CIMIT

Workshop on: Potentials and Realities of Certification
in Light of Open Technology Development
May 20, 2008

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Getting connected for patient safety™
www.MDPnP.org

How can we leverage medical device integration to improve safety at the sharp edge of healthcare delivery?

a grand challenge

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Medical Device Plug-and-Play (MD PnP) Program
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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 lack of interoperability of medical devices and systems, especially in high-acuity clinical settings (ICU, OR, ED, CCAT, tec.)
- We propose that the ability to "integrate the clinical environment" is an essential step to address these issues and create error-resistant systems

Ref. IOM/NAE Report 2005: "Building a Better Delivery System"

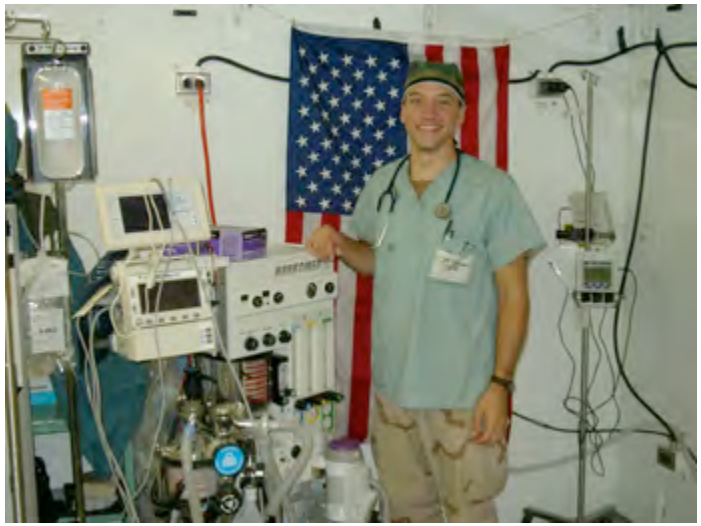
Adverse Events

- An 'event' can be defined as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm.
- 'Patient safety' is defined as the avoidance and prevention of patient injuries or adverse events resulting from the processes of health care delivery.

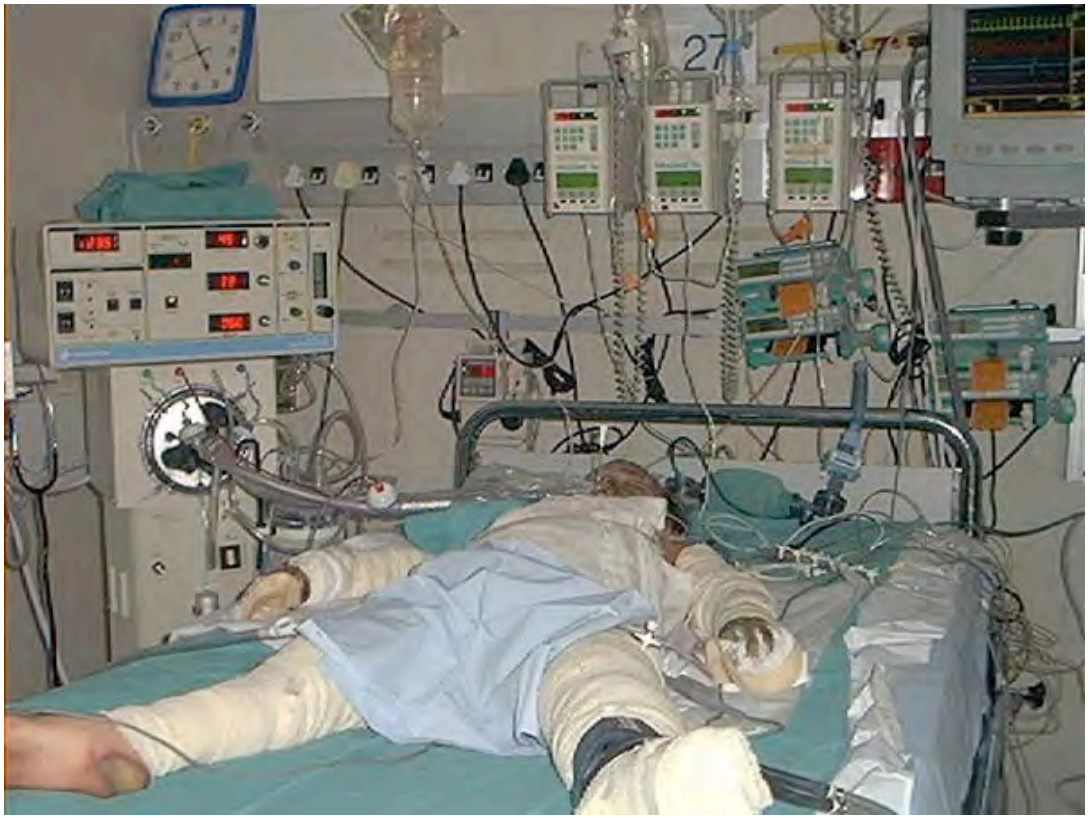
Source: PHS

Current state

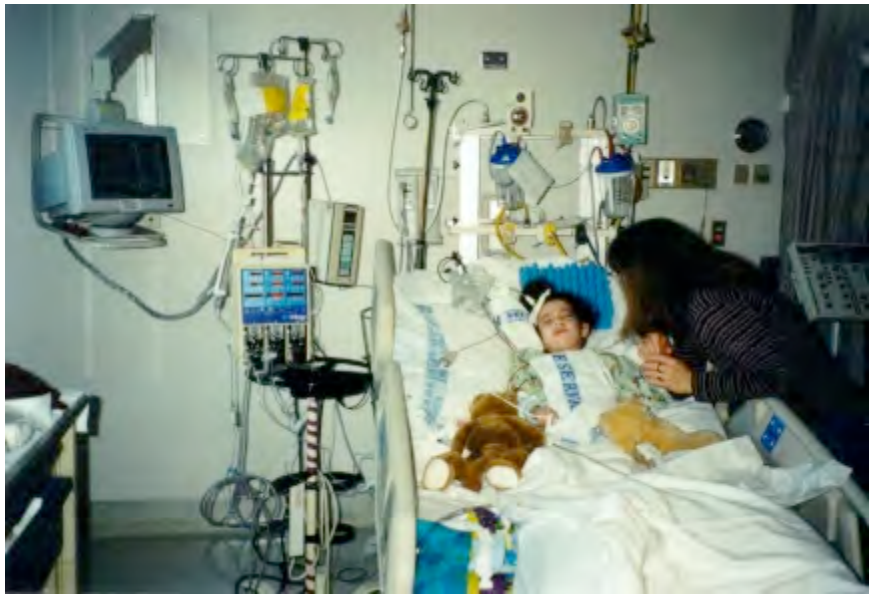
… at the sharp edge of high-acuity patient care …

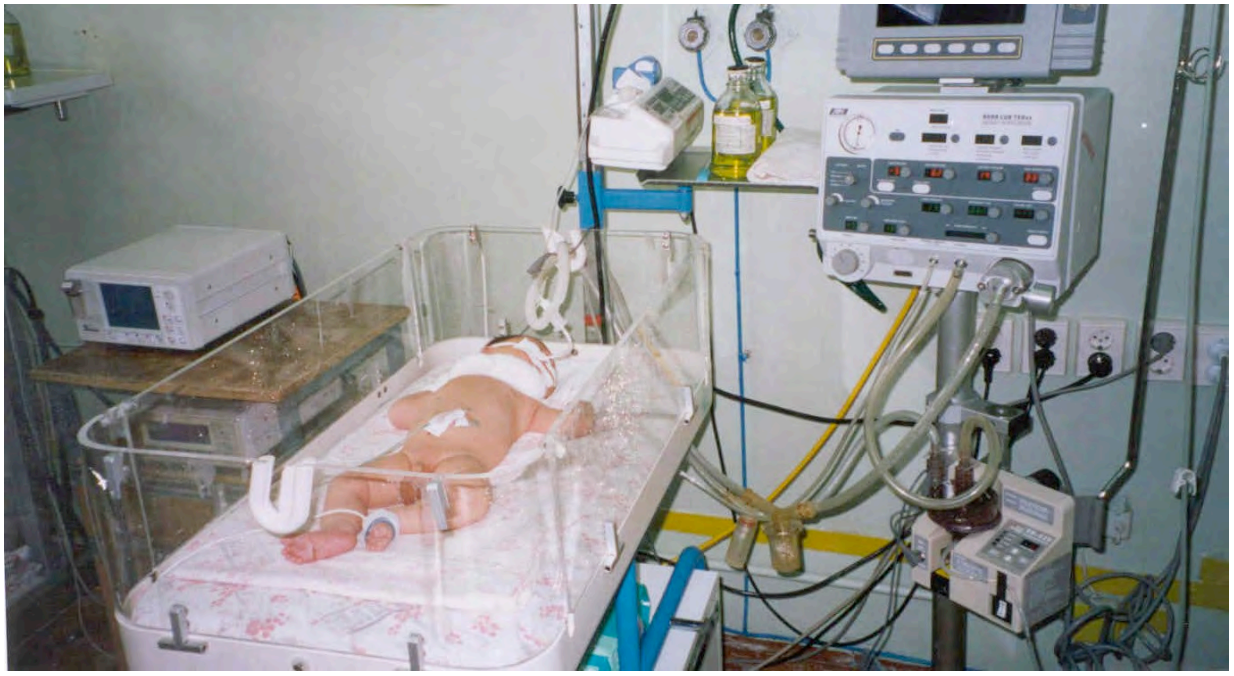


Iraq



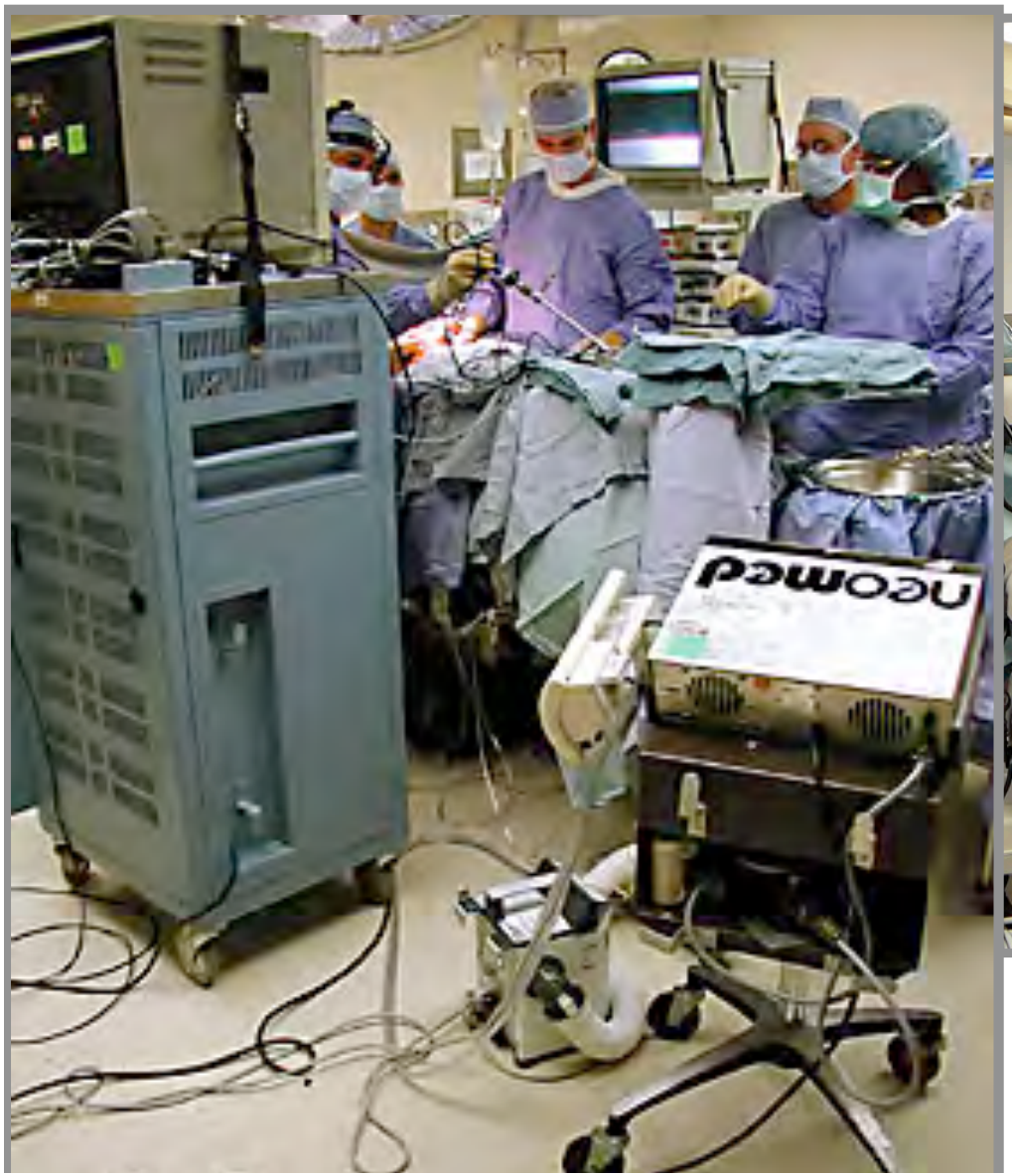
This is the current state

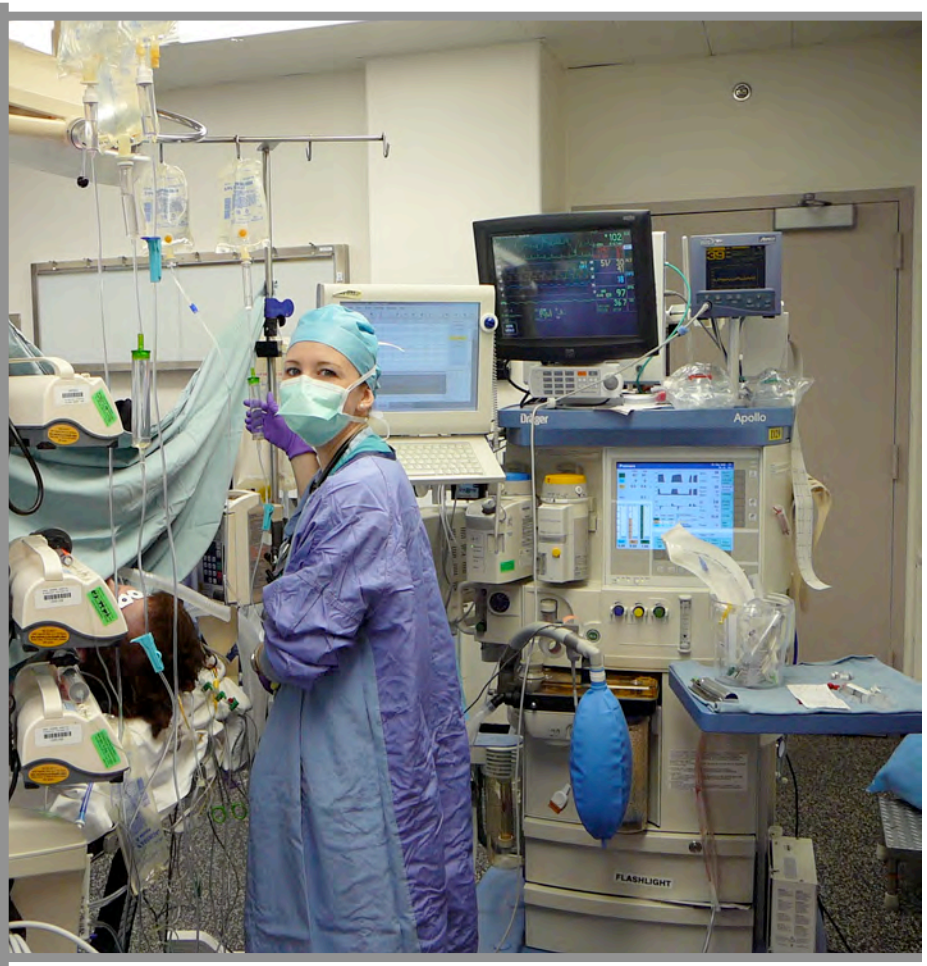




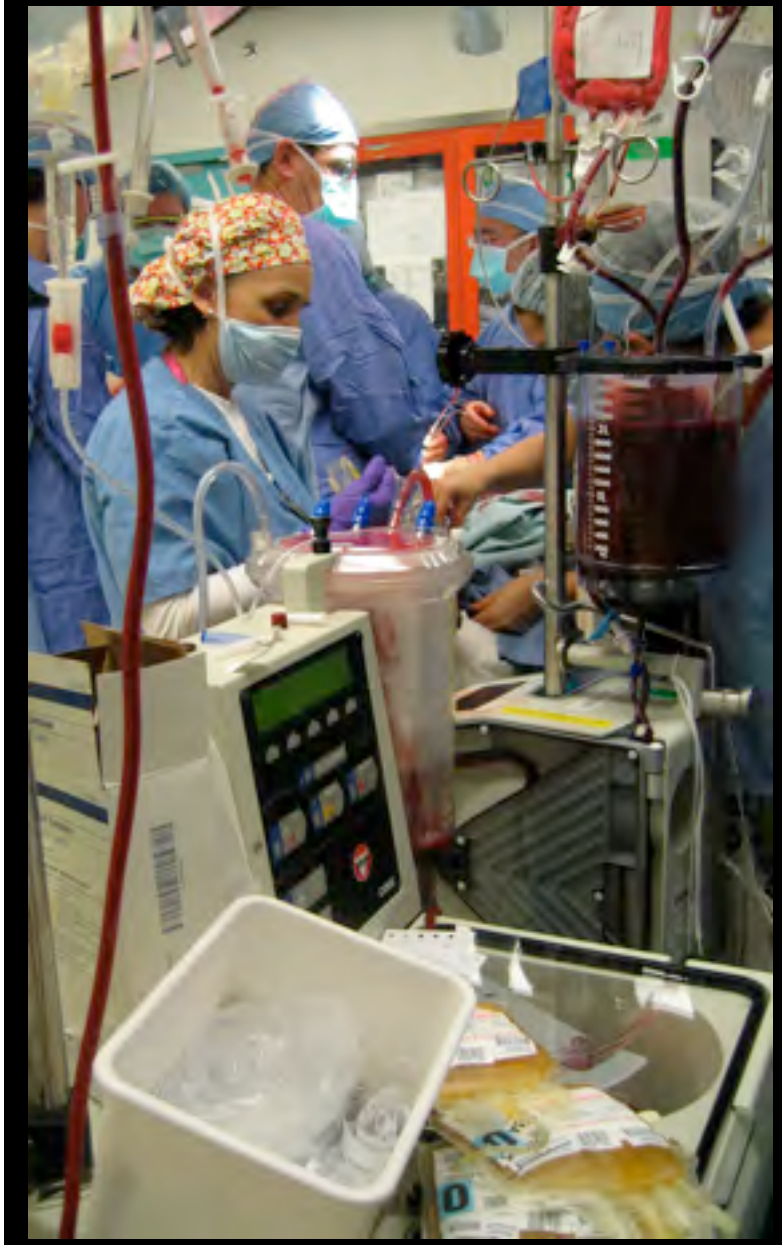
Reality

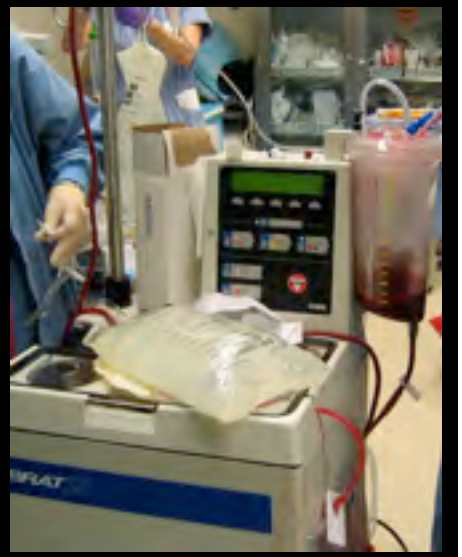
Typical ORs of “today”





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

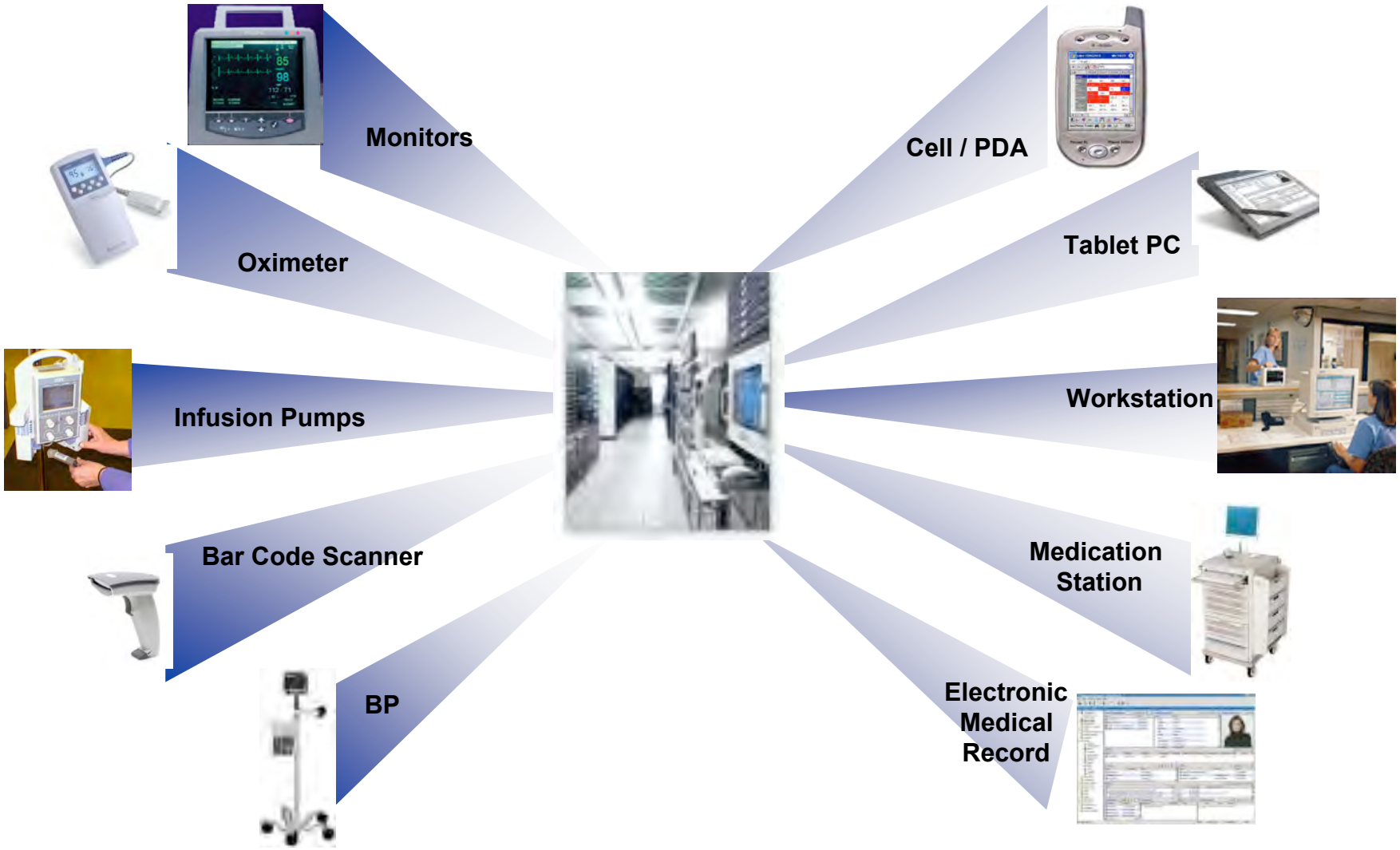




Demand and complexity will only increase …

Point-of-Care Medical Devices (wired ⇒ wireless and mobile)

Data Integration, Analysis, and Display



Credit: P. Carleton, RN

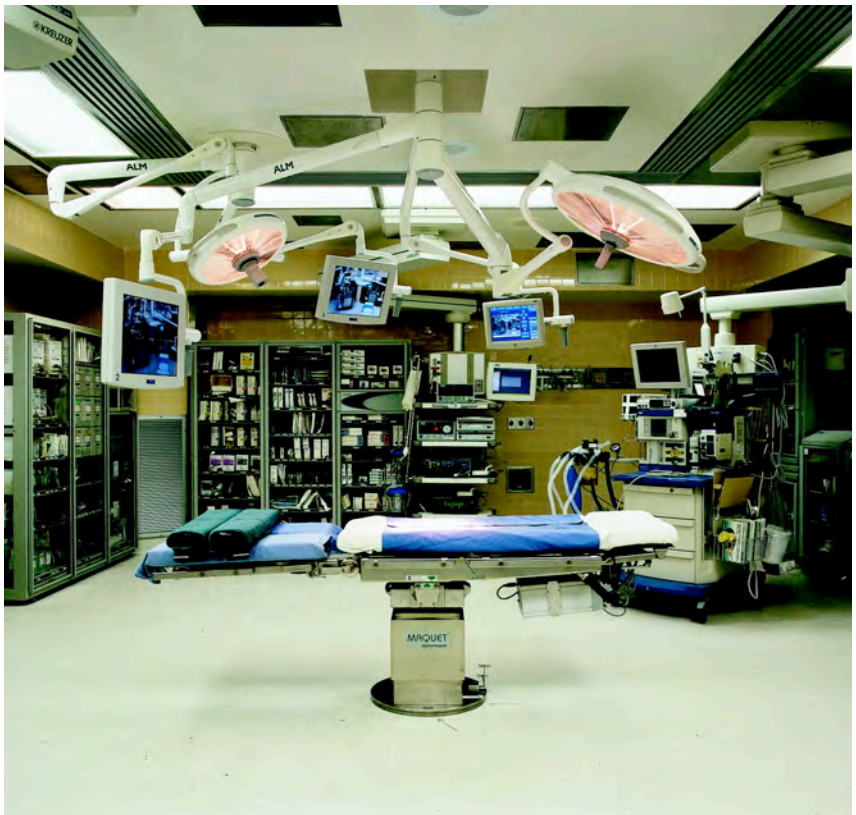
Connectivity challenge extends beyond the OR

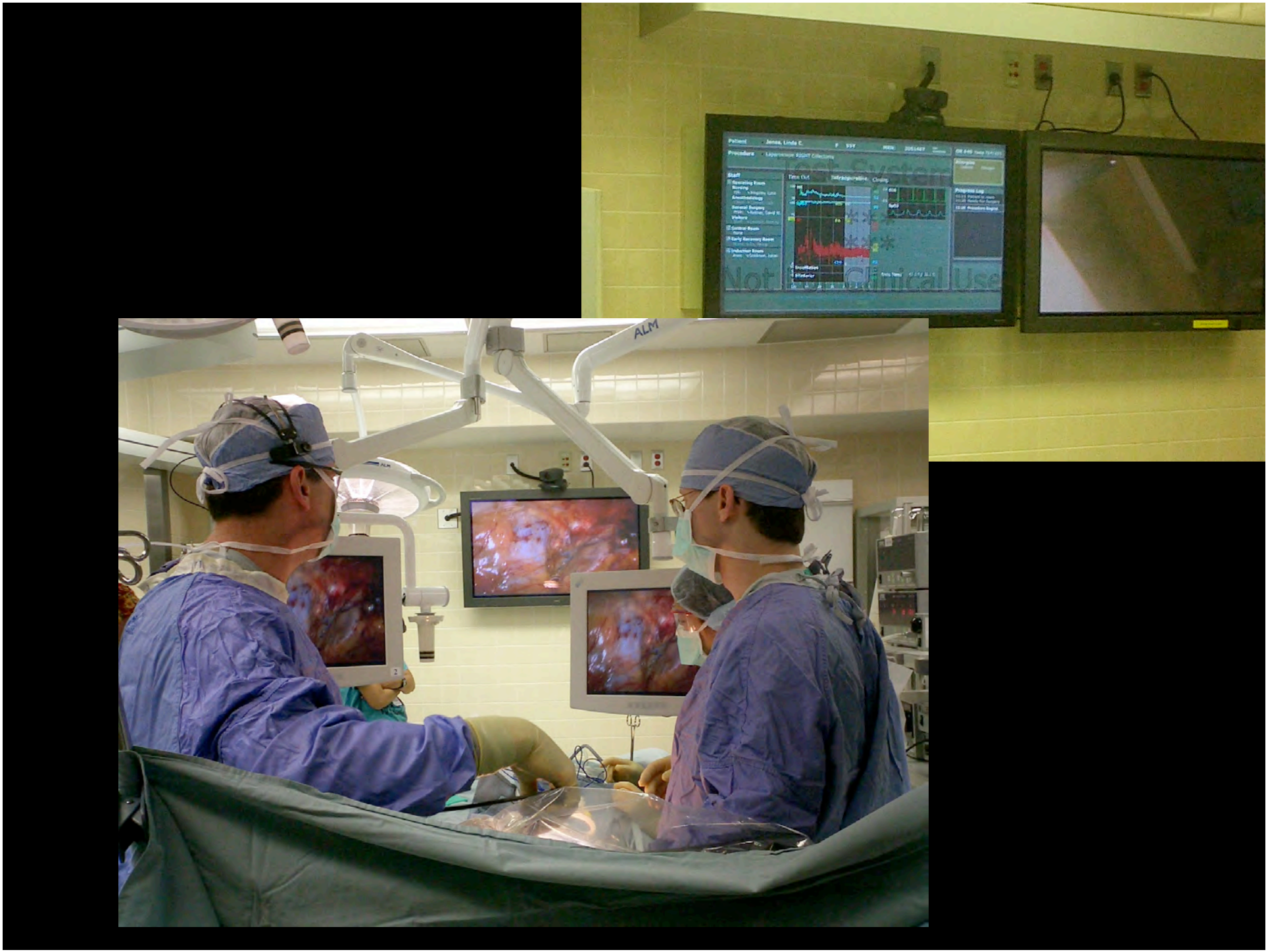
Mass General Hospital/CIMIT
Operating Room of the Future

CIMIT/MGH OR of the Future Project

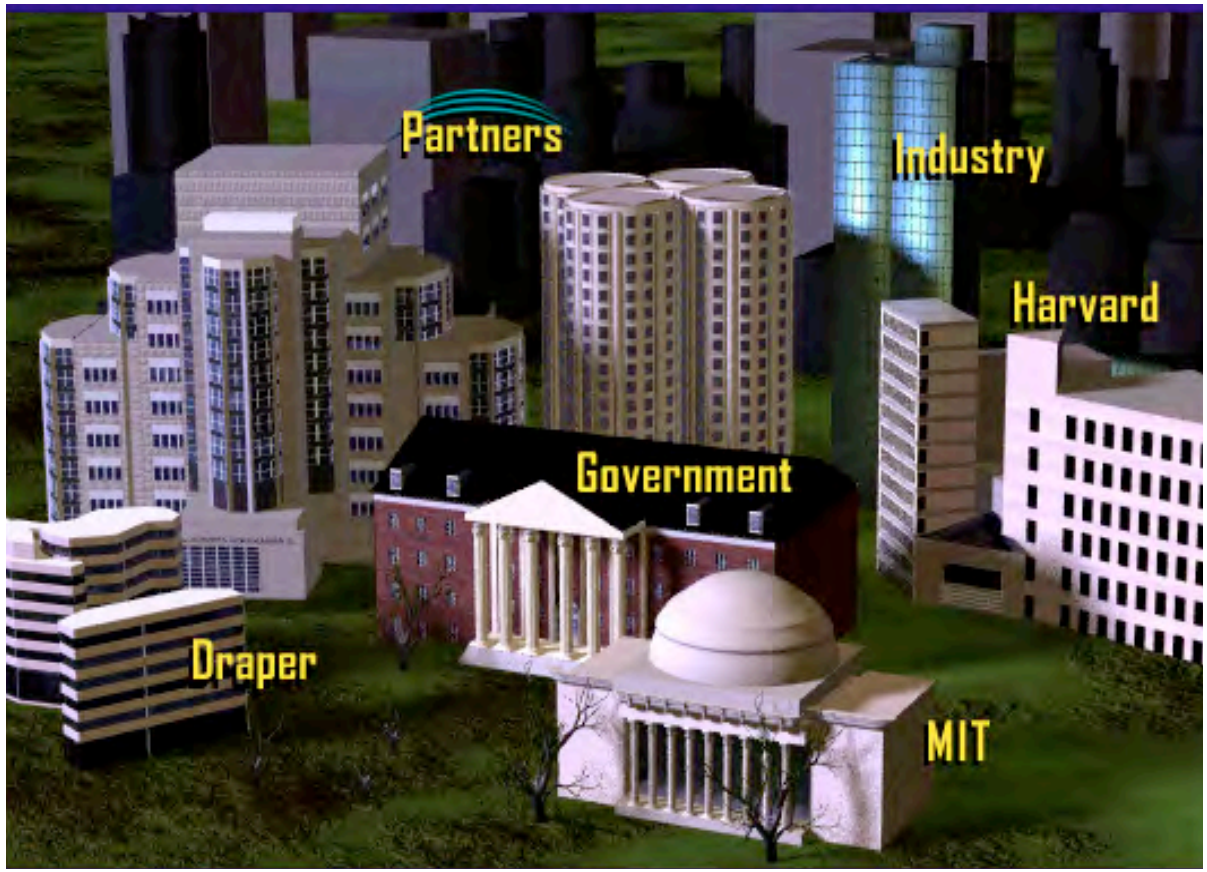
Center for Integration of Medicine and Innovative Technology

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




ALM

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 device and data 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.

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Lessons from the OR of the Future: perspective on device and 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*

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Interoperability => Empowerment

- Cross-vendor standards-based interoperable Consumer Electronics have empowered consumers
  - Created markets and solutions
  - Internet standards brought interoperability to PCs
    - Result -> Google!
  - Consumer Electronics Experience: When you buy a digital camera
    - Purchasing decision: depends on cost, resolution, image stabilization - you no longer worry about connectivity
    - You may do many different things with the camera? Buy big SD card, use USB cable, manipulate jpeg on Mac or Win OS, email, view in browser, etc
    - You ASSUME that STANDARDS and MARKET ensure your needs will be supported!

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

- Medical Devices have a unique place in the "interoperability ecosystem"
  - 1. Medical Devices are key data sources (to EMR/CIS etc.)
  - 2. Medical devices can be better utilized to deliver care
  - 3. Medical Devices are at the sharp end of patient care. Adverse Events/Near Misses that involve medical devices must be mitigated using medical devices as part of system solutions

Adoption of medical device interoperability framework (standards and technologies) 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 medical 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
7. Automated system readiness assessment (prior to starting invasive clinical procedures or critical care transport)
8. Increased quality and completeness of international research databases
9. Reduce cost of devices and their integration, and reduce accelerating EMR-adoption costs
10. Closed-loop control of therapeutic devices and safety interlocks (e.g. ventilation, medication and fluid delivery)

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Value of data integration:
Landing gear not deployed? -> Smart ALARM

"smart" = high sensitivity and high specificity

Contextual awareness requires data integrated from several device and systems

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

(From the MD PnP Program "Clinical Requirements Database")

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Scenario:
Failure to ventilate #1

Cardio-Pulmonary 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

11 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."

Cardio-Pulmonary Bypass

NOT AVAILABLE

← and →

Smart system would provide warning if ventilator off and bypass pump flow = 0.
Almost every surgical team has experienced this error!

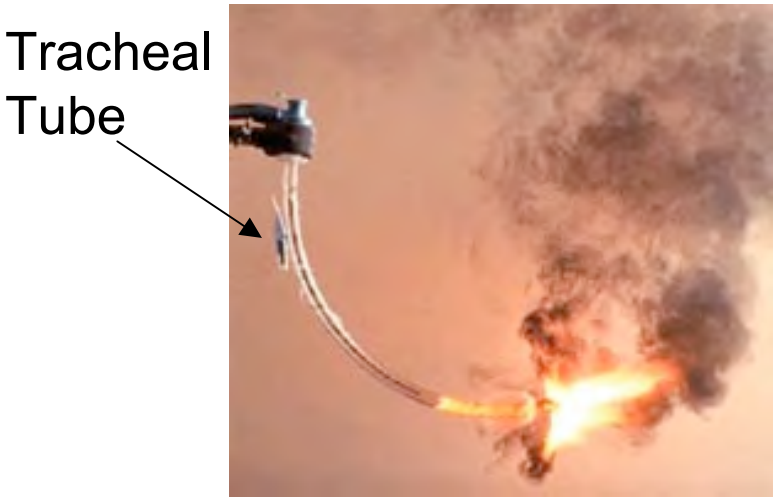
Scenario: Surgical Fires

- 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

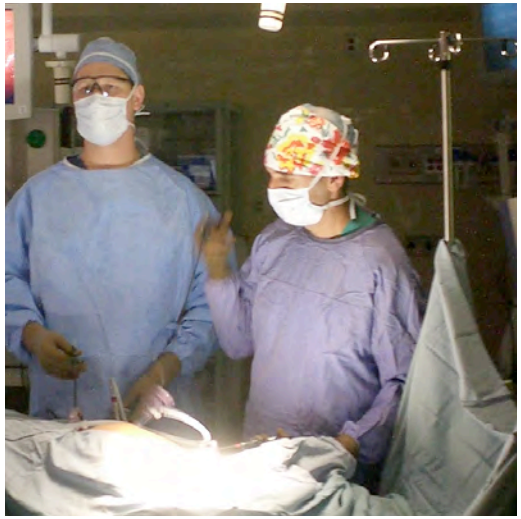
Scenario:
Failure to ventilate #2

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

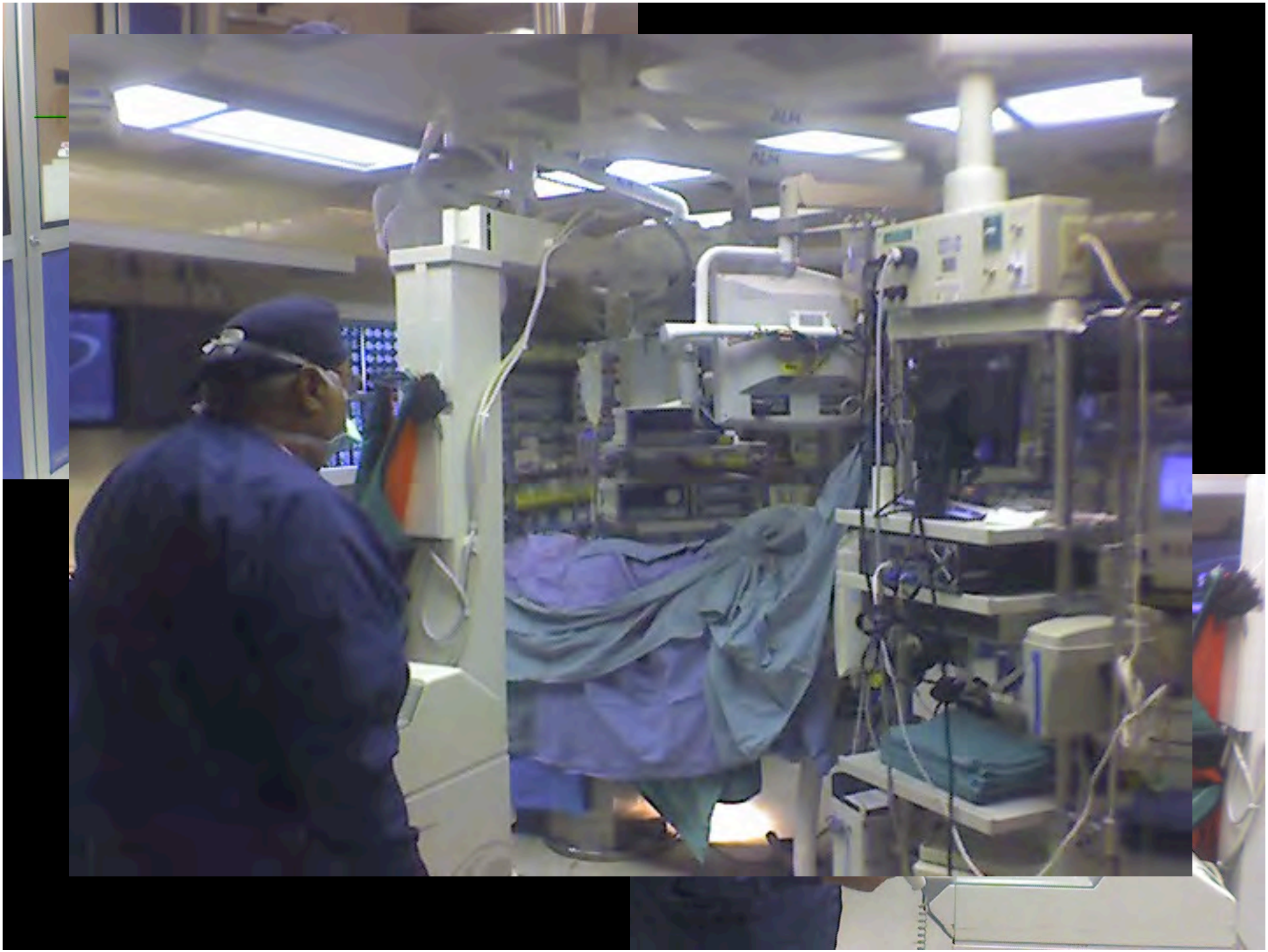
Workflow: 1) Ventilation is stopped. 2) Intraoperative cholangeography (bile duct x-ray) is performed with contrast to identify internal structures.

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…*

Synchronize x-ray with ventilator:
@ expiration: cholangiogram, CVP, CO
@inspiration: routine chest radiograph

NOT COMMERCIALLY AVAILABLE

In this case, integration of devices into a networked, smarter system can improve safety by avoiding ventilator shut-off, improve image quality (especially on serial images), and decrease re-imaging.

Synchronization of Radiograph Film Exposure with the Inspiratory Pause
Am. J. Respir. Crit. Care Med., Volume 160, Number 6, December 1999, 2067-2071

9 years

Solution has been demonstrated in MD PnP Lab

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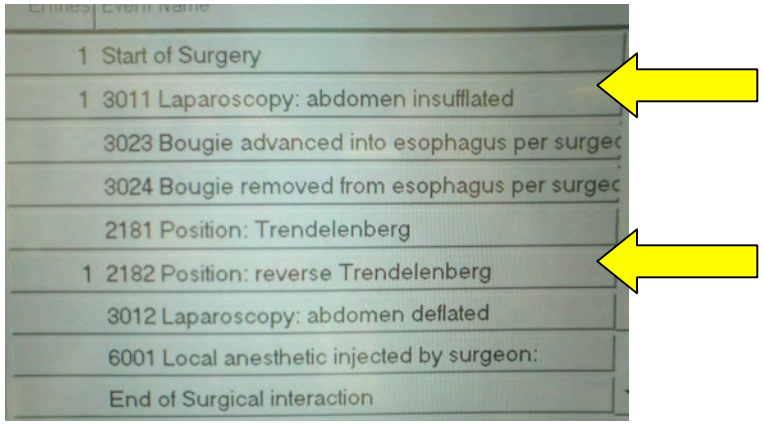
Medical Device “Plug-and-Play” Interoperability Lab at CIMIT
Cambridge, MA
Opened May 2006
Photos includes collaborators from MGH, U Penn, and LiveData)

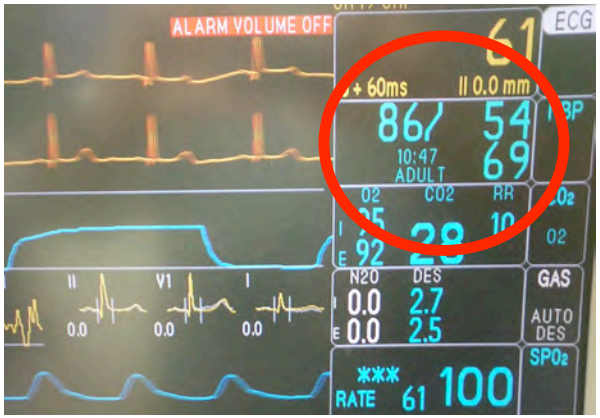
Ventilator - Xray Simulation at ASA Scientific Exhibit
October 15, 2006

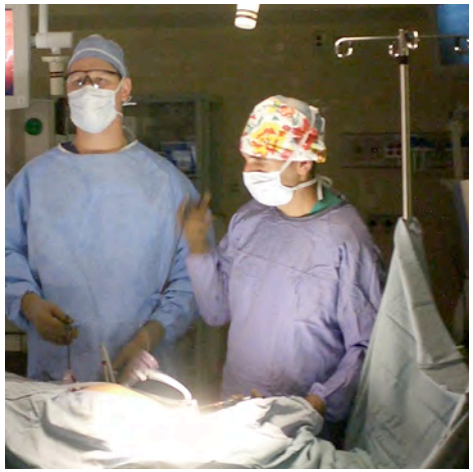
Scenario:
Detect/Prevent Hemodynamic Instability from Pneumoperitoneum (Insufflation) during Minimally Invasive Abdominal Surgery

The Problem: Insufflation-induced hemodynamic instability:

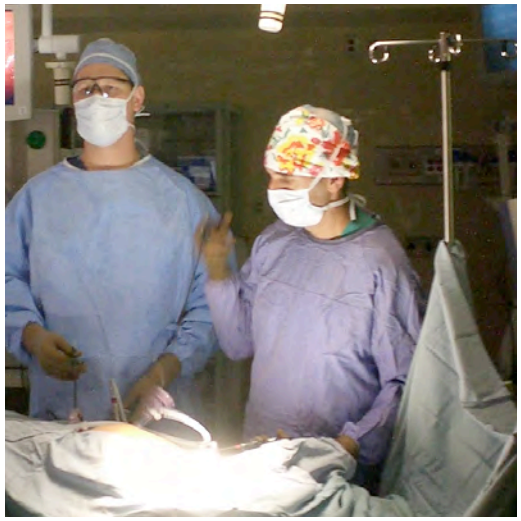
Initial insufflation of CO_2 into the abdomen (peritoneal cavity), especially combined with head-up table tilt ("reverse Trendelenburg Position"), may severely decrease blood pressure and heart rate.







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

14 years

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

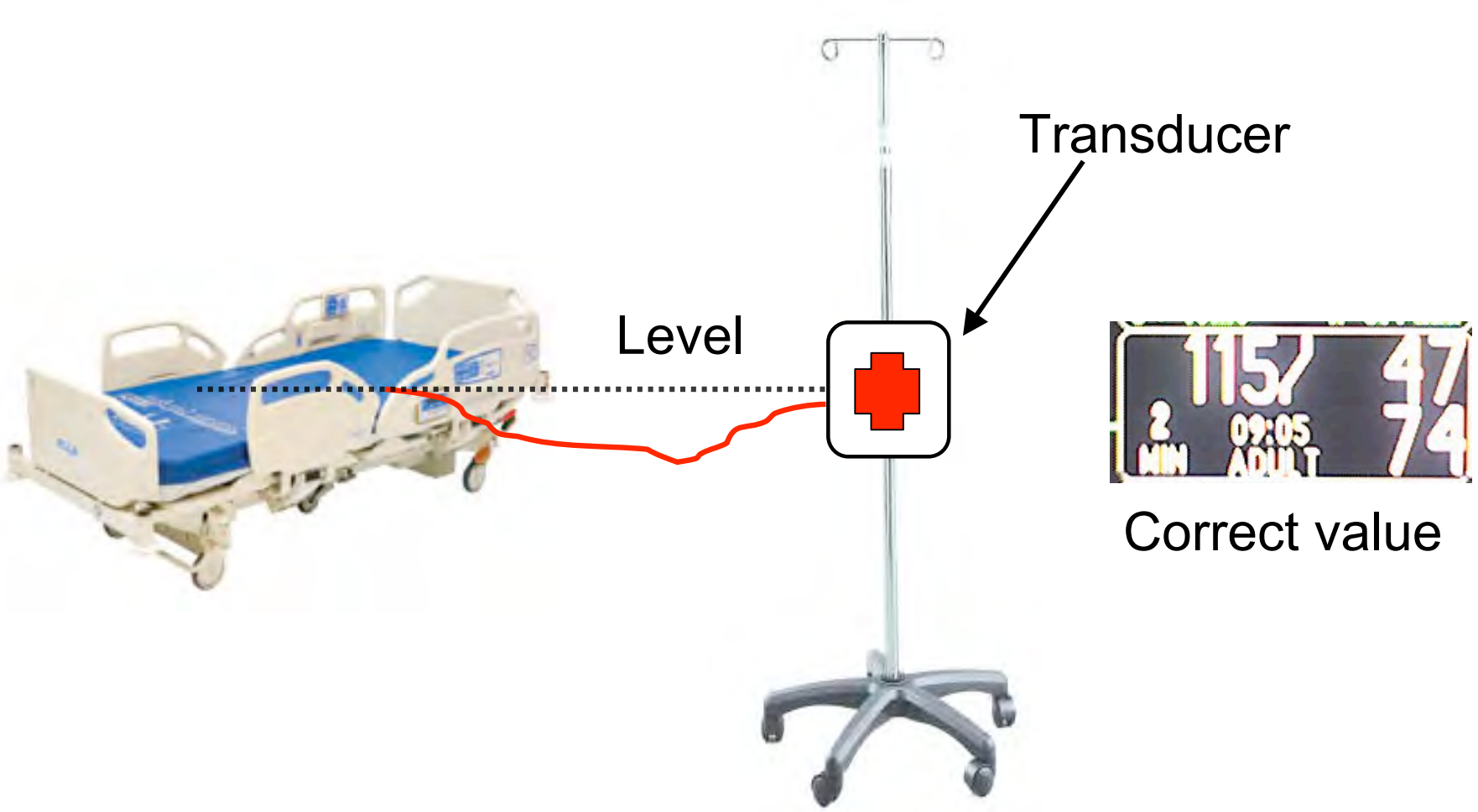
Laparoscopic Cholecystectomy (or similar):

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
  - 3. Control BP monitor: Trigger BP measurement upon insufflation + table tilt

Scenario: Blood Pressure Measurement Errors

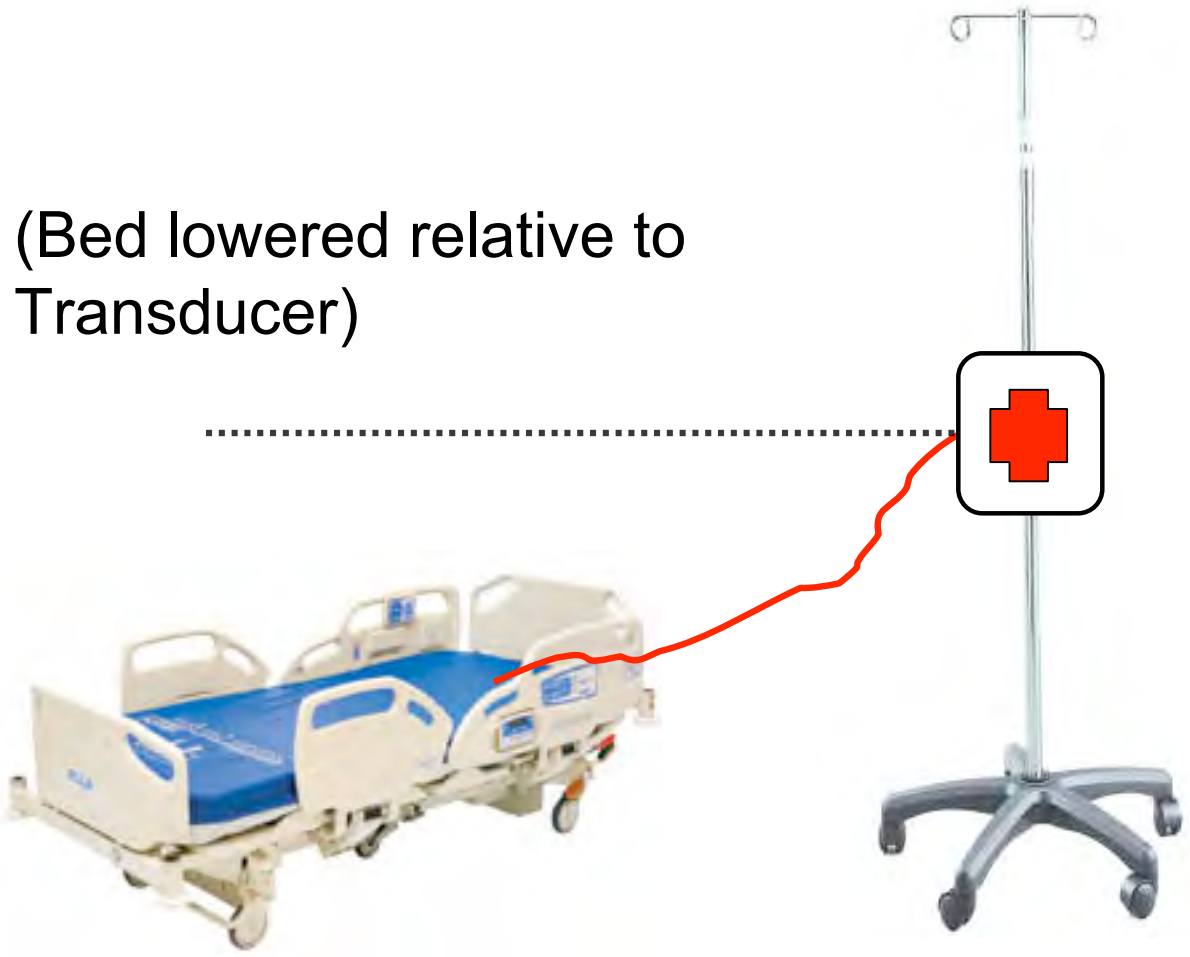
Invasive BP Measurement



Correct value

Invasive BP display error

(Bed lowered relative to Transducer)



Error: too low

This offset can introduce > 50% measurement error!

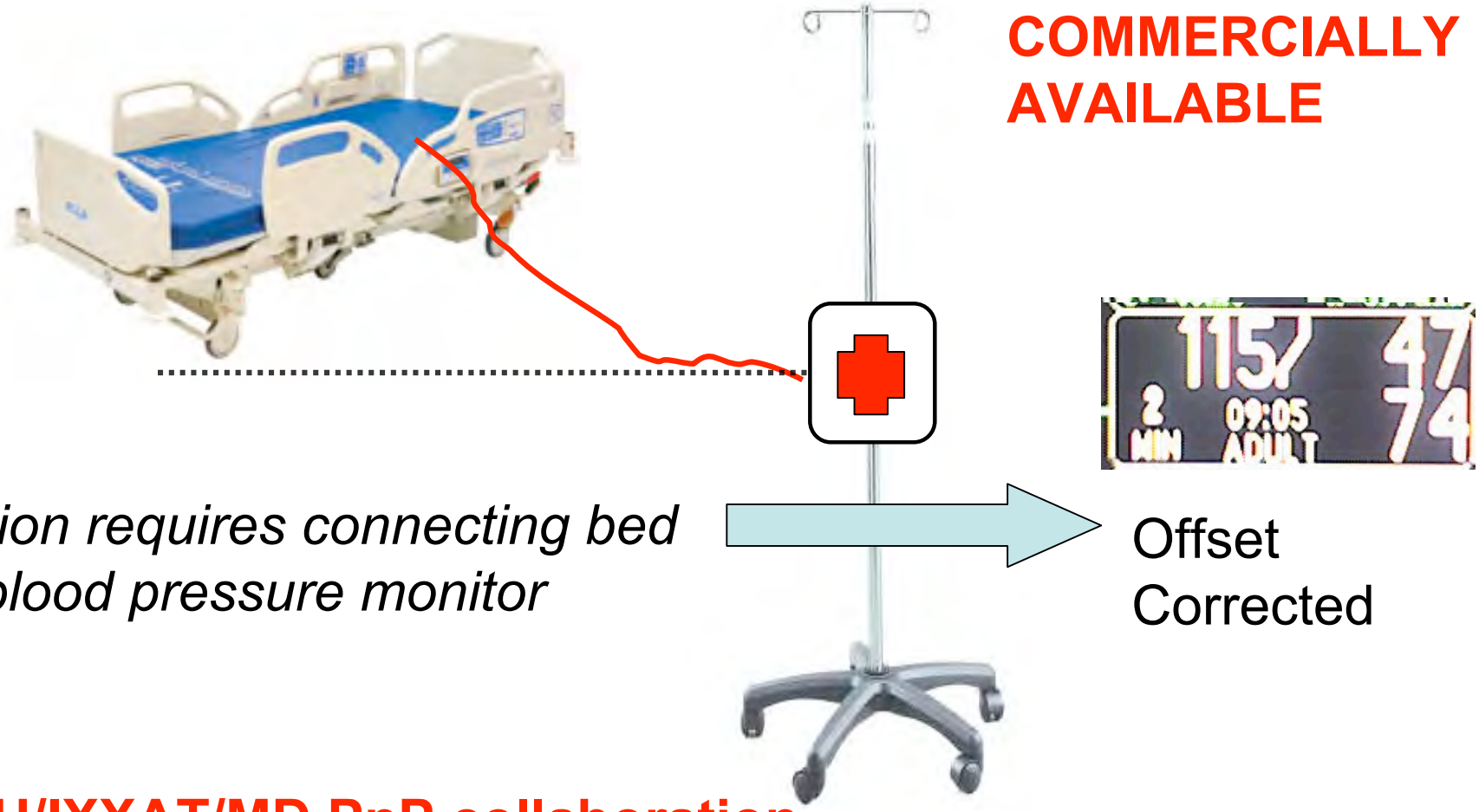
BP Measurement Error

- 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

UNH/IXXAT/MD PnP collaboration
Demonstrated at HIMSS Feb 07

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

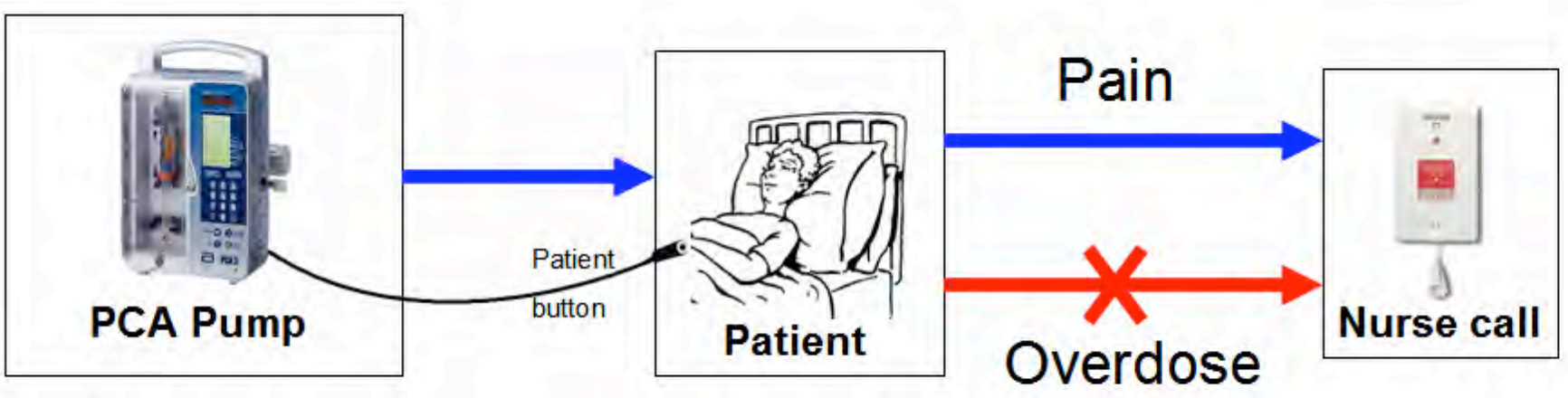
Dangers of Postoperative Opioids

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

APSF PCA Recommendations

- “A particularly attractive feature may be the ability to automatically terminate or reduce PCA … 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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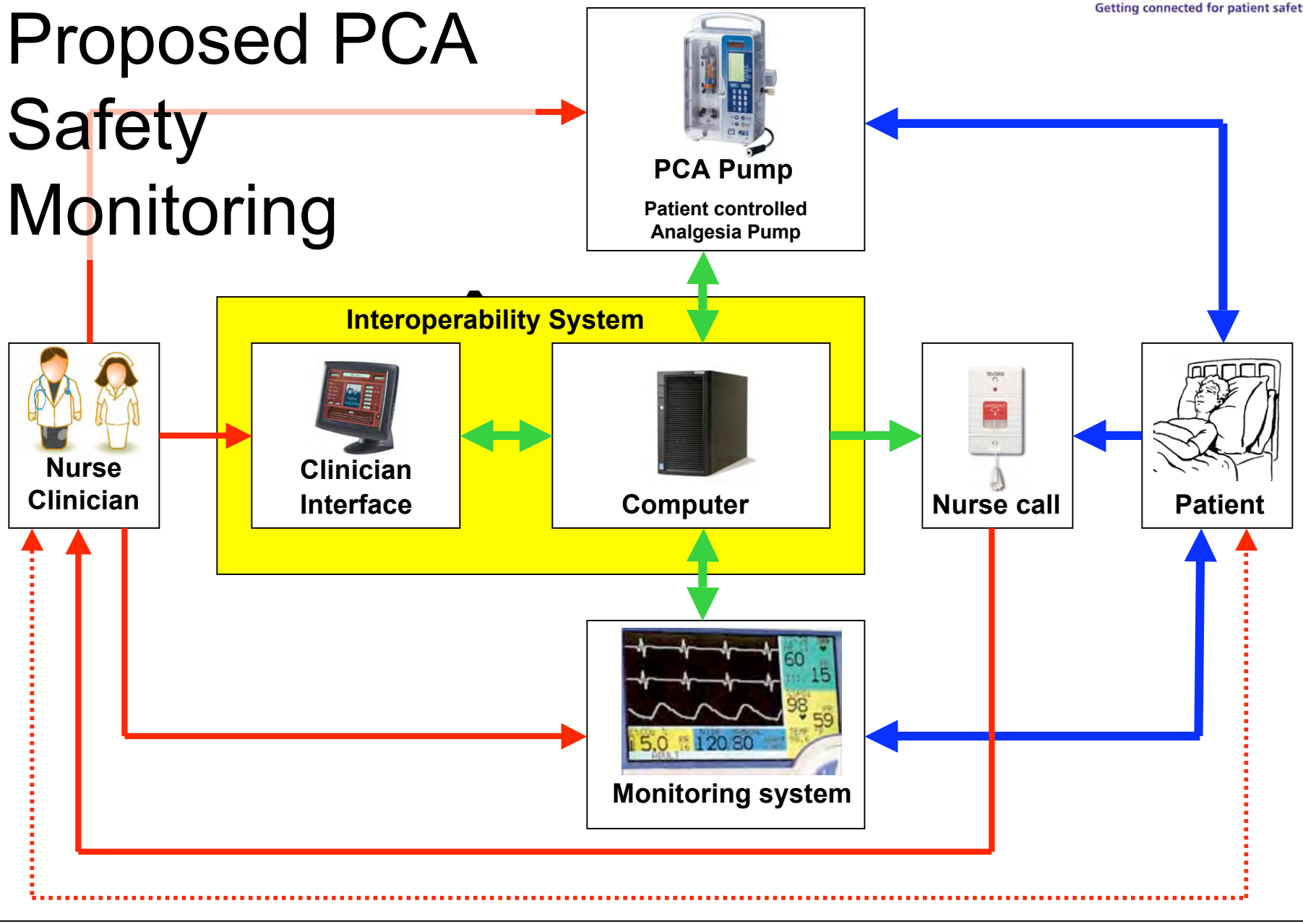
Proposed PCA Safety Monitoring



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

Which other clinical challenges could be addressed with:

- Plug-and-play device integration with auto-recognition of device type and model
- Identification of all available devices, presentation of relevant smart monitoring algorithms for selection by the clinician, auto-configuration of alarm limits, and targeted remote alarm annunciation

Back to IOM report: “To err is Human:

- 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 platform to deliver these - and similar -innovative solutions.

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What is the scope of effective medical device interoperability ?

There are two distinct – but closely related – capabilities of medical device interoperability required to mitigate these hazards:

1. Bidirectional medical device data communication

2. Medical device control capability to permit the integration of medical devices into networks to produce “error-resistant” systems.

“Control” should be defined as exposure of selected features or device functions over the network, to enable classes of clinical scenarios cases. (Example: “activate pre-set ventilatory pause to enable an x-ray”).

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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.

MD PnP stakeholder community: key issues must be addressed for adoption of interoperability:

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

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USA TODAY

May 6, 2008

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Identity thieves prey on patients' medical records

By Julie Appleby, USA TODAY

Doctors' offices, clinics and hospitals are a fruitful hunting ground for identity thieves, who are using increasingly sophisticated methods to steal patient information, lawyers and privacy experts say.

Recent disclosures that hospital workers snooped into the medical files of Maria Shriver, Britney Spears and George Clooney highlight the vulnerability of patients to the merely curious and the criminal.

Legal experts say lawbreakers use medical information to get credit card numbers, drain bank accounts or falsely bill Medicare and other insurers.

In Florida last year, a front-desk coordinator at the Cleveland Clinic was convicted of identity theft, computer fraud and other charges after downloading patient information and selling it to a cousin, who submitted more than $2.5 million in phony bills to Medicare.

In April, a former New York-Presbyterian Hospital employee was arrested for participating in an identity theft scheme in which he allegedly accessed nearly 50,000 patient records over two years.

False information from fake billings can end up in patients' medical files — and creditors might seek payment from the patients. Until the creditors call, patients might not know their medical information has been accessed.

In a recent survey of 263 health care providers, 13% said their facility had experienced a data breach. Of those, 56% said they notified the patients involved, according to the survey by HIMSS Analytics, a non-profit data analysis firm, and Kroll Fraud Solutions, which offers security-related services.

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

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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)

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MD PnP Program collaborators

- NIST (National Institute for Standards and Technology)
- NSF (National Science Foundation)
- Society for Technology in Anesthesia
- DocBox
- Philips Healthcare
- Etc.

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.

Req #	Clinical Scenario	Current Hazards	Proposed State	Future Hazards
CLN-050	ESU causes interference on ECG	Risks to patient safety due to poor diagnostics	Notify devices of ESU activity to eliminate/reduce ESU interference, or flag bad data	none
CLN-011	Difficult to reposition patient, cables, devices due to cluttered physical environment ("malignant spaghetti")	Devices could get disconnected, causing patient harm; it is difficult to maintain a clean environment with cables; visual paths of clinicians can be obstructed	Uncluttered environment, allowing appropriate communication between devices, information system, and patient; ease of movement of desired resources without barriers (NOT WIRELESS)	Possible interference of communication paths
CLN-052	Operating room lights and anesthesia task lights are not coordinated	Can end up in total darkness	Interconnect lighting, such that when room lights go off, anesthesia machine task light goes on	May want to work in the dark. Must permit override
CLN-048	Electronic medical record is missing medical device-generated data	Lack of adequate data for clinical decision-making	Comprehensive medical record, with capture of all medical device-related data in EMR: patient ID, personnel, equipment IDs, "ESU on" vs. "ESU off" (especially for later analysis)	EMR may become "bloated", overly complex
CLN-017	Laser, x-ray use in the OR	Unprotected personnel may enter OR unknowingly	Laser/xray outputs network message for automatic notification outside clinical environment during laser use	Failure of notification system; wrong room, wrong device activated

EXAMPLE Clinical Scenario worksheet

Requirements Engineering

Published 2/26/2006

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

These limitations are being recognized and addressed …

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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."

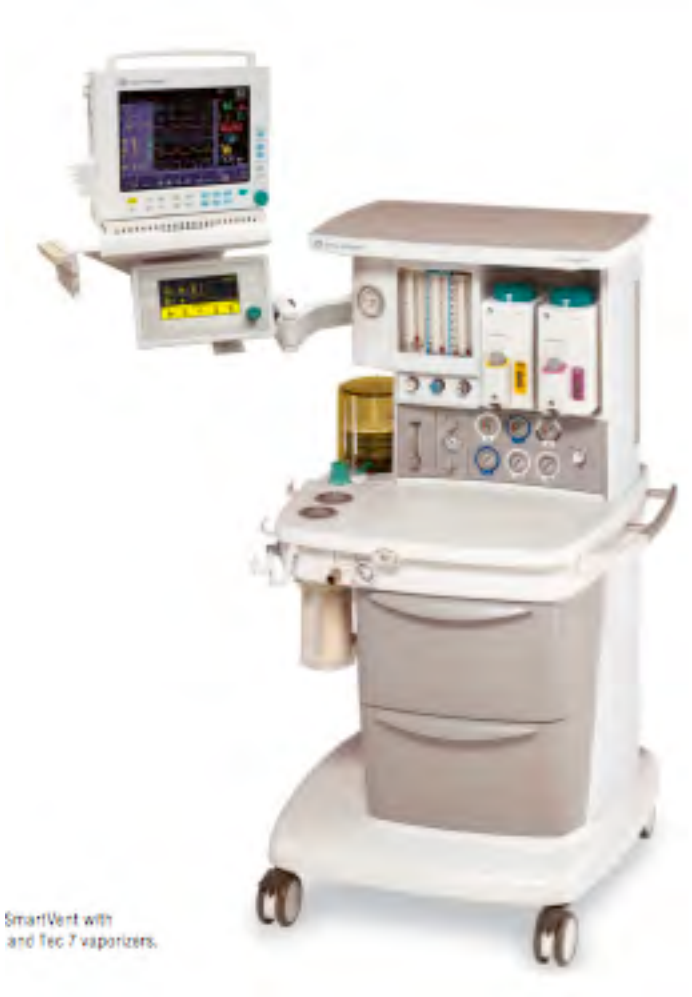
February 2008

Kaiser Permanente 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)

the role of “Standards” in regulatory approval



Example:GE Aespire 7900 Anesthesia Workstation

MAR 2 5 2005

K 050626

Date: March 9th, 2005

Subject: 510(k) Summary of Safety and Effectiveness Information for the GE Datex-Ohmeda Aespire 7900 Anesthesia System

Proprietary: GE Datex-Ohmeda Aespire 7900 Anesthesia System

Common: Gas Machine, Anesthesia

Classification: Anesthesiology, 73 BSZ, 21 CFR 868.5160

ISO International Organization for Standardization

The GE Datex-Ohmeda Aespire 7900 Anesthesia System was designed to comply with the applicable portions of the following voluntary standards;

IEC

1. UL 2601 – General requirements for Medical Electrical Equipment
2. EN 740 – Anesthetic Work Stations
3. EN/IEC 60601-1: General requirements for Medical Electrical Equipment
4. EN/IEC 60601-1-2: 2001 - Medical Electrical Equipment - Electromagnetic Compatibility
5. EN 475 – Electrically Generated Alarm Signals
6. ASTM F1463-93 – Standard Specification for Alarm Signals
7. ASTM F1208-94 – Anesthesia Breathing Circuit Standard
8. ASTM F1101-90 – Standard Specification for Ventilators Intended for Use During Anesthesia

ASTM INTERNATIONAL Standards Worldwide

1

Anesthesia Workstation (AWS) Standard Being Updated to Support "Ventilatory Pause"

"If an **anaesthetic ventilator** is equipped with an **operator**-controlled means to pause automatic ventilation:
[JMG comment: operator = clinician in standards parlance]

a) Both the duration of the ventilatory pause and the **abs** [anesthesia breathing system] pressure level during the ventilatory pause shall be **operator**-configurable or adjustable.

b) During the ventilatory pause, any ventilatory **alarm condition** that would be caused by this ventilatory pause shall be **audio paused** or **alarm paused** for the duration of the ventilatory pause.

c) During the ventilatory pause, an **information signal** or **low priority alarm condition** shall be indicated.

d) The maximum duration of this ventilatory pause shall be 60 s.

e) Means may be provided to initiate the ventilatory pause from a **network/data coupling**. [JMG comment: this is to support synchronization with an imaging device, or remote pause activation from, for example, the Interventional Radiology control room.]

Check compliance by inspection and functional testing.

Rationale: Pausing mechanical ventilation is necessary for certain clinical **procedures**. "

Note: This language will be considered at the international standards committee meeting in June 2008 (First drafted in 2006 w/ Drs. Dorsch, Weitzner, Hedley-Whyte, and Drager, Philips, and GE).

Laser - O_2 Interlock

- ISO Technical Committee 121, Subcommittee 2 (airway device standards) standardizes laser resistance of tracheal tubes
- London February 2008: SC/2 formally asked the Laser standards committee to investigate implementing a safety interlock
- May 2008: They said yes - the interlock feature is already present, and will be improved:
- "*These are ways to provide the proposed functions using the existing laser equipment. However, we may in the future work on IEC 60601-2-22 consider to let manufacturers of medical lasers provide an additional remote connector, which for instance contains TTL signal lines which upon a 5 Volts input voltage deactivate the foot switch and give a deactivation signal in order make the operator aware of the situation…."*
- Next steps: we need a standards-based system to monitor FiO2 and the logic and communication capability to appropriately prevent Laser activation. That system is ICE.

"ICE" Standard - Integrated Clinical Environment

- New draft standard describes requirements for safe and effective "plug-and-play" integration of devices in high-acuity environments
- Draft produced by MD PnP Program writing group convened under the authority of ASTM Committee F29:
  - Writing group formed June 2006
  - Six meetings held June 2006 - August 2007
  - First international draft circulated September 2007 for comments
  - Will be completed in 2008 by ASTM International

Scope of ICE Part I

- “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

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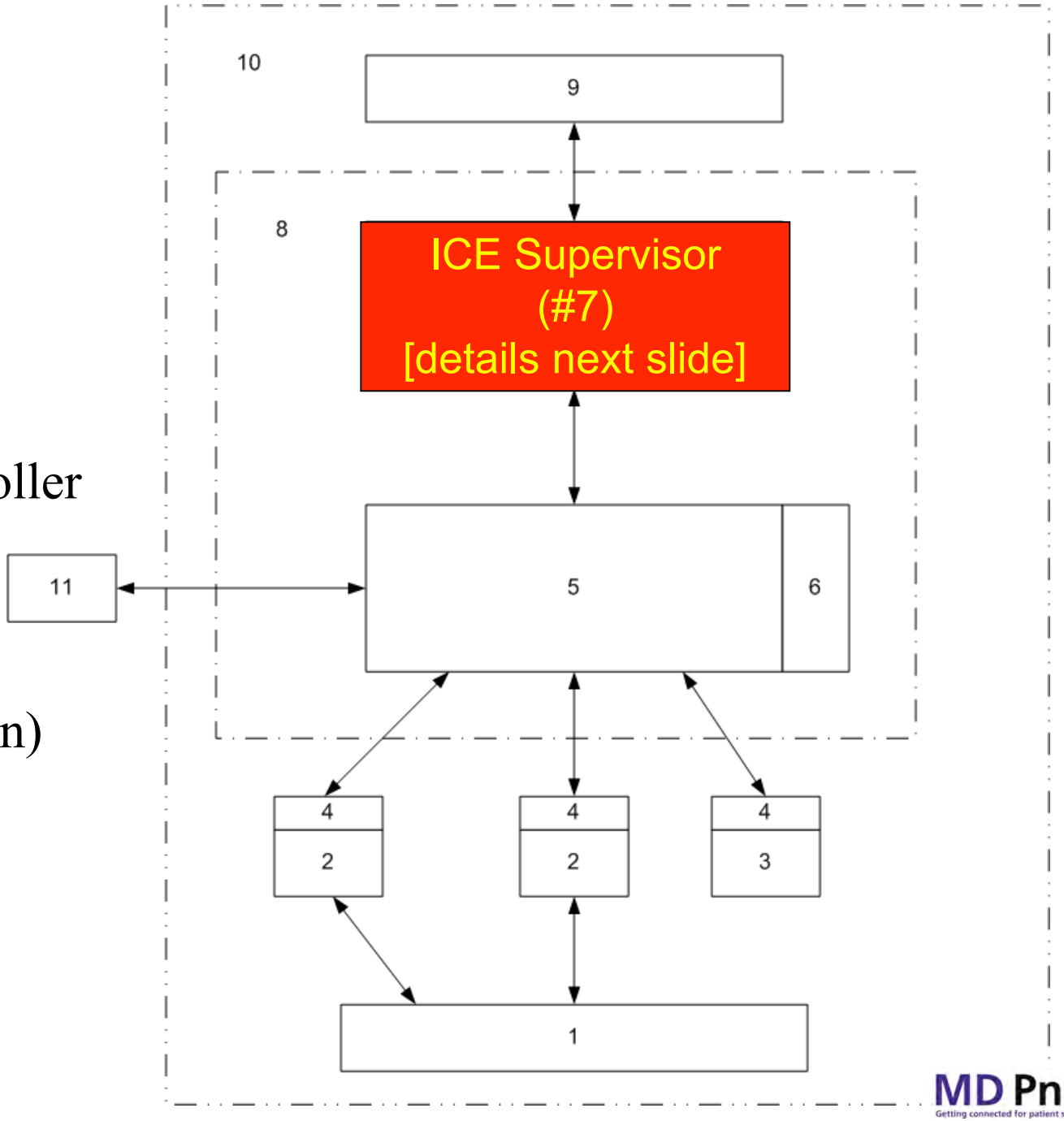
Figure 1: Functional Elements of the Integrated Clinical Environment

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 ICE supervisor supports the following patient-centric capabilities of the integrated clinical environment

- Provide safety interlocks
- Distribute integrated alarm conditions to relevant operators
- Provide context-aware clinical decision support
- Set command input variables of other medical devices, per operator-defined, context-appropriate rules in order to manage their operation (e.g. change NIBP cycle interval)
- Assess the readiness of medical devices in a clinical environment to support specified functions or clinical workflow
- Perform integration of alarm conditions from multiple medical devices
- Perform automated record keeping
- Support integrated control* of devices

•Control of those features made available through the ICE interface

From ICE Part I NWIP September 2007

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Figure 1: Functional Elements of the Integrated Clinical Environment

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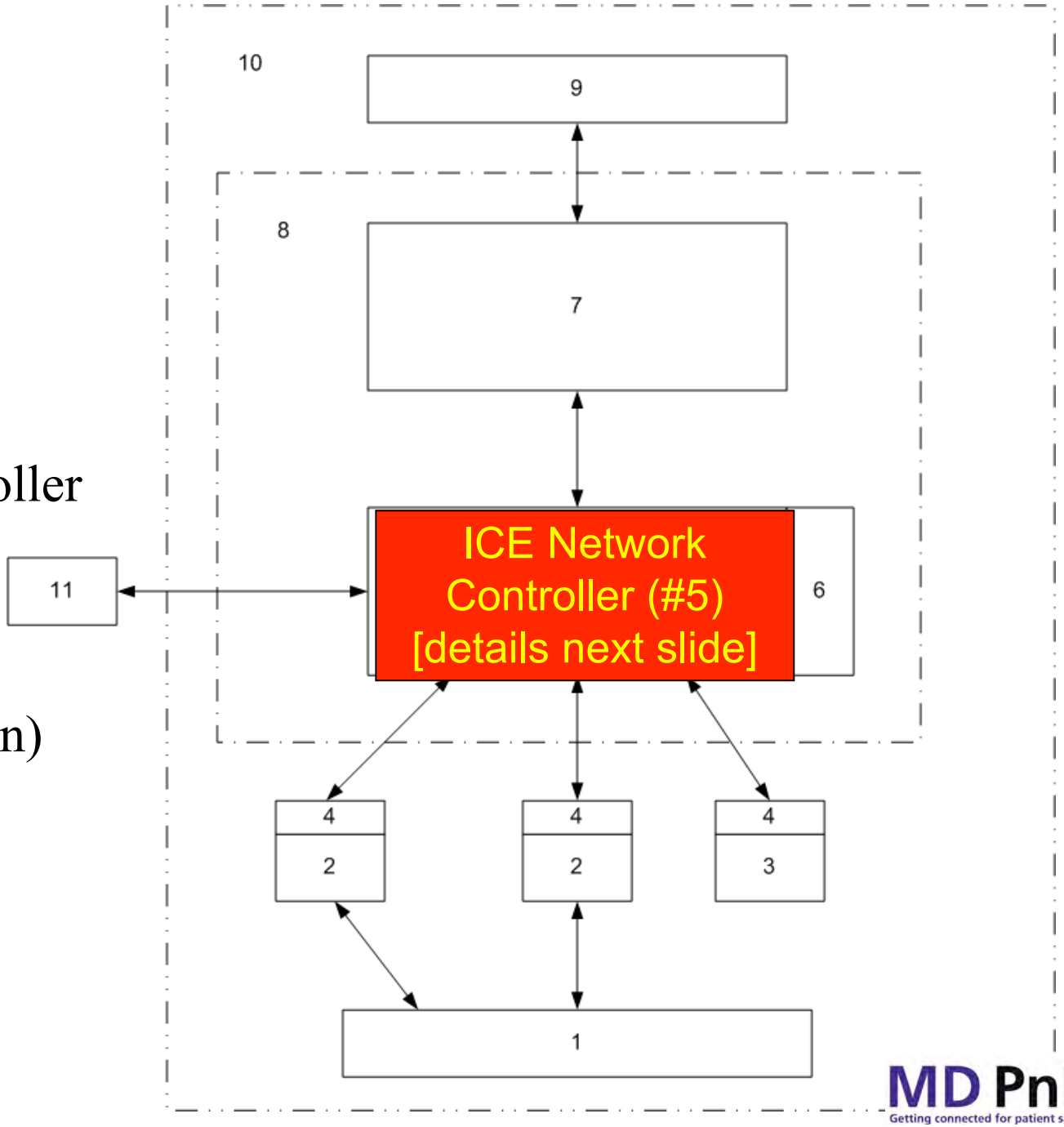

From ICE Part I NWIP
September 2007

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The ICE network controller supports the following patient-centric capabilities of the integrated clinical environment

- Provide “Plug and Play” (PnP) connectivity with medical devices and other devices
- Interface with equipment that contains an ice equipment interface
- Provide data logs for forensic analysis (flight recorder)
- Perform network control functions independently of the underlying data communication mechanization
- Provide relevant information to support a healthcare equipment management system
- Also provides a common time base and binding of data to patient identity
- Also can provide and retrieve relevant clinical data to a healthcare information system/electronic medical record/electronic health record (HIS/EMR/EHR)

From ICE Part I NWIP September 2007

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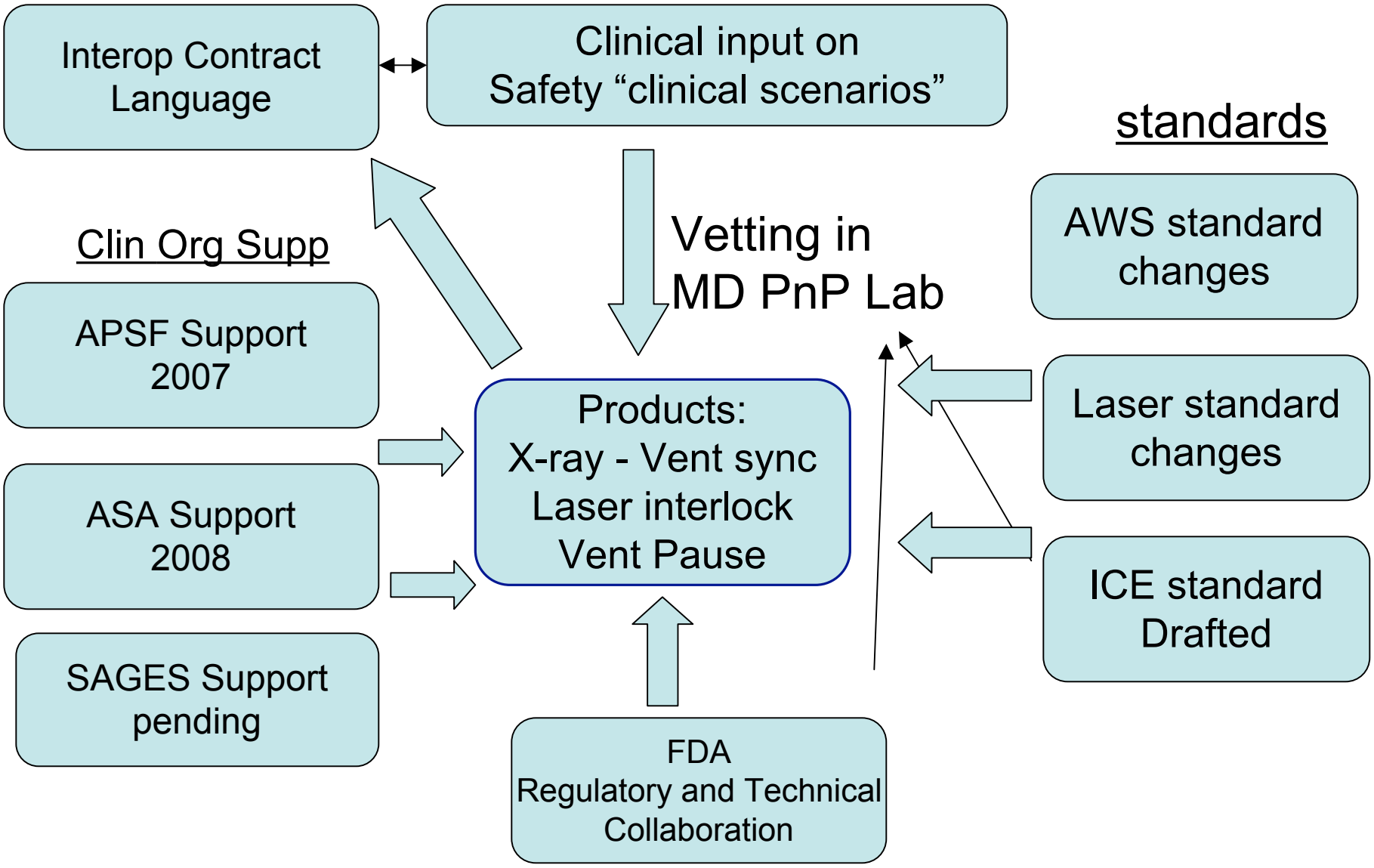
May 2008

- ASTM ICE meeting in Denver
- 4 Days to resolve 50 comments
- Participants: Clinicians, Medical device manufacturers
- ASTM Executive Committee voted to advance ICE as US Standard … ASAP
- Re-submit to ISO when published

Making it real



Some benefits of MD PnP infrastructure 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-promoted UDI (Unique Device ID)
- Reliable, seamless data integration
- Support single “source of truth” for patient ID, time stamps, etc.
- Close workflow loops and support medication safety systems and interlocks

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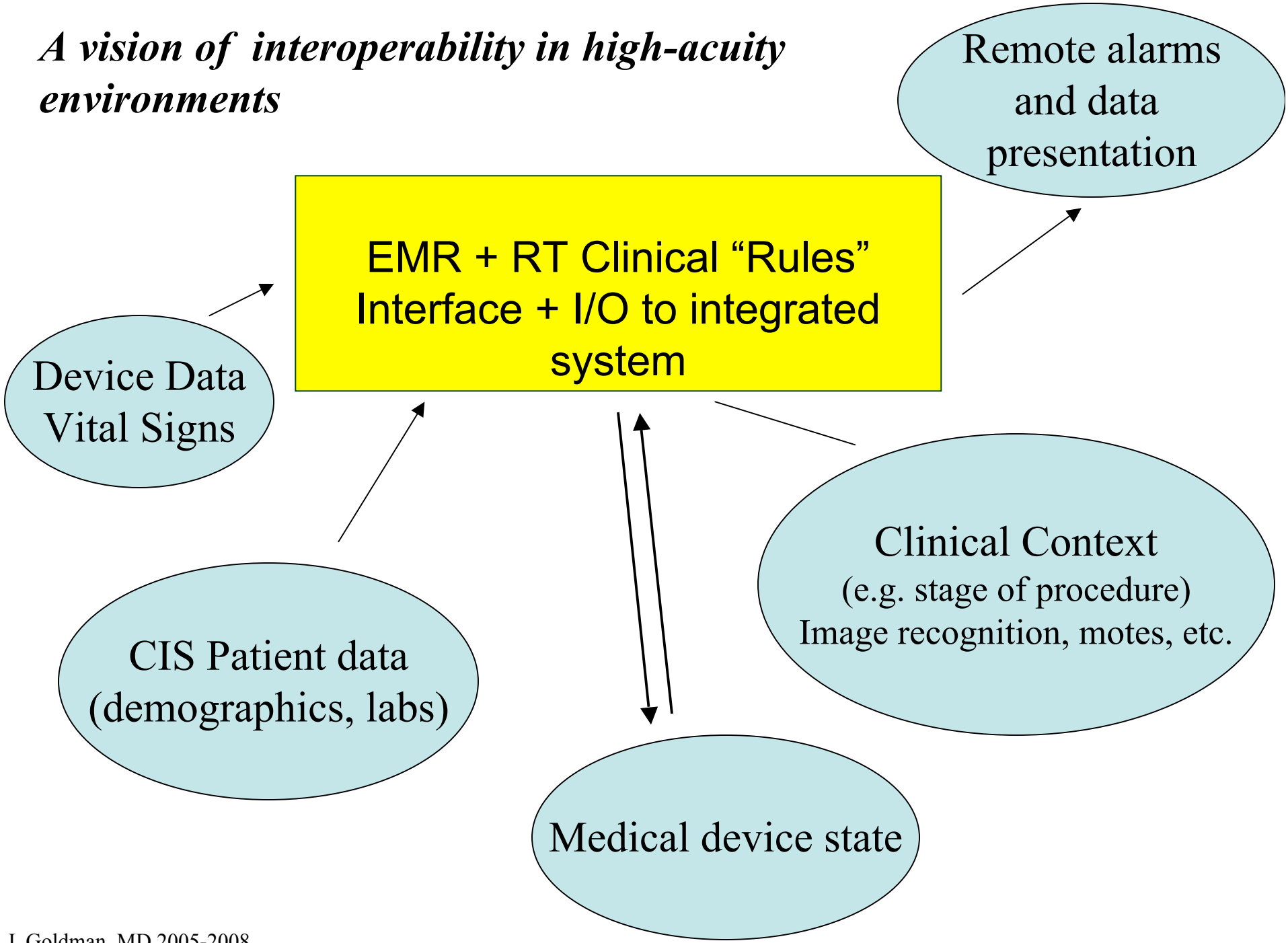
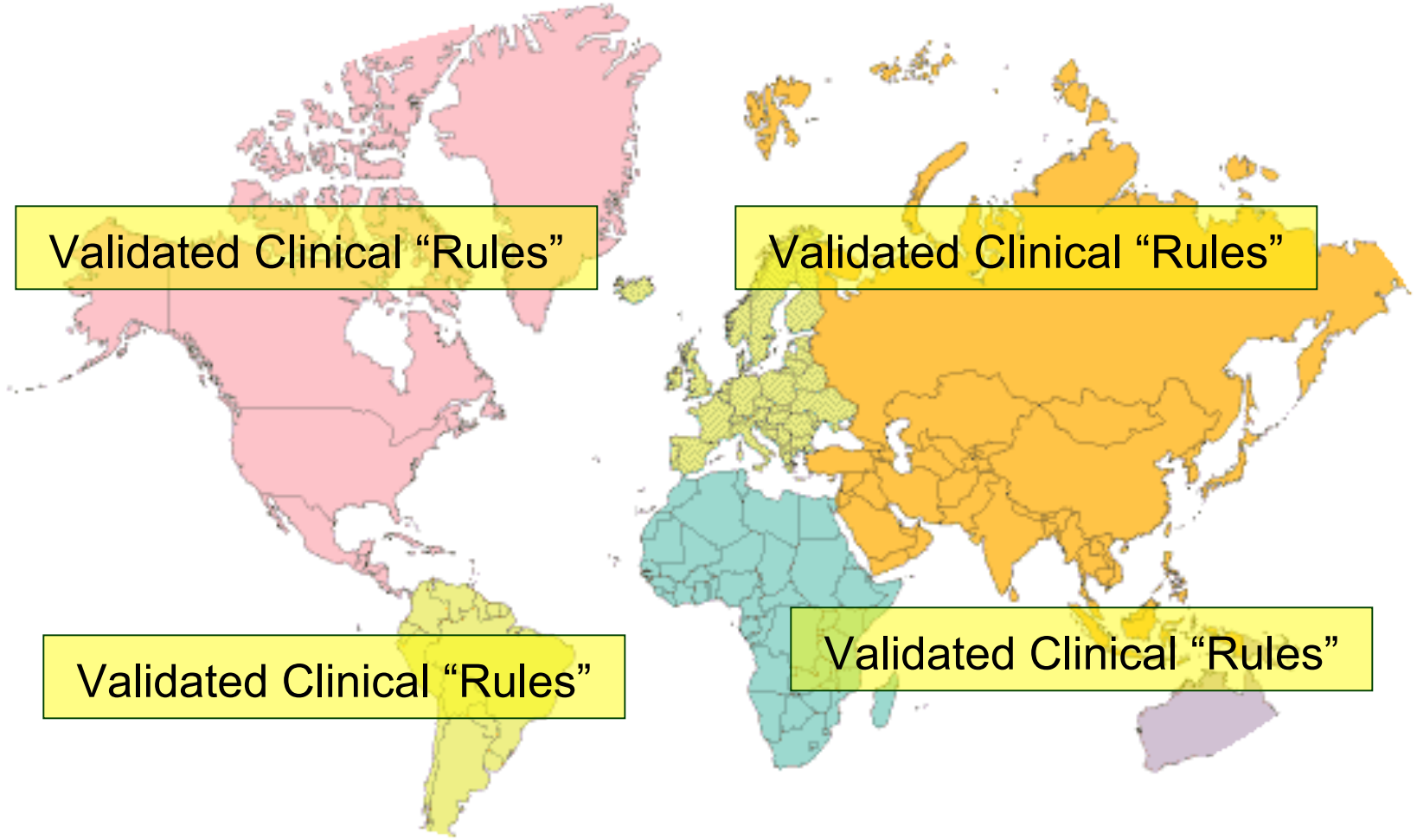
The Vision

change expectations;
change technology;
change healthcare

A vision of interoperability in high-acuity environments



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



Coupled with tools like "VB for HealthCare" or "LabView for Clinical Care"
This technology will change the world

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Participation Pathways:

- Clinicians can contribute clinical scenarios (or “use cases”) to ensure that new interoperability standards and technologies will enable meaningful clinical solutions.
- Healthcare delivery organizations can specify performance requirements, and require adherence to medical device interoperability language in purchasing contracts.
- Engineers can analyze clinical use cases to generate functional specifications, assess current standards to perform gap analyses, and evaluate proposed technologies.
- Medical device manufacturers can participate in the development and adoption of interoperability standards.
- Interoperability promoting organizations can support revising existing standards to meet clinical requirements.
- $


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Action Steps

Implement adoption of 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, and incorporate into contracts (like Kaiser)- NOW
2. Identify Adverse Events that could be mitigated with MD PnP
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. A shared test platform and 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

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