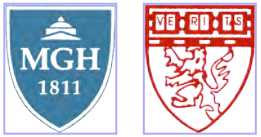

CIMIT

National Forum on the
Future of the Defense Health Information System
Track D: Interoperability
March 25, 2008

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www.MDPnP.org

Standards and Interoperability to Integrate the Clinical Environment for High-Acuity Care

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Medical Device Plug-and-Play (MD PnP) Program
User-Vice Chair, ASTM Committee F29

Problem statement

- It is becoming increasingly clear that many improvements in patient safety, patient care, and healthcare efficiency require systems solutions which cannot be implemented due to the barriers of integrating medical devices and systems, especially in high-acuity clinical settings
- The ability to "integrate the clinical environment" is an essential step to address these issues and create error-resistant systems

*98,000 annual deaths attributable to medical errors
http://www.iom.edu/Object.File/Master/4/117/0.pdf
Ref. IOM/NAE Report 2005: "Building a Better Delivery System"

Why should we be concerned about medical devices?

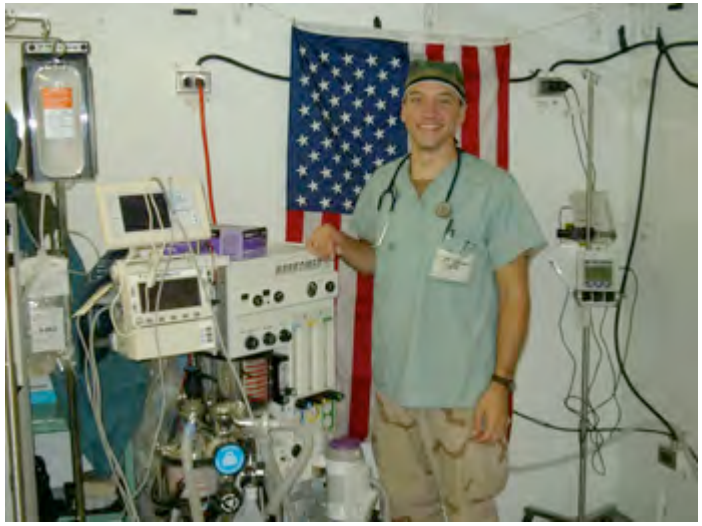
Medical Devices have a unique place in the “interoperability ecosystem” because they bridge Health Informatics and Biomedical Engineering

1. Medical Devices are key data sources (to EMR/CIS etc.)
2. Medical Devices are at the sharp end of patient care. Adverse Events that involve medical devices must be mitigated using medical devices as part of system solutions

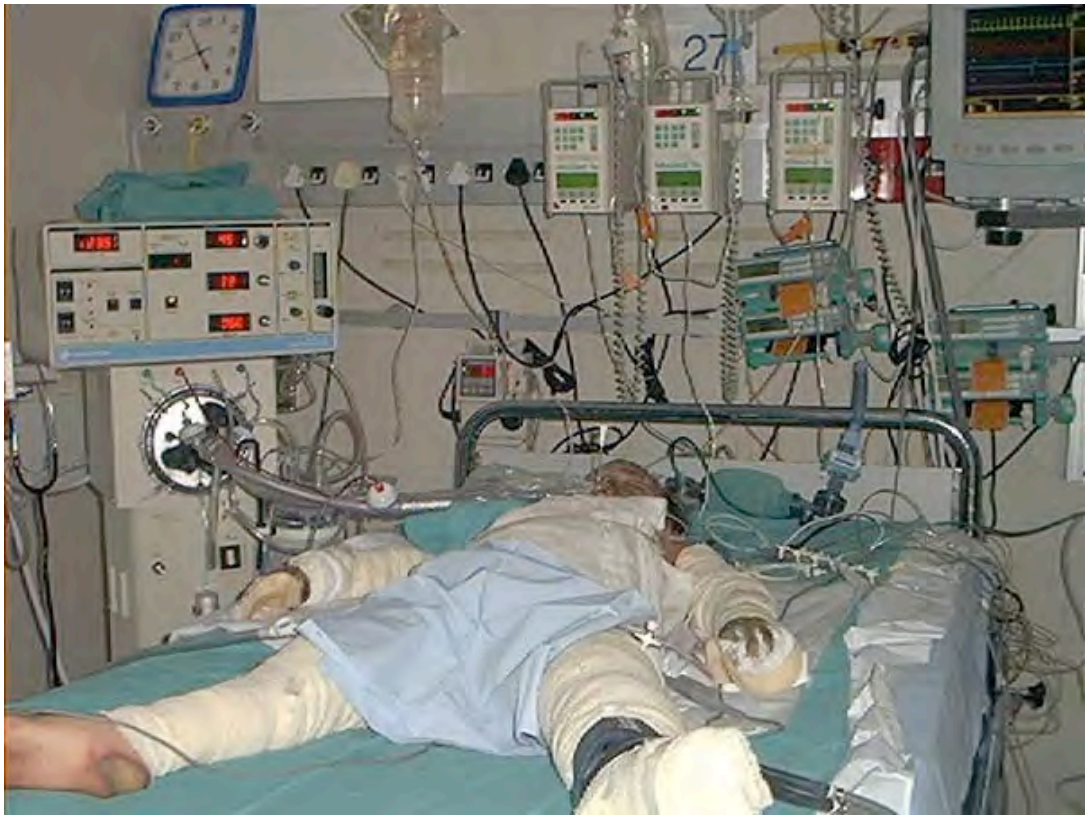
Therefore, healthcare providers need a pathway to build error-resistant systems by implementing and managing solutions that leverage patient-centric medical device systems integration

Current state

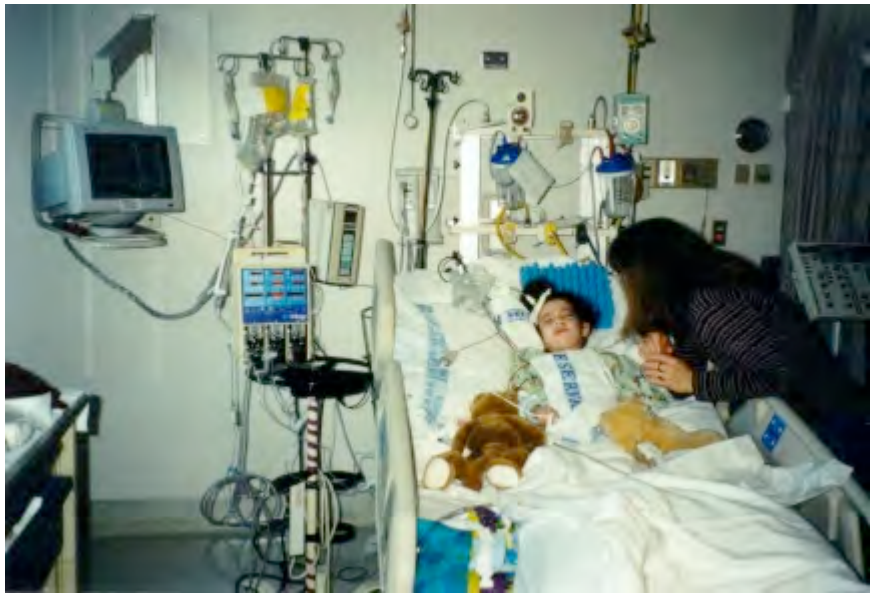
… at the sharp edge of high acuity patient care …

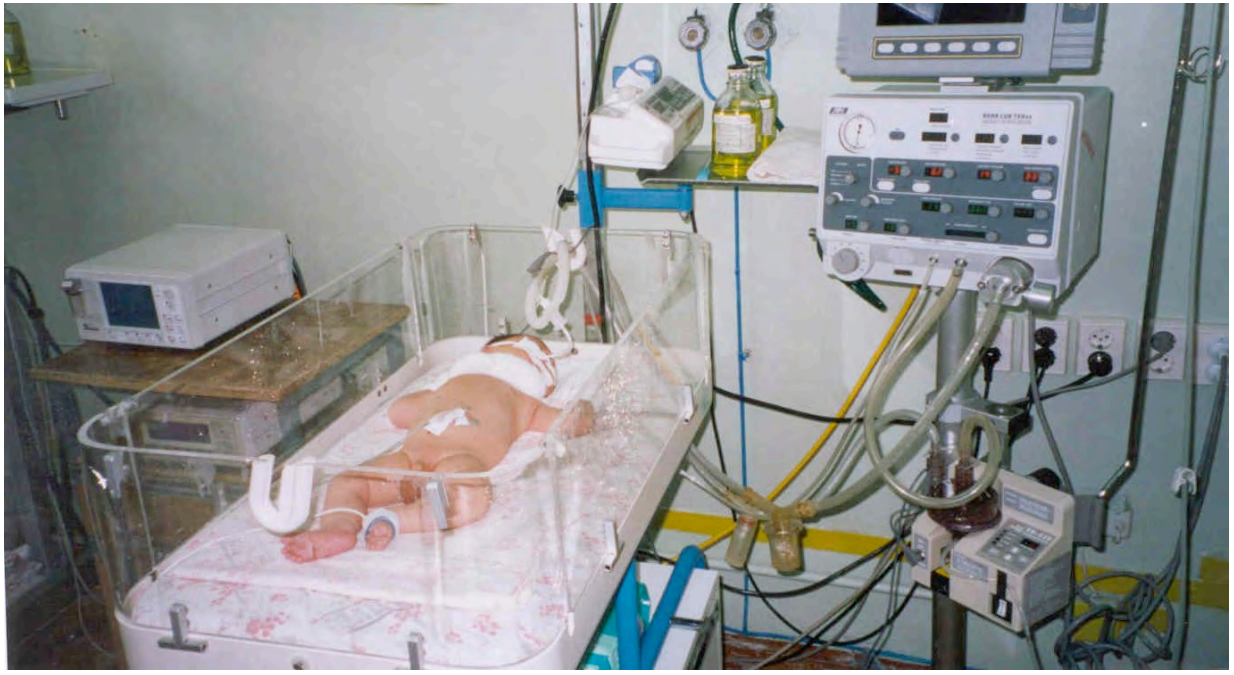


Iraq



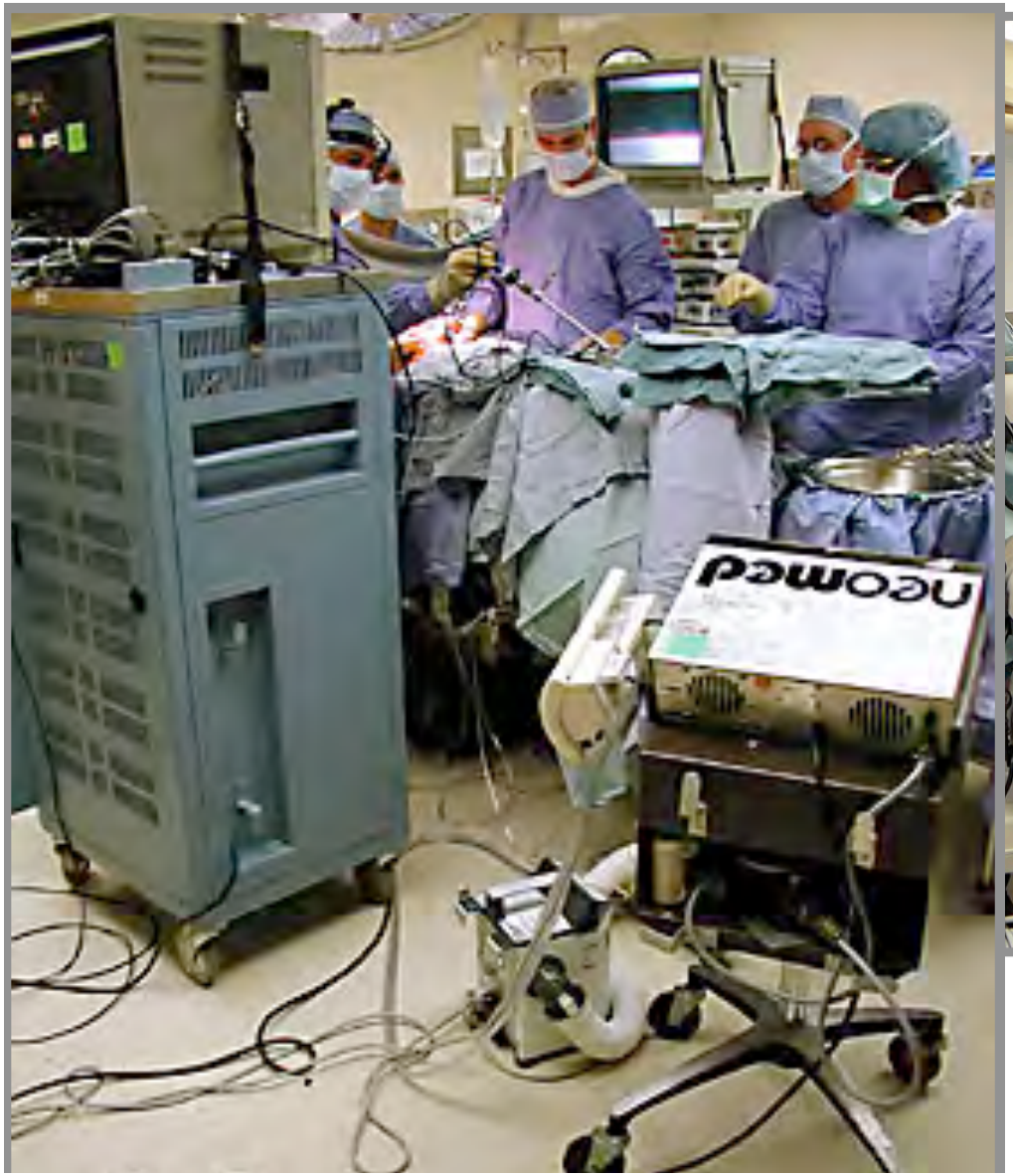
This is the current state

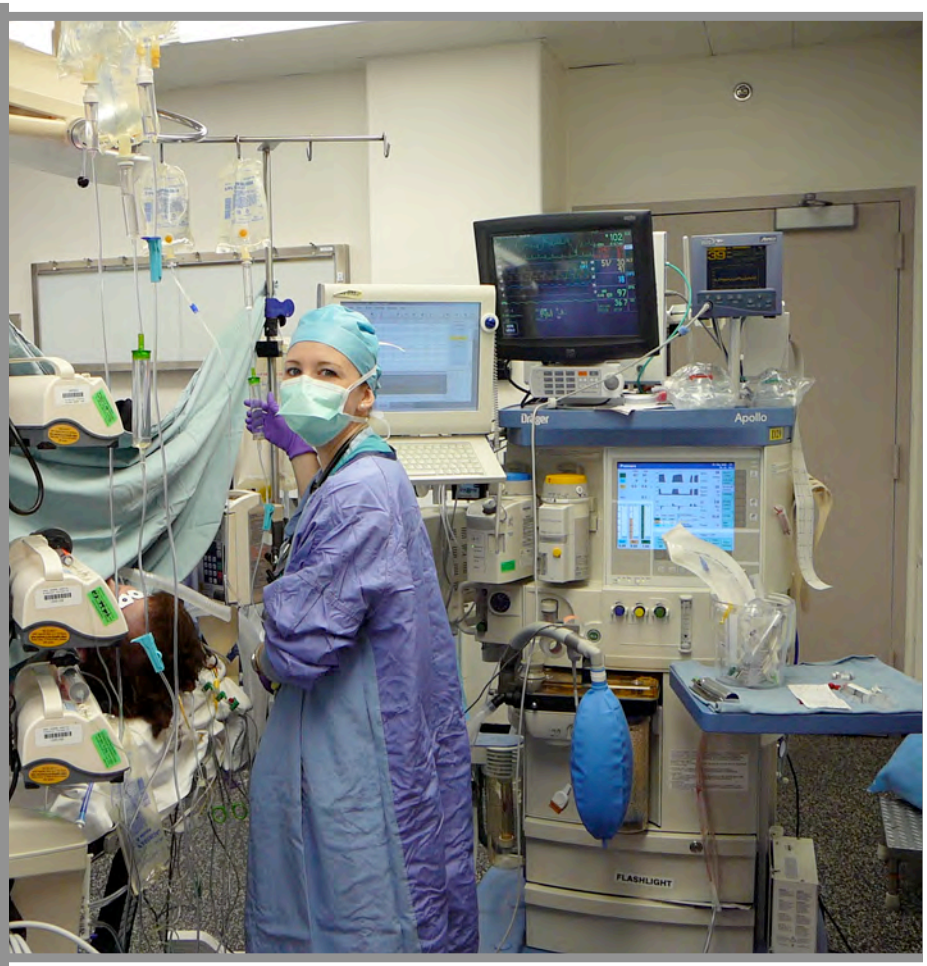




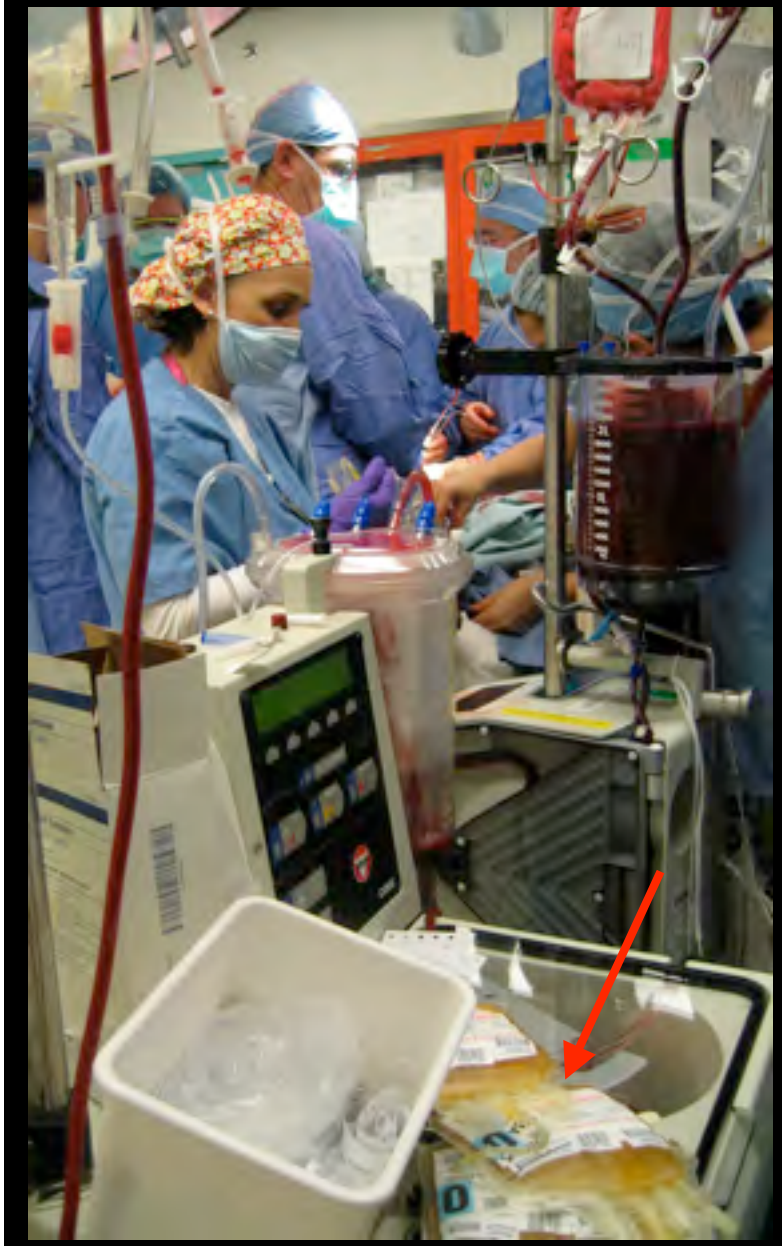
Reality

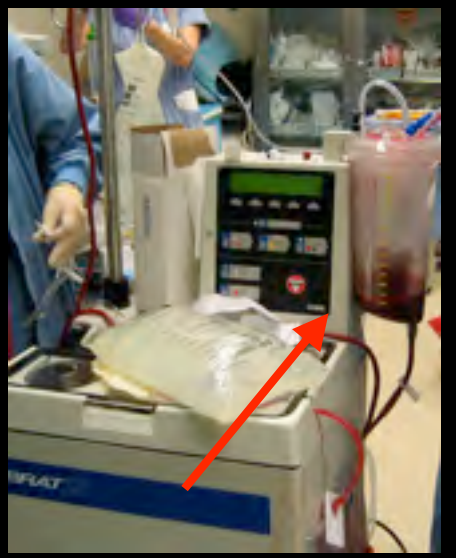
Typical ORs of “today”





High-acuity care today:
How do we prevent errors?
How do we keep track of all this?



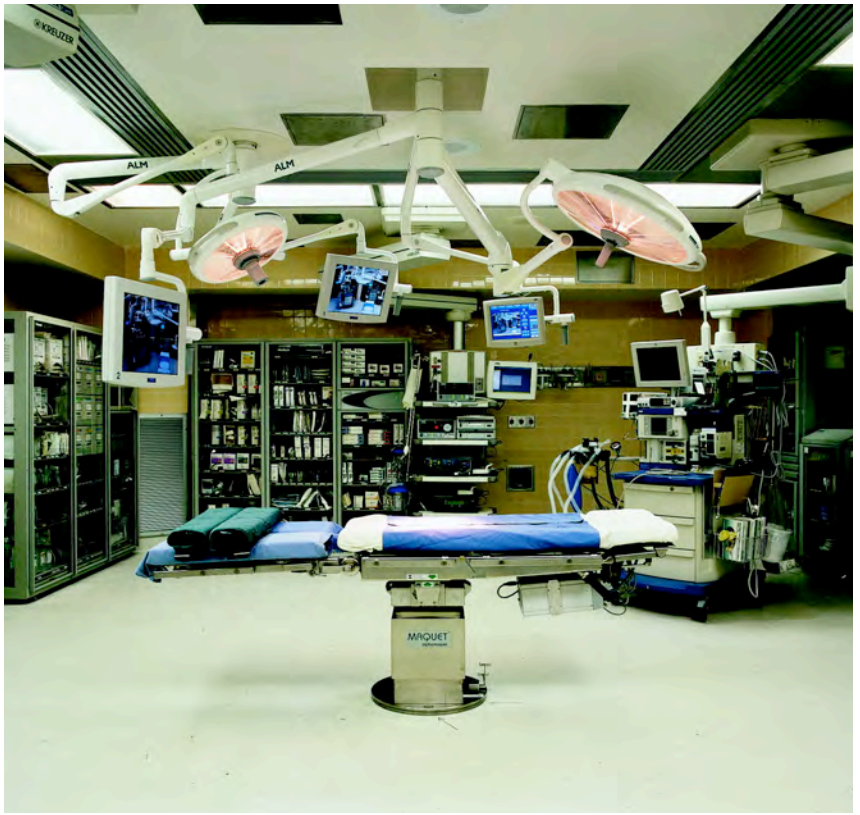


Mass General Hospital/CIMIT
Operating Room of the Future

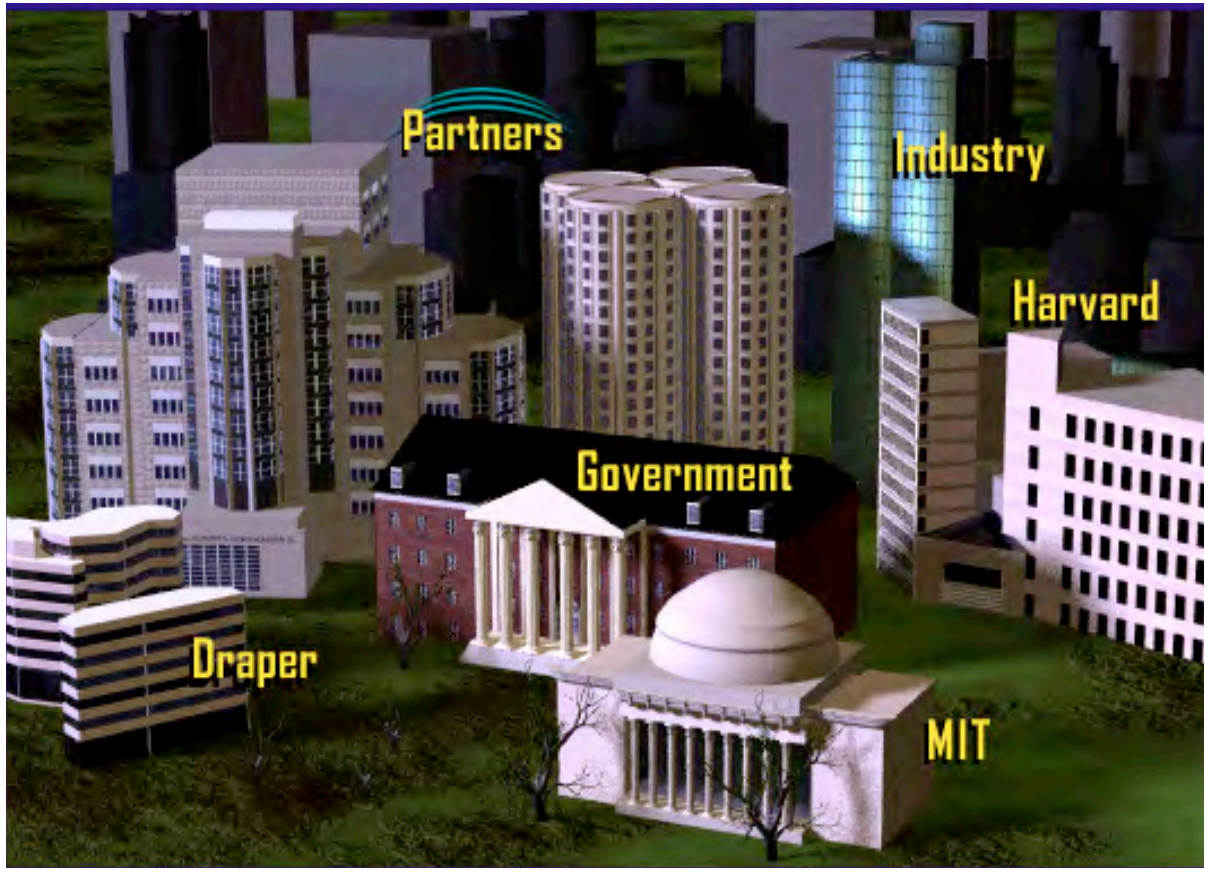
CIMIT/MGH OR of the Future Project

Center for Integration of Medicine and Innovative Technology

The ORF is a “living laboratory” to study the impact of process change, technology, and team work, on safety and productivity.



CIMIT: Center for Integration of Medicine and Innovative Technology



CIMIT Mission: To improve patient care by facilitating collaboration of engineers and clinicians to catalyze development of innovative technologies emphasizing minimally invasive diagnosis and therapy.

Lessons from the OR of the Future: perspective on systems integration

- Comprehensive integration of data from clinical and environmental systems, can prevent errors and inefficiencies across the continuum of care:
  - Smart Alarms
  - Workflow support
  - Safety Interlocks
- Not limited to the OR: in the ICU, ER, home, etc.

Lessons from the OR of the Future: perspective on data integration

- Comprehensive integration of data from clinical and environmental systems, can prevent errors and inefficiencies across the continuum of care:
  - Smart Alarms requires “contextual awareness”
  - Workflow Support requires “closing the loop”
  - Safety Interlocks require system integration
- Not limited to the OR: in the ICU, ER, home, etc.
- *All require seamless connectivity*

Interoperability = Empowerment

- Medical System Interoperability Can Create Healthcare Provider Empowerment
  - Allow healthcare institutions to leverage medical devices and IT systems to solve clinical problems, improve patient safety, and improve efficiency … by providing an infrastructure for innovation to create error resistant systems
- There are no widely adopted standards for point-of-care medical device interoperability!
- Interoperability requires more than standards

Standards <> Interoperability

- **Standards only create the opportunity for interoperability**
- **True interoperability requires…**

1. Market viable use cases (a real need for interoperability)
2. A Standard or collection of Standards to enable the use cases
3. Business conditions that support interoperability
4. Interoperability Guidelines that describe how to use the Standards to achieve interoperability
5. Interoperability compliance testing (formal and/or informal)
6. Enabling technology
7. Promotion (marketing, education, conferences, evangelists)

Credit: D. Whitlinger, Intel/Continua Health Alliance

Examples of clinical procedures that could benefit from integration of medical devices to address system safety issues ->

(From the MD PnP Program's "Clinical Scenario Database")

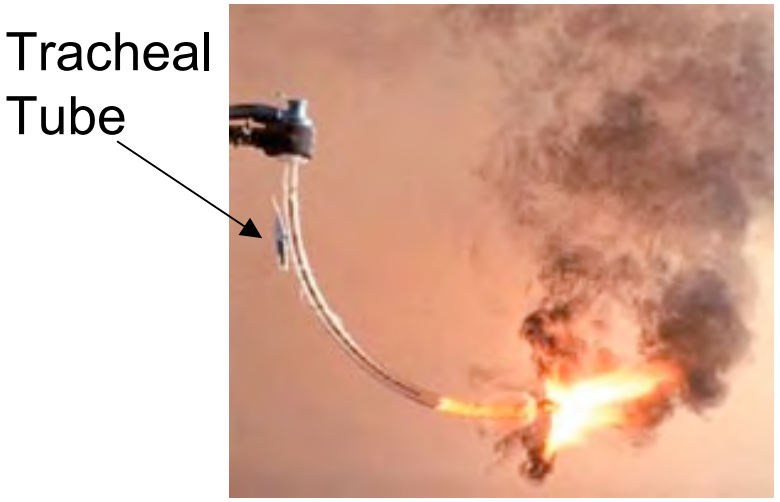
Scenario: Surgical Fires

- ASA Closed Claims Analysis of Burn Injury in the OR

Source: ASA Newsletter, June 2004

Airway Laser + O_2 -> Fire

- High inhaled O_2 concentration typically used for anesthesia
- But, O_2 enriched respiratory gas supports combustion, especially > 28% *
- Therefore, surgical team must “remember” to minimize O_2 prior to laser use in the airway



* ISO/TR 11991:1995

Airway Laser-O_2 Interlock

- Measure O_2 during anesthesia
- Warn surgeon and prevent activation of airway laser if inspired O_2 > 28%

Tracheal Tube

Solution requires connecting laser equipment and anesthetic equipment / O_2 monitor

NOT Commercially AVAILABLE

(initially proposed in 1990s by Sem Lampotang, PhD, Univ. of Florida, Gainesville

Scenario:
Failure to ventilate #1

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

- Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.
- Anesthesiology. 87(4):741-748, October 1997
- "… 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

NOT AVAILABLE

← and →

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

Requires contextual data to activate smart alarm

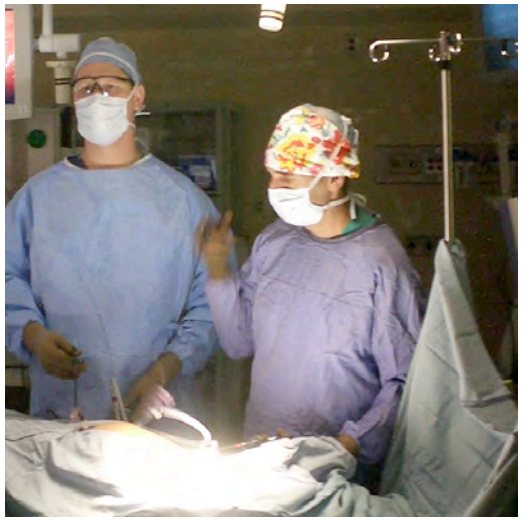
Scenario:
Failure to ventilate #2

Example: Cholecystectomy (Gall Bladder removal) w/ intraop cholangiography

Workflow: 1) Ventilation is stopped. 2) Intraoperative cholangeography (bile duct x-ray) is performed with contrast to identify internal structures.

No breath -> No lung movement. Helps achieve better x-ray quality.

X-ray



Ventilator

"With the advent of sophisticated anesthesia machines incorporating comprehensive monitoring, it is easy to forget that serious anesthesia mishaps still can and do occur."

APSF Newsletter Winter 2005

A 32-year-old woman had a laparoscopic cholecystectomy performed under general anesthesia. At the surgeon's request, a plane film x-ray was shot during a cholangiogram. The anesthesiologist stopped the ventilator for the film. The x-ray technician was unable to remove the film because of its position beneath the table. The anesthesiologist attempted to help her, but found it difficult because the gears on the table had jammed. Finally, the x-ray was removed, and the surgical procedure recommenced. At some point, the anesthesiologist glanced at the EKG and noticed severe bradycardia. He realized he had never restarted the ventilator. This patient ultimately expired.

What are the “root causes”?

- Inadequate alarms?
- Inadequate vigilance?
- *At its root, this is a system problem, because the ventilator never should have been turned off…*

Solution - don't turn off ventilator: synchronize x-ray with ventilator

NOT COMMERCIALLY AVAILABLE

Synchronize or "gate" x-ray to expose image at end of expiration. May require integration of x-ray and ventilator to briefly pause ventilator (under operator control) if respiratory rate is too high to sync. (Similar approach useful for CO and CVP measurement.) Consider: Is it safer to add pause capability or to maintain the status quo (reliance on operator memory)?

Solution has been demonstrated in MD PnP Lab

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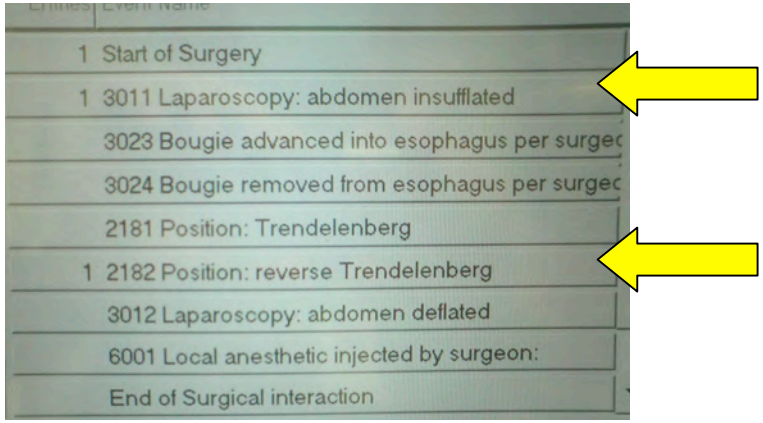
Medical Device “Plug-and-Play” Interoperability Lab at CIMIT
Cambridge, MA
Opened May 2006
Photos includes collaborators from MGH, U Penn, and LiveData)

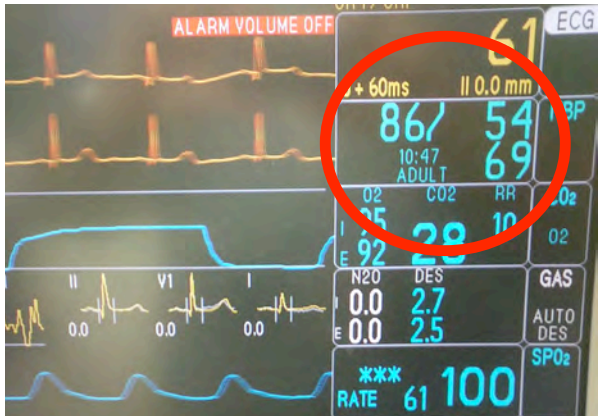
Ventilator - Xray Simulation at ASA Scientific Exhibit
October 15, 2006

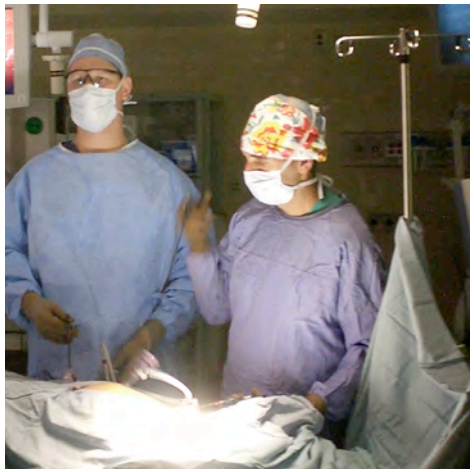
Scenario:
Detect/Prevent Hemodynamic Instability from Pneumoperitoneum (Insufflation) during Minimally Invasive Abdominal Surgery

The Problem: Insufflation-induced hemodynamic instability:

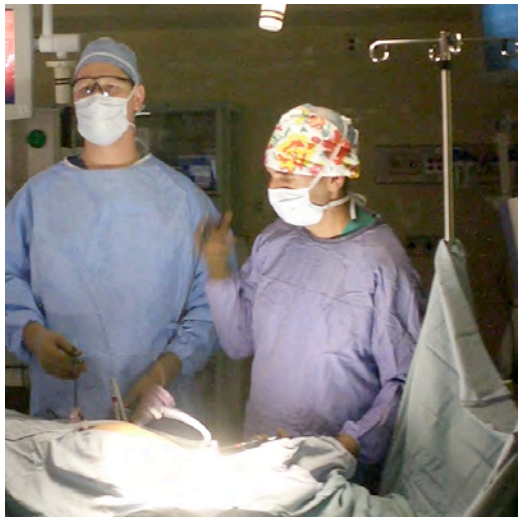
Initial insufflation of CO_2 into the abdomen (peritoneal cavity), especially combined with head-up table tilt ("reverse Trendelenburg Position"), may severely decrease blood pressure and heart rate.







Surprisingly, the occurrence of insufflation-induced bradycardia (low heart rate) and hypotension (low blood pressure) are well known:



Cardiopulmonary complications during laparoscopy: two case reports

South Med J. 1995 Oct;88(10):1072-5

"The first case describes a patient who developed bradycardia and asystole [cardiac arrest] during insufflation for a laparoscopic hernia repair."

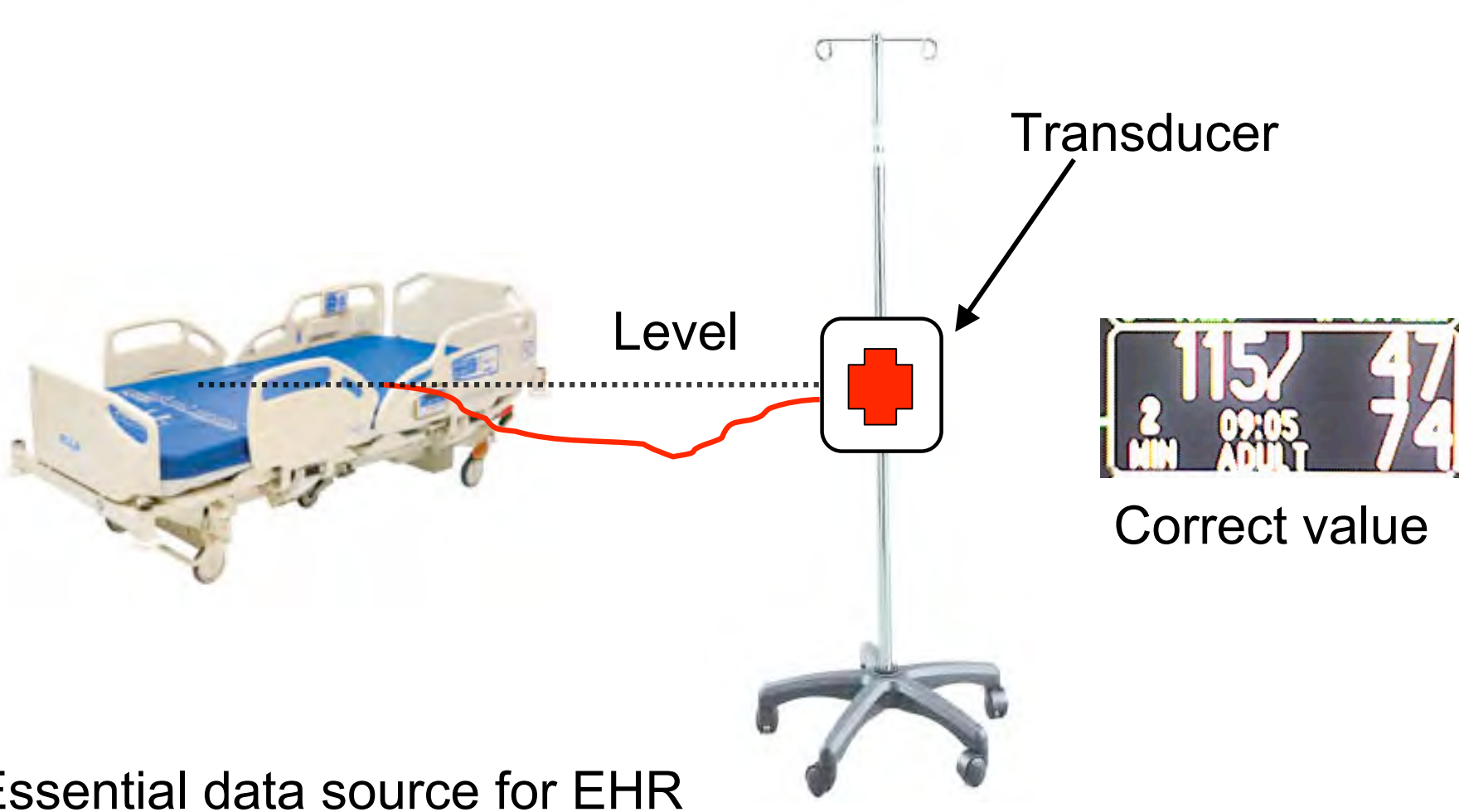
Laparoscopic Gall Bladder Surgery:

What can we do to improve safety?

- Integrate surgical and anesthetic devices to provide:
  - 1. Safety interlock: “can’t insufflate if BP and ECG not actively monitoring”
  - 2. Smart alarms: Contextual information permits high sensitivity and specificity of clinical alarms (to detect HR and BP changes)
    - 70% of anesthesiologists disable alarms
  - 3. Activate NIBP measurement: Trigger BP measurement upon insufflation + table tilt

Scenario: Blood Pressure Measurement Errors

Invasive BP Measurement

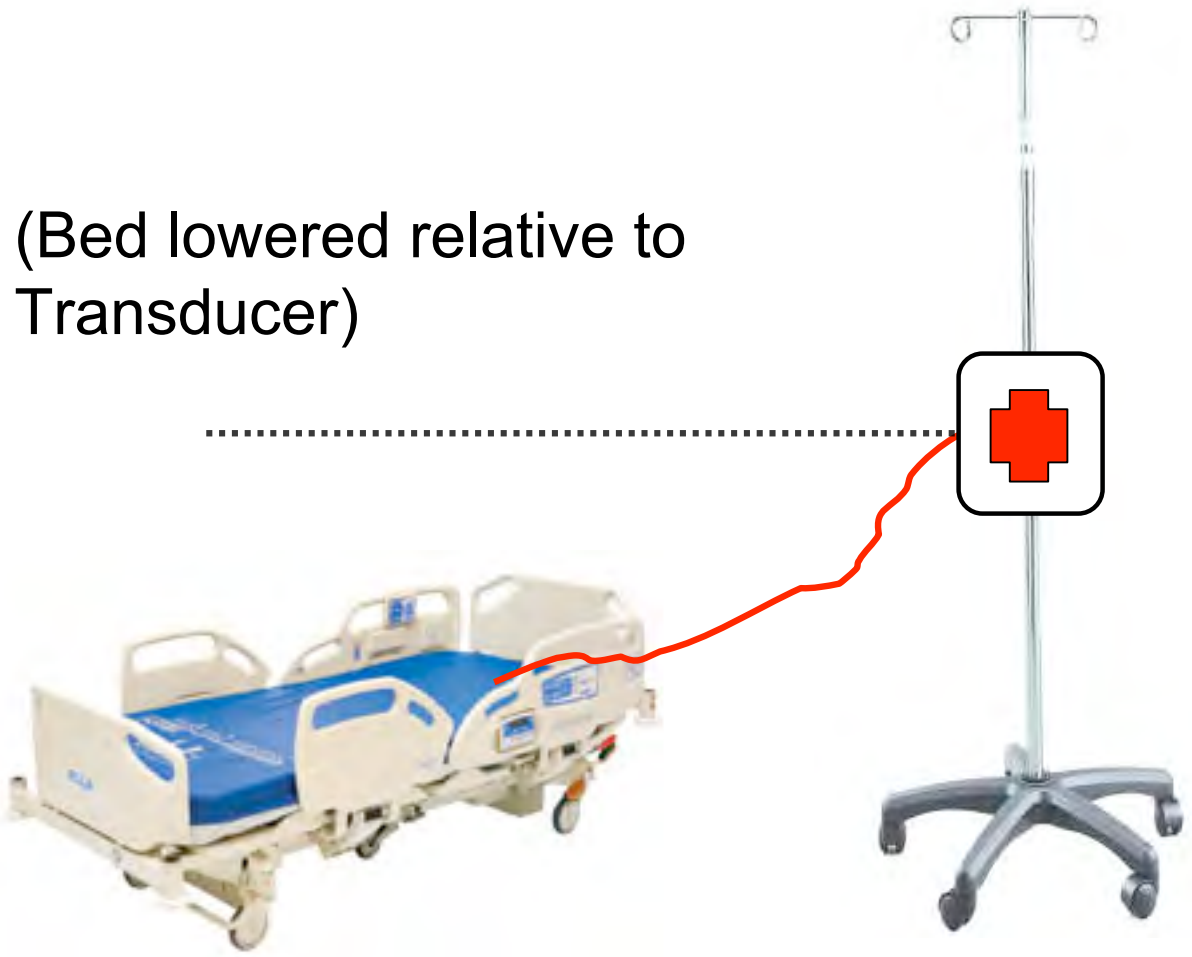


Correct value

Essential data source for EHR

Invasive BP display error

(Bed lowered relative to Transducer)



Error: too low

This offset can introduce > 50% measurement error!

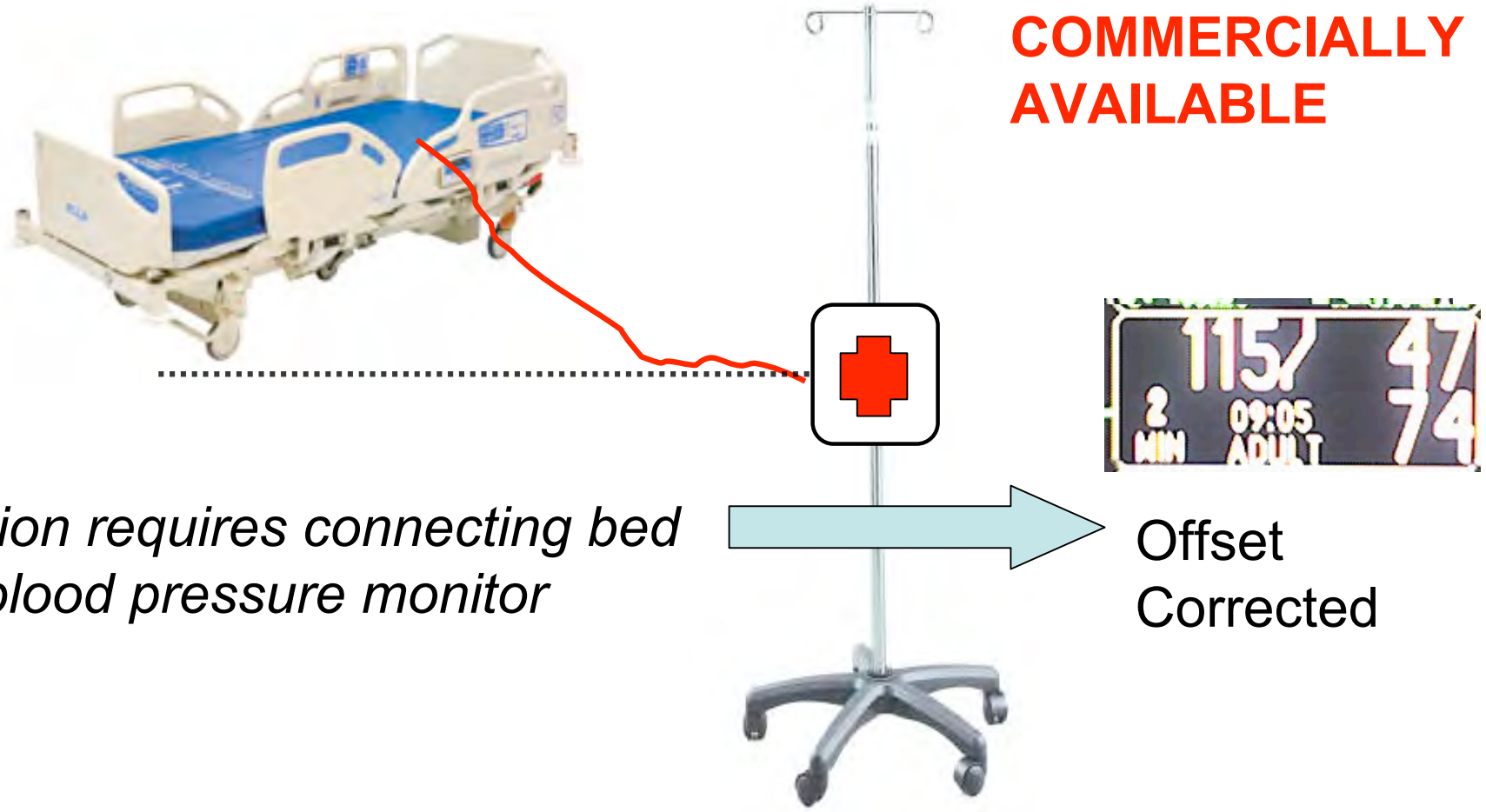
BP Measurement Error

- Acta Anaesthesiol Scand. 2006 May;50(5):600-3: "Practical sources of error in measuring pulmonary artery occlusion pressure (PAOP)

- "When PAOP values were adjusted for the differences from the reference transducer level, the median differences from the reference PAOP values were 2 mmHg (-6 to 9 mmHg) for physicians and 2 mmHg (-6 to 16 mmHg) for nurses"

Automatic BP display correction is possible with currently available bed network data (bed reports changes to height and angle)

NOT COMMERCIALLY AVAILABLE



Solution requires connecting bed and blood pressure monitor

Offset Corrected

Solution demonstrated in MD PnP Lab

HIMSS 2007 New Orleans, USA: two clinical scenarios demonstrated

NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Volume 21, No. 4, 61-88 Circulation 80,350 Winter 2006-2007

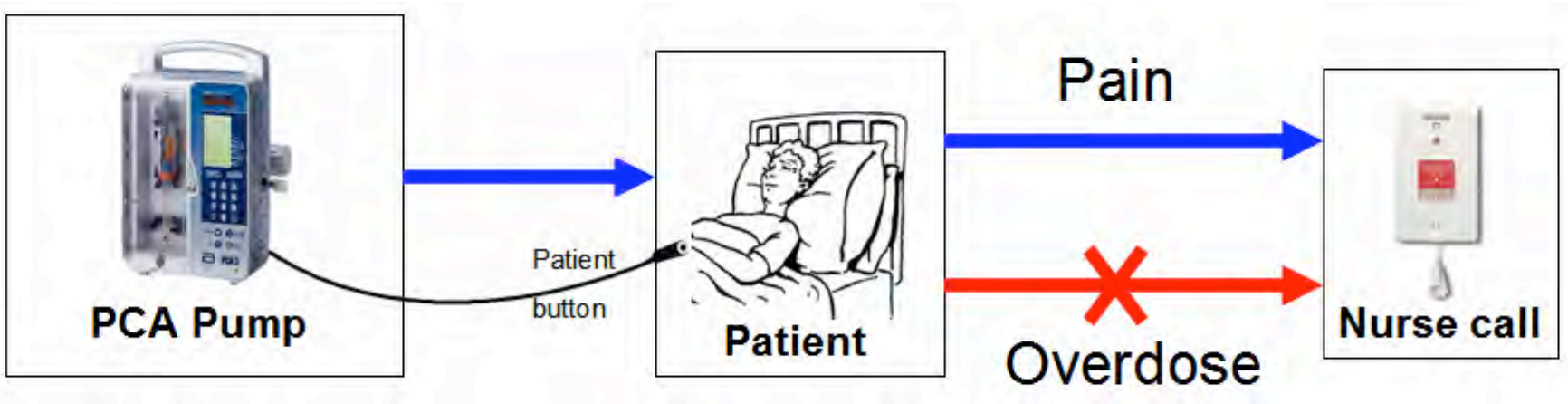
Dangers of Postoperative Opioids

APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications

Based on APSF Board of Directors Workshop
October 2006

Typical PCA System

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



PCA = Patient-Controlled Analgesia

“Not Uncommon” PCA pump scenario

A 49-year-old woman underwent an uneventful hysterectomy... while in the post-anesthesia care unit (PACU), she began receiving a continuous infusion of morphine via a patient-controlled analgesia (PCA) pump.

A few hours after leaving the PACU and arriving on the floor, she was found pale with shallow breathing, a faint pulse, and pinpoint pupils.... The patient ultimately died.

-AHRQ Morbidity and Mortality website

PCA = Patient-Controlled Analgesia

APSF PCA Recommendations

- “We advocate widespread acceptance of the goal that no patient shall be harmed by opioid-induced respiratory depression in the postoperative period.
- Thus, immediately, we urge health care professionals to consider the potential safety value of continuous monitoring of oxygenation (pulse oximetry) and ventilation in patients receiving PCA or neuraxial opioids in the postoperative period.”

APSF PCA Recommendations

- “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.”

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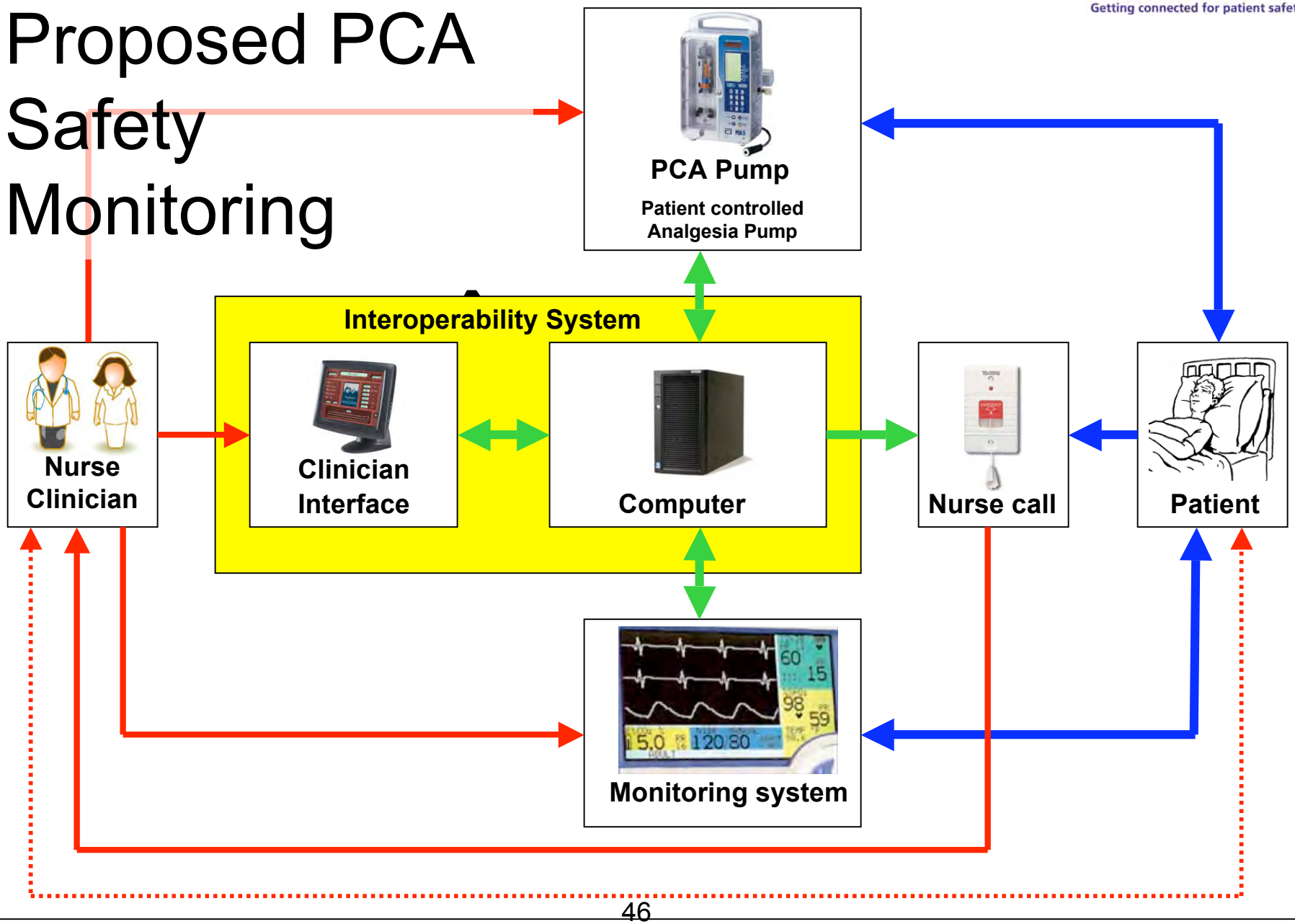
Proposed PCA Safety Monitoring



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

These are elegant solutions!

- Isn't concerning that adverse events that can be predicted from clinical workflow analysis, may be reported in focus groups, and are documented in the literature, but solutions to mitigate these clinical hazards have not been adopted?
- Why are solutions not being implemented?
- Because hospital-implemented "one-off" solutions - especially when integrating medical devices - are frequently complicated and expensive, and there are concerns about safety, regulatory compliance, and liability.
- We need a standardized means to deliver these - and similar -safety-enhancing innovative solutions.

Current State of Med Device Connectivity

- Stand-alone point-of-care devices:
  1. No user-accessible I/O port, or
  2. Legacy (RS-232) I/O, or
  3. Modern I/O but proprietary, or
  4. Rarely, standards based I/O
- And, in best of connectivity scenarios, data set is probably inadequate for use cases

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Overview of the Medical Device "Plug-and-Play" Interoperability Standardization Program (MD PnP)

MGH and CIMIT, with TATRC support, initiated the MD PnP program in 2004 to lead the adoption of open standards and technology for medical device interoperability to improve patient safety.

Four plenary conferences, working group meetings, and clinical focus groups have elicited input to shape the mission and strategy and identify clinical requirements.

Over 70 institutions and > 600 experts (clinicians and engineers) have participated. Many support provider-mandated conformance to interoperability standards.

We learned from the 2004 MD PnP kick-off meeting that key issues must be addressed for adoption of interoperability:

- Must be clinical-requirements based
- Regulatory obstacles were perceived
- Legal concerns in multi-vendor systems
- What is the business case?
- No widely adopted integration standards
- In summary: Interoperability requires many elements to be aligned

Goals of the MD PnP Program

1. Lead the adoption of open standards and related technology to support medical device interoperability
2. Define a regulatory pathway in partnership with the FDA and other regulators.
3. Elicit clinical requirements for the proposed interoperable solutions to maintain focus on patient safety.
4. Use our vendor-neutral laboratory to:
   - evaluate interoperability standards and solutions
   - model clinical use cases (in simulation environment)
   - serve as a resource for medical device interoperability

MD PnP Program Plenary Meetings
2004-2007

- May 24-25, 2004 Kick-Off Symposium: sponsored by TATRC & CIMIT, Cambridge, MA – 84 attendees: 37 from industry, 43 from academic and healthcare institutions, 4 from government agencies
- Nov 15-16, 2004 Second Meeting, hosted by FDA, Rockville, MD – 75 attendees: 31 from industry, 29 from academic and healthcare institutions, 15 from government agencies
- June 6-7, 2005 Symposium: Third Meeting, sponsored by TATRC & CIMIT, Cambridge, MA – 85 attendees: 40 from industry, 40 from academic and healthcare institutions, 3 from government agencies, 2 from engineering societies
- June 25-27, 2007 Joint Workshop on High Confidence Medical Devices, Software & Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability, sponsored by NSF, TATRC & CIMIT, Cambridge, MA – 145 attendees: 38 from industry, 88 from academic and healthcare institutions, 17 from government agencies, 2 from the media. Proceedings published Feb 2008.
- (Presentations are freely available on www.MDPnP.org)

MD PnP collaborators

- and,
- NIST (National Institute for Standards and Technology)
- NSF (National Science Foundation)
- Society for Technology in Anesthesia
- DocBox
- And others …

Conference on "Improving Patient Safety through Medical Device Interoperability and High Confidence Software"

- Co-Chairs: Drs. Insup Lee (Penn) and Julian Goldman (MGH/CIMIT)
- June 25-27, 2007
- Cambridge, Mass. USA
- Combined MD PnP and HCMDSS
- 145 attendees: Federal agencies, FDA, clinical researchers, CE/BMEs, manufacturers
- Proceedings published by IEEE January 2008

Conference: June 2007

Videos from June conference agenda available at http://www.cimit.org/mdpnpjune07/start.htm

Insup Lee, Rob Kolodner, Julian Goldman

Clinical Requirements

- Clinical scenarios are being collected from clinicians and clinical engineers, to assure that interoperability standards and manufacturer-provided solutions will support clinical improvements in safety and efficiency.

Progress is being made …

The Anesthesia Patient Safety Foundation endorsement of interoperability March 2007

"APSF believes that intercommunication and interoperability of devices could lead to important advances in patient safety, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind.

APSF also recognizes that as in all technologies for patient safety, interoperability poses safety and medicolegal challenges as well. Development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety and outcome benefit."

AMERICAN SOCIETY OF ANESTHESIOLOGISTS

ASA BOD STATEMENT ON THE INTEROPERABILITY OF MEDICAL DEVICES

"ASA 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.

ASA also recognizes that, as in all technological advances, interoperability poses safety and medico legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit."

Kaiser Procurement Contract Language
(24 new hospitals planned in USA)
(in use now)

- **Medical Device Plug and Play.** Supplier agrees to participate with Kaiser in the development of a medical device plug and play integration standard (the "Integration Standard"), and … will make reasonable efforts to conform to the Integration Standard when approved and formulated by the parties in writing. Until the Integration Standard is approved, Supplier intends to continue … to provide open interfacing protocols …

(sample text)

“ICE” - Integrated Clinical Environment

- ICE draft standard describes requirements for safe and effective “plug-and-play” integration of devices in high-acuity patient-centric environments to provide an infrastructure for innovation
- ICE incorporates many of the requirements identified by participants in MD PnP program workshops, to support deployment of error-resistant systems capable of mitigating long-standing clinical hazards and improving Adverse Event analysis (per FDA request)
- Prepared by ASTM F29 writing group convened by CIMIT MD PnP Program

Scope of ICE (excerpt)

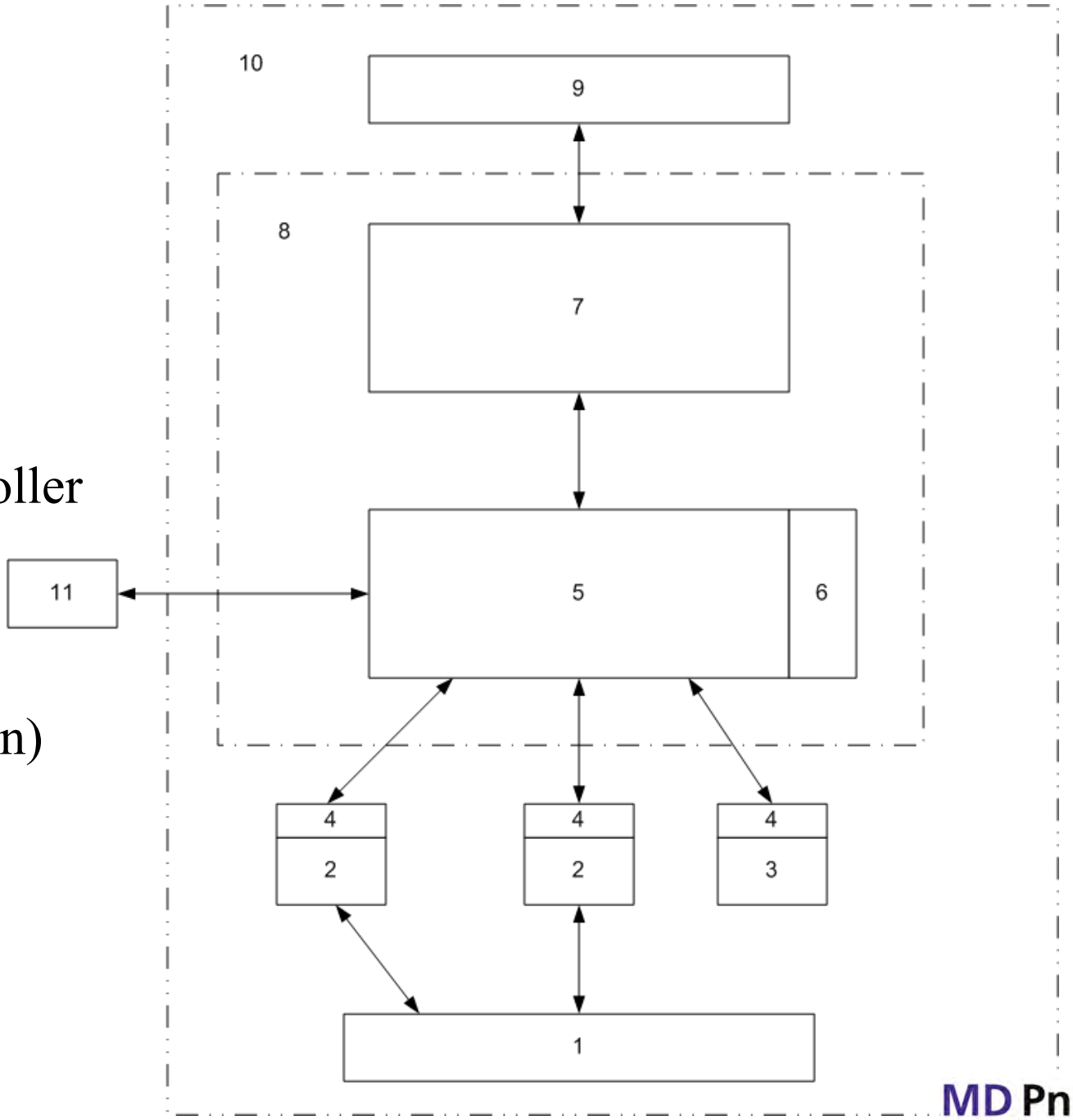
- "This International Standard is … for managing a network of medical devices in a medical system in support of a single patient in the integrated clinical environment (ICE)...
- This standard series establishes the general principles for the design, verification, and validation of a model- based integration system that enables the creation of an integrated clinical environment intended to facilitate cross-manufacturer medical device integration..."

Next slides -> draft functional architecture

Figure 1: Functional Elements of the Integrated Clinical Environment

Key

1 **patient**
2 medical device
3 Equipment
4 ice interface
5 ice network controller
6 data logger
7 ice supervisor
8 ice manager
9 **operator** (clinician)
10 ICE
11 external interface



From ICE Part I NWIP
September 2007

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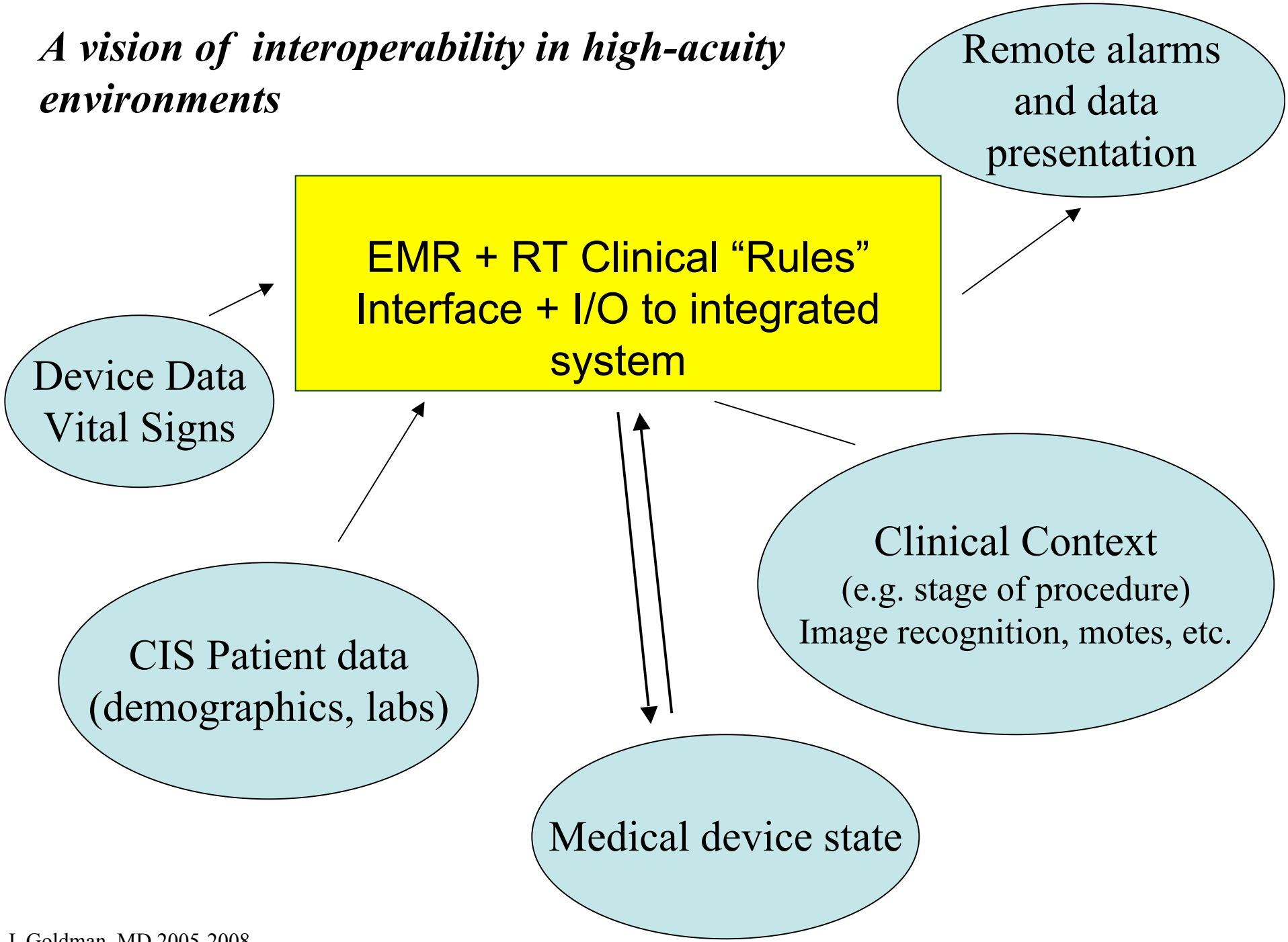
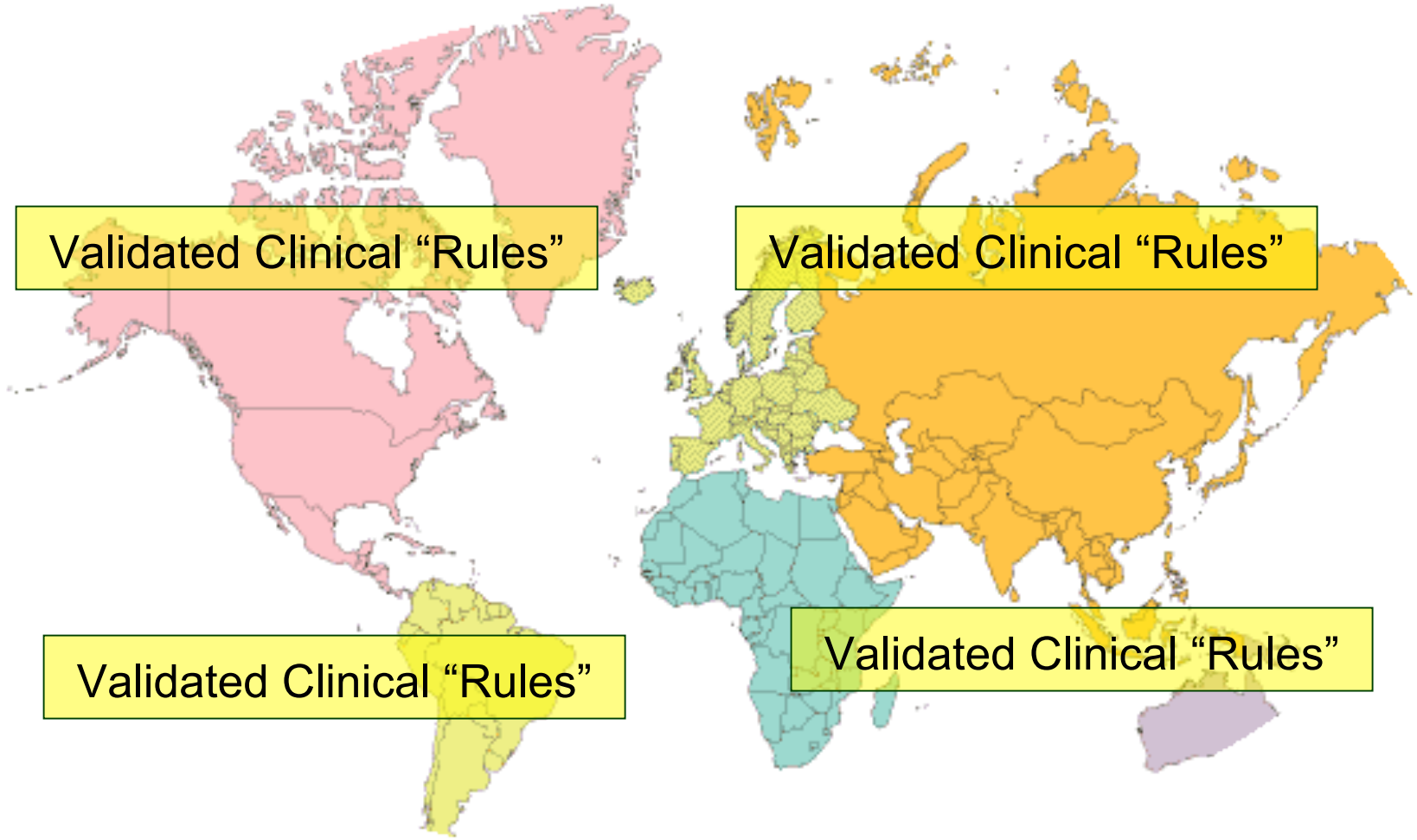
The Vision

A vision of interoperability in high-acuity environments



J. Goldman, MD 2005-2008

When standardized clinical databases are populated via standardized data and system interfaces, Validated Clinical "Business Rules" will be Shared Globally



Adoption of medical device interoperability will support:

1. Complete, accurate electronic medical records
2. Reduce errors caused by manually entered data, and provide single “source of truth” for patient ID and other key data
3. Facilitation of disaster preparedness: real-time inventory of hospital equipment in-use and national stockpiles
4. Rapid deployment of devices in makeshift emergency care settings
5. Clinical decision support systems and smart clinical alarms
6. Support of remote healthcare delivery (home, battlefield, e-ICU)
7. Automated system readiness assessment (prior to starting invasive clinical procedures)
8. Increased quality and completeness of international research databases
9. Reduce cost of devices and their integration, TCO, and reduce accelerating EMR-adoption costs
10. Understanding key issues at the heart of Biomedical Engineering (BME) - IT “convergence”
11. Closed-loop control of therapeutic devices and safety interlocks (e.g. ventilation, medication and fluid delivery)

Some benefits of medical device interoperability for muti-vendor system integration in the“Hospital of the Future”

- Network-based inventory of
  - Devices (tens of thousands)
  - Device status, including software/firmware
  - Push device patches/upgrades
  - Could significantly reduce TCO of devices (per Kaiser data)
  - Leverage FDA-initiated UDI (Unique Device ID)
- Enable system solutions at the “sharp edge” of healthcare delivery

Action Steps

Implement an integrated healthcare ecosystem by using a roadmap to drive standards, research, and technology solutions:

1. Develop a portfolio of “boilerplate” contract clauses to support adherence to standards, especially the emerging ICE standard
2. Incorporate integration and interoperability roadmap into contracts (like Kaiser)- NOW
3. Expand collection and codification of clinical requirements to ensure that emerging solutions will meet clinical and operational needs
4. Integration of devices produces new systems. Verification and Validation tools must be developed to assure the safety, performance, and regulatory acceptance of these systems.
5. Facilitate development of commercial products to deliver components of the ICE

Thank you

MD PnP Program: www.MDPnP.org

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