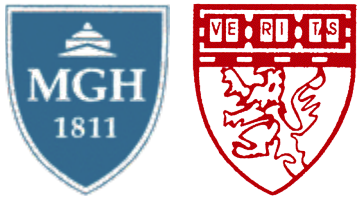


2014 National Workshop on
Research Frontiers in Cyber-Physical Systems
February 6, 2014

MD PnP™
Getting connected for patient safety™

Patient Safety Challenges and Medical Device Innovation (*in a CPS context*)

Julian M. Goldman, MD
Director, Medical Device Interoperability Program
Medical Director, Partners HealthCare Biomedical Engineering
Physician, Mass Gen Hospital/Harvard Medical School

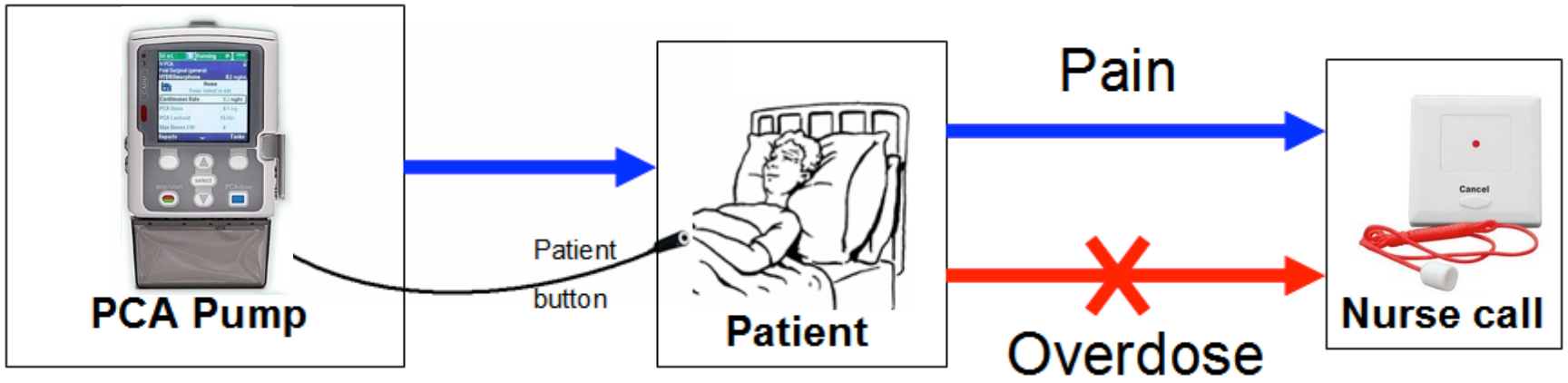
www.jgoldman.info

Safety Challenges:
Adverse Event and Near-miss
Reporting and Analysis

- When medical device-HIT "system related" adverse events occur, it is often difficult or impossible to find the root cause of the failure.
- The current Medical Device - HIT system does not lend itself to complete data logging for later analysis (no black box recording)
- There is no national reporting pathway for gaps/ needs/failures of heterogeneous medical device (and HIT) systems

PCA as an example:

Patient-Controlled Analgesia (PCA)
system safety concerns



- *Patients can call to request more analgesia, but, cannot call for help when over-medicated.*
- *Over-medication can cause respiratory and cardiac arrest*
- *Comprehensive monitoring is not typically used due to high false/ nuisance alarm rate*

- "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."
- Proposed "smart PCA system" requires the use of physiologic data for earlier detection of respiratory depression + capability to stop medication infusion

How would you create a smarter PCA system?

SENSORS:

- SpO_2 – probably
- Respiratory Rate (RR) – probably, but from which source?
  - Capnography?
  - ECG (impedance)?
  - Other (acoustic, TBI, thermistry, Vt,etc.)?
- $ETCO_2$ – can be used for hypercarbia, RR, etc.

- Algorithms – how would you use the signals?
  - Threshold?
  - Trends?
  - Create an alarm, warning, or stop the PCA?
  - Do you have the enough data to develop the algorithms? To personalize sensors and algorithms for different patient populations? Plug-and-play devices as needed?

Is other clinical / contextual information needed:

- Is patient on supplemental O_2?
- Co-morbidities? (e.g. sleep apnea)

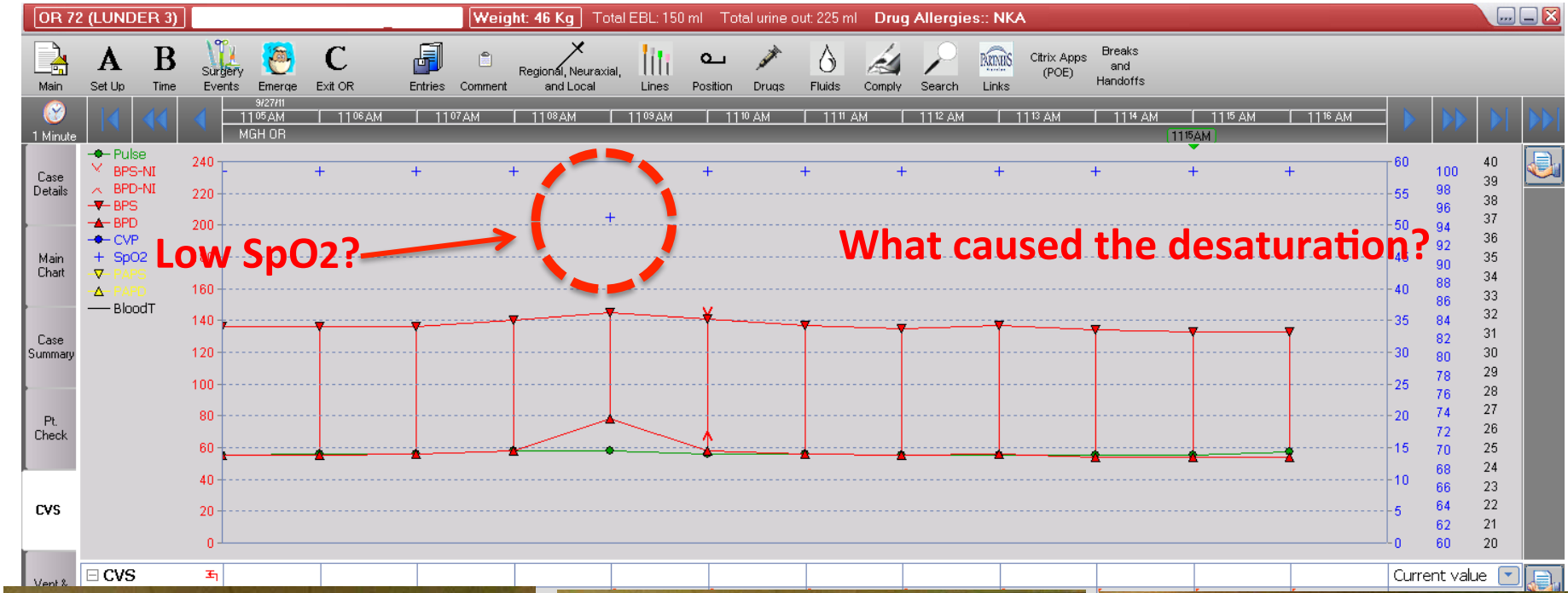
PCA Safety

See
http://mdpnp.org/MD_PnP_Program___Clinical_S.html

Assembling a smarter PCA system seems easy

Do you have one in your hospital?
Let's examine the challenges …

NIBP-SpO_2 Interaction



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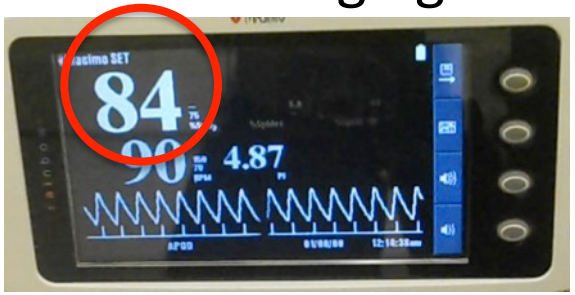
Clinical Requirements:

- Means for smart PCA algorithm ("system") to know if pulse oximeter and NIBP are on same limb (context)
- System should have real-time NIBP cuff inflation status to filter unreliable data
- Want pulse oximeters to be interchangeable? Need standardized data communication
- What else?

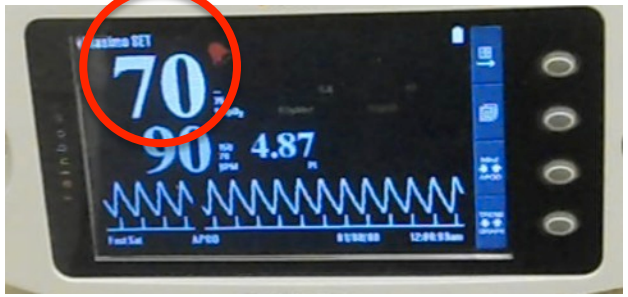
Pulse Ox is set to:

16 sec averaging time



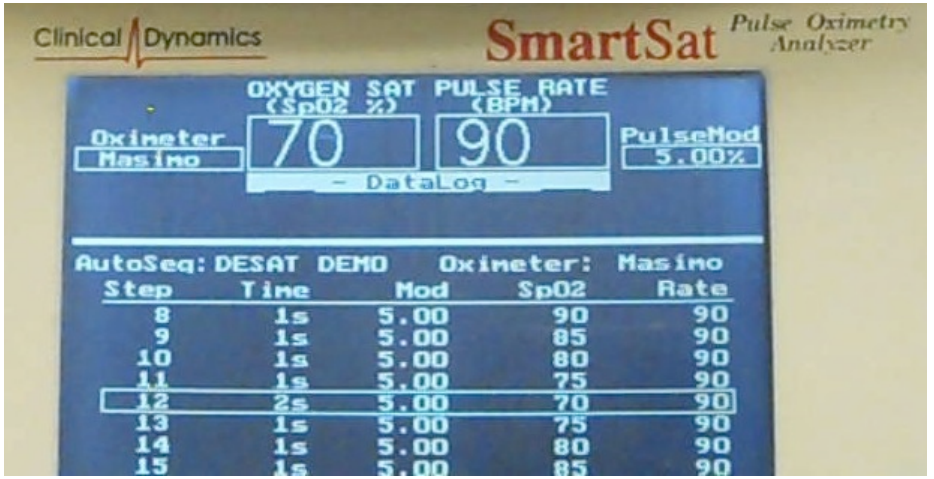
8 sec averaging time

2 sec averaging time



Effect of averaging time: What is the real O_2saturation? Which value will be sampled?

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



Pulse Oximeter averaging time must be known to interpret transient desaturations (e.g. Apnea Hypopnea Index for sleep apnea dx)

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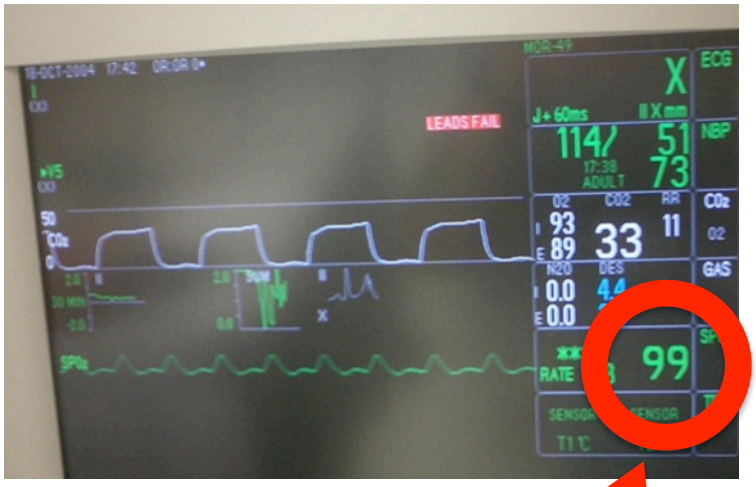
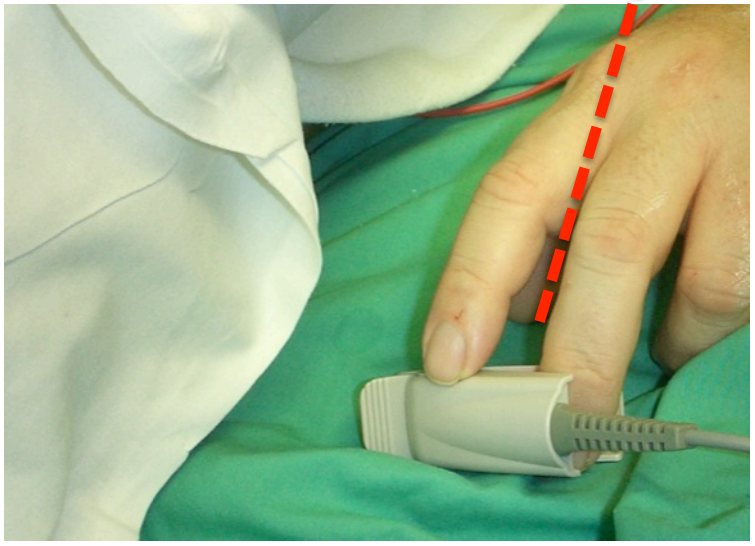
Clinical requirements:

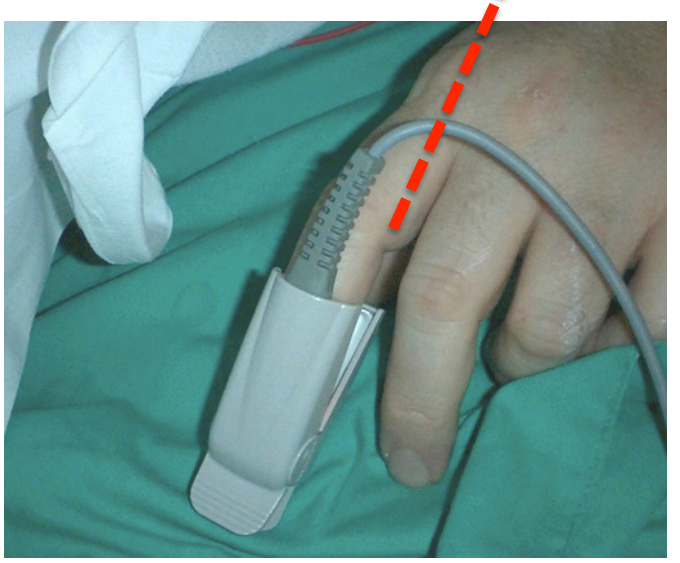
- Pulse oximeter should send averaging time settings (state) to smart PCA algorithm
- Should the pulse oximeter be capable of permitting averaging time to be adjusted by supervisory system?
- Note: Clinical requirements are used by engineering development team to design the system and the interoperability capabilities to be useful and not introduce new hazards (if possible)

Mis-applied probe hidden under bed sheet



Corrected probe application





Pulse Oximeter could communicate standardized signal metrics to help identify this state

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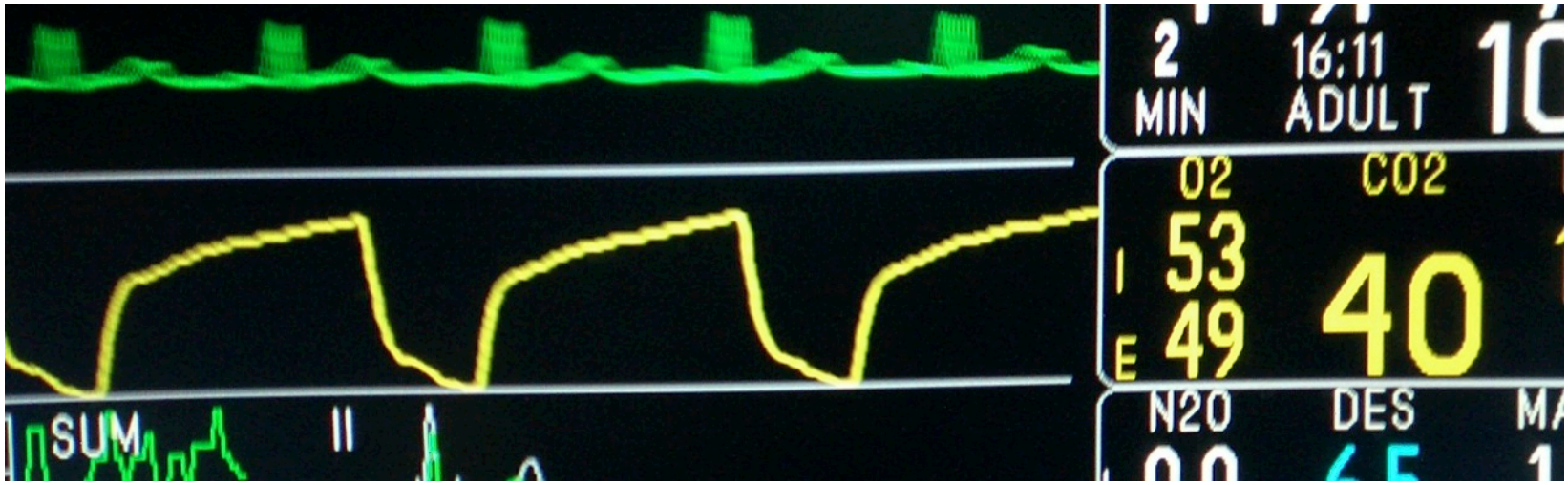
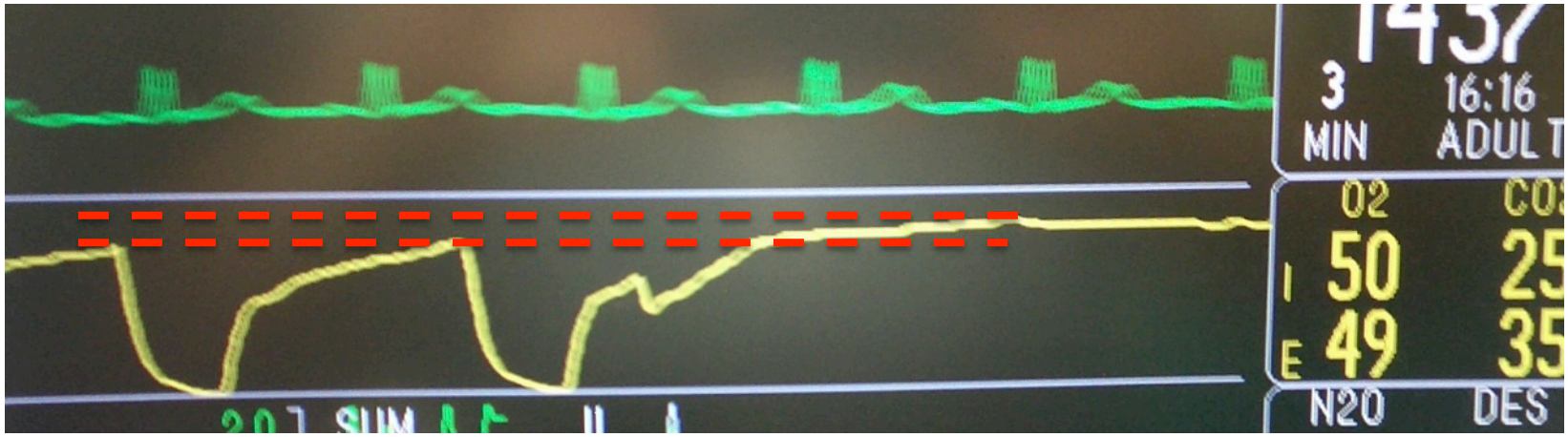
$ETCO_2$ appears to be 40 mmHg



Pausing the ventilator shows that $ETCO_2$ measurement was not representative of alveolar sample



Capnography analysis can identify steep alveolar plateau – analytic module can be part of ICE

Clinical requirements:

- Exhaled breath morphology should be used to assess quality of derived value
  - E.g. steep “alveolar plateau” may under-represent true physiological value

Pulse-rate counting error due to atypical plethysmogram.
Other monitor data could be used to detect and reject this error.
Waveforms could be recorded to enable manufacturers to improve device algorithms.

Result: False alarms, incorrect data in permanent record and used for PCA.

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Clinical requirements:

- Orthogonal measurements could be used to assess pulse rate signal reliability
- Plethysmogram (waveform) should be recorded to enable algorithm improvements
- Consider - better signal processing algorithms could be developed and shared as interchangeable components

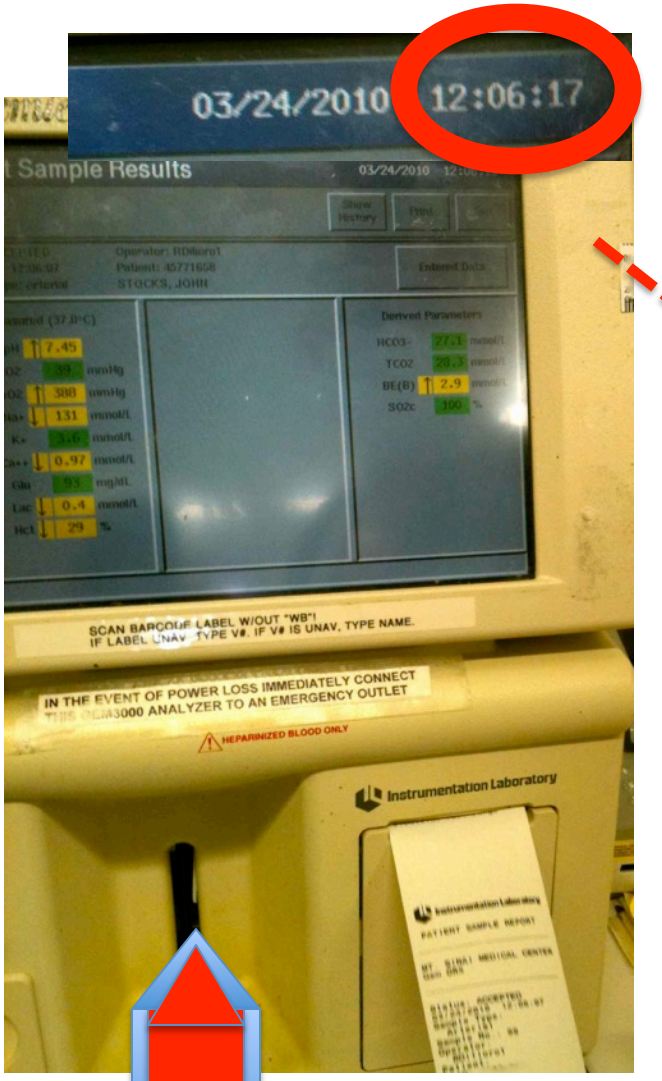
Medical devices

A ticking time-bomb

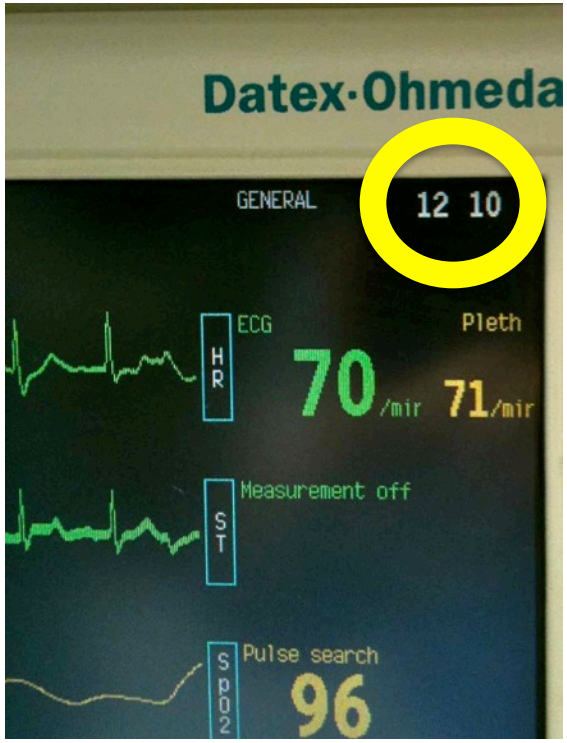
May 23rd 2012, 10:46 by M.H. | SEATTLE

The Economist

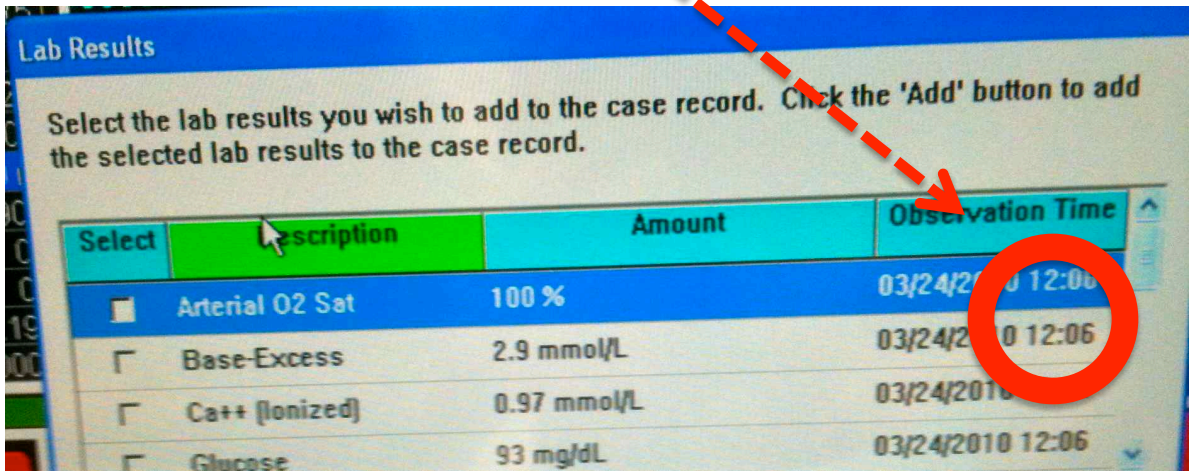
A MAN with one clock knows what time it is, goes the old saw, a man with two is never sure. Imagine the confusion, then, experienced by a doctor with dozens. Julian Goldman is an anaesthetist at Massachusetts General Hospital in Boston. Like many modern health care facilities, it has become increasingly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



Blood gas analyzer in OR



EMR time stamp error



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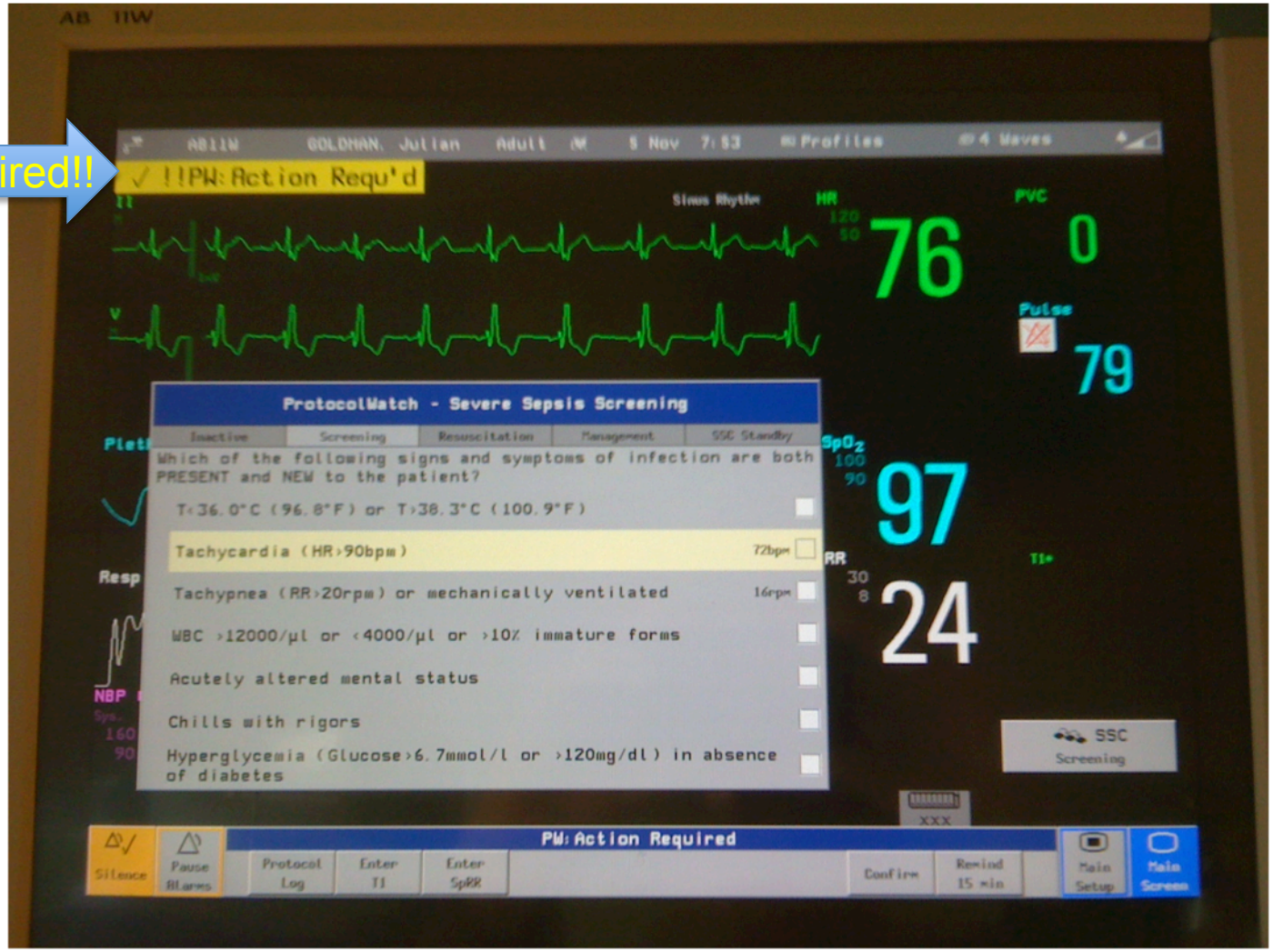
Clinical requirements:

- Components of the smart PCA system should have the correct clock time for enable accurate data alignment for clinical use and system failure analysis
- Devices should set their clocks using a standardized time reference
- PCA system could provide the correct time to each device over the network
- In each example, ask “what are the implications of not meeting these requirements”

A system engineering perspective is essential to identify and apply clinical requirements

“Protocol Watch: severe sepsis screening”



Nuisance alarm … all day and night

Algorithm did not have access to: temp, white bc, glucose, …

Innovative algorithm, but requires connectivity and context to personalize

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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

- **Funded Collaborators:**
  - Massachusetts General Hospital (Julian Goldman P.I.)
  - Anakena Solutions, California (Michael Robkin)
  - DocBox Inc, 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)

An HHS ONC Health IT SHARP affiliated program (by MOU NIH-ONC)

Quantum "Clinical Scenarios"

1. **PCA Safety Interlock:** example of component-level medical device interoperability to improve safety of medication infusions; multi-parameter "smart alarms"
2. **ICU preparedness:** example of ability to support safer in-hospital patient transfer & dynamic checklists to reduce errors
3. **Tele-health** devices in hospital: example of transferring care from home to hospital and use of devices for high-acuity care
4. **FDA regulatory/Safety:** sedation for G.I. procedure as a framework for levels of interoperability and associated levels of hazards and their mitigation


Monitor
Smith, Dana
87
94
30
36.4
130/88

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

What could be accomplished 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

Testbeds:

Non-clinical ←→ Clinical

Non-Clinical Lab Medical CPS ICE Testbed

- Resource Development: Devices, tools, simulators, SMEs
- Test at component level
- Test at system level
- Data and workflow simulation
- Assess compatibility with other devices and networks
- Assess security

Initial Applications:

- MD PnP lab "Virtual Hospital" for Smart America CPS Testbed Challenge
- Device and system verification prior to MGH deployment

Clinical Environment ICE Testbed

Use Clinical Testbed to <u>study</u>:

- New sensors
- New actuators
- Pharmaceuticals
- Care pathways
- Decision support tools
- Clinical studies that require the testbed
- <u>Validate</u> apps and
- Identify GAPS in existing tools and technologies
- Introduce CS&E to clinical environment

Initial Applications (MGH pilot):

- Data fusion (Neuro)
- Smart alarms
- Closed-loop medication administration

Example of CPS Themes:

1. Time synchronized clinical + device data recording
2. Data fusion and patient context (state); app interactions
3. Command & Control in system-of-systems

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OpenICE™

OPEN ICE PLATFORM
TO CLOSE THE LOOP ON SAFETY

ICE – Integrated Clinical Environment

OpenICE™

- OpenICE encompasses
  - Medical Device Interfaces
  - Patient Simulation
  - HIS Connectivity
  - Safety Assurance
  - Validation and testing
  - Regulatory Pathway
  - ICE Application eXchange (ICE AX)
    - Med apps, device management
- Everything is open source
- OpenICE™ is a work in progress
  - Now at an initial beta level of development
  - Currently has useful pieces for clinical and CS research

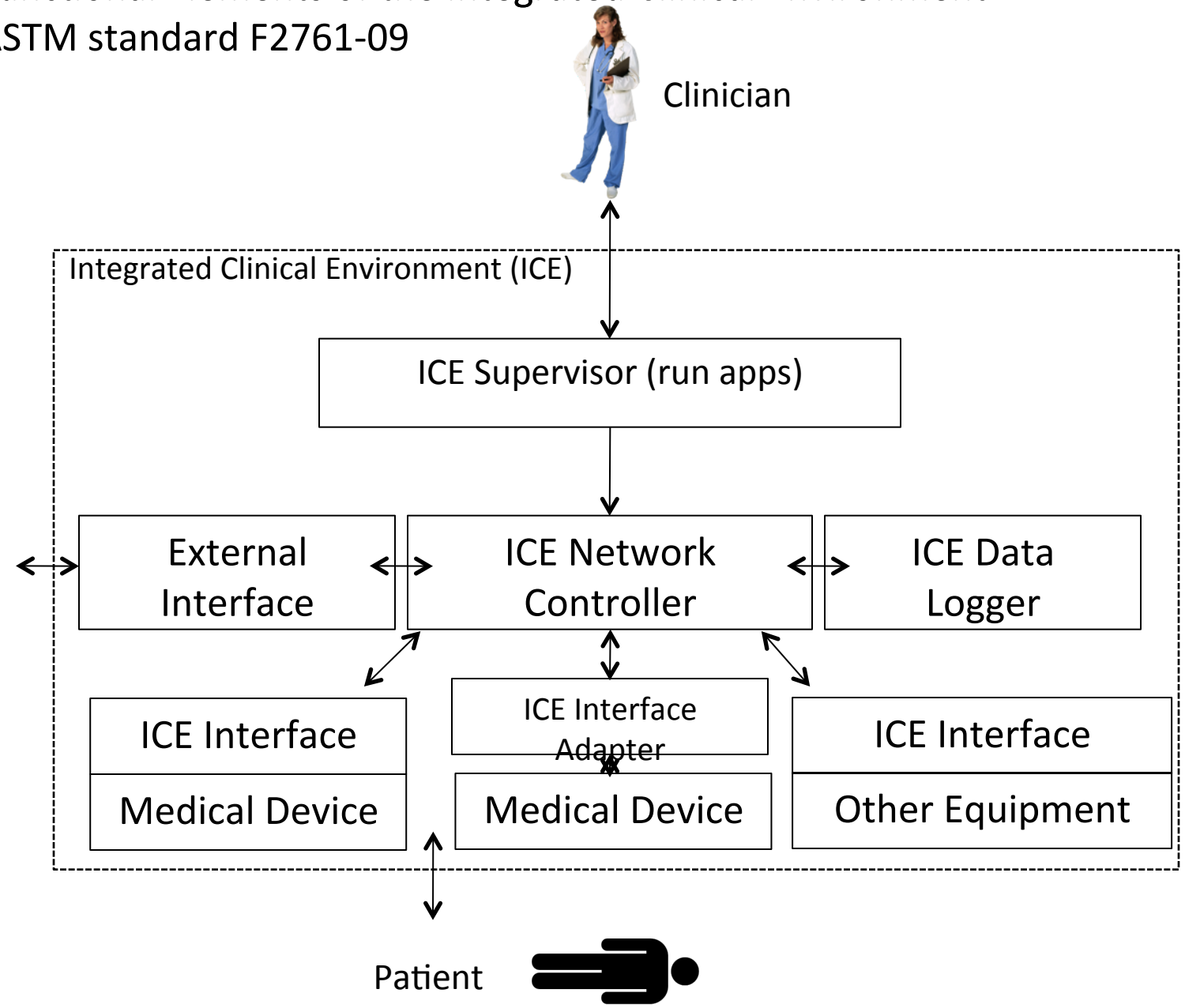
Standard for the "Integrated Clinical Environment" ASTM F2761-09

"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

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

Functional Elements of the Integrated Clinical Environment
ASTM standard F2761-09



http://mdpnp.org/mdice.html

MD PnP | Medical Device "Plug-and-Play" Alpha

MD PnP | Medical Device "Plug-and-Play" Interoperability Program

Brought to you by: dasf, davearney, jeff-mdpnp, jmgoldman

Browse Commits
Fork

Branches
master
csr_acks
javapsm
newnaming
tkt49

Tags
0.0.2
0.0.3
0.0.4
0.0.5
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0.1.1
0.1.2

Tree [ad626e] master / devices / Download Snapshot History

RO HTTP Read Only access git clone git://git.code.sf.net/p/mdpnp/code mdpnp-code

File	Date	Author	Commit
common	4 days ago	jeffplourde	[e58995] additional options for some utilities
cpc	2013-10-02	jeffplourde	[85adbf] TEMP is to tenth of degree C and IBP has no label
draeger	2013-09-19	jeffplourde	[aa808f] Overhaul of Medibus and AbstractDraegerVent to ...
fluke	2013-09-03	Michael Szwaja	[d8e365] The application is now single threaded, and inc...
masimo	2013-04-18	jeffplourde	[654536] remove eclipse .classpath and .project files
mindray	2013-10-03	jeffplourde	[ec7c9a] Merge branch 'master' of ssh://git.code.sf.net/...
nellcor	2013-09-19	jeffplourde	[de8665] tabs to spaces; need to do this globally
nonin	2013-09-19	jeffplourde	[a1fdd2] See ticket #124. Reduced threads by giving the...
oridion	2013-10-10	jeffplourde	[f1a61d] Refactors several things to allow an RS232 Inte...
philips	4 days ago	jeffplourde	[93f02c] moved NetworkLoop to common project. no longer...

Defining Interoperability

- *"The ability of two or more medical devices and other equipment, which are intended by their manufacturers to exchange information via an electronic data interface (EDI), to safely perform a clinical function with a specific intended use, and in a assembled configuration not necessarily foreseen by the manufacturers."

*Our definition, in press

Gap!

Alignment of healthcare national needs

Federal Advisory Committees (FACAs)
FACA Calendar
Health IT Policy Committee
Health IT Standards Committee
FACA Membership Application

Policy: FDASIA Regulations Subgroup

Meeting Date: Wednesday, July 3, 2013, 12:00 pm to 2:00 pm

Event Type: FDASIA

Web Conference Information

Participate online:

- http://altarum.adobeconnect.com/FDASIA/

Audio:

- US toll free: 1-877-705-2976
- International Direct: 1-201-689-8798

Meeting Materials

- Agenda [PDF - 30.33 KB]
- FDASIA Regulations Issues* [PPTX - 517.84 KB]
- Event Reporting Paradigms* [PPTX - 77.35 KB]

Meeting Audio

0:00:00 / 1:55:56

- Audio [MP3 - 6.64 MB]
- Transcript [PDF - 262.09 KB]

Recommendation #5
Must align national patient safety interests with the use of clinical technology: "HITSA"

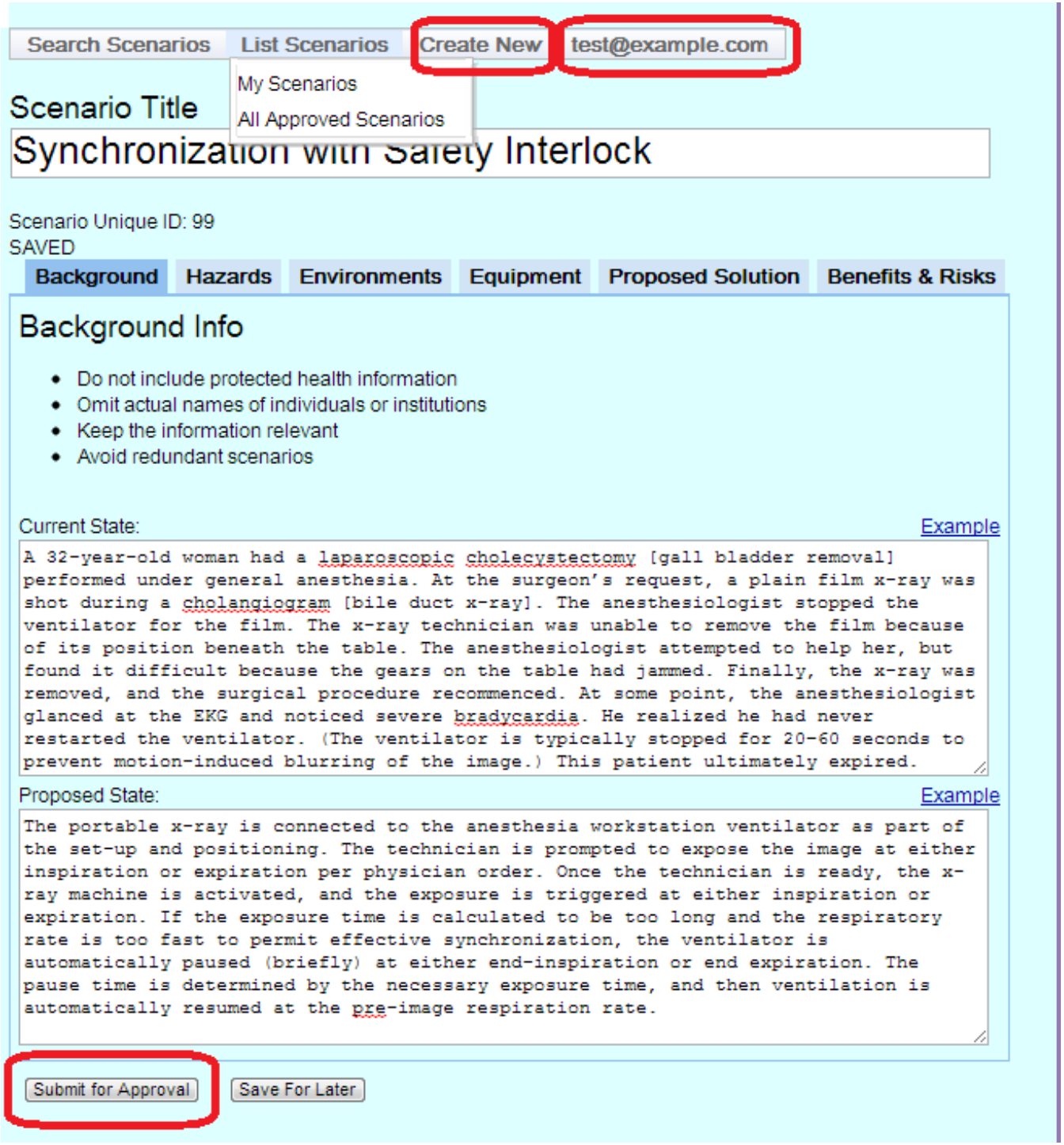
- Need - a national approach for evolving the safety and capabilities of healthcare system technologies
- Centralized reporting, analysis, recommendations, shared solutions. Regulatory enforcement + Market incentives
- Health IT Safety Administration or Board (HITSA) modeled on other national reporting initiatives (NHTSA, ASRS, MedSun, NTSB, ASTERD, PSO, etc.):
  - Adverse event reporting (expanded definition)
  - Include FDA Regulated and non-regulated (IT) devices
  - Multi-stakeholder
    - Regulators, clinical representatives, manufacturers, etc.

http://www.mdpnp.org/HITSA.html

Clinical Scenario Repository (DOD/TATRC)

- **Clinical Scenario**: A brief description of a clinical situation or event that could be improved through better system solutions. The purpose is to inform technical solutions.
- **Clinical Scenario Repository**: A web portal to allow clinicians, clinical engineers and other users to enter, revise and annotate clinical scenarios.

A place to document and share these scenarios will help to identify clinical and technical challenges, address healthcare needs and guide improvements in patient safety and quality of healthcare delivery.



DoD-Funded
"Clinical Scenario Repository" project

http://mdpnp.org/MD_PnP_Program_CS_Reposit.php

Wrap up

1. Big data isn't necessarily better data
2. Need comprehensive logging and analysis – shared nationally
3. PLATFORMS (with actuation)
4. Open-ness and crowdsourcing
5. Passion – make it personal

MD PnP Program of Work Supported in Part By:

- Department of Defense US Army Medical Research and Materiel Command, award numbers W81XWH-12-C-0154 and W81XWH-09-1-0705
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- Department of Defense US Army Medical Research Acquisition Activity, award number W81XWH-09-2-0001
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- National Institute of Standards and Technology, grant number 70NANB10H258

The contents of this presentation are solely the responsibility of the MD PnP Program and do not necessarily represent the official views, opinions, or endorsements of the granting agencies.

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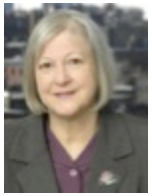
Getting Connected for Patient Safety™

CIMIT
Center for Integration of Medicine & Innovative Technology

MD PnP Cambridge, Mass Team

Julian Goldman, MD
Director, PI



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