
CIMIT

MD PnP™
Getting connected for patient safety™
www.MDPnP.org

Malignant Spaghetti
Wireless Technologies in Hospital Health Care
November 14, 2008

# The "Operating Room of the Future"
## and medical device interoperability:
## *preparing for system solutions at the sharp edge of healthcare*

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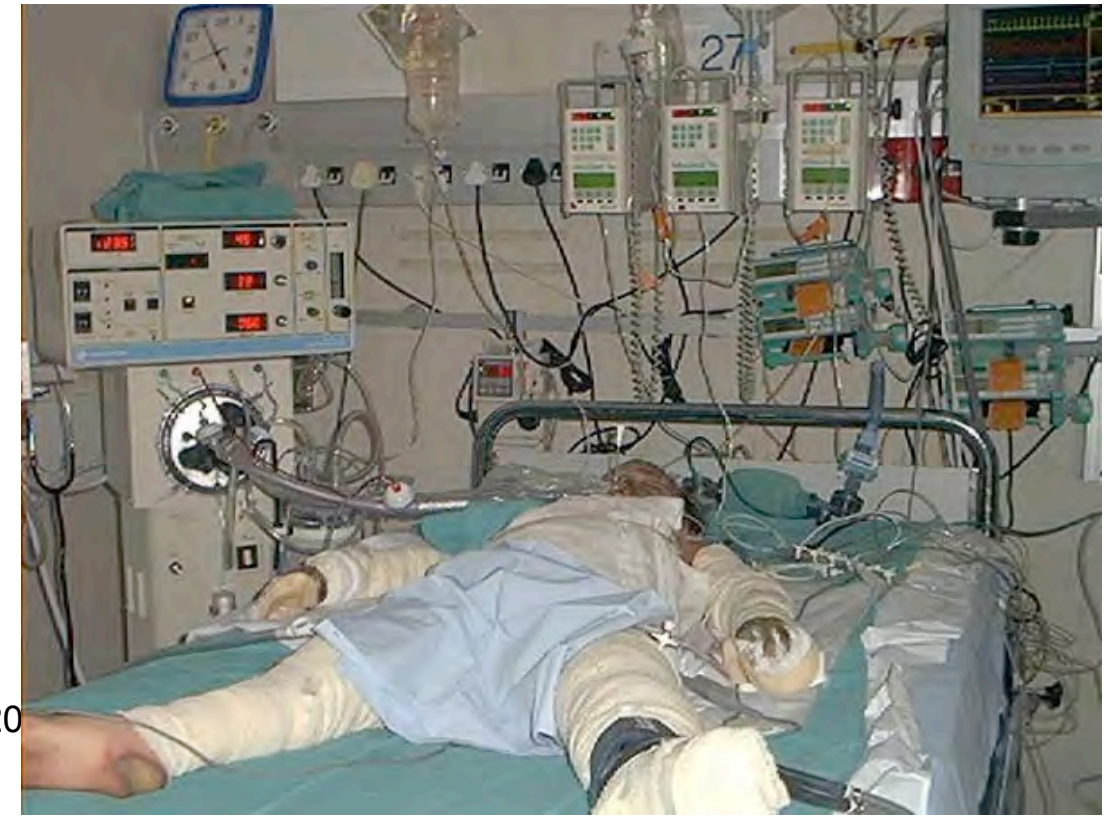
# Overview

1. Clinical Scenarios (Use Cases)
2. MD PnP Program scope and activities
3. Clinical society endorsements
4. Contracting Language
5. ICE Standard

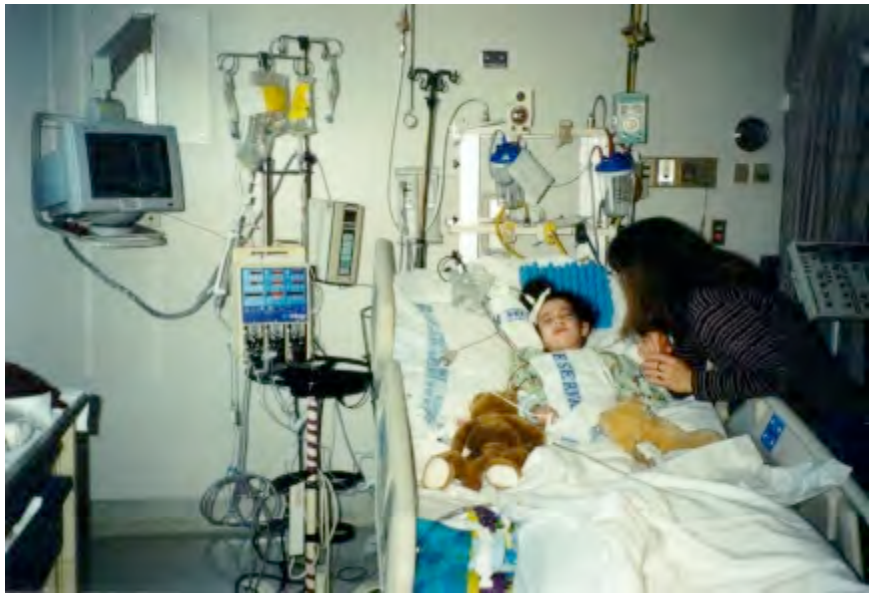
# Current state

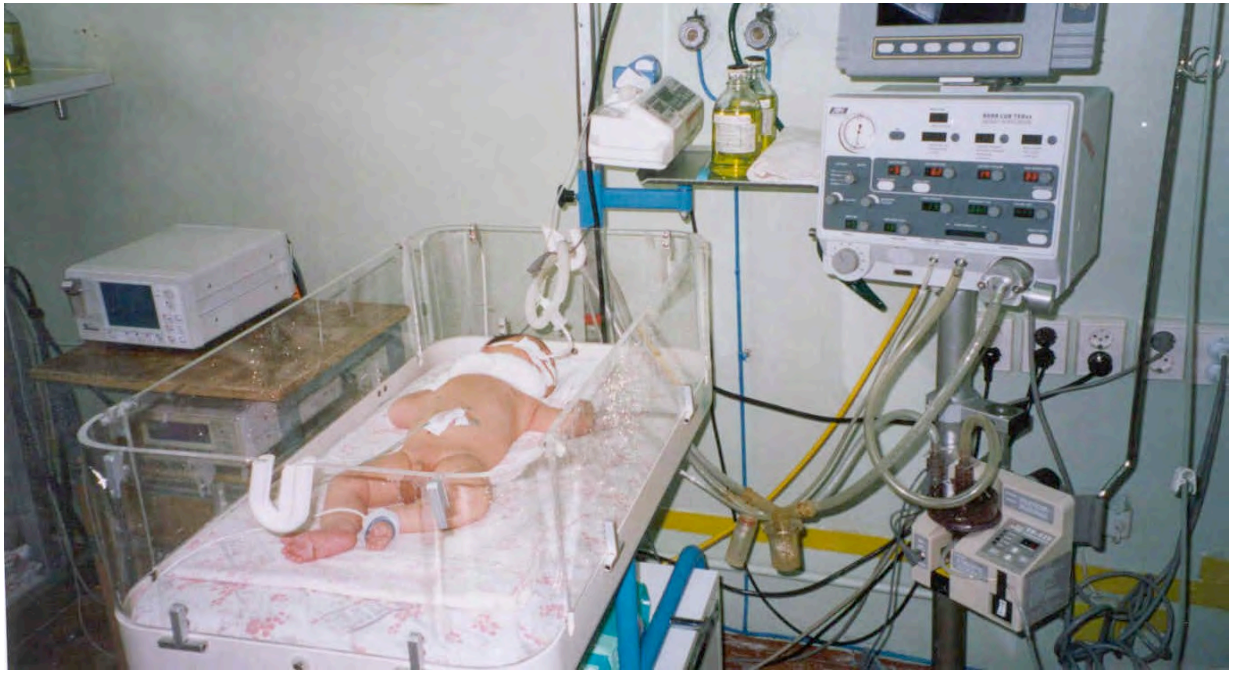
… at the sharp edge of high-acuity patient care …

Iraq



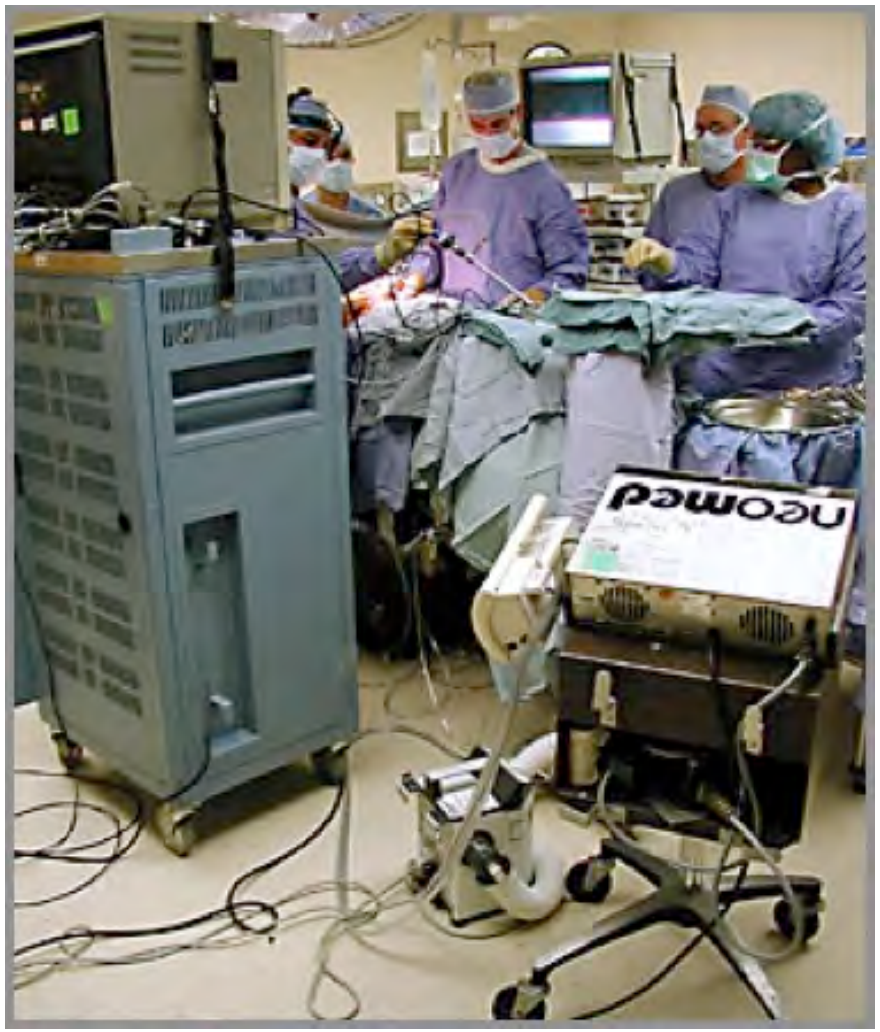
This is the current state

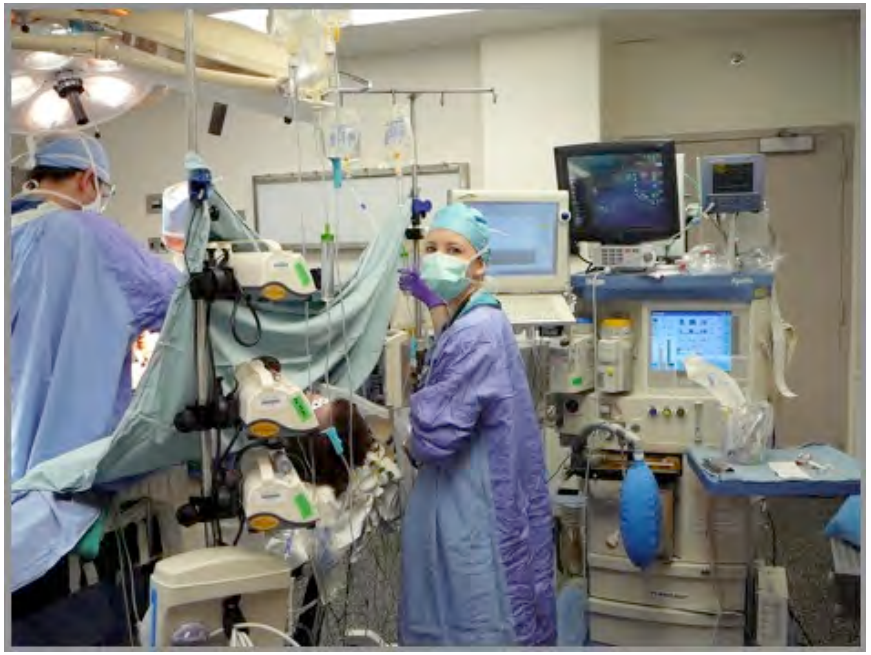




Reality

# Typical ORs of “today”

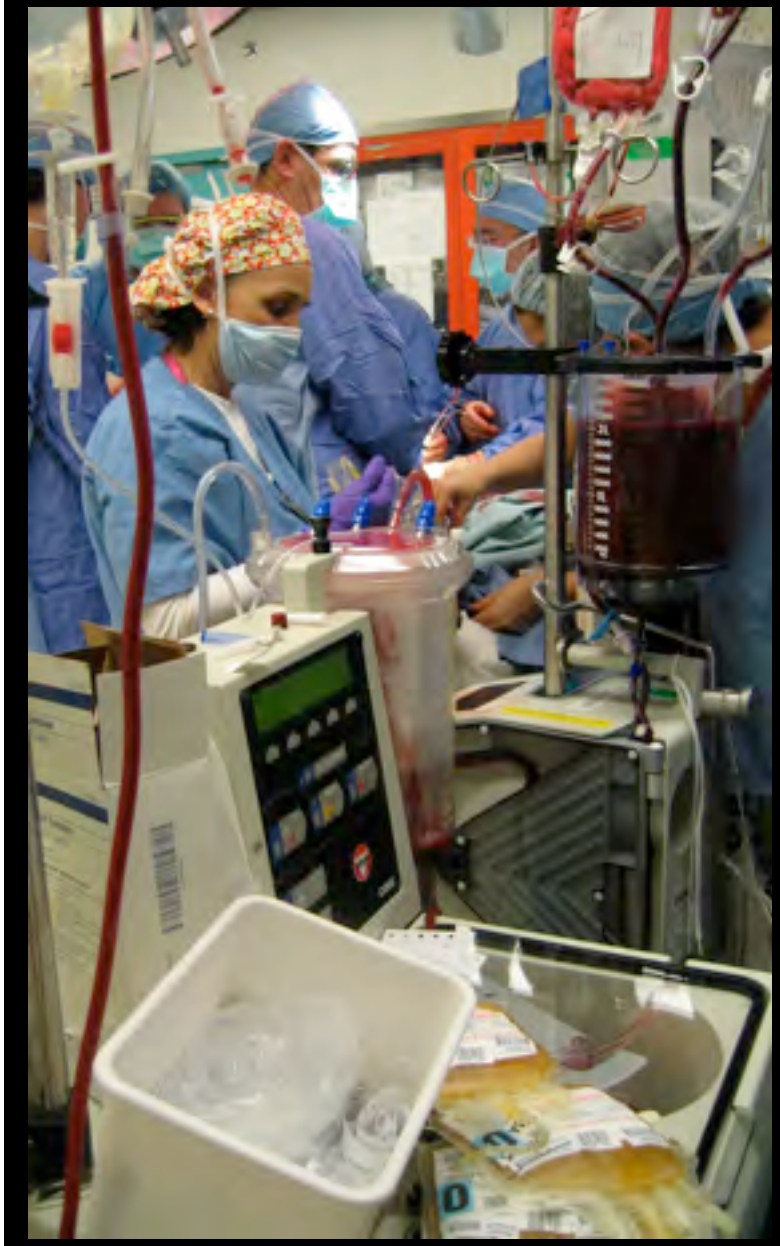


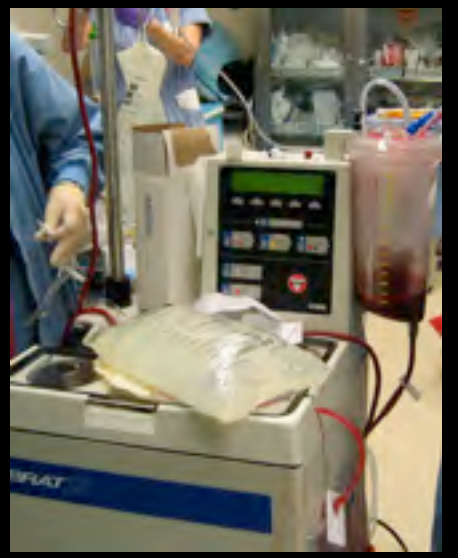





Clinical environments are crowded with advanced, life-saving technology

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

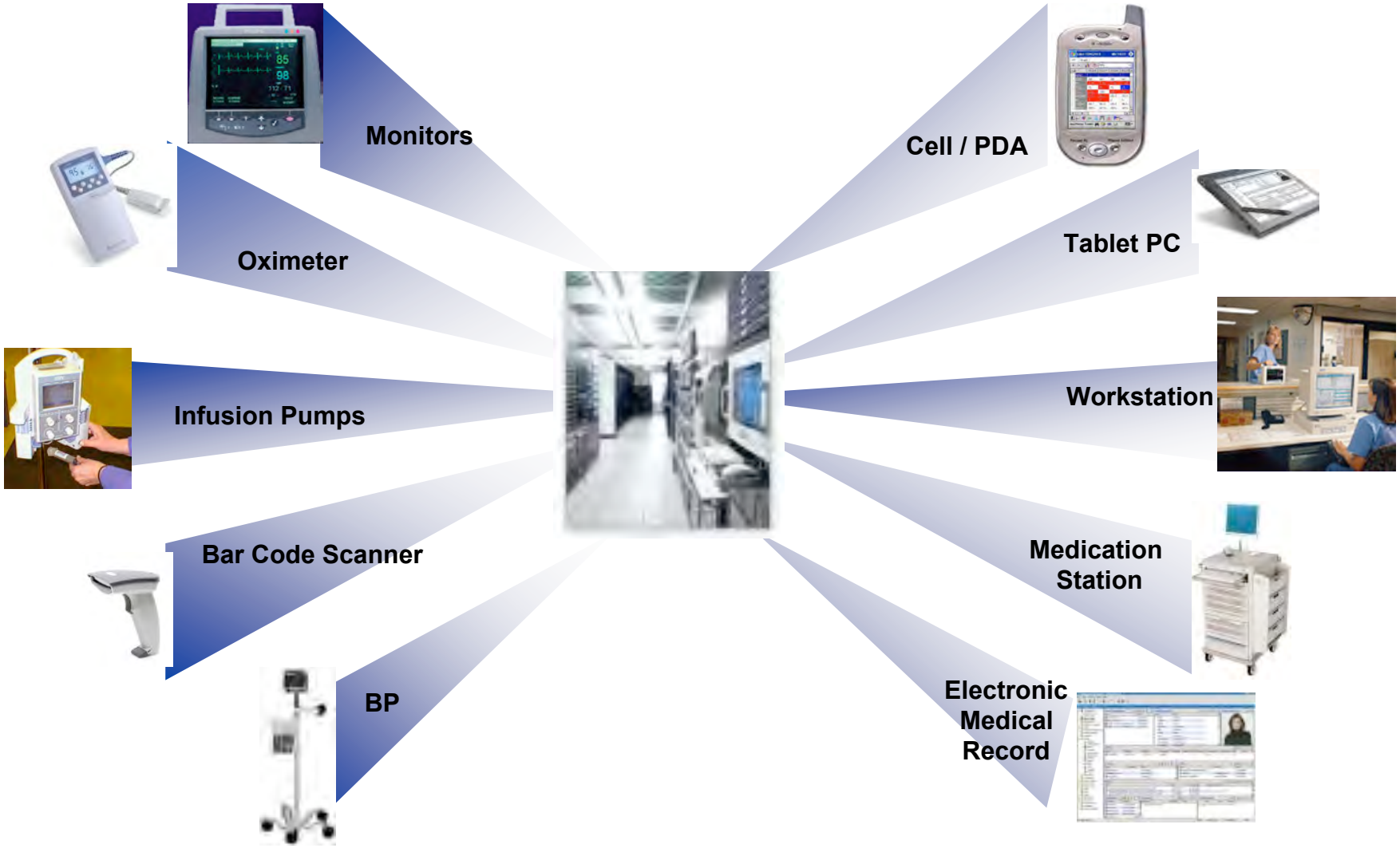




# Demand and complexity will only increase …

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

**Data Integration, Analysis, and Display**



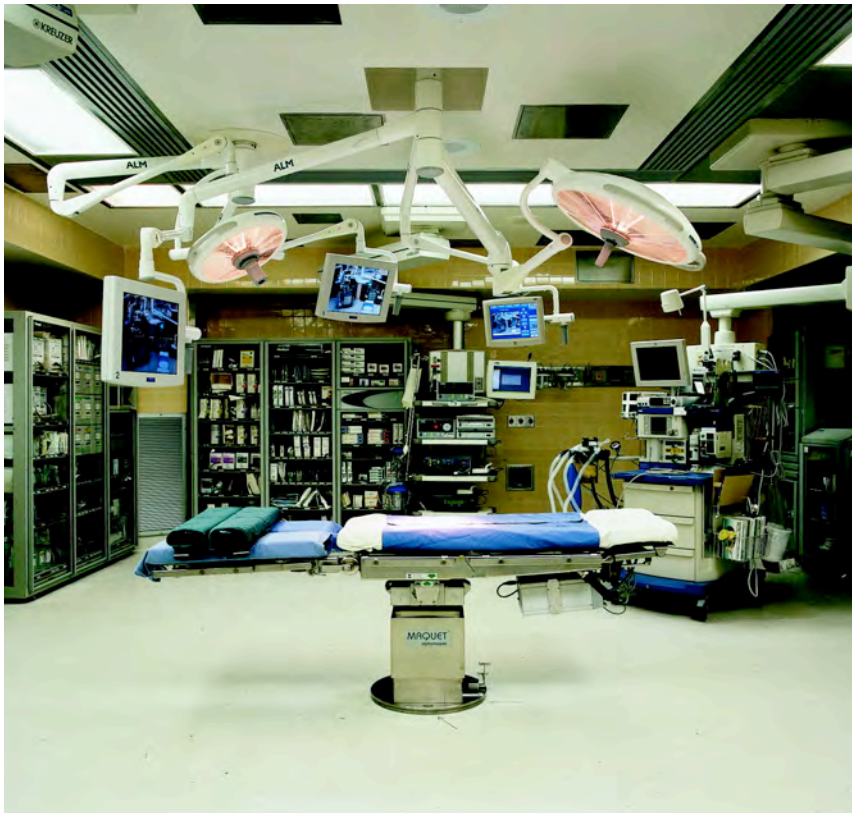

Credit: P. Carleton, RN

**Connectivity challenge extends beyond the OR**

# CIMIT/MGH OR of the Future Project

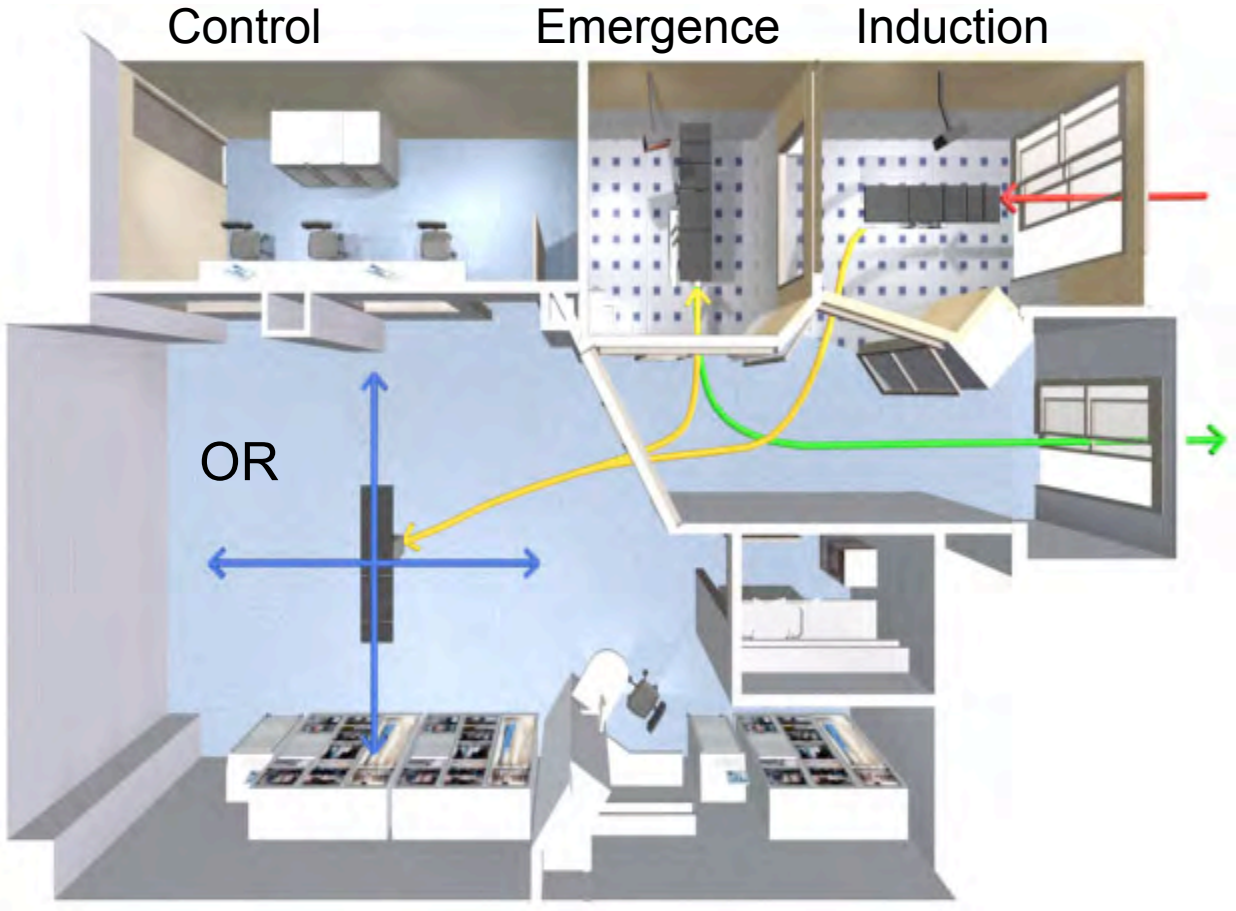
*Center for Integration of Medicine and Innovative Technology*

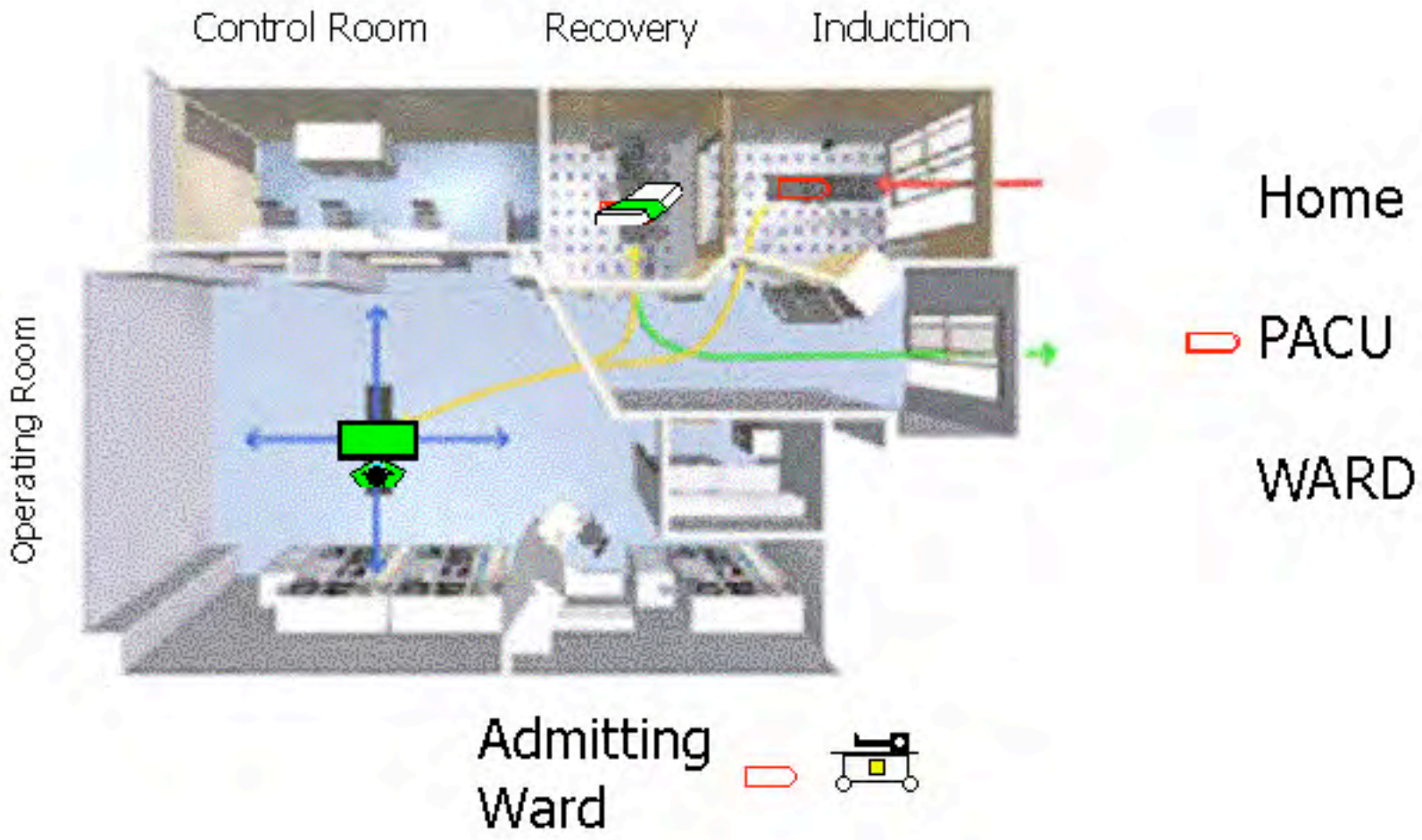
The ORF is a “living laboratory” to study the impact of process change, technology, and team work, on safety and productivity.



# OR of the Future Suite at MGH

Self contained OR suite






Simulation courtesy of Dr. James Stahl, MGH

# Mass General Hospital/CIMIT Operating Room of the Future

# CIMIT "Center for Integration of Medicine and Innovative Technology"

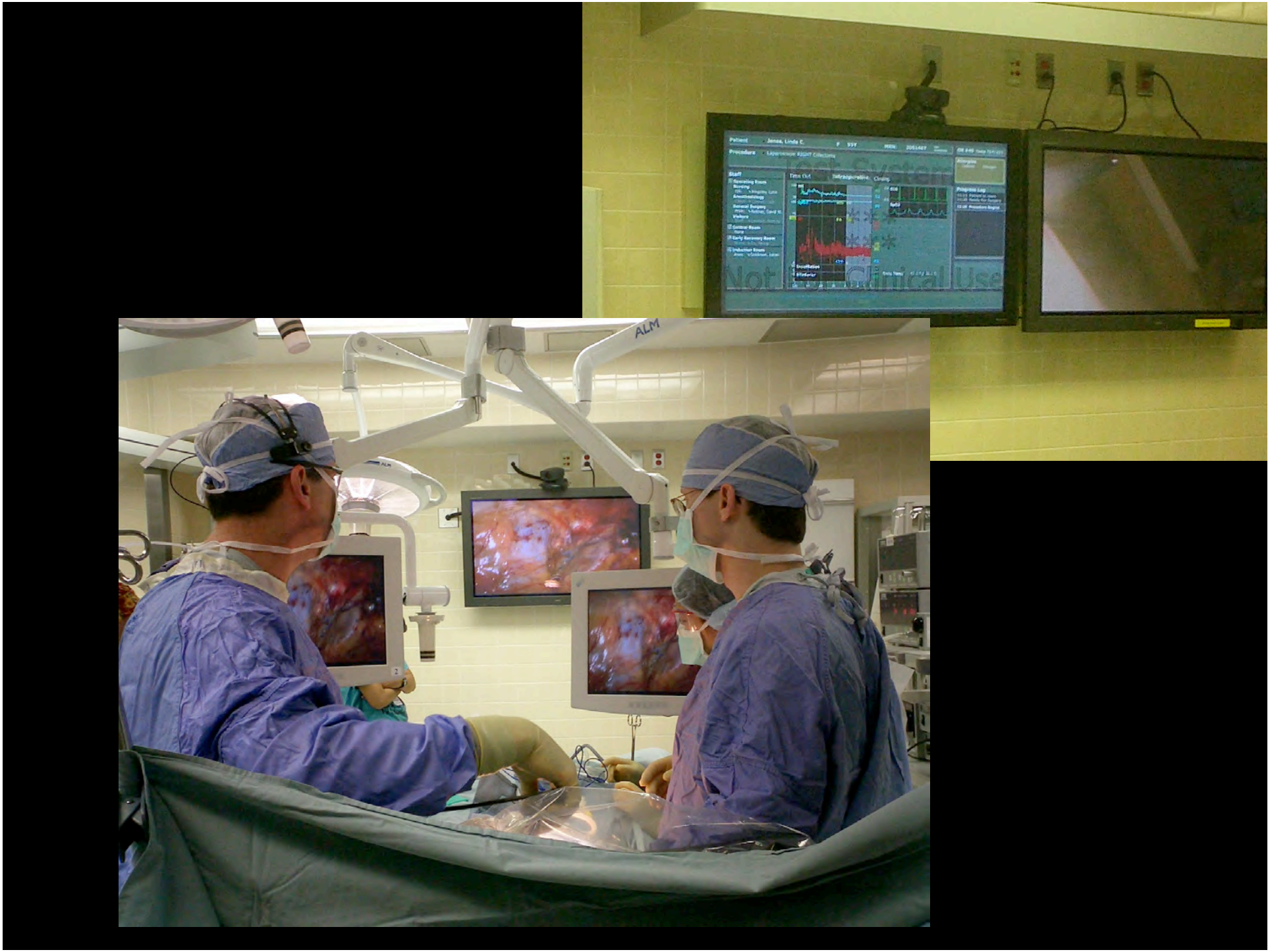
*an Engine for Inter-Disciplinary, Inter-Institutional Innovation*

## CIMIT Mission

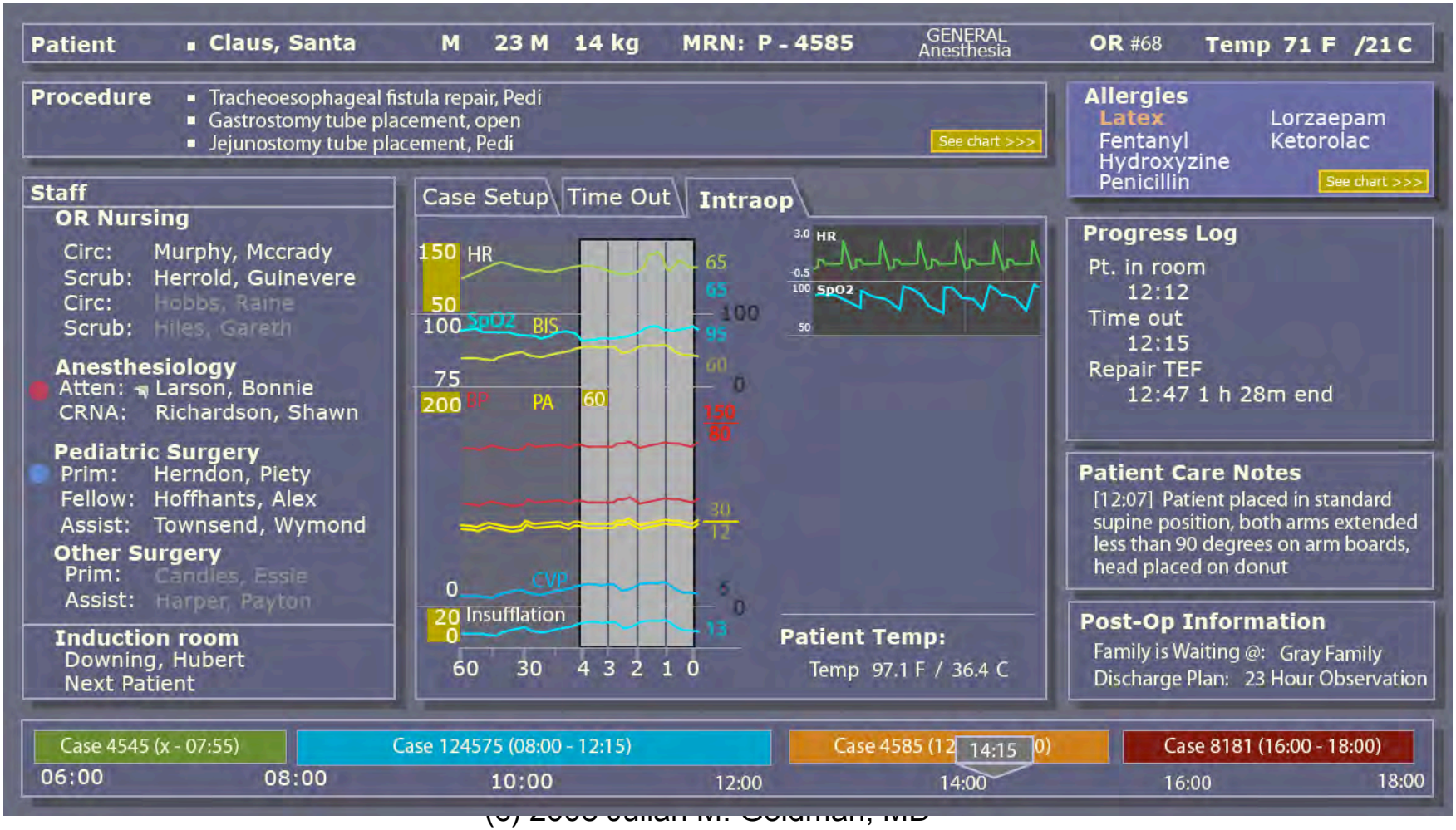
*To improve patient care by bringing scientists, engineers and clinicians together to catalyze development of innovative technology, emphasizing minimally invasive diagnostics and therapy.*

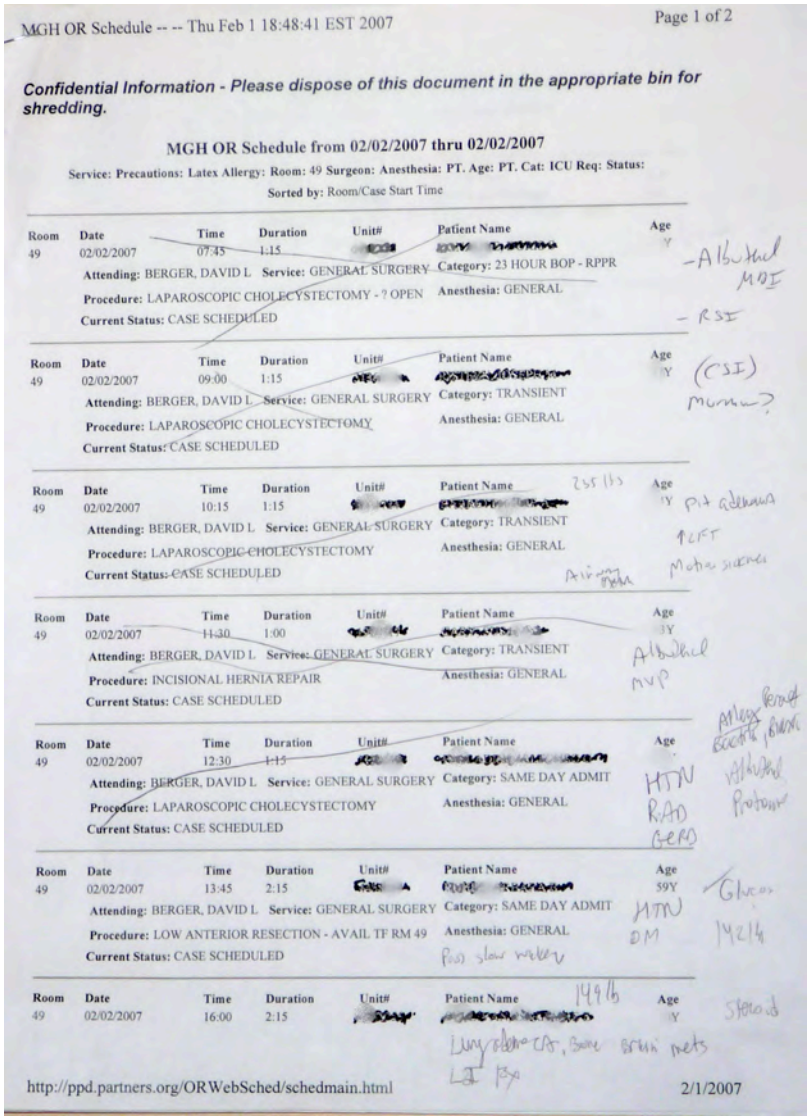
- **Major Supporters & Collaborators:**
  - Partners HealthCare System
  - Department of Defense
- **Academic Medical Centers:**
  - **Massachusetts General Hospital**
  - **Brigham and Women's Hospital**
  - Beth Israel Deaconess Medical Center
  - Children's Hospital Boston
  - Newton-Wellesley Hospital
  - Boston Medical Center
- **Universities:**
  - **Massachusetts Institute of Technology**
  - Boston University
  - Harvard Medical School
- **Engineering/Research Laboratory:**
  - **Charles Stark Draper Laboratory**
- **Private Sector Companies:** 60+

"Program on Interoperability"


ALM

# LiveData OR-Dashboard





MGH OR Schedule -- -- Thu Feb 1 18:48:41 EST 2007 Page 1 of 2

***Confidential Information - Please dispose of this document in the appropriate bin for shredding.***

**MGH OR Schedule from 02/02/2007 thru 02/02/2007**

**Service:** **Precautions:** **Latex Allergy:** **Room:** 49 **Surgeon:** **Anesthesia:** **PT. Age:** **PT. Cat:** **ICU Req:** **Status:**

**Sorted by:** Room/Case Start Time

| Room | Date | Time | Duration | Unit# | Patient Name | Age |
|---|---|---|---|---|---|---|
| 49 | 02/02/2007 | 07:45 | 1:15 | [redacted] | [redacted] | [redacted]Y |

**Attending:** BERGER, DAVID L **Service:** GENERAL SURGERY **Category:** 23 HOUR BOP - RPPR
**Procedure:** LAPAROSCOPIC CHOLECYSTECTOMY - ? OPEN **Anesthesia:** GENERAL
**Current Status:** CASE SCHEDULED

| Room | Date | Time | Duration | Unit# | Patient Name | Age |
|---|---|---|---|---|---|---|
| 49 | 02/02/2007 | 09:00 | 1:15 | [redacted] | [redacted] | [redacted]Y |

**Attending:** BERGER, DAVID L **Service:** GENERAL SURGERY **Category:** TRANSIENT
**Procedure:** LAPAROSCOPIC CHOLECYSTECTOMY **Anesthesia:** GENERAL
**Current Status:** CASE SCHEDULED

| Room | Date | Time | Duration | Unit# | Patient Name | Age |
|---|---|---|---|---|---|---|
| 49 | 02/02/2007 | 10:15 | 1:15 | [redacted] | [redacted] | [redacted]Y |

**Attending:** BERGER, DAVID L **Service:** GENERAL SURGERY **Category:** TRANSIENT
**Procedure:** LAPAROSCOPIC CHOLECYSTECTOMY **Anesthesia:** GENERAL
**Current Status:** CASE SCHEDULED

| Room | Date | Time | Duration | Unit# | Patient Name | Age |
|---|---|---|---|---|---|---|
| 49 | 02/02/2007 | 11:30 | 1:00 | [redacted] | [redacted] | [redacted]Y |

**Attending:** BERGER, DAVID L **Service:** GENERAL SURGERY **Category:** TRANSIENT
**Procedure:** INCISIONAL HERNIA REPAIR **Anesthesia:** GENERAL
**Current Status:** CASE SCHEDULED

| Room | Date | Time | Duration | Unit# | Patient Name | Age |
|---|---|---|---|---|---|---|
| 49 | 02/02/2007 | 12:30 | 1:15 | [redacted] | [redacted] | [redacted] |

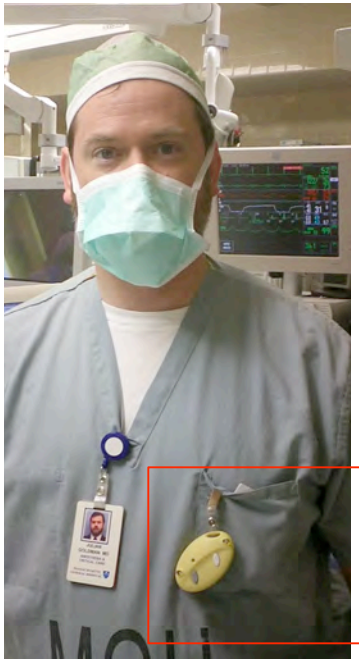
**Attending:** BERGER, DAVID L **Service:** GENERAL SURGERY **Category:** SAME DAY ADMIT
**Procedure:** LAPAROSCOPIC CHOLECYSTECTOMY **Anesthesia:** GENERAL
**Current Status:** CASE SCHEDULED

| Room | Date | Time | Duration | Unit# | Patient Name | Age |
|---|---|---|---|---|---|---|
| 49 | 02/02/2007 | 13:45 | 2:15 | [redacted] | [redacted] | 59Y |

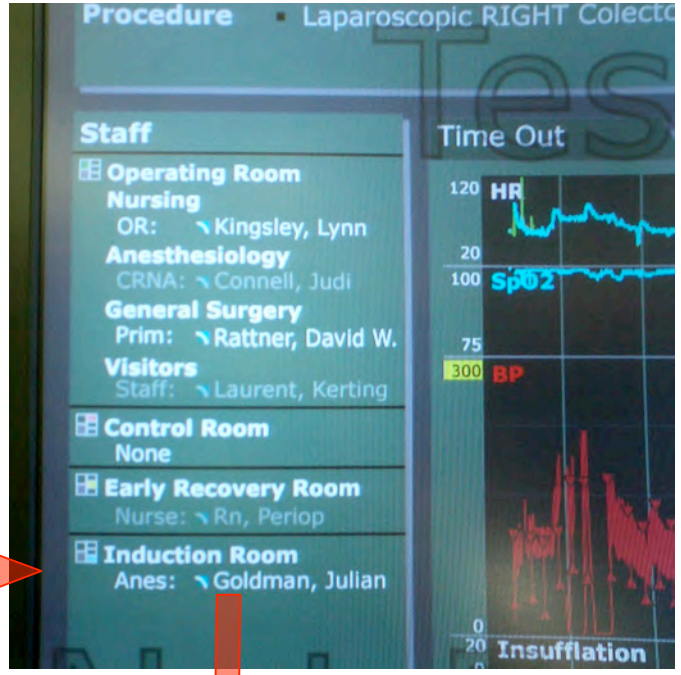
**Attending:** BERGER, DAVID L **Service:** GENERAL SURGERY **Category:** SAME DAY ADMIT
**Procedure:** LOW ANTERIOR RESECTION - AVAIL TF RM 49 **Anesthesia:** GENERAL
**Current Status:** CASE SCHEDULED

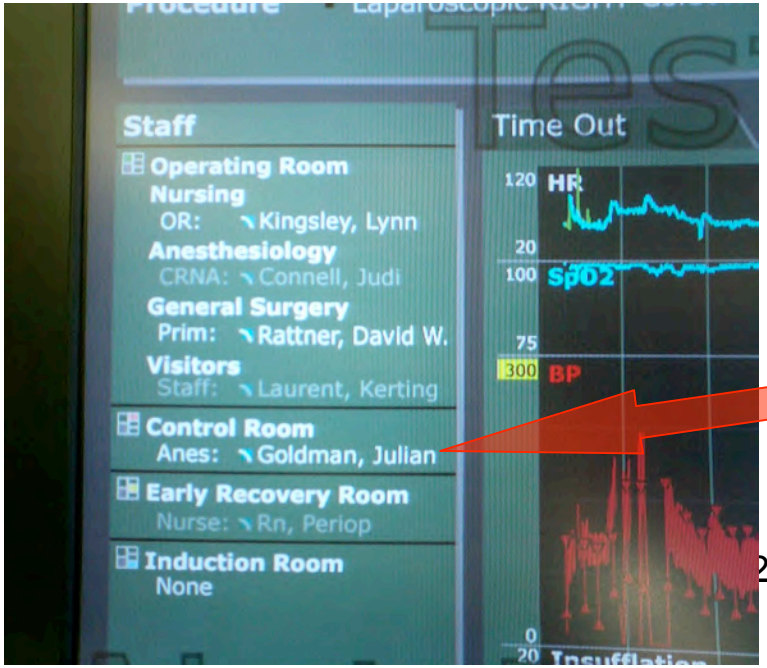
| Room | Date | Time | Duration | Unit# | Patient Name | Age |
|---|---|---|---|---|---|---|
| 49 | 02/02/2007 | 16:00 | 2:15 | [redacted] | [redacted] | [redacted]Y |

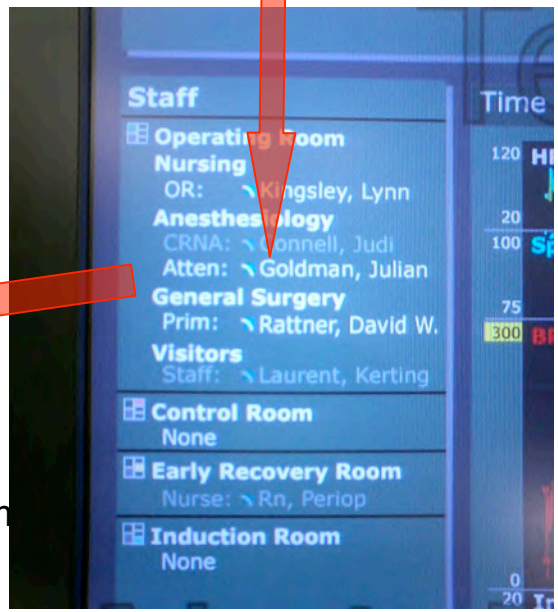
http://ppd.partners.org/ORWebSched/schedmain.html 2/1/2007



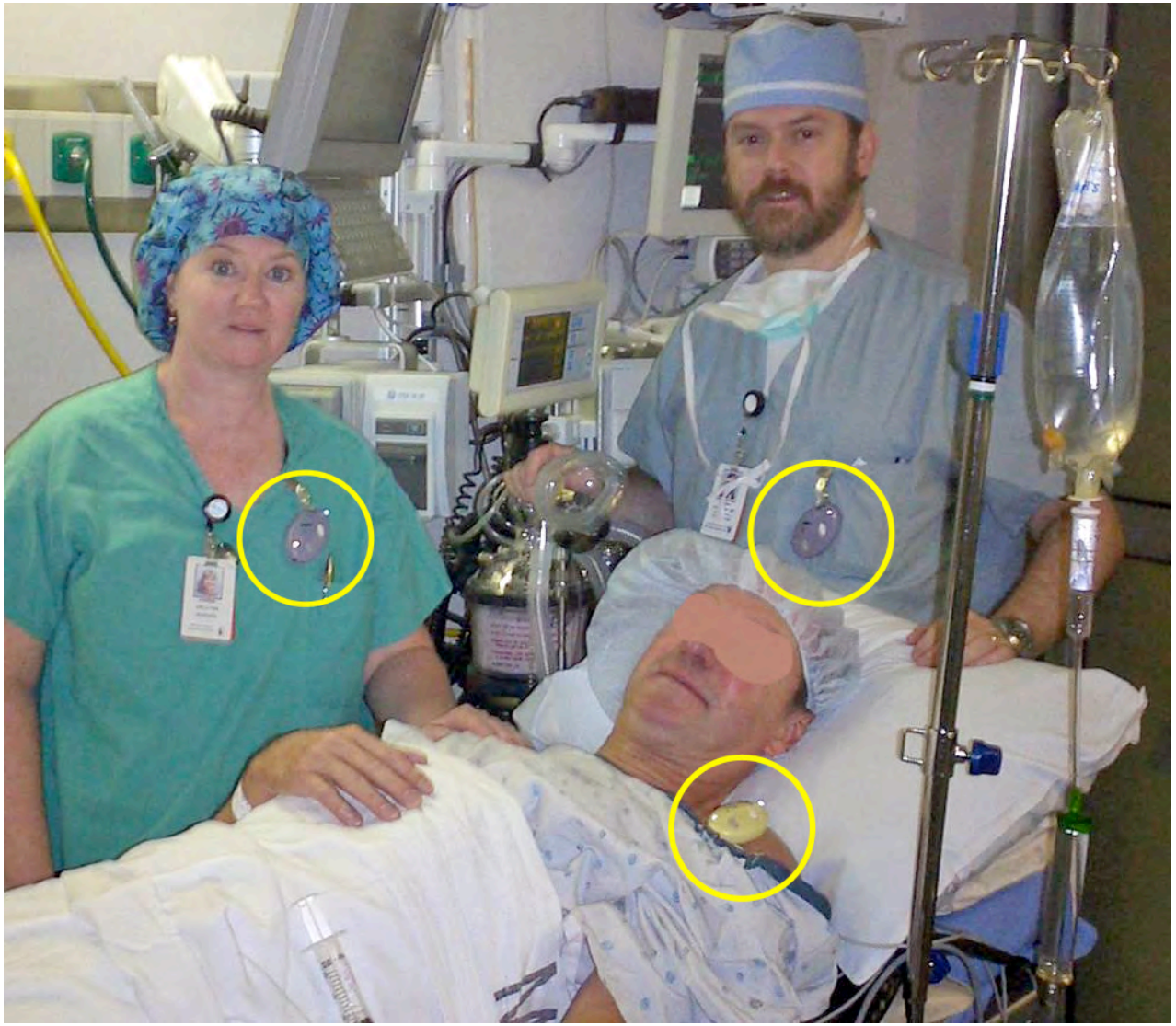
Real-time data integration
Using indoor positioning system



**Association**: Indoor Positioning System used to automatically determine the time of “start of anesthesia care” for documentation



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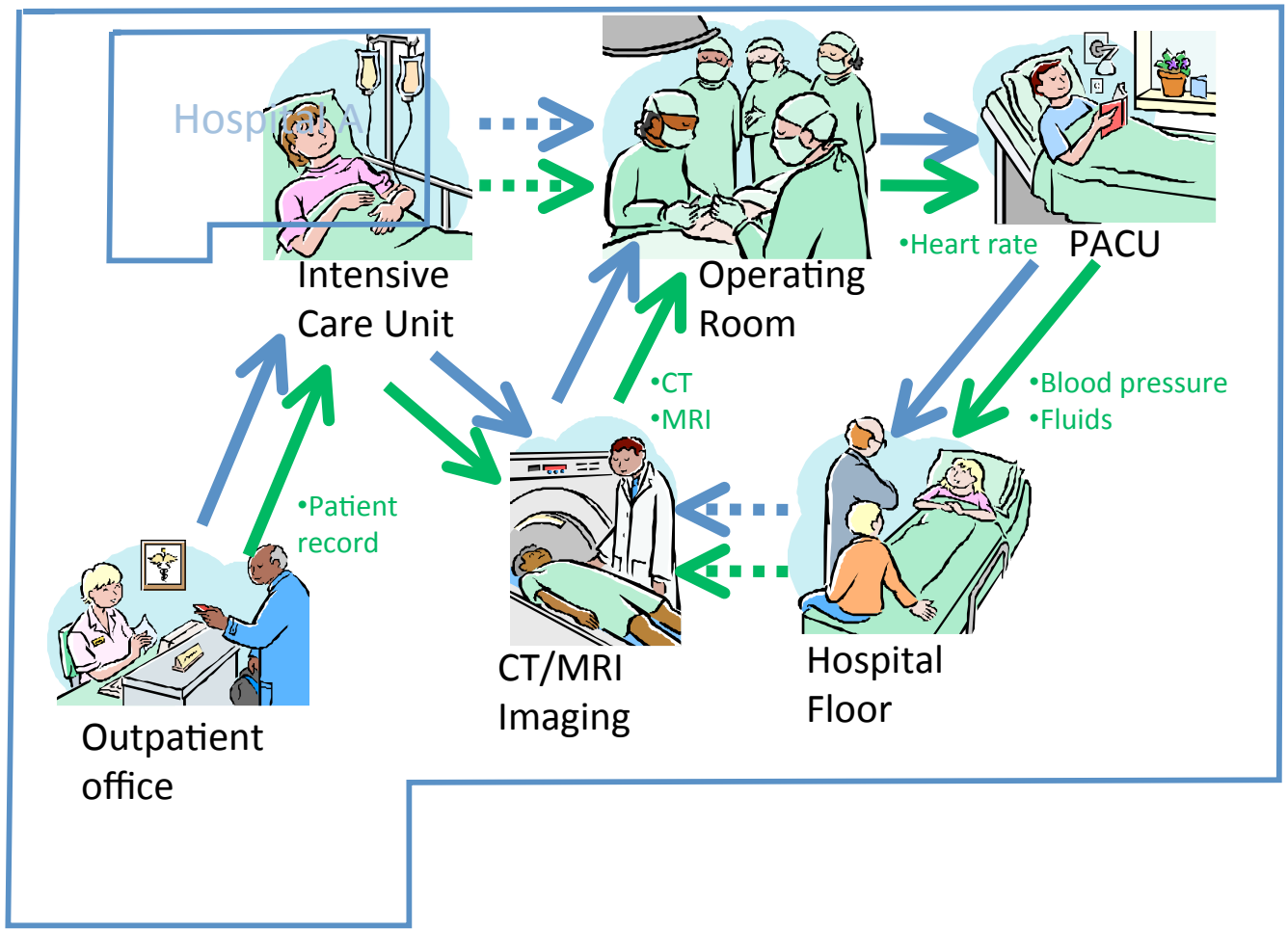
# Movement of Patients and Data Within an Institution



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# OR of the Future project perspective on device and data integration

- Comprehensive integration of data from clinical and environmental systems, can provide “error-resistance” and reduce 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.
- *These solutions require seamless cross-vendor connectivity, which currently can only be provided by vertically integrated companies*
  - Hospitals, researchers, and small companies cannot implement potentially important solutions

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

**Contextual awareness and safety interlocks require data from several device and systems**

# Interoperability => Empowerment

- We need to provide an infrastructure for innovation to create error resistant systems

- Medical Devices have a unique place in the “interoperability ecosystem”
  - 1. DATA - Medical Devices are key data sources ( to EMR/CIS etc.)
  - 2. CARE DELIVERY -Medical devices can be better utilized to deliver care
  - 3. INJURIES - 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

# Examples of clinical procedures that could benefit from interconnected medical devices (system solutions) to address safety issues ->

(From the MD PnP “Clinical Requirements Repository”)



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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!*

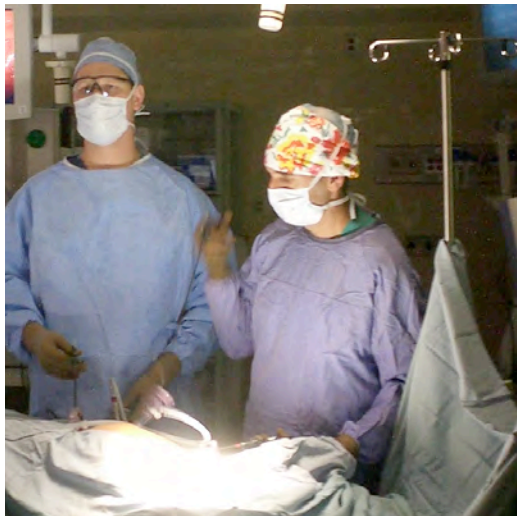
# Scenario:
# Failure to ventilate #2

# Example: Cholecystectomy (gall bladder removal) w/ intraop cholangiography (x-ray)

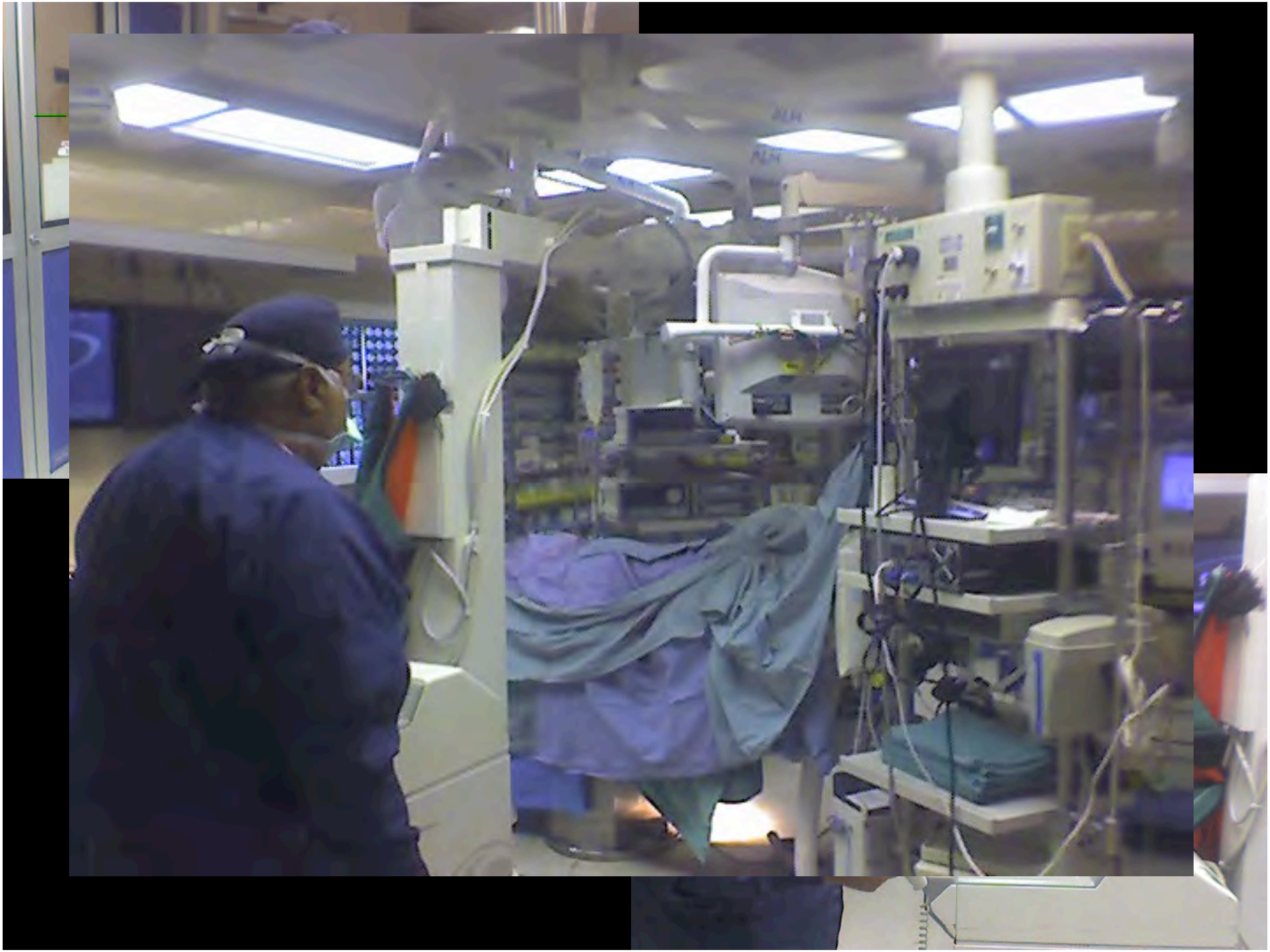
Workflow: 1) Ventilation is stopped. 2) Intraoperative cholangeogram is performed with contrast to identify internal structures.

Breath hold -> improve 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

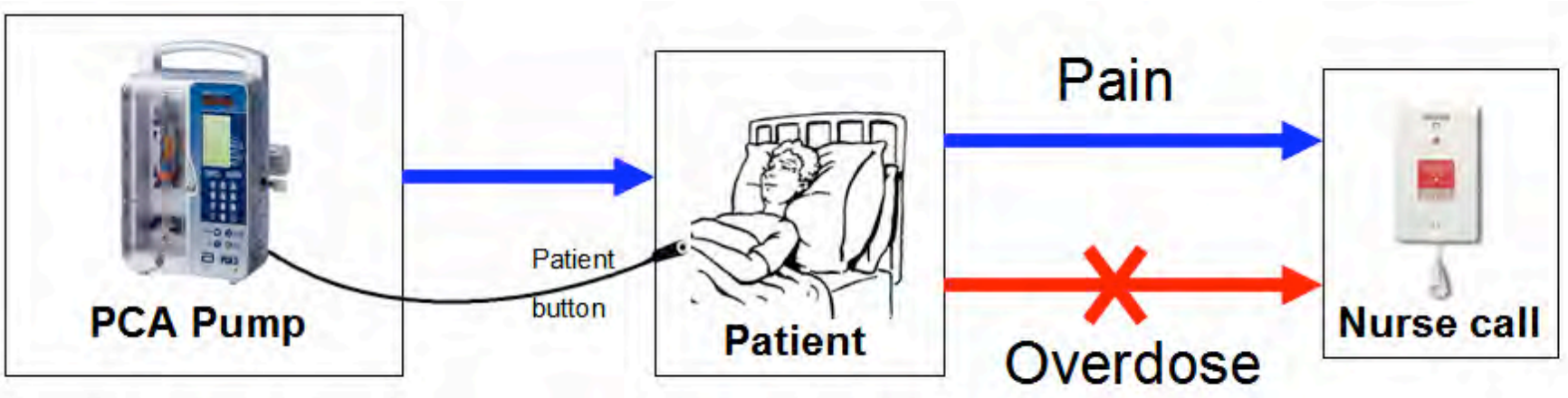
# End-to-End Approach of analyzing and prototyping X-Ray Ventilator Use Case

1. Elicited use case (STA conference in 2004)
2. Analyzed requirements and workflow (MD PnP multi-institutional interdisciplinary team)
3. Vetted by clinicians, vendor, engineers
4. Rapid prototype in lab
5. Public presentations, publication
6. Refinement with clinical data and clinical engineers
7. Inform change to existing ventilator standards (OR and ICU) and functions of “ICE” standard


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…"

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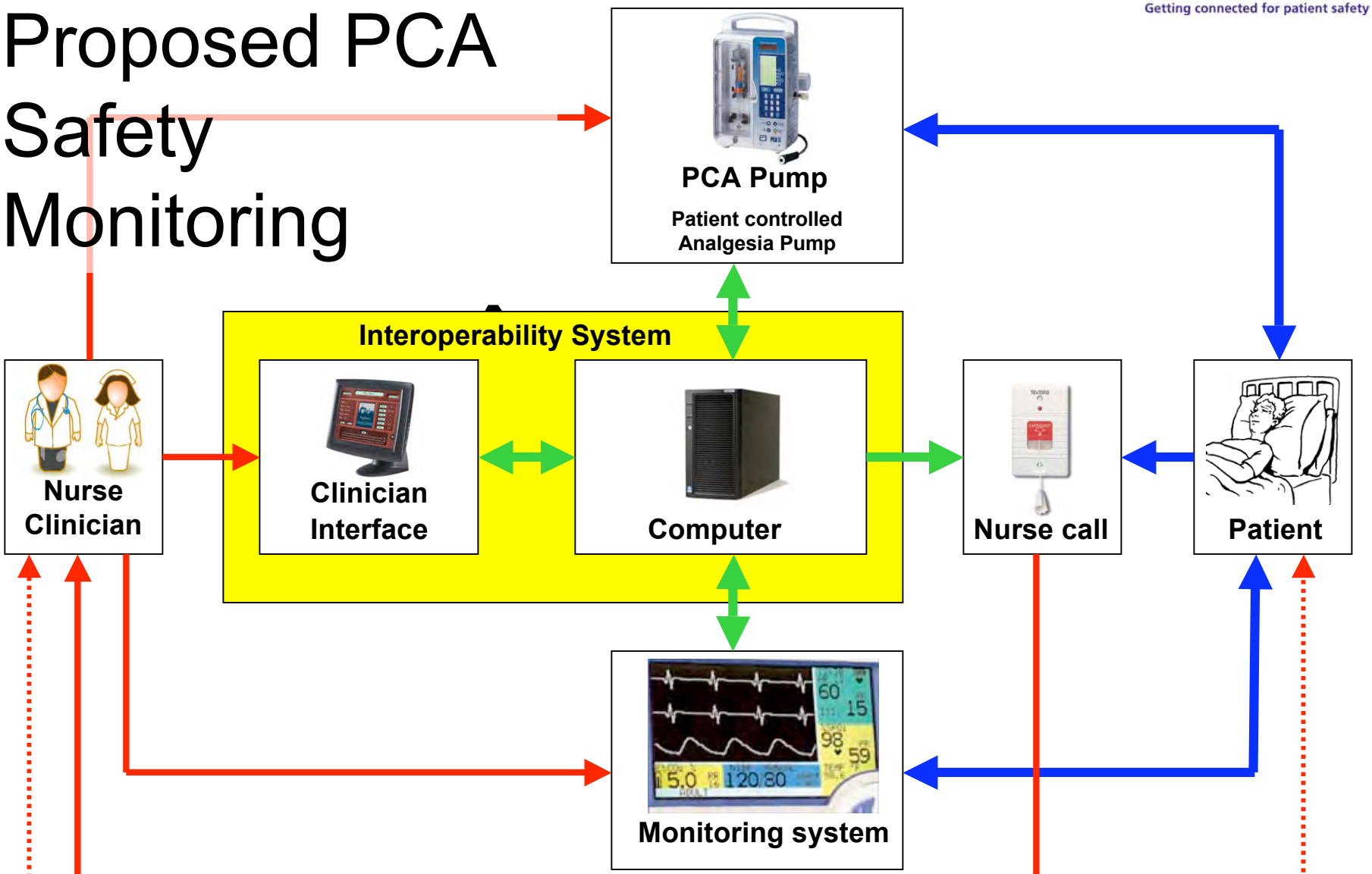
# Proposed PCA Safety Monitoring



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

# Clinical Requirements

- Clinical scenarios must be 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 to clinical environment during laser use | Failure of notification system; wrong room, wrong device activated |

# Data integration is hard!
# Example of cables required to connect devices to the Anesthesia EMR (AIMS)


The cables represent one aspect of the “interoperability barrier”

ASA NEWSLETTER

May 2006
Volume 70

Number 5

# Medical Device Connectivity for Improving Safety and Efficiency

*Julian M. Goldman, M.D.*
*Committee on Electronic Media and Information Technology*

***"Use wireless technologies to eliminate the 'malignant spaghetti' of cable clutter that interferes with patient care, creates hazards for the clinical staff and delays positioning and transport."***

***"Synchronize the respiratory cycle of the anesthesia machine ventilator with portable X-ray exposure so that an X-ray will be triggered at end-expiration, thus avoiding the need to turn-off the ventilator for an intraoperative cholangiogram."***

***"Trigger the portable X-ray at end-inspiration by synchronizing with the ICU ventilator."***

***"Why can't a pulse oximeter be connected to a PCA infusion and automatically interrupt the infusion and activate an alarm when a patient is hypoxemic?"***

***"Support the recording of infusion pump data in the electronic anesthesia information system and permit control of the infusion rate at the anesthesia machine."***

STA Jan 2005

# these clinical scenarios represent ongoing system problems

- Isn't it 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?

# What is interoperability?

"The capability to communicate, execute programs, or transfer data among various functional units in a manner that requires the user to have little or no knowledge of the unique characteristics of those units"

*Definition of interoperability from ISO/IEC 2382-01, Information Technology Vocabulary, Fundamental Terms*

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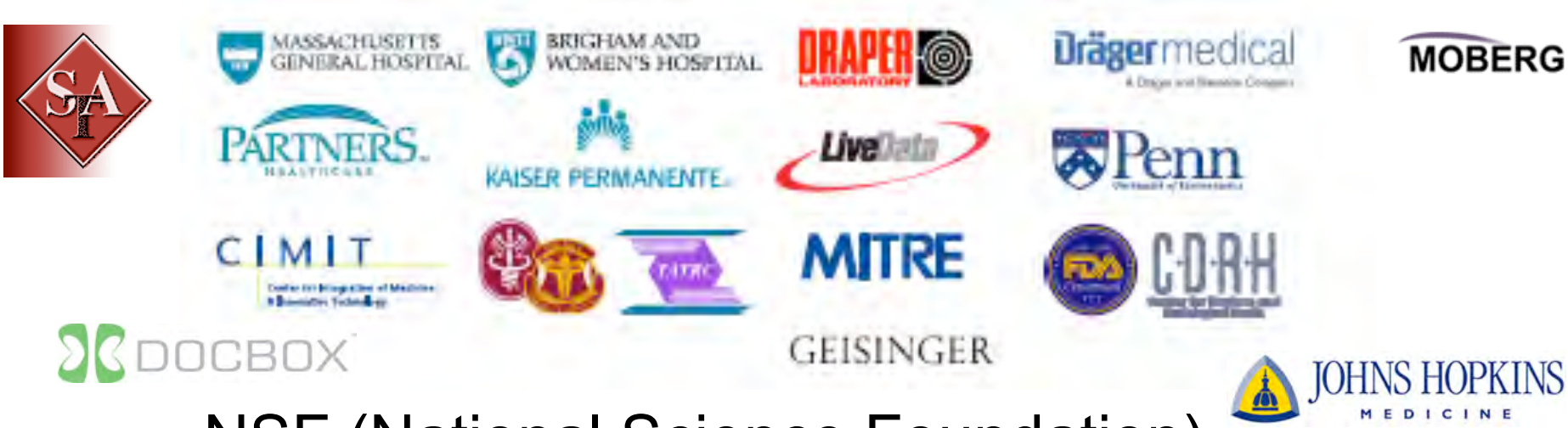
# Overview of the Medical Device "Plug-and-Play" Interoperability Standardization Program (MD PnP)

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.

More than 85 companies and institutions and > 700 experts (clinicians and engineers) have participated in four plenary conferences, working group meetings, and clinical focus groups to shape the mission and strategy and identify clinical requirements.

# MD PnP Program collaborators 2004-2008




- NSF (National Science Foundation)
- Philips Healthcare
- and others

# 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
5. Investigate safety of proposed engineering solutions

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# What are we doing?

- Requirements
- Researching safe design
- Standards - ICE and others
- Education/Outreach
  - Clinical user - what is possible
  - Manufacturer - what is needed

# Workshop/ Lab Demos: June 2007


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

Insup Lee, Rob Kolodner, Julian Goldman

# What is the scope of effective high-acuity medical device interoperability?



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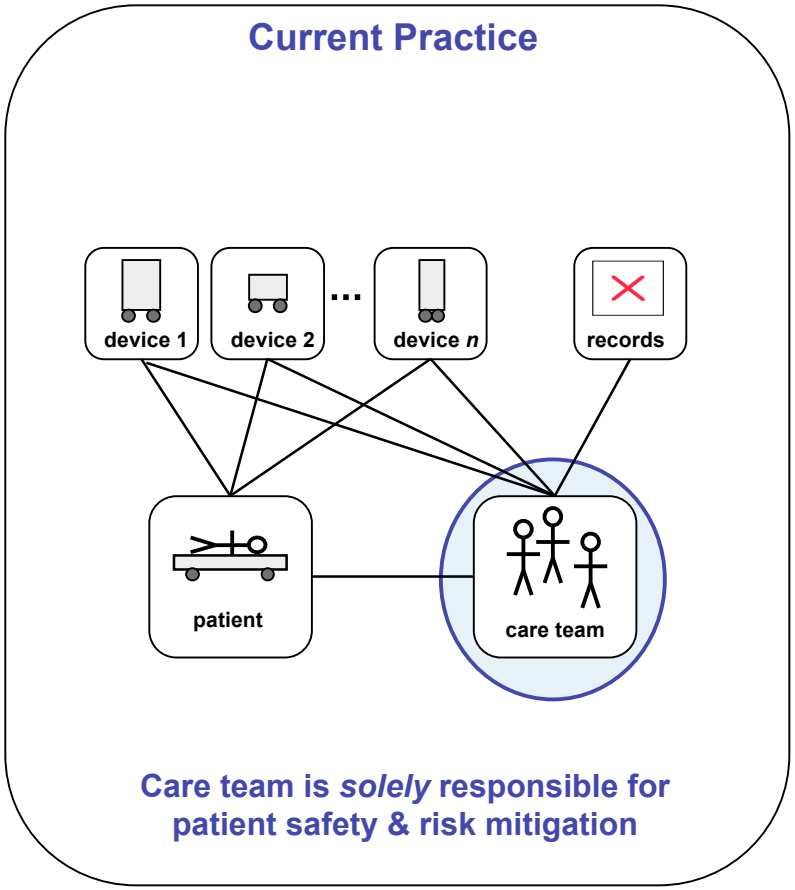
# There are two distinct – but closely related – capabilities of medical device interoperability that are required

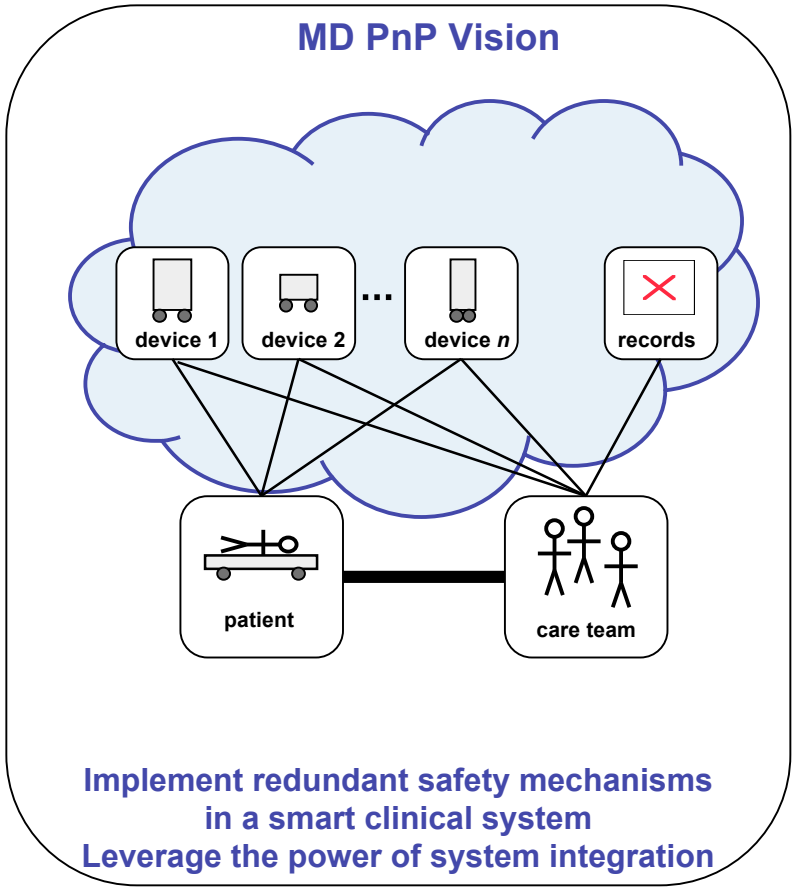
1. Bidirectional medical device data communication

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”).*

The ultimate goal of the MD PnP Program is to **improve patient safety** by enabling the integration of automated oversight and intervention into clinical systems, and managing the emerging complexity of networked medical devices and IT systems.



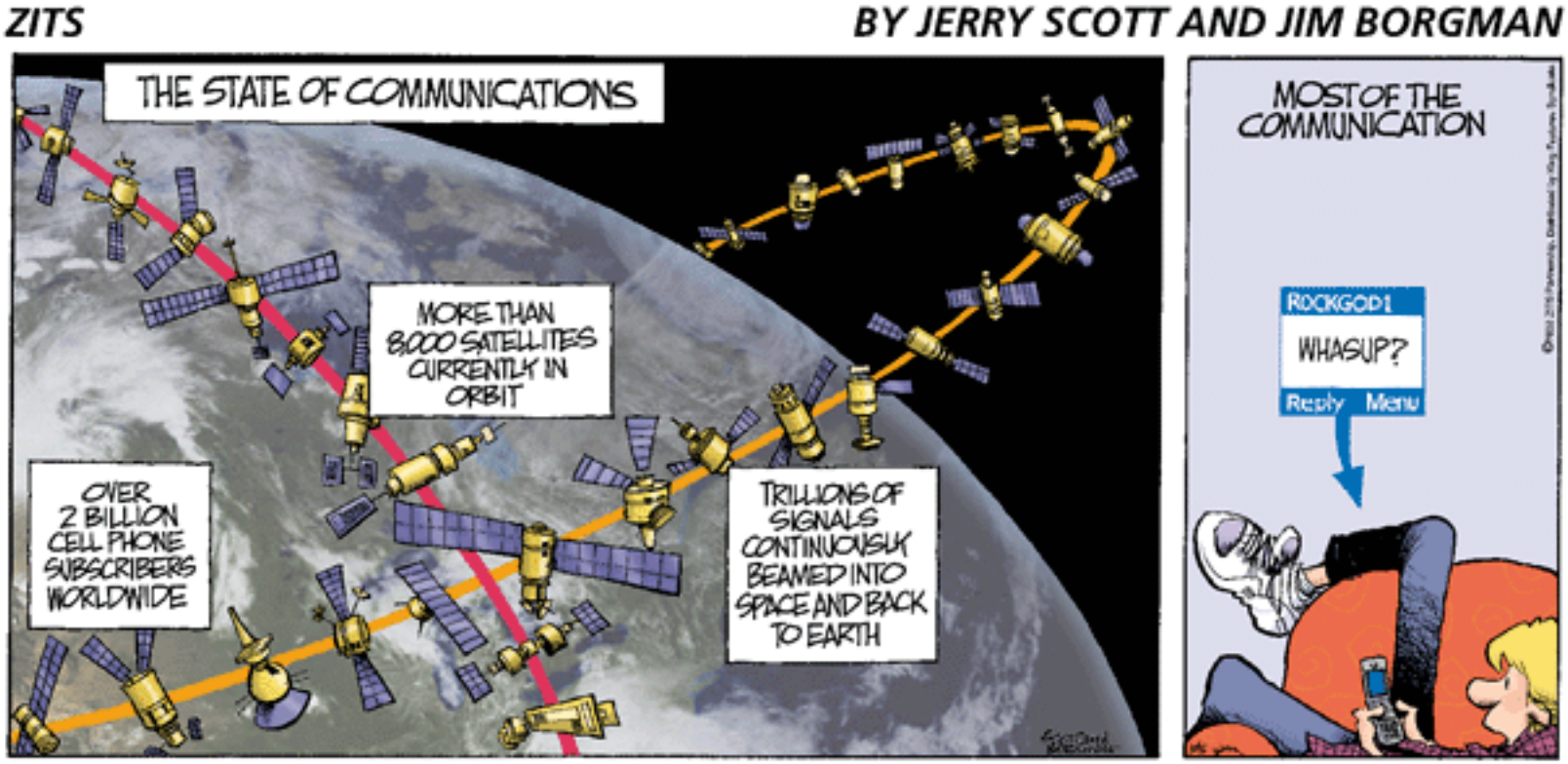



**MD PnP Program** leads initial development process by

- Defining system function and architecture
- Driving market creation
- Identify and analyze requirements
- Engaging industry, advising

**Industry**
can lead implementation and deployment based on the framework developed by the MD PnP Program

**Regulatory Agencies**
Provide guidance and implement regulatory processes




"with great power comes great responsibility" - SM



*sync*

# Clinical Society Support of Interoperability

"We believe 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.

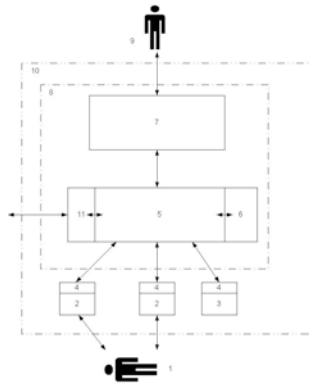
We also recognize that, as in all technological advances, interoperability poses safety and medico legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit."

# Medical Device Free Interoperability Requirements for the Enterprise

- "MD FIRE"
- Developed by MGH, Partners, Hopkins, Kaiser
- To convey healthcare needs to industry, and simplify purchasing specifications
- RFP and Contract samples
- Standards-based
- Released for public use Oct 17, 2008
  - See www.mdpnp.org

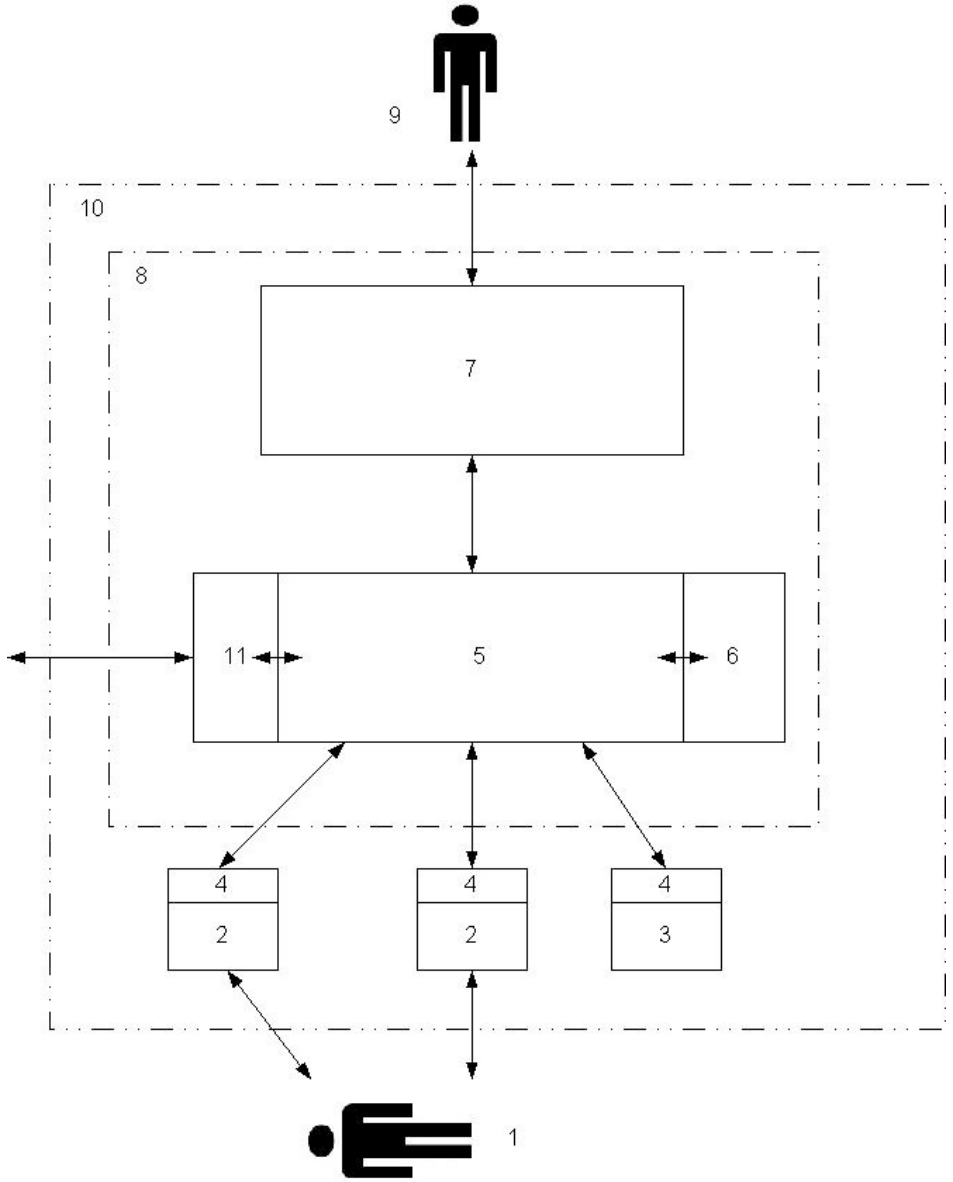
## "ICE" Standard - Integrated Clinical Environment

- 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:
  - Will be completed Q3 2009 by ASTM International
  - http://www.astm.org/DATABASE.CART/WORKITEMS/WK19878.htm



Additional information available at www.MDPnP.org

# ICE Functional Diagram



# Scope of ICE Part I

"This International Standard specifies requirements for integrating equipment to create the Integrated Clinical Environment (ICE). It is intended to facilitate the safe integration of medical devices and other equipment from different manufacturers into a medical system for the care of a single high acuity patient.

ICE is a medical system that has greater capability to support error resistance and improvements in patient safety, treatment efficacy and workflow efficiency than that achievable from independently used individual medical devices."

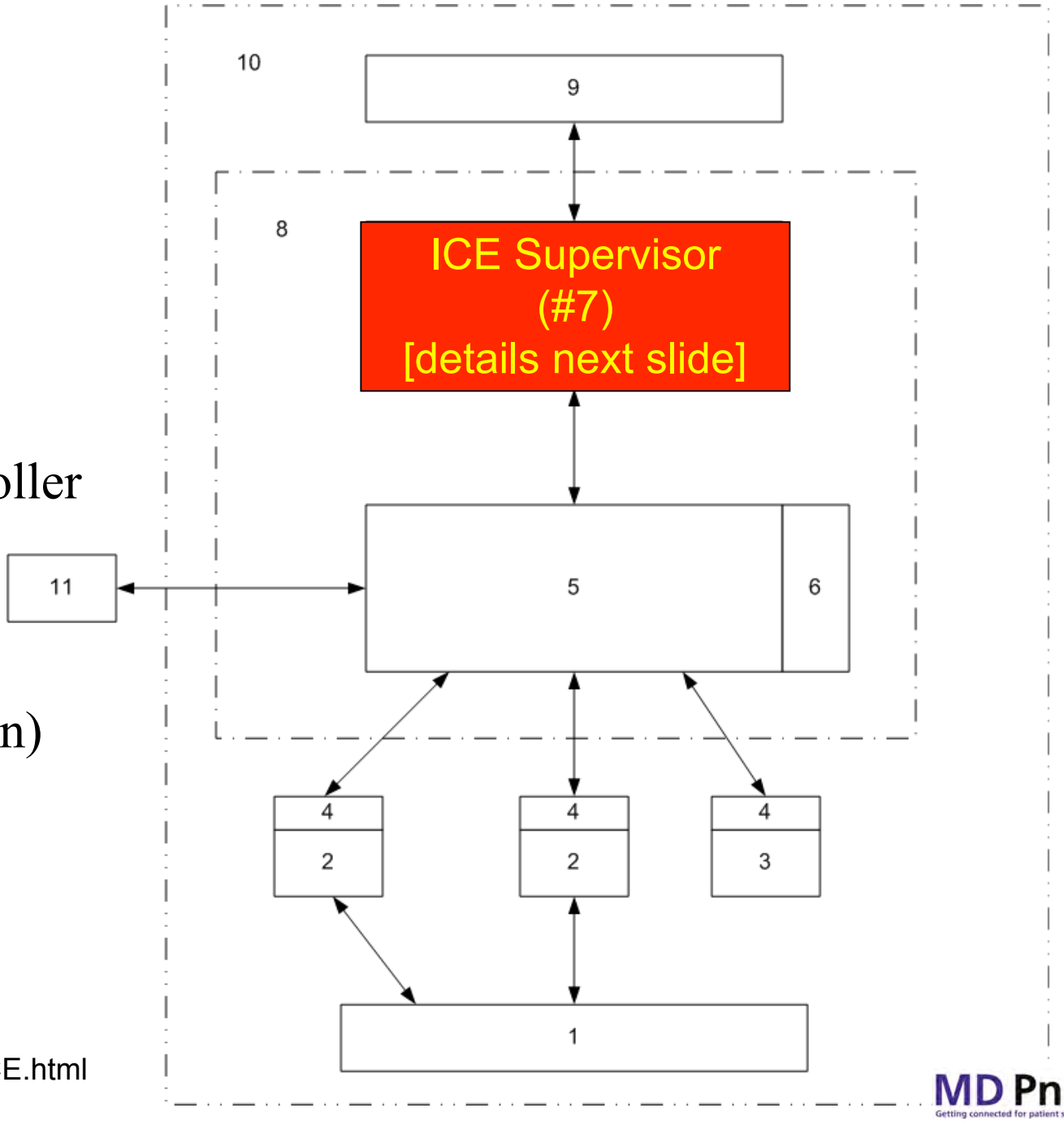
Figure 1: Functional Elements of the Integrated Clinical Environment

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

Current draft: http://mdpnp.org/ICE.html




MD PnP
Getting connected for patient safety

## The ICE supervisor supports i.a. 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 (box #4)

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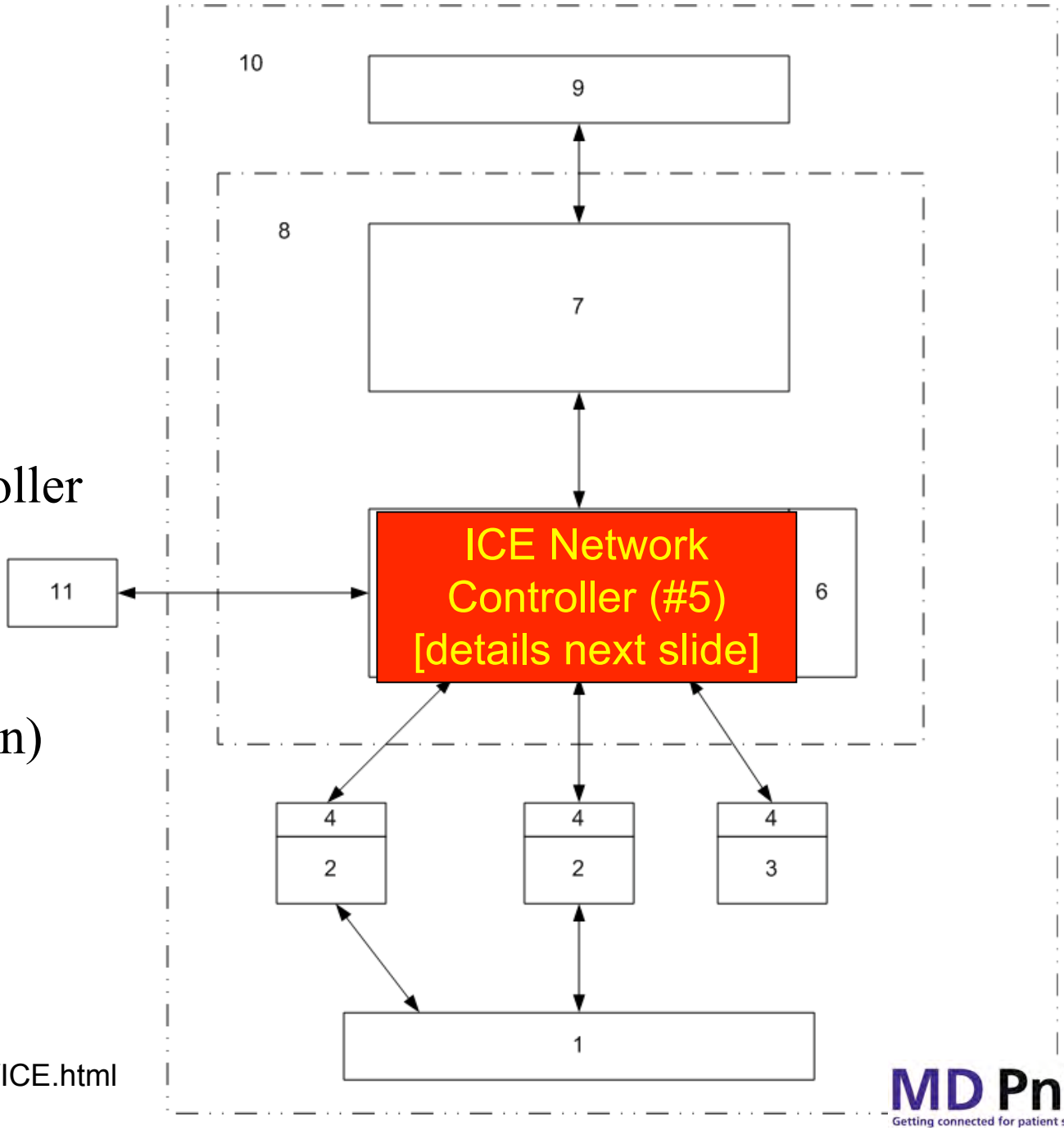



MD PnP
Getting connected for patient safety

# The ICE network controller supports i.a. the following patient-centric capabilities of the integrated clinical environment

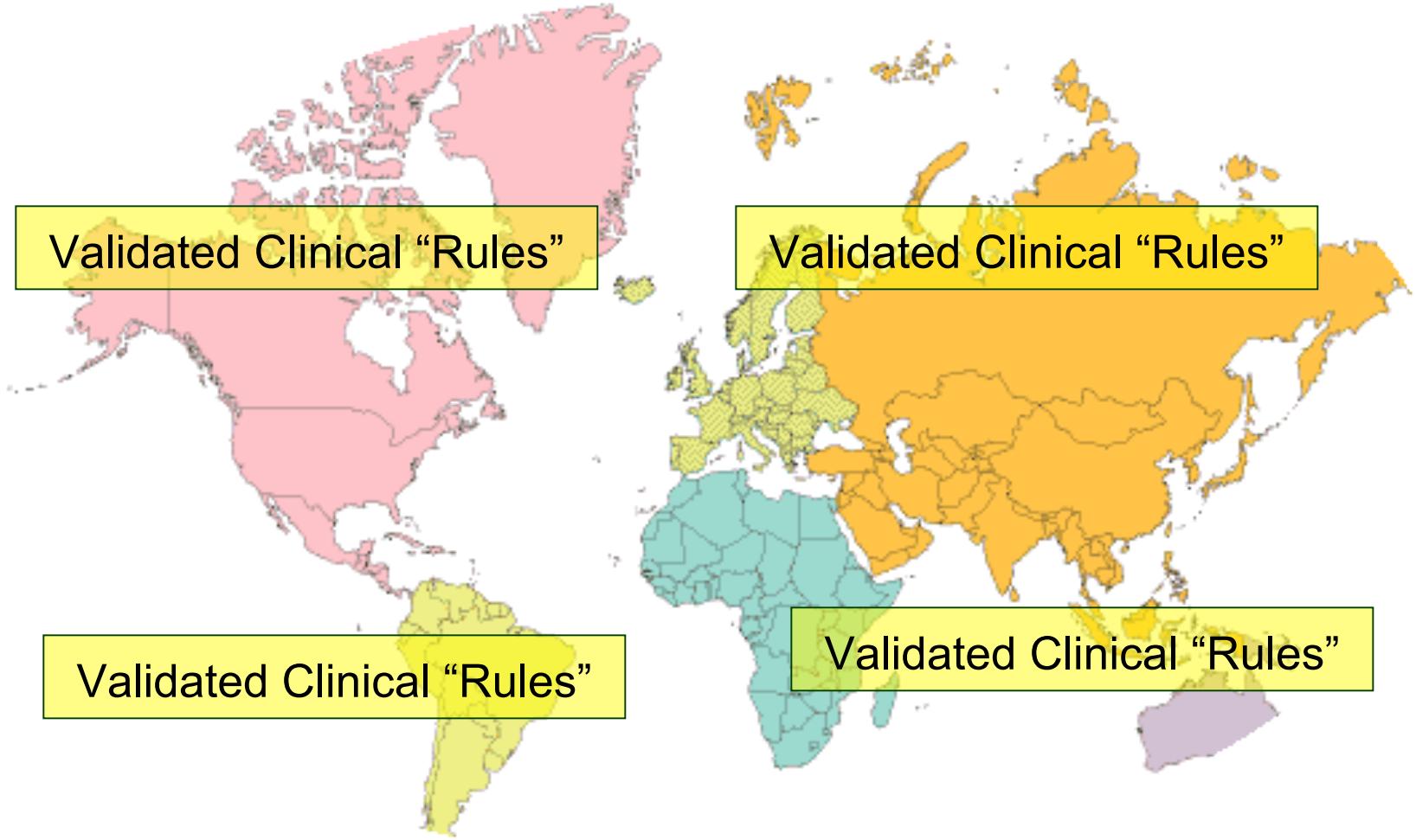
- Provide “Plug and Play” (PnP) connectivity with medical devices and other devices
- Interface with equipment that contains an ice equipment interface
- Provide data logs for forensic analysis (flight recorder)
- Perform network control functions independently of the underlying data communication mechanization
- 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

# Adoption of medical device interoperability (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. "flight data recorder" to facilitate adverse events analysis
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. Reduce cost of devices and their integration, and reduce accelerating EMR-adoption costs
9. Closed-loop control of therapeutic devices and safety interlocks (e.g. ventilation, medication and fluid delivery)

# 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 Alarms"*
*This technology will change the world*





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