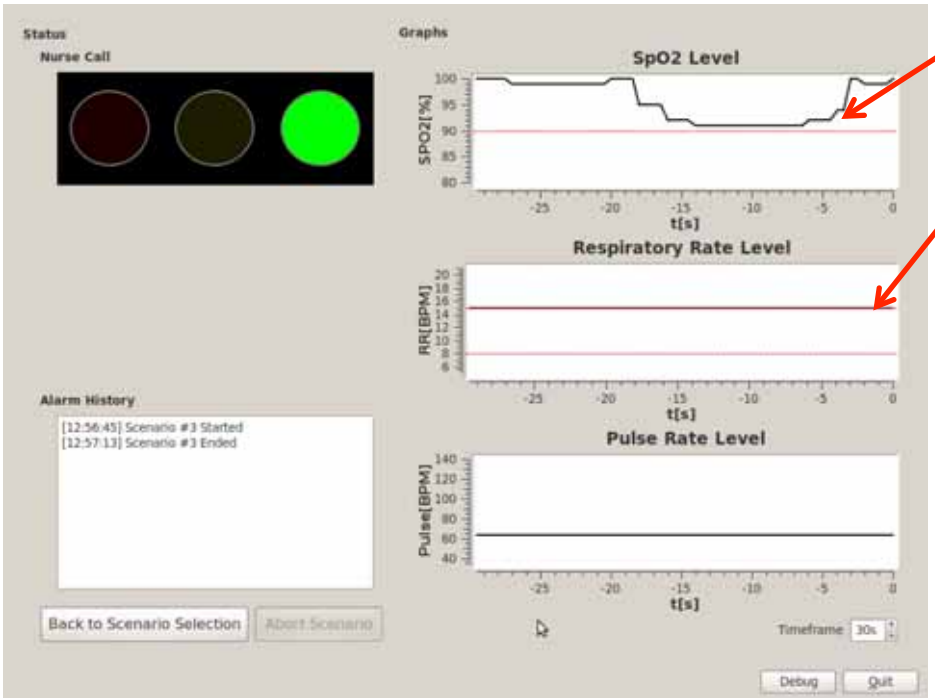
Smart PCA monitoring system
American Society of Anesthesiologists
Scientific Exhibit October 2007

Plug-and-play detection of monitors connected to patient,
Permits selection of "best" monitor and alarm algorithm at point of care

Exhibit recognized with First Place award

PCA Example:
Smart PCA App could increase alarm specificity & sensitivity, stop the pump, and call nurse

Data fusion algorithm masks nuisance Spo_2 alarm



SpO_2 drops transiently, but Respiratory Rate and Pulse Rate are steady, therefore SpO_2 alarm is not activated.

Greater <u>specificity</u>: This potential <u>nuisance</u> <u>alarm</u> has been prevented, because more information is available from other devices.

Greater <u>Sensitivity</u>: Similarly, respiratory depression may be detected earlier by monitoring trend of RR AND SpO2

Example 2

Cardio-Pulmonary Bypass (heart-lung bypass)

← or →

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

Failure to Ventilate after Bypass

- Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.
- Anesthesiology. 87(4):741-748, October 1997 15 years
- "… In the second case, the anesthesiologist forgot to resume ventilation after separation from cardiopulmonary bypass. The delayed detection of apnea 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."

Almost every surgical team has experienced this error!

Cardio-Pulmonary Bypass

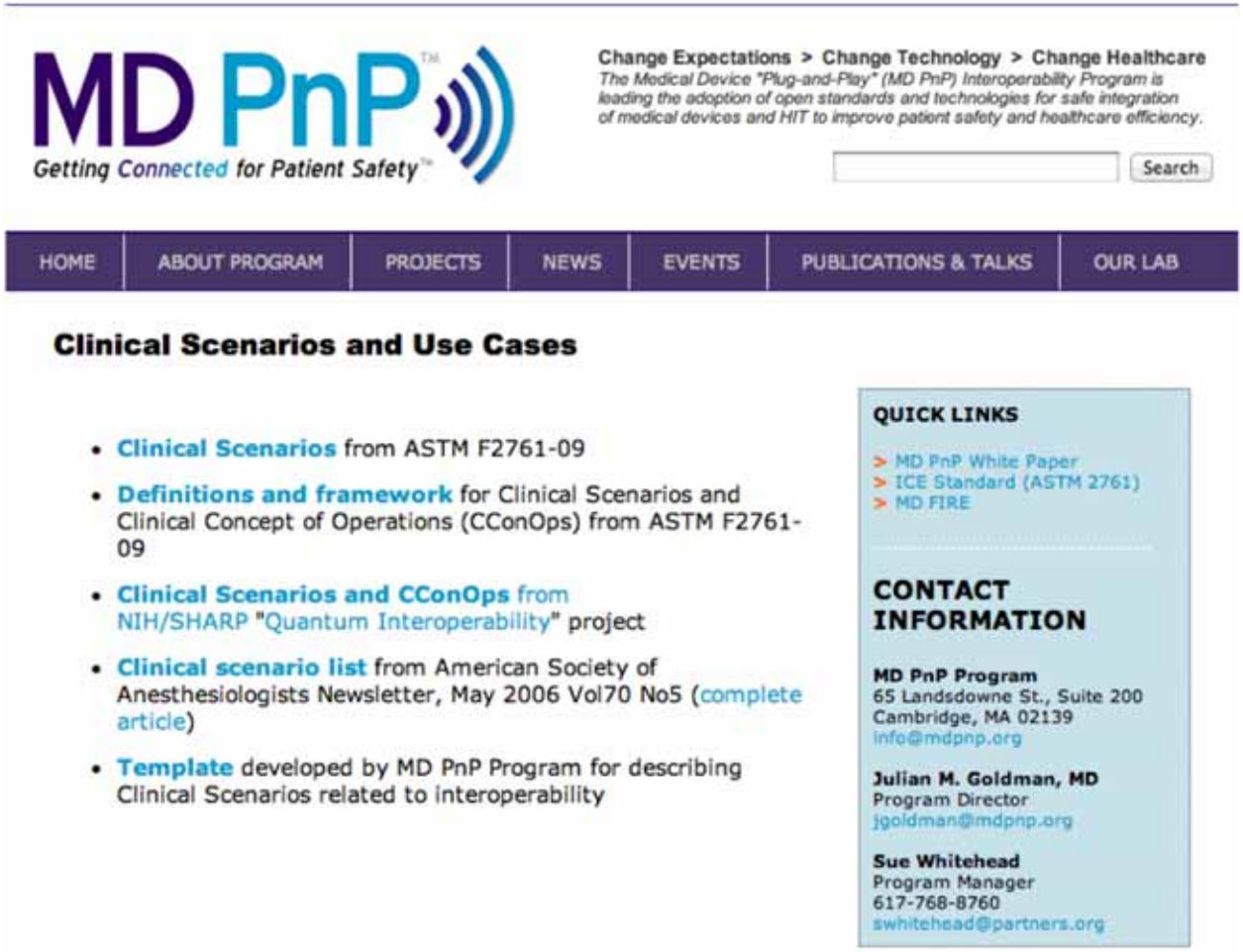
and

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

No App for that

Example n?

- How many more examples? Too Many



MD PnP™
Getting Connected for Patient Safety™

Change Expectations > Change Technology > Change Healthcare
The Medical Device "Plug-and-Play" (MD PnP) Interoperability Program is leading the adoption of open standards and technologies for safe integration of medical devices and HIT to improve patient safety and healthcare efficiency.

Search

HOME | ABOUT PROGRAM | PROJECTS | NEWS | EVENTS | PUBLICATIONS & TALKS | OUR LAB

Clinical Scenarios and Use Cases

- **Clinical Scenarios** from ASTM F2761-09
- **Definitions and framework** for Clinical Scenarios and Clinical Concept of Operations (CConOps) from ASTM F2761-09
- **Clinical Scenarios and CConOps** from NIH/SHARP "Quantum Interoperability" project
- **Clinical scenario list** from American Society of Anesthesiologists Newsletter, May 2006 Vol70 No5 (complete article)
- **Template** developed by MD PnP Program for describing Clinical Scenarios related to interoperability

QUICK LINKS

> MD PnP White Paper
> ICE Standard (ASTM 2761)
> MD FIRE

CONTACT INFORMATION

MD PnP Program
65 Landsdowne St., Suite 200
Cambridge, MA 02139
info@mdpnp.org

Julian M. Goldman, MD
Program Director
jgoldman@mdpnp.org

Sue Whitehead
Program Manager
617-768-8760
swhitehead@partners.org

Essential Healthcare Needs

- Needs: Improvements in patient safety and healthcare efficiency require innovative system solutions.
- Barriers: Medical systems cannot be fully integrated due to the lack of effective interoperability of medical devices and Health IT systems, especially in high-acuity clinical settings.
- Solutions:
  - Ability to "integrate the clinical environment" is an essential ingredient to create complete EHRs and error-resistant systems

MD PnP™
Getting connected for patient safety™

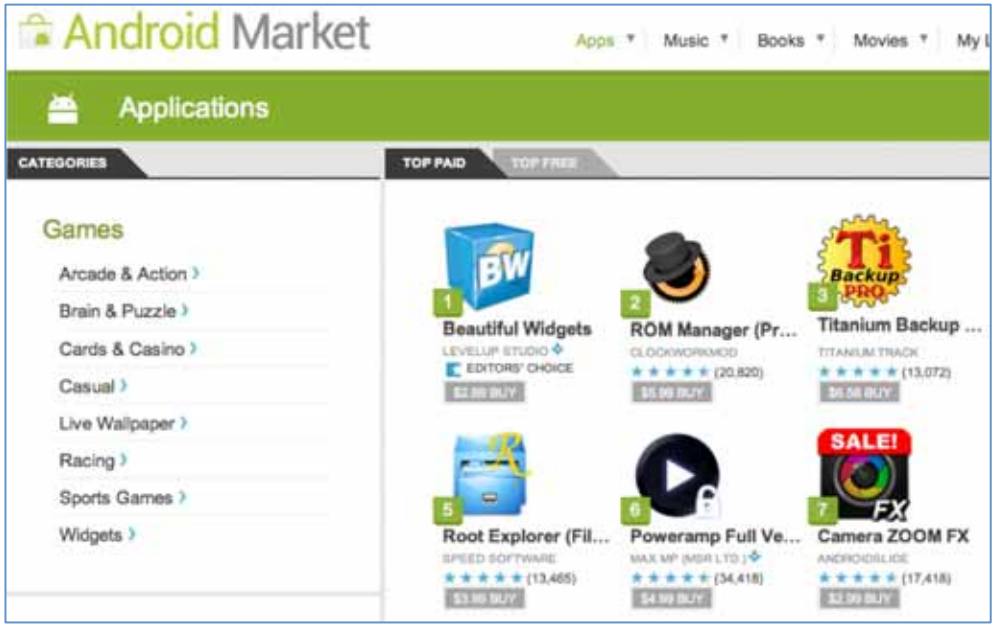
Why have these been intractable problems?

- Solution Involves Multiple Parties: Physicians, Hospitals, Medical Device Manufacturers, FDA, SDOs
  - Not just a business problem
  - Not just a clinical problem
  - Not just a standards problem
  - Not just a software problem
- This is a medical systems problem and a formidable challenge

A Solution Pathway …

"Smart Phones" are "App Platforms", designed to enable developers to use processors, sensors, data, and screen UI to deliver Apps.

- Gyro/motion sensors
- Mic and speakers
- Radios (many!)
- GPS
- Operating System designed to effectively deliver App requirements



What could healthcare “apps” do?

That depends on the “app platform”

Epocrates Rx for Apple iOS

This type of app is very useful.
But it is not the subject of today’s discussion

Imagine if apps could connect to the sensors/devices in the physical environment, they could finally solve some of these clinical problems

Landing gear not down? -> Smart Cockpit ALARM

Contextual awareness requires data from several device and systems. e.g. altitude, attitude, flap position, etc.
But, we must respect the complexity of these safety critical systems

ICE - “Integrated Clinical Environment”

MD PnP

Clinical Environments of the Future will be Integrated

- Silos of stand-alone medical devices and IT will be plug-and-play integrated.
- “Apps” will leverage the ICE:
  - Smart alarms, safety interlocks, and closed-loop control will enable “error resistant” systems
  - Comprehensive data acquisition for clinical care, research, and adverse event analysis (Black-box recorder)
  - Biomed equipment management
  - Patient ID and correct clock time will be bound to device data
- Apps for Clinical Decision Support (CDS) will run on standardized ICE platforms, which enables global sharing of apps
- Specialized app development tools will empower clinicians/ researchers to rapidly prototype and then customize apps on the fly

Monitor
Smith, Carla
87
94
30
36.4
130/88

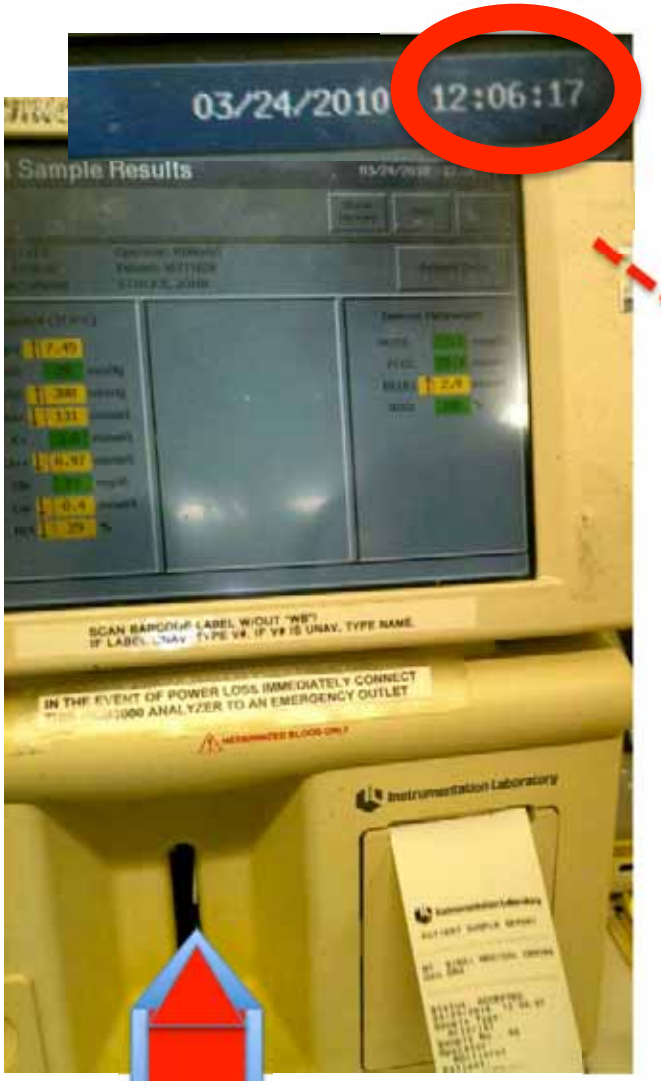
Many Challenges …

Why is clock time important?

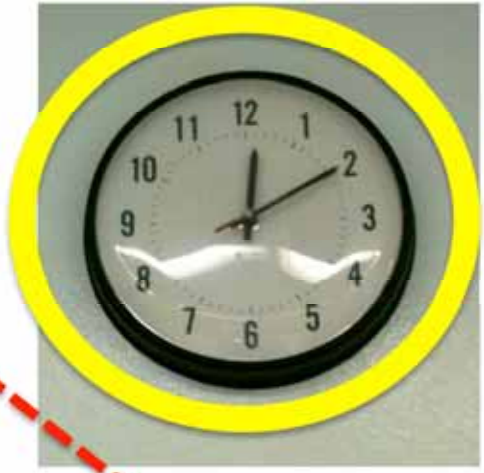
- Undermine integrity of EMR
- May lead to inappropriate therapy
- Complicate QA analysis
- Introduce liability concerns
- Security implications

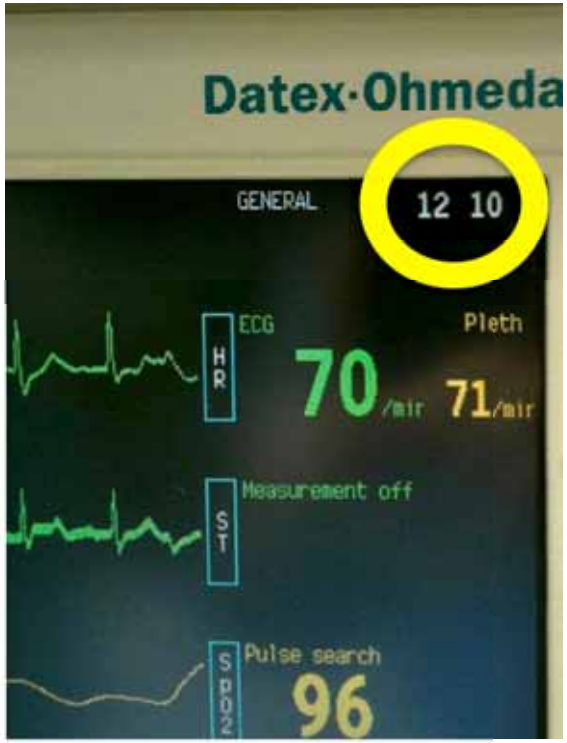
① Challenge: Who owns this problem? Med device manufacturers? EMR vendors? System integrators? Middleware vendors?

② Challenge: What methods are available to synchronize time in intermittently connected clinical systems?

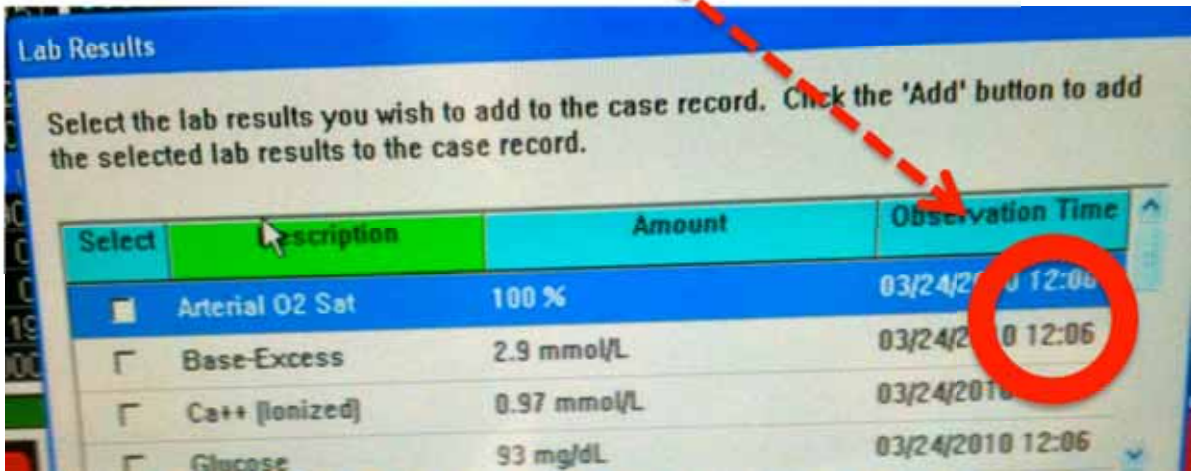


Blood gas analyzer in OR





EMR time stamp error



Medical Device Clock Accuracy Study

- Institutions (4) :
  - Massachusetts General Hospital (MGH),
  - Brigham and Women's Hospital (BWH)
  - Hospital of University of Pennsylvania (HUP)
  - Johns Hopkins Hospital (JHH)
- Total number of clocks: 1732
- Total number of medical devices (Excl. Work Stations & Wall Clocks): 1323

- Types of devices, included:
  - Physiological Monitors
  - Infusion Pumps
  - Anesthesia Machines
  - Ventilators
  - Ultrasound Machines
  - Portable Vital Signs Monitors
  - Transport Monitors
  - Pulse Oximeters
  - Dialysis Machines
  - Defibrillators
  - EKG Analysis Systems
  - And others…

Draft – unpublished data

Draft – unpublished data

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

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.

Clock Study Collaborators

Hospital of University of Pennsylvania (HUP)

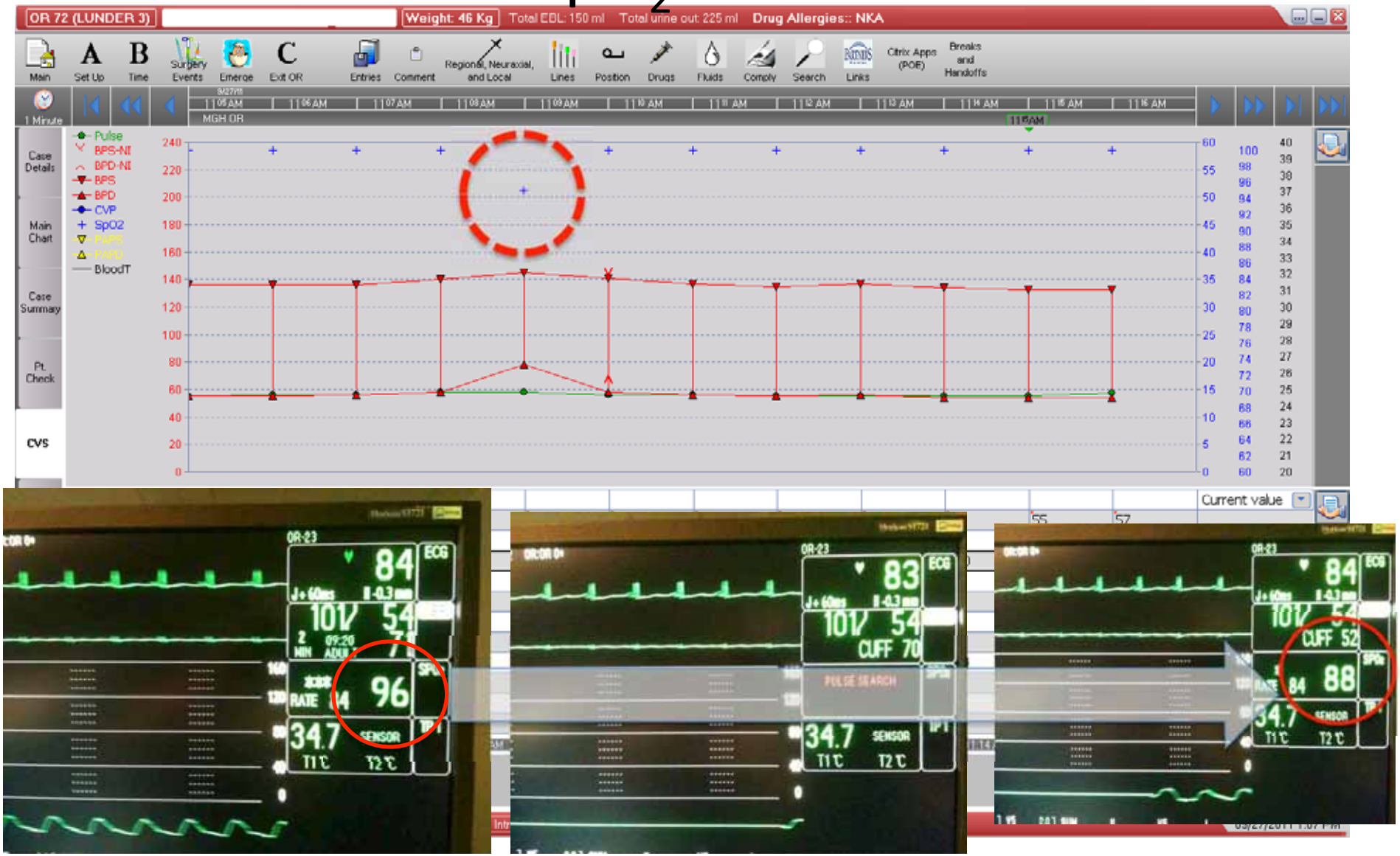
- Dr. Insup Lee - Cecilia Fitler Moore Professor, Department of Computer and Information Science, Upenn.
- Dr. Oleg Sokolsky - Research Associate Professor, Department of Computer and Information Science, Upenn.
- Soojin park, MD - Director of Neurocritical Care Monitoring and Informatics
- Margie Fortino, MSN, RN - Operations Director, Penn e-lert eICU

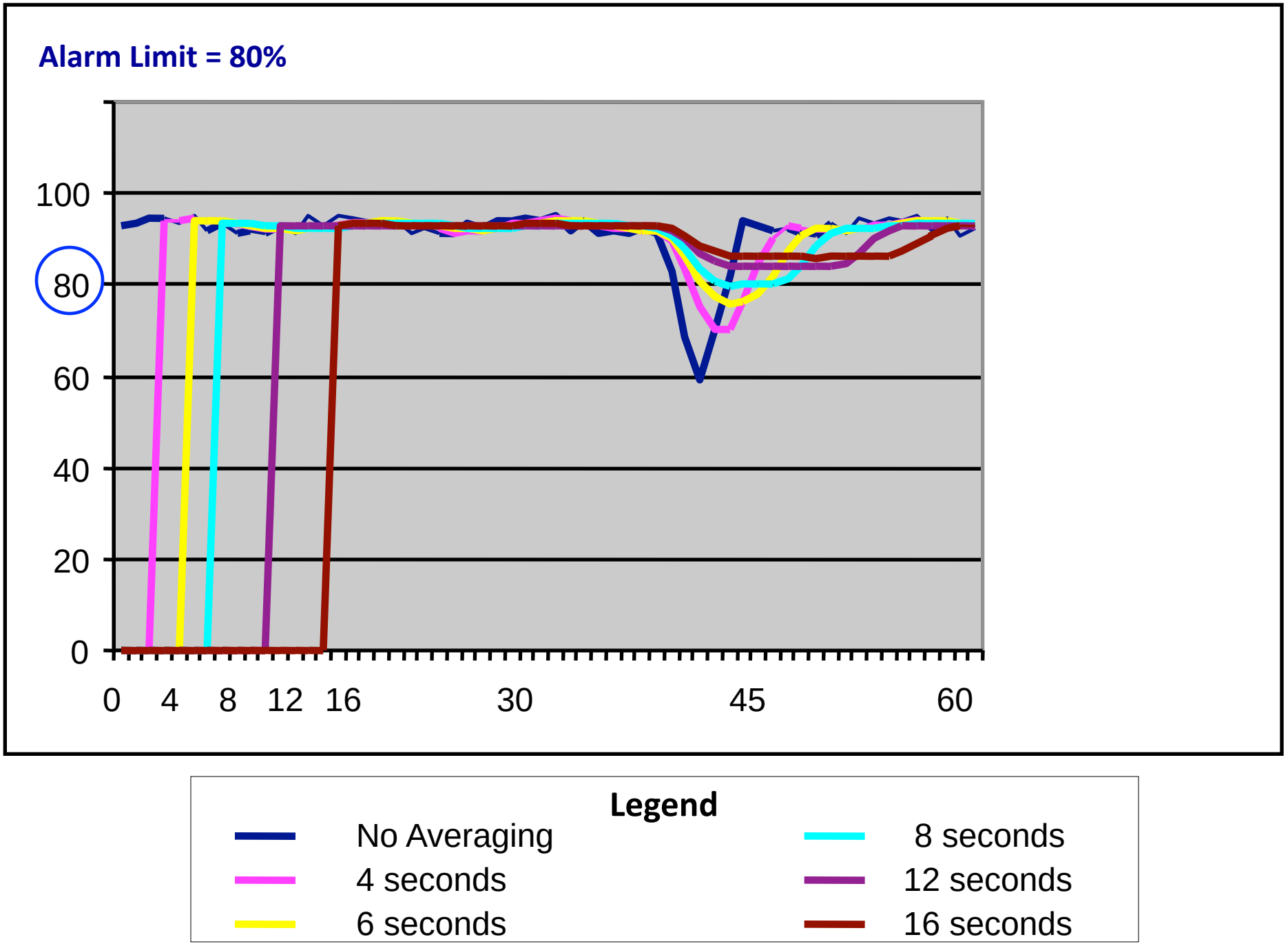
Johns Hopkins Hospital (JHH)

- James C. Fackler, MD – Anesthesiology & Pediatrics
- Maria Cvach MS, RN, CCRN - Assistant Director of Nursing, Clinical Standards
- Dina A. Krenzischek, PhD, MAS, RN, CPAN – PACU Nurse Manager
- Jeff Frank – Clinical Engineering Manager
- Judy Ascenzi, MSN – Clinical Nurse Specialist, Pediatrics

Integration is needed to personalize.

NIBP-SpO_2 Interaction




Alarm Limit = 80%
100
80
60
40
20
0
0
4
8
12
16
30
45
60
Legend
No Averaging
4 seconds
6 seconds
8 seconds
12 seconds
16 seconds

Simulator is set to create transient desaturation 99%->70%->99%

8 sec averaging time

2 sec averaging time

16 sec averaging time

How would data be interpreted if averaging time is not known?

Solutions in Process

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 CIMIT, and supported by Massachusetts General Hospital (MGH), CIMIT, and Partners HealthCare.

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

US Federal Funding and Collaboration: DoD/TATRC, NSF, NIST, FDA, AHRQ, NIH, VAH

MD PnP LAB

Center for Integration of Medicine and Innovative Technology (CIMIT)

65 Landsdowne St., Cambridge, MA

Collaborators

Geographically-dispersed stakeholders who want to improve patient safety and healthcare efficiency through innovations enabled by medical device system integration

RESOLVED, That our American Medical Association (AMA) believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well … ”

as of July 2009:

Anesthesia Patient Safety Foundation
Society for Technology in Anesthesia
Society of American Gastrointestinal Endoscopic Surgeons

American Medical Association
World Federation of Societies of Anesthesiologists
American Society of Anesthesiologists
Massachusetts Medical Society

News & Events (Medical Devices)

Workshops & Conferences (Medical Devices)

Past Workshop & Conference

Medical Device Interoperability, January 25, 2010

The public workshop was held on January 25 and 26, 2010, from 9 a.m. to 5 p.m. and on January 27, 2010, from 9 a.m. to 12 noon.

Location: The public workshop was held at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

FR Doc E9-30871

Related Document

- Transcript: Medical Device Interoperability, January 25, 2010 (PDF - 574KB)
- Transcript: Medical Device Interoperability, January 26, 2010 (PDF - 320KB)
- Transcript: Medical Device Interoperability, January 27, 2010 (PDF - 244KB)

MD FIRE

Medical Device "Free Interoperability Requirements for the Enterprise"

- Position Statement & Sample of Interoperability RFP and Contract language
- Developed by Mass General Hospital / Partners, Johns Hopkins, Kaiser Permanente via MD PnP research program
- Conveys healthcare needs to industry, and simplify purchasing specifications
- Released Oct 17, 2008 (V1.7 published in May 2012)
- VA signed June 28, 2012

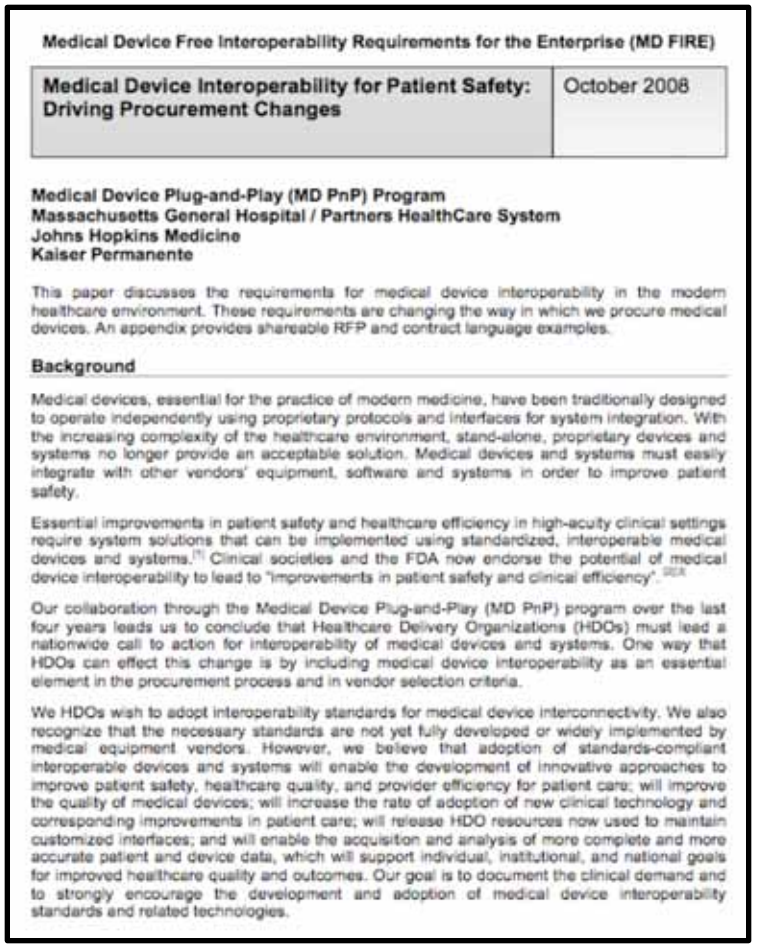
5 Stakeholder groups from each organization:

Purchasing/materials management, BME, IS, Clinical, Legal

Download MD FIRE from www.mdpnp.org

MD FIRE

- "Healthcare Delivery Organizations (HDOs) must lead a call to action for interoperability of medical devices and systems.
- One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria."



Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)

Medical Device Interoperability for Patient Safety: Driving Procurement Changes	October 2008

Medical Device Plug-and-Play (MD PnP) Program
Massachusetts General Hospital / Partners HealthCare System
Johns Hopkins Medicine
Kaiser Permanente

This paper discusses the requirements for medical device interoperability in the modern healthcare environment. These requirements are changing the way in which we procure medical devices. An appendix provides shareable RFP and contract language examples.

Background

Medical devices, essential for the practice of modern medicine, have been traditionally designed to operate independently using proprietary protocols and interfaces for system integration. With the increasing complexity of the healthcare environment, stand-alone, proprietary devices and systems no longer provide an acceptable solution. Medical devices and systems must easily integrate with other vendors' equipment, software and systems in order to improve patient safety.

Essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and systems.[1] Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency".[2][3][4]

Our collaboration through the Medical Device Plug-and-Play (MD PnP) program over the last four years leads us to conclude that Healthcare Delivery Organizations (HDOs) must lead a nationwide call to action for interoperability of medical devices and systems. One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria.

We HDOs wish to adopt interoperability standards for medical device interconnectivity. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. However, we believe that adoption of standards-compliant interoperable devices and systems will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency for patient care; will improve the quality of medical devices; will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; will release HDO resources now used to maintain customized interfaces; and will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual, institutional, and national goals for improved healthcare quality and outcomes. Our goal is to document the clinical demand and to strongly encourage the development and adoption of medical device interoperability standards and related technologies.

Download: mdpnp.org/MD_FIRE.php

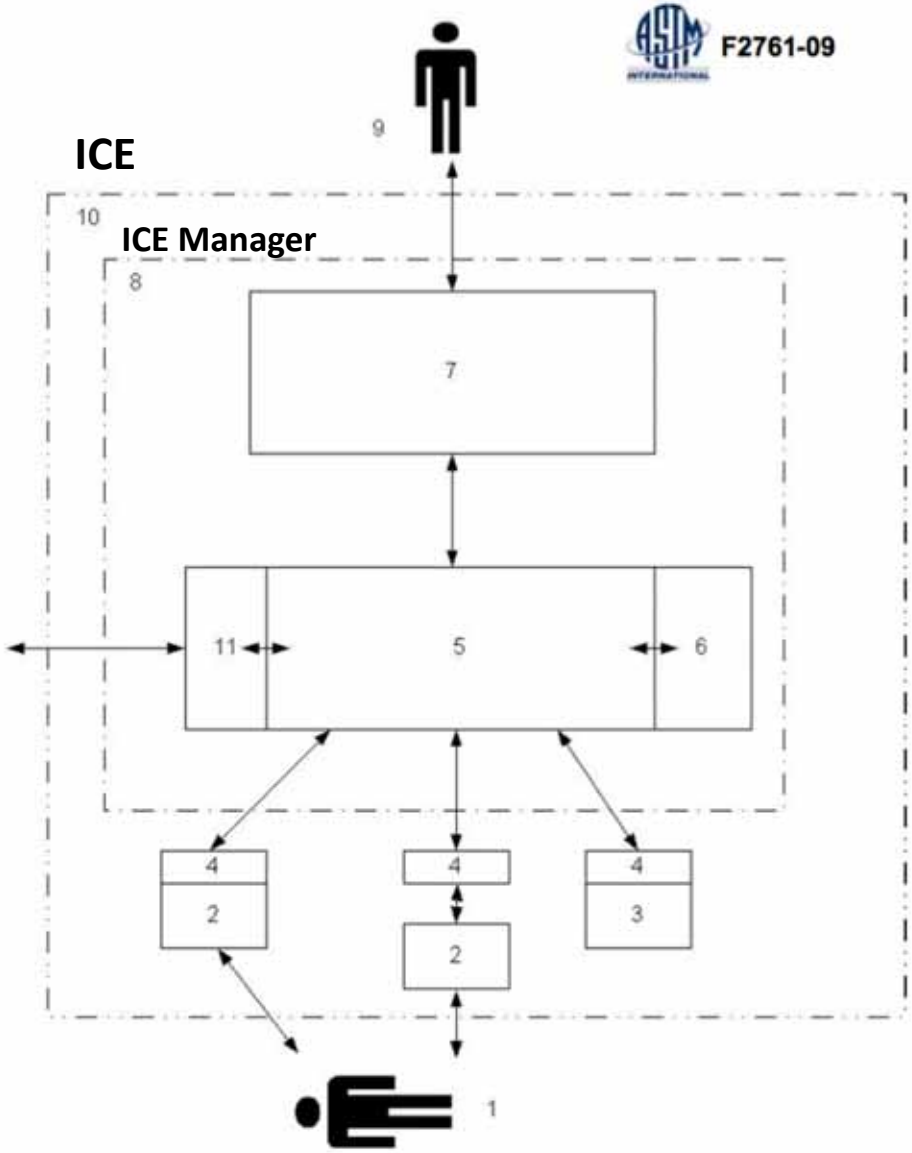
Standard for the "Integrated Clinical Environment" ASTM F2761-09

"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

ICE 2761-09 Conceptual Architecture

- Clinician[9]
- ICE Supervisor[7]- presents information and accepts operator controls to operate an ICE Device Suite
- Forensic Data Logger[6]
- ICE Network Controller[5] – Manages external Interfaces, and device controllers
- External interface[11] (e.g. EMR)
- ICE Equipment Interface[4] – Abstract devices and present a consistent interface
- Equipment[3]
- Medical Devices[2]
- Patient[1]
- ***Needs further development both conceptually and in software***



Smart PCA monitoring system

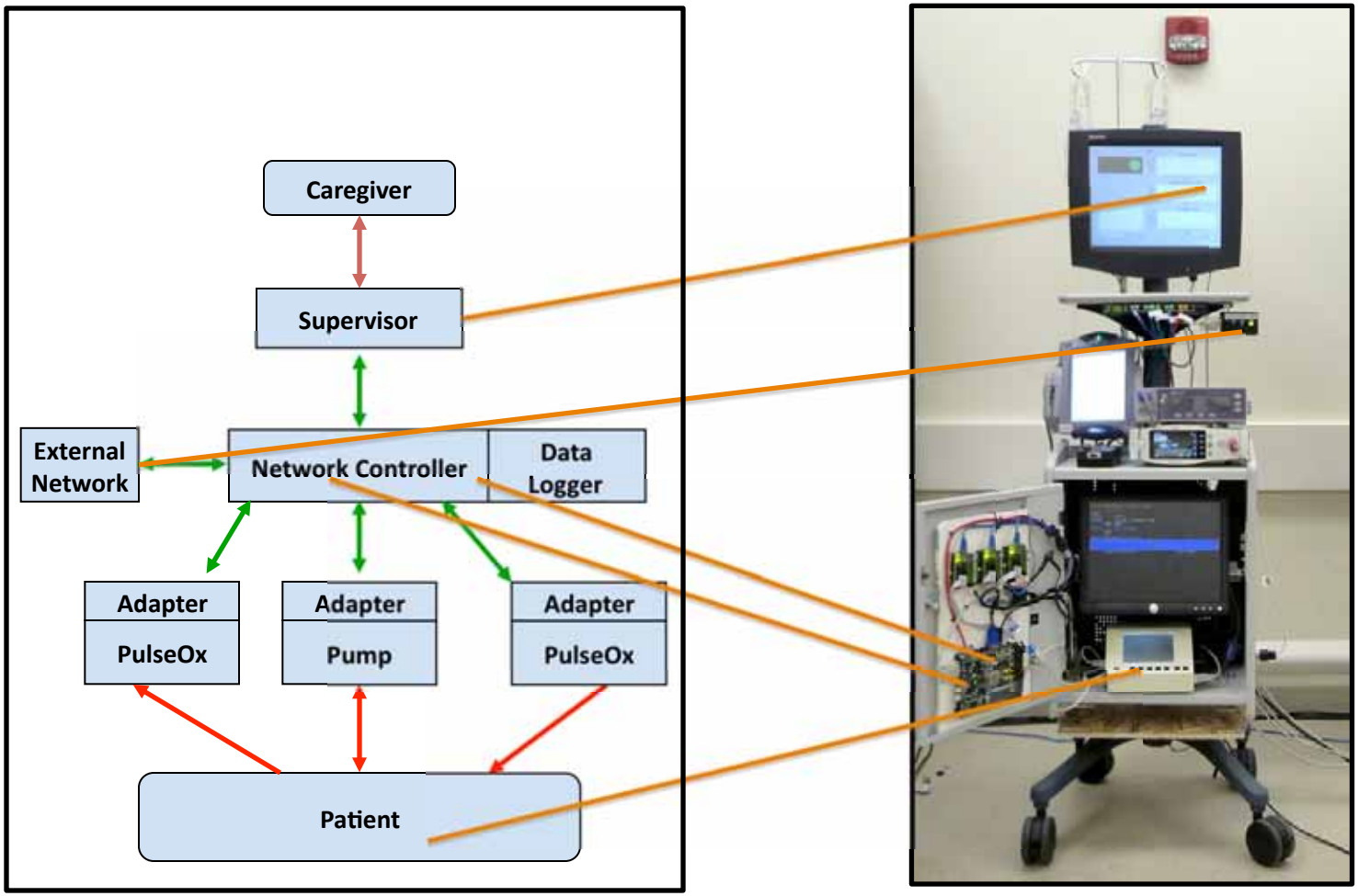
- *Plug-and-play integration of monitors/pump connected to patient.*
- *Hosts "apps" to detect respiratory problems -> stop IV pump*
- *Permits selection of "best" monitor and alarm algorithm at point of care*

American Society of Anesthesiologists
Scientific Exhibit October 2007

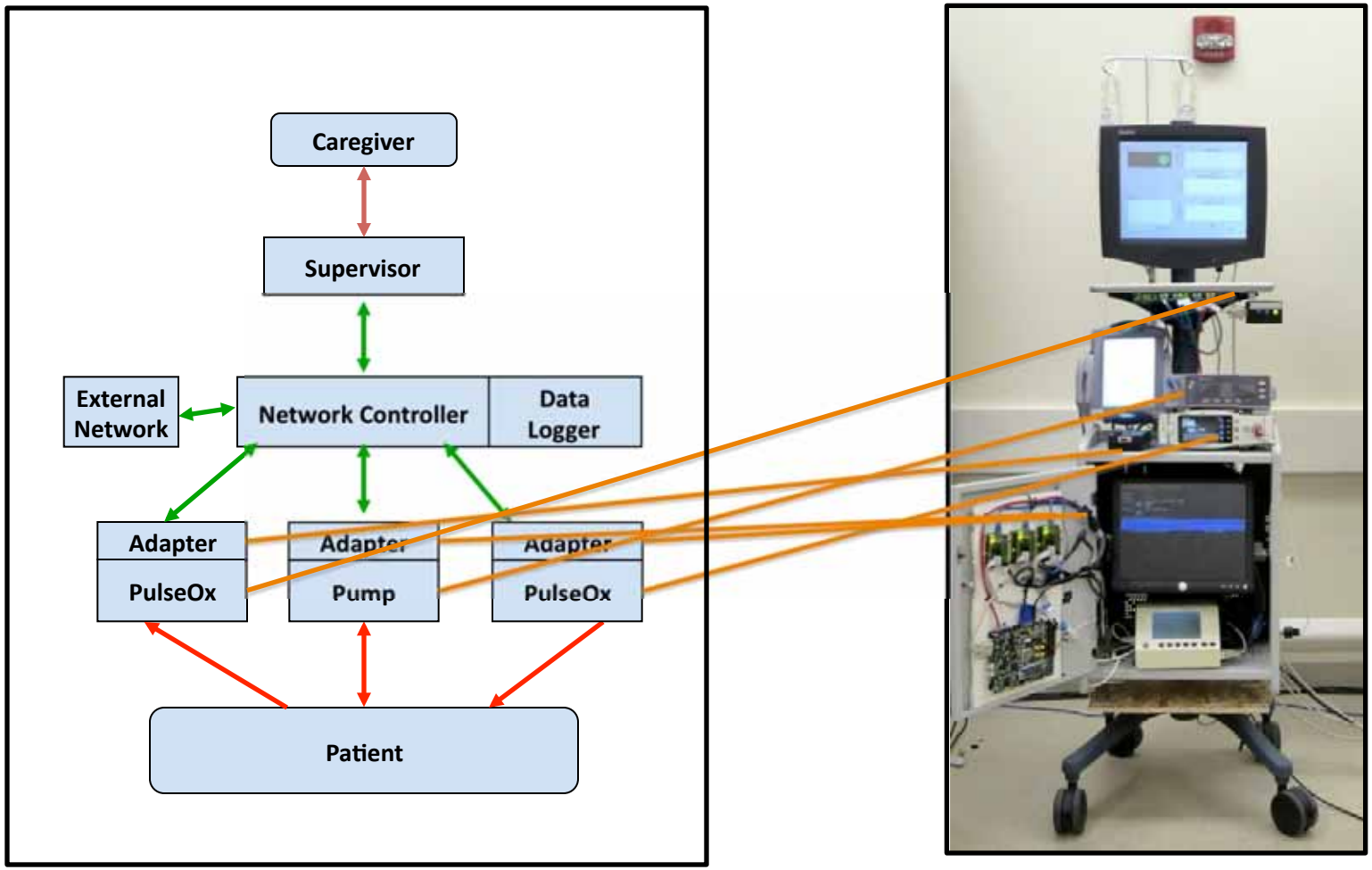
2011
version

Exhibit recognized with First Place award

Mapping from ASTM ICE Standard



Mapping from ASTM ICE Standard (Contd.)



Data Logger (ASTM F2761)

- The purpose of the data logger is to record low-level device data in an open, standardized, and time-synchronized manner.
- The log includes:
  - Commands
  - Button presses
  - Location
  - Physiologic and technical alarms
  - Physiologic data from patients
  - Information about the status of devices
  - Device connections and disconnections from ICE manager

- Data Log supports Analysis and Playback for two complementary purposes:
  - Analysis of device interactions (debugging)
  - Analysis of adverse events involving patients (clinical)

MD PnP NIH Quantum Grant
Development of a Prototype Healthcare Intranet for Improved Health Outcomes

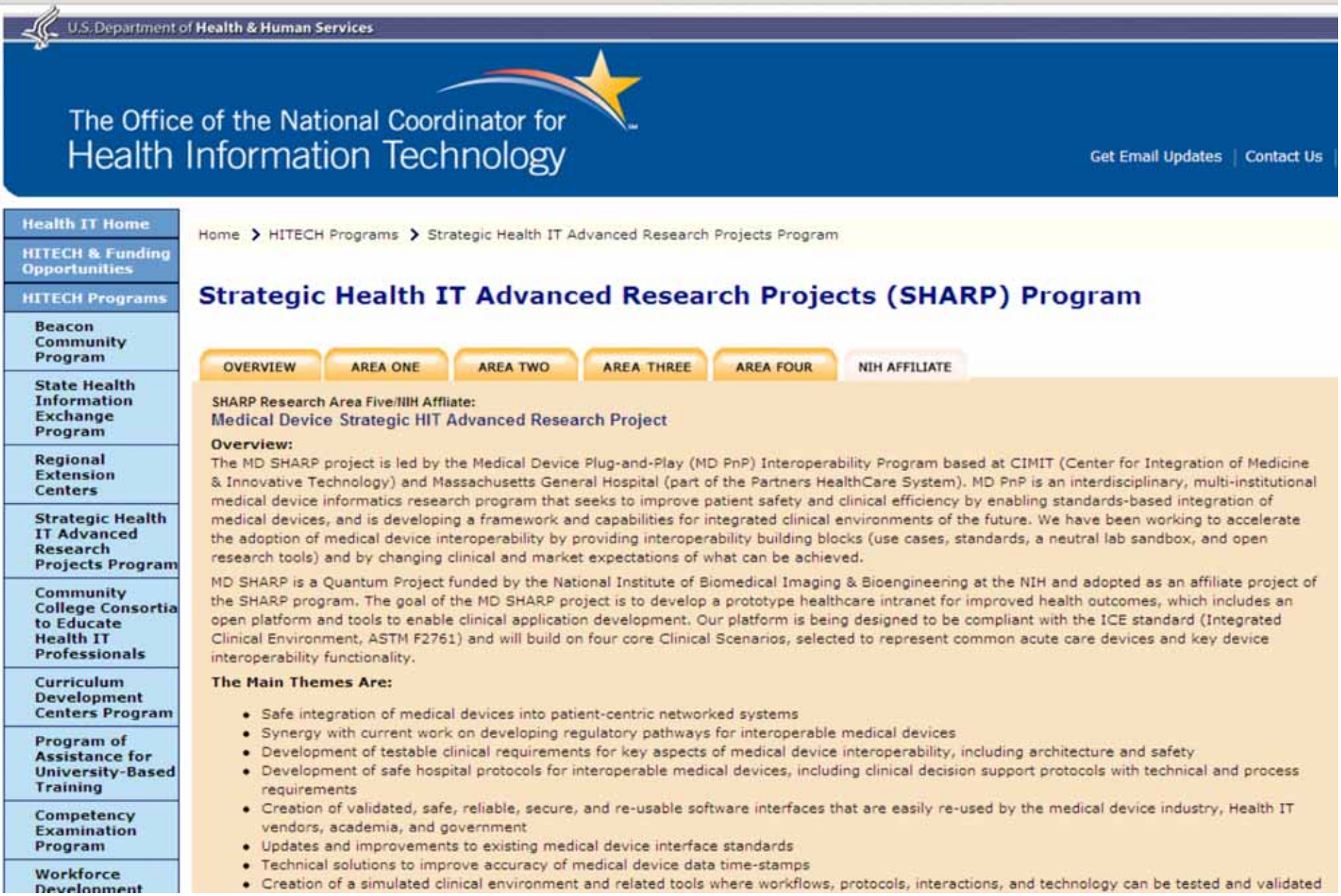
- The creation of an eco-system for interoperability of medical device and clinical information systems to support innovation in patient safety and healthcare quality

- **Award:** 5 Years (starting 2010) $10M

- **Collaborating Organizations:**
  - CIMIT/Massachusetts General Hospital (Julian Goldman P.I.)
  - Anakena Solutions, California (Michael Robkin)
  - DocBoxInc, Waltham, MA (Tracy Rausch)
  - Penn (Insup Lee)
  - Kansas State University (J. Hatcliff)
  - Moberg Research, Ambler, PA (Dick Moberg)
  - University of Illinois at Urbana-Champaign (Lui Sha)
  - Tim Gee - Medical Device integration consultant
  - VA – OHI/Office of JIV

An HHS ONC Health IT SHARP affiliated program

ONC HIT SHARP Program



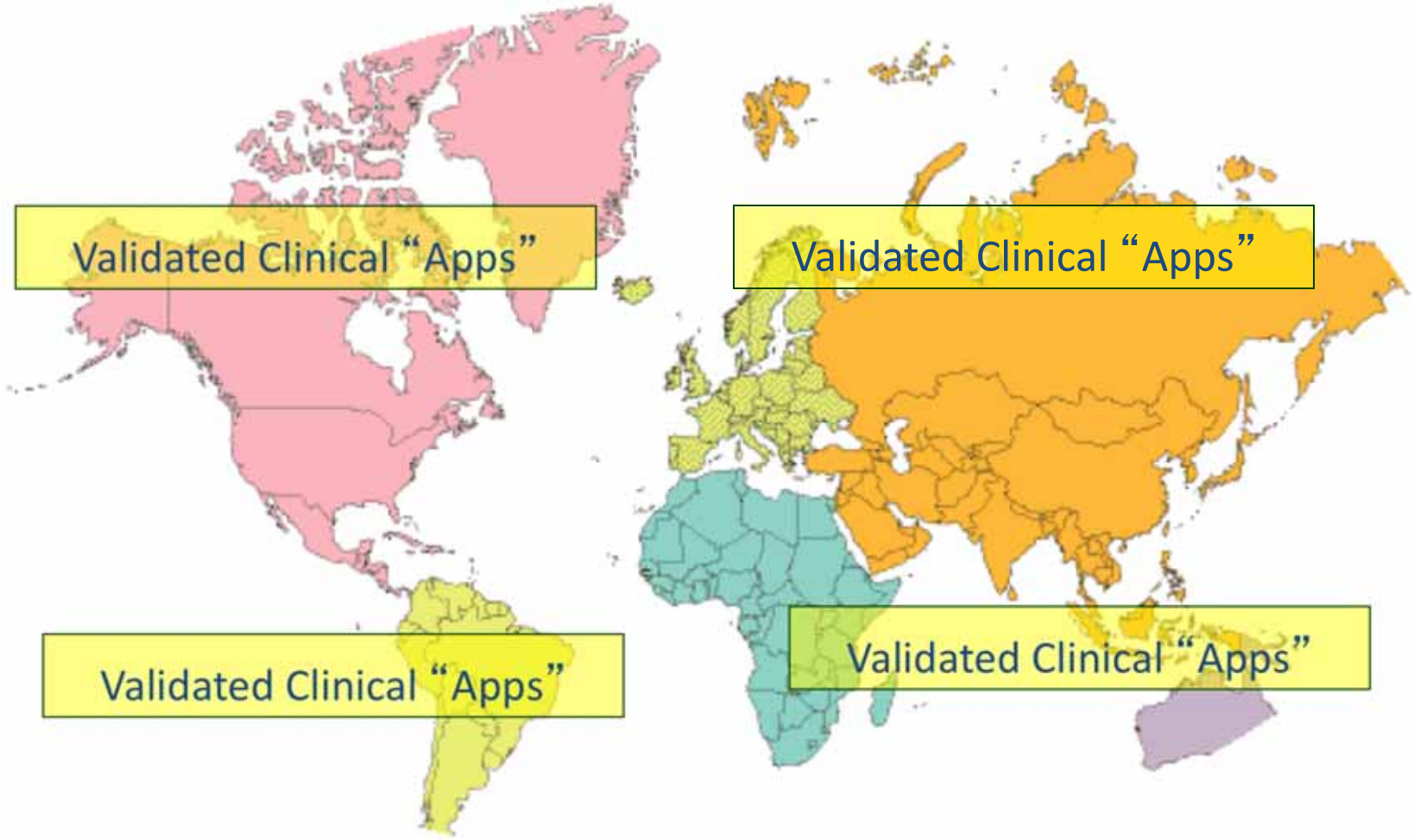
Quantum Scenarios

1. **PCA Safety Interlock,** example of component-level medical device interoperability
2. **ICU preparedness,** example of in-hospital patient transfer and rich clinical context
3. **Tele-health (TH)** devices in hospital, example of transferring care from home to hospital and use of TH devices for high-acuity care
4. **FDA regulatory** – staged implementation of framework for levels of interoperability and associated levels of hazards and their mitigation

What could we accomplish in healthcare with open, interoperable medical device app platforms?

- Innovation
  - Rich contextual data (for clinical decision support)
  - Means for rapid prototyping of new sensors and algorithms
  - Facilitate validation for regulatory clearance
  - Swap devices as needed to optimize selection
- And what we have seen in other domains
  - Crowd-sourcing of “Apps”: If device platform is standardized, apps can be developed by global expert community

When standardized clinical databases are populated with standardized data, validated clinical rules or "Apps" will be shared globally



Crowdsourcing of clinical apps could transform healthcare

J. Goldman, MD 2005-2012

MD PnP™
Getting connected for patient safety™