HIMSS07 New Orleans

The OR of the Future:
Current activities and Health IT implications

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Lecture Goal:
You will be able to answer 2 Questions

- What is an “OR of the Future”?
- How can the Health IT community improve patient safety in acute care environments?

Massachusetts General Hospital

- Established 1811 (Ether demonstrated in 1846)
- 875 bed quaternary care center
- 50 Operating Rooms
- Roughly 30,000+ operations per year

- 14,000 ambulatory
- 16,000 inpatient
- 2.4 cases per OR-day

A trip down memory lane…

The early days

Farnam Operating Amphitheatre
Yale New Haven
http://www.ynhh.org/general/history/oldsur.html

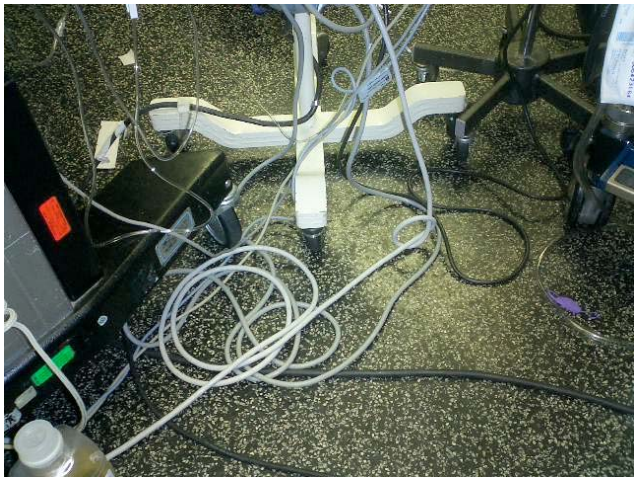
Fast forw

Clinical environments are crowded with technology

Anesthesia EMR or AIMS
(Anesthesia Information Management System)

Lifesaving surgery using modern equipment in typical older OR

Typical OR: Advanced surgery,modern equipment, “legacy” supporting systems



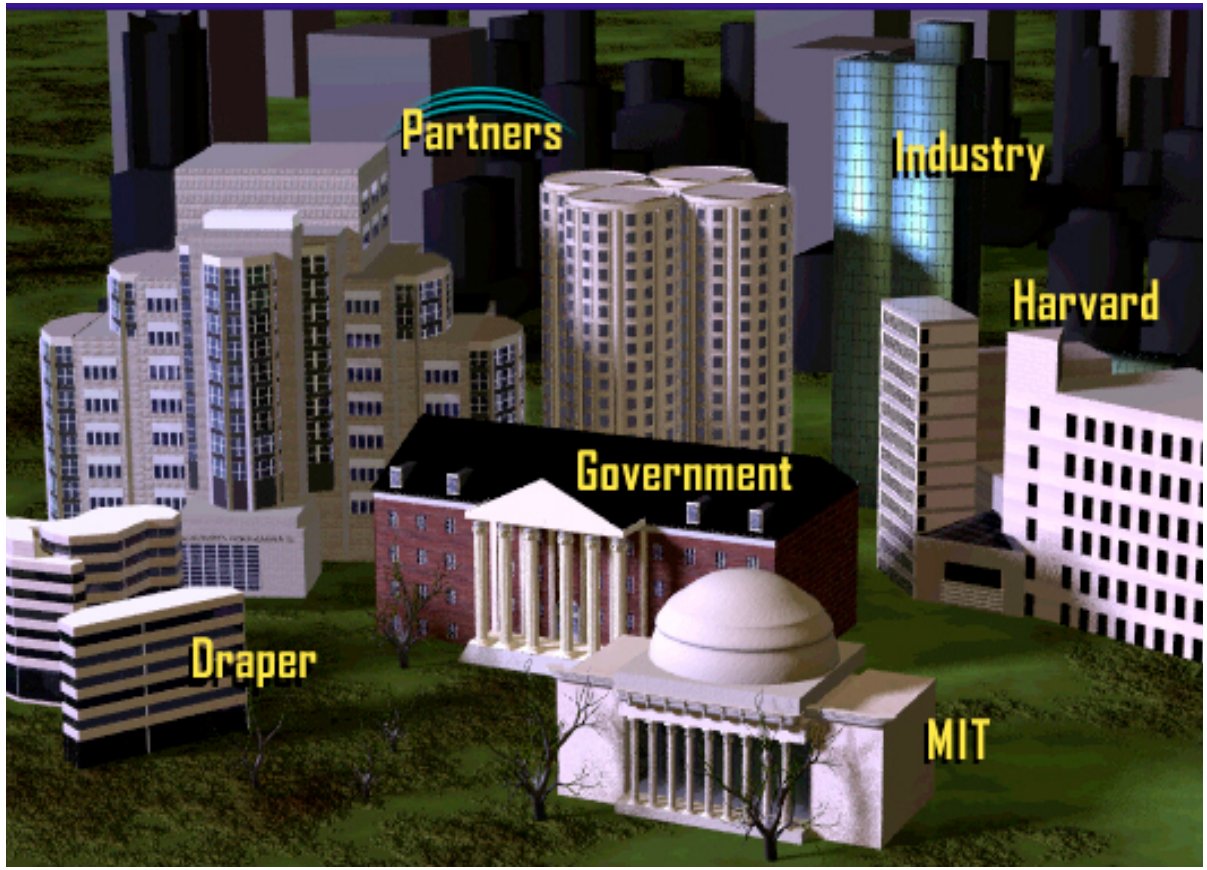

The Paradox:
“minimally invasive surgery” yields
“maximally invasive” technology!

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.

Re-engineering the perioperative process: Goals of the ORF

- Improve processes
- Improve ergonomics
- Integrate technologies
- Optimize patient safety
- Increase throughput
- Improve staff satisfaction
- Maintain protected research environment

ORF Timeline

1999-2000 Discovery

Assemble Team

Technology scavenging

2001 Model-Design

Computer Animated Model

Outcome Measurement: Built discrete event simulation model that Validated concept of 3 rooms and parallel processing

Full Size Mock up

Est. new model for multi-industry collaboration

2002 Construction

Industry: 9 Partners > $2m

Training: Multiple dry runs

Room opened Aug 2002

150 Cases 9/1-12/31

50% reduction in turnover

Education-Outreach: Live post grad course

2003 Implementation

>780 cases performed (9-5PM)

Team training: Designed 1st interdisciplinary OR team simulation

Education-Outreach, publications

Part of DOD ORF Nat'l Initiative

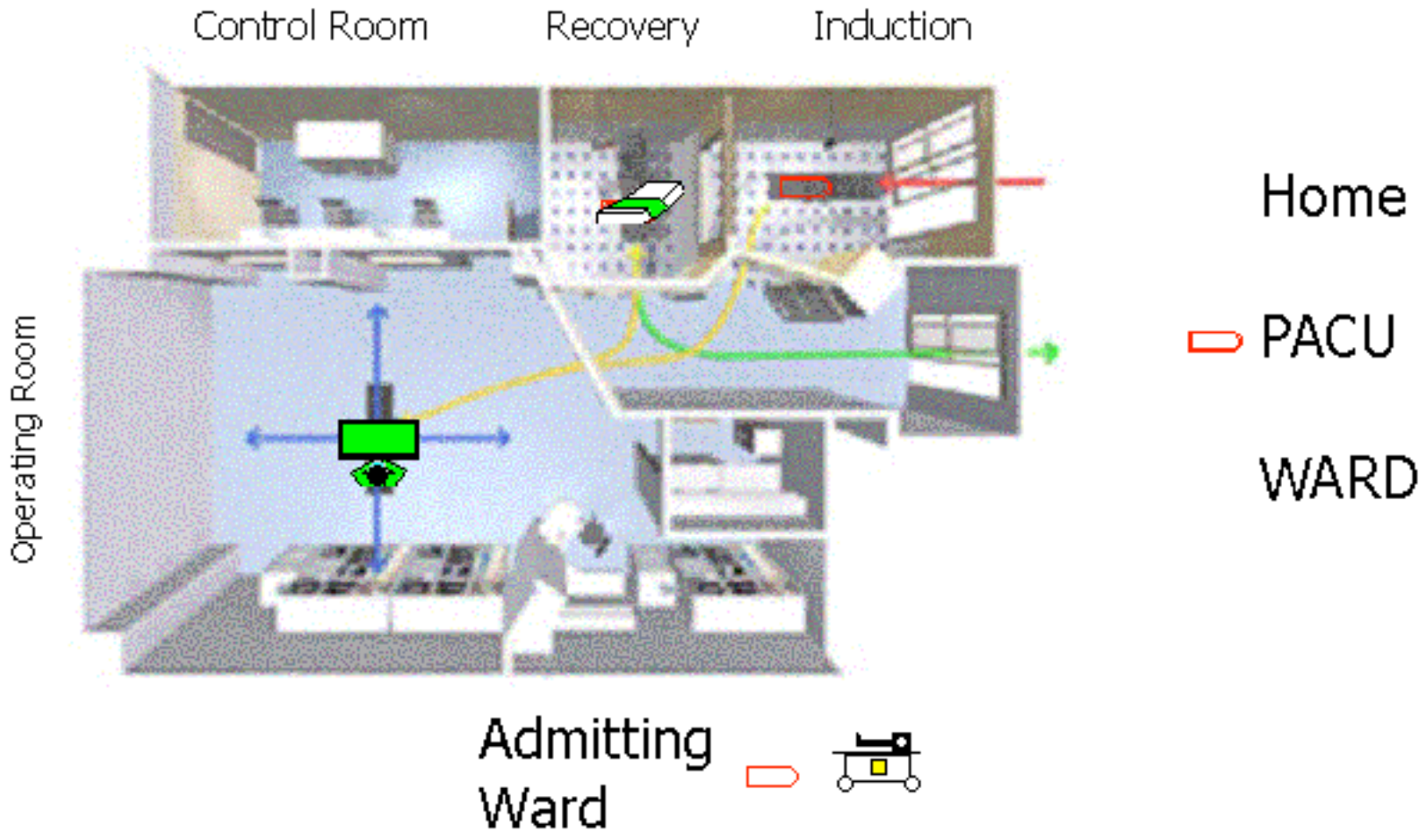
Won Healthcare Design Team Award

2004-2007 Measure - Iterate

Outcome Measurements

Applications of RFID

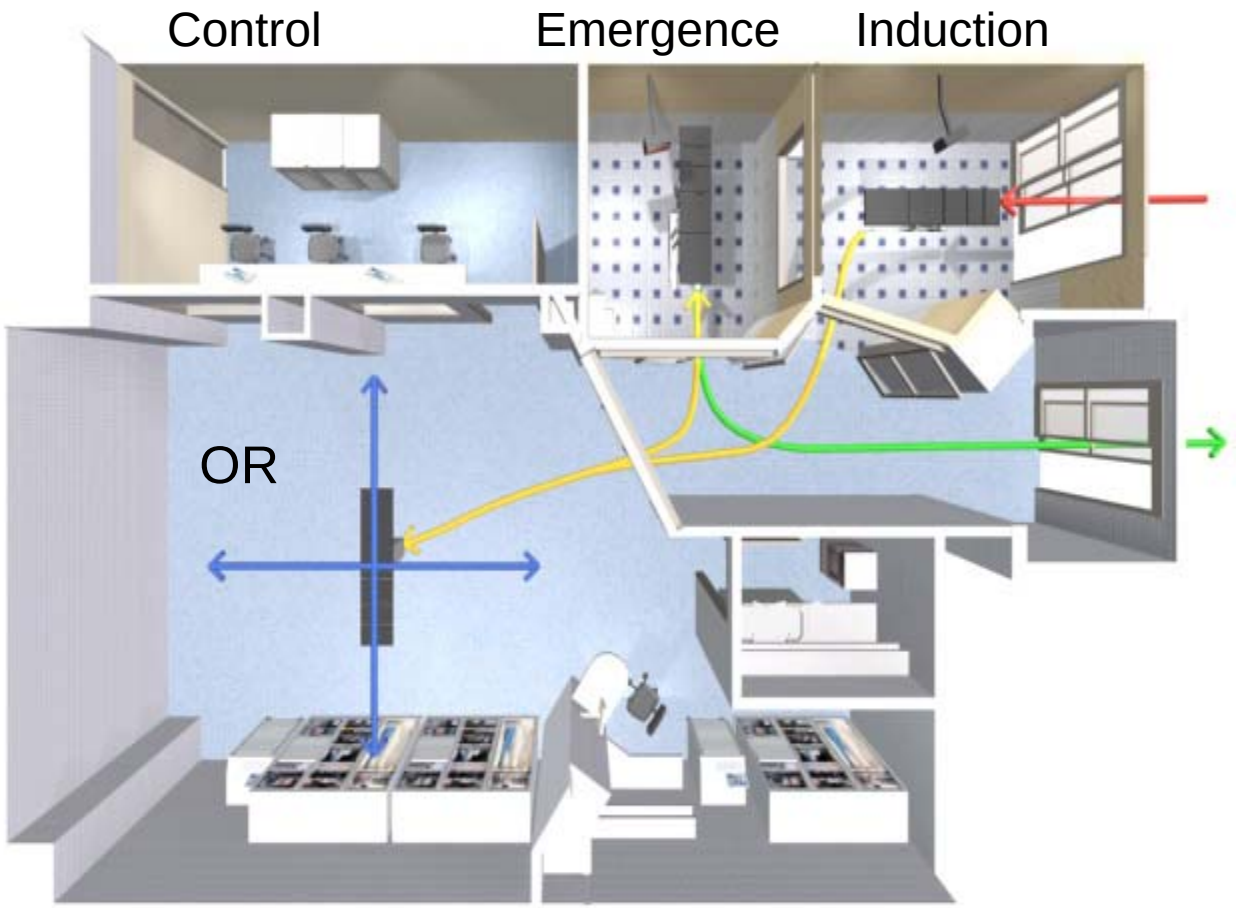
Convened consensus conference on interoperability (MD PnP program)



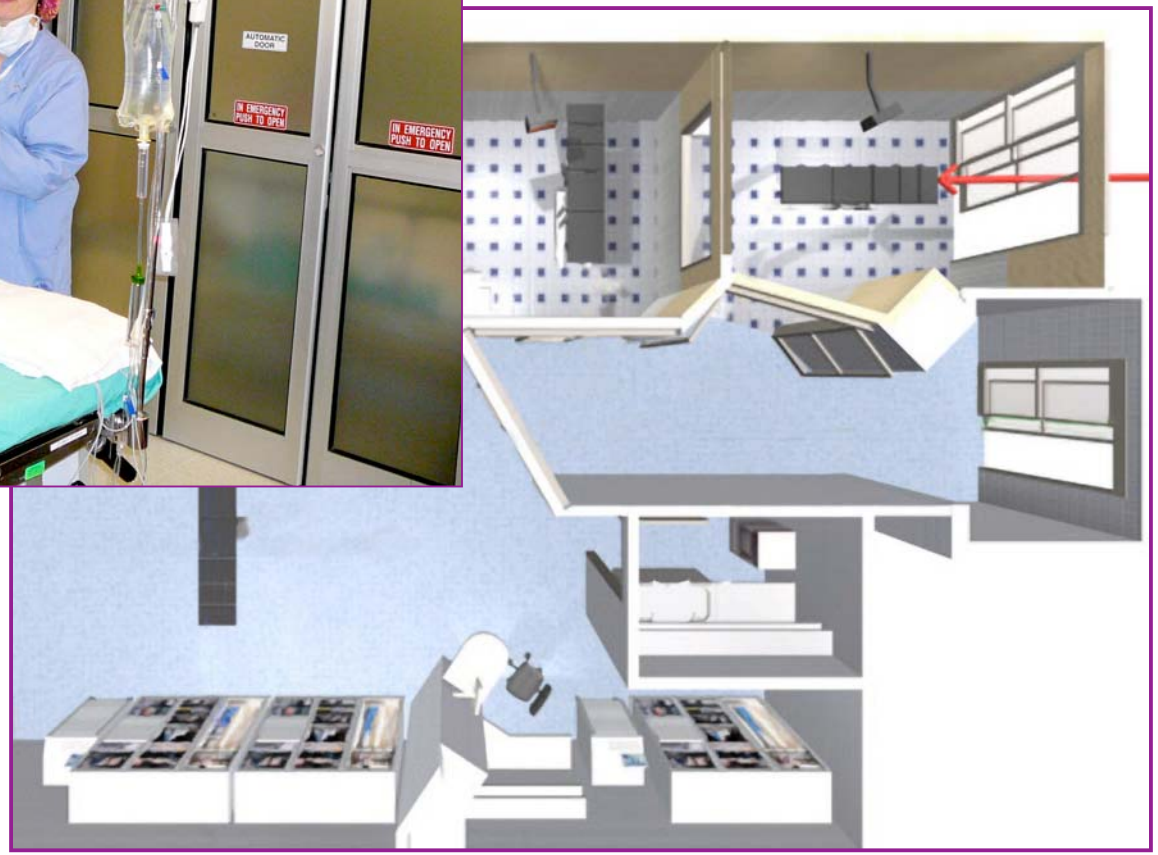
Simulation courtesy of Dr. James Stahl

ORF Suite at MGH

Self contained OR suite



Induction Room



Induction of anesthesia

Entering OR

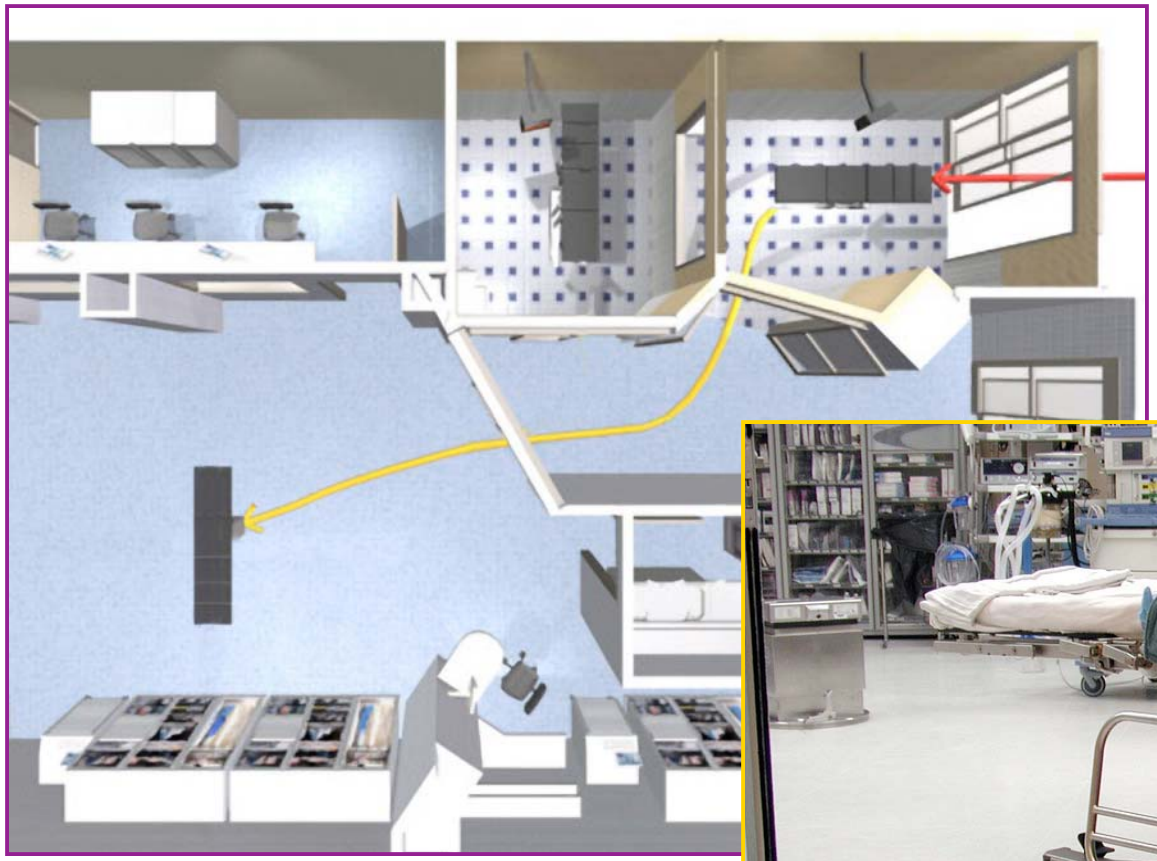


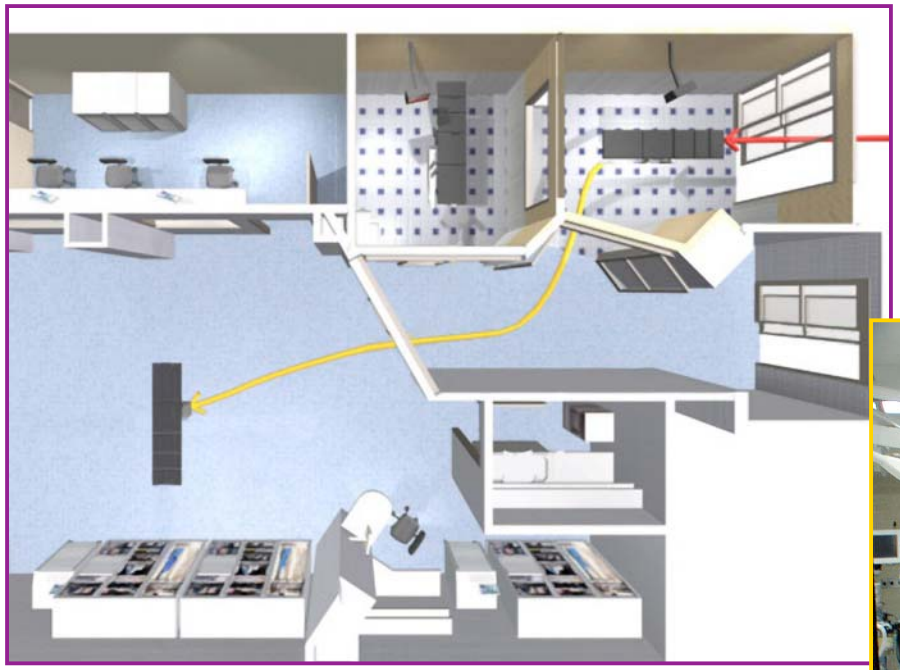
Photo: Dr. W. Sandberg

Click and go


M.G.H.


ALM

Emergence/early recovery room




ALM
ALM

LiveData, Cambridge, MA, USA

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

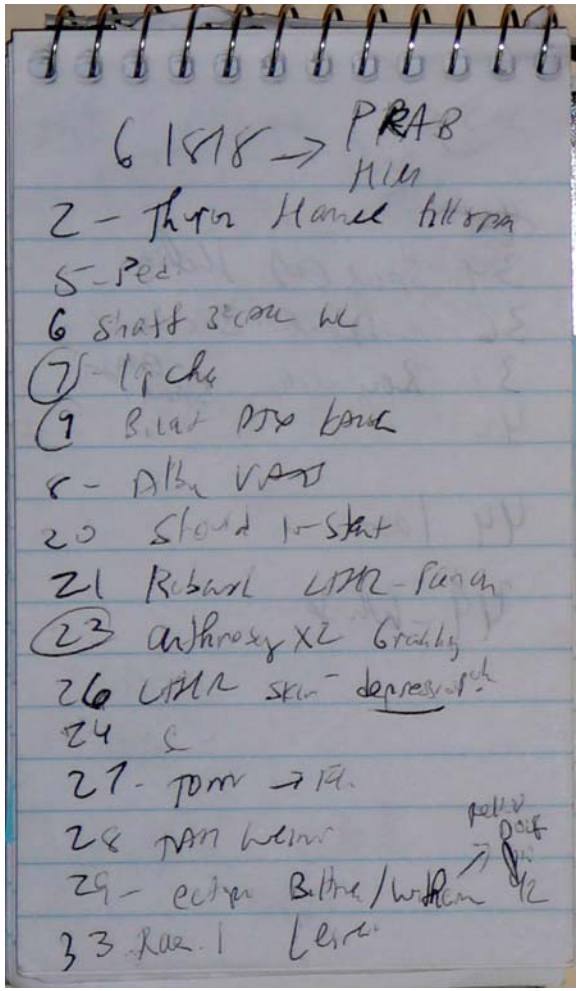
Room	Date	Time	Duration	Unit#	Patient Name	Age
49	02/02/2007	13:45	2:15	[redacted]	[redacted]	59Y

Attending: BERGER, DAVID L **Service:** GENERAL SURGERY **Category:** SAME DAY ADMIT

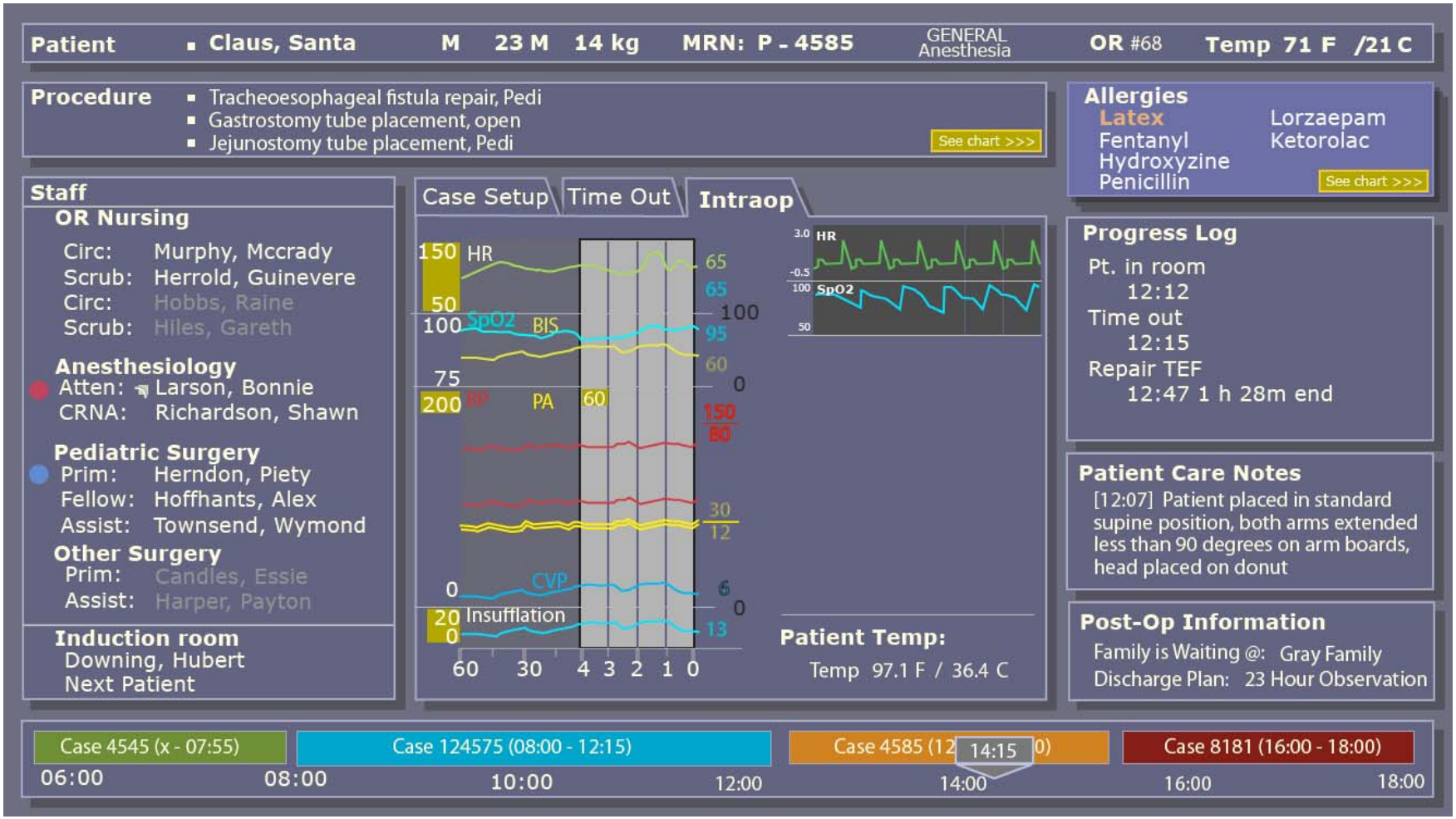
Procedure: LOW ANTERIOR RESECTION - AVAIL TF RM 49 **Anesthesia:** GENERAL

Current Status: CASE SCHEDULED

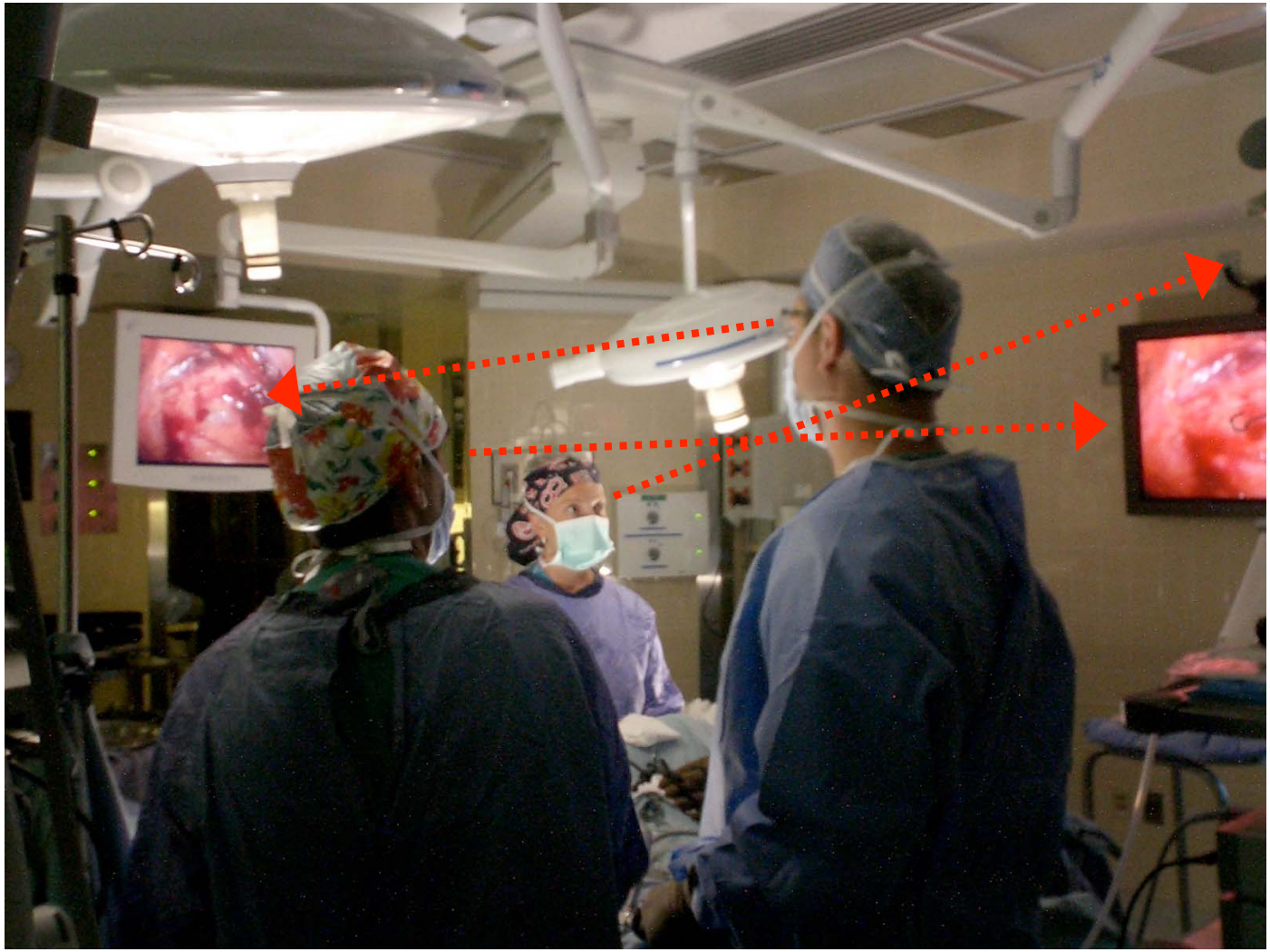
Room	Date	Time	Duration	Unit#	Patient Name	Age
49	02/02/2007	16:00	2:15	[redacted]	[redacted]	[redacted]Y



LiveData OR-Dashboard



Optimized monitor placement



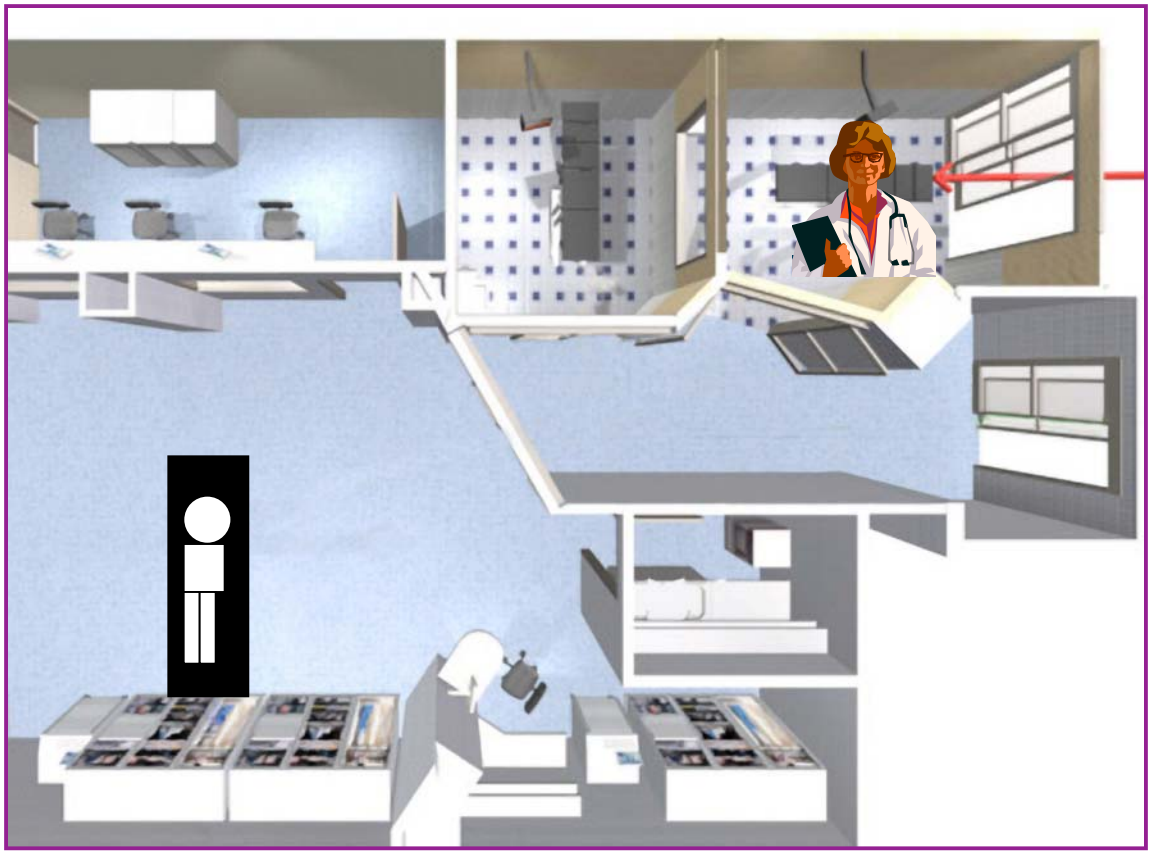
Re-direct traffic

“Perioperative Nurse”

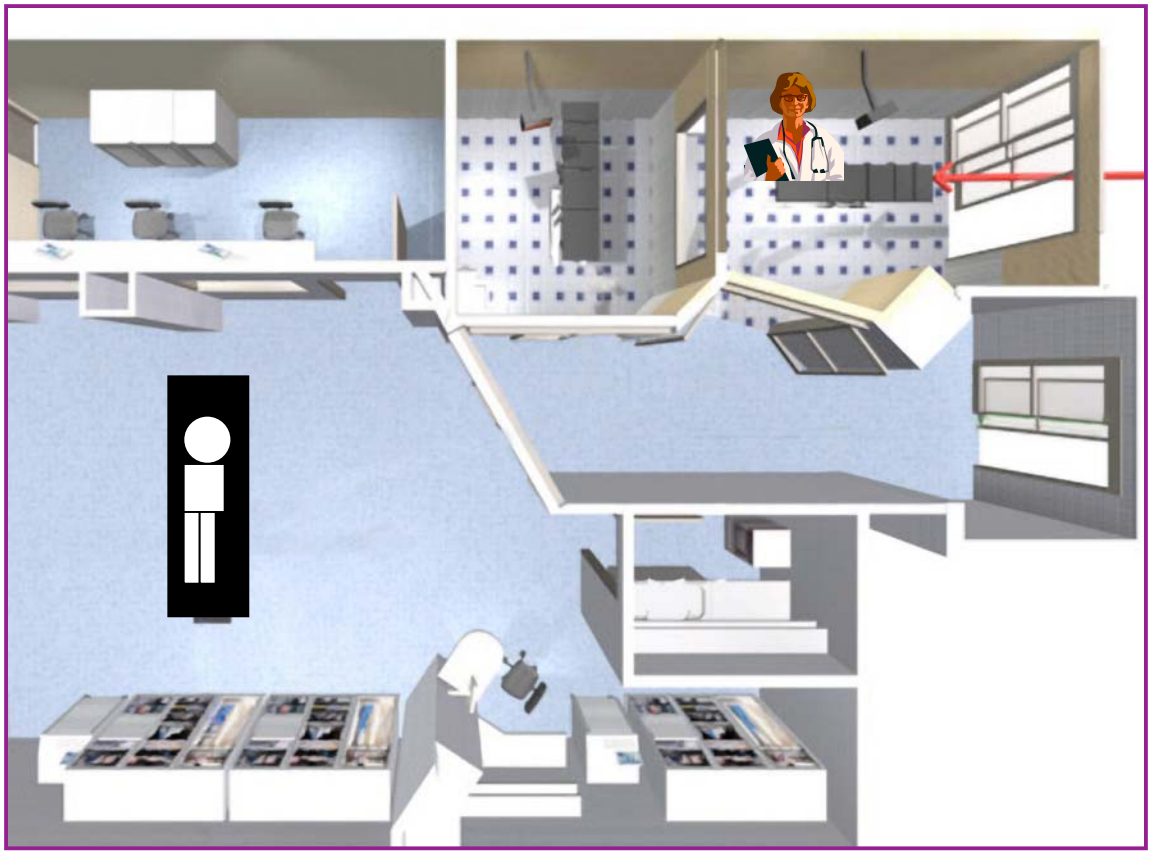
- Trained to perform pre-op and *PACU functions
- Admits patient in induction room, checks records and consent forms, applies anesthesia monitors
- Visits OR to obtain update on patient status
- Recovers patient for 10-20 minutes
- Transports patient to PACU (and performs handoff to PACU nurse)

- * PACU = “post anesthesia recovery unit”

Perioperative Nurse

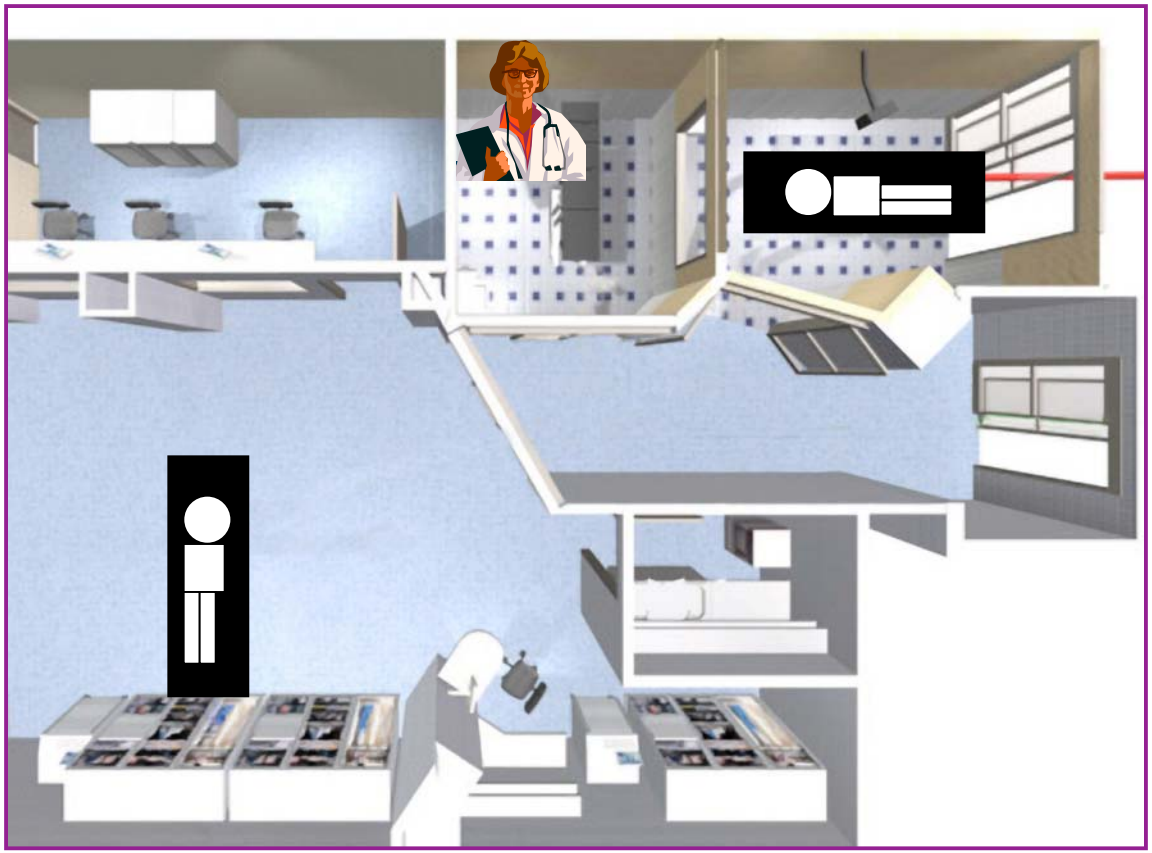


Perioperative Nurse

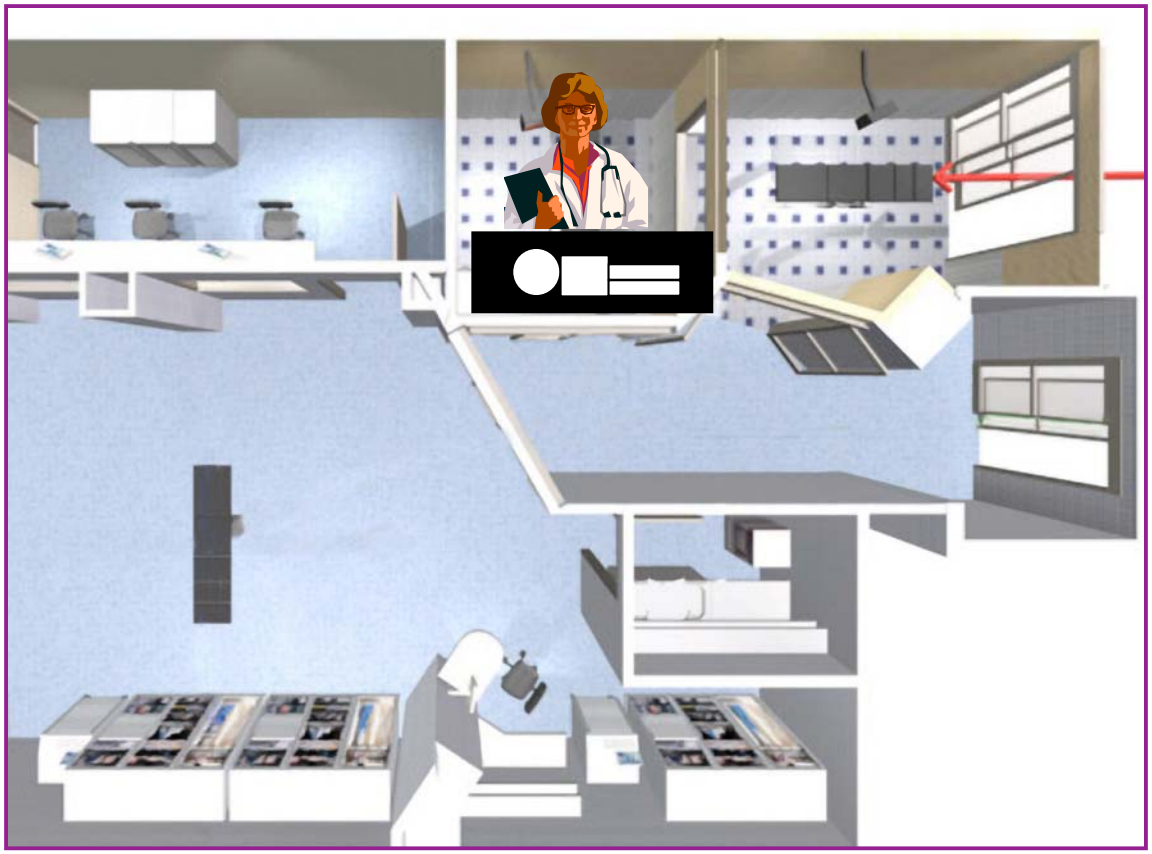


Perioperative Nurse

Perioperative Nurse



Perioperative Nurse



Benefits of Emergence Room or “early recovery room”

- Early transport out of ORF (even if asleep/intubated or airway not completely stable)
- Proximity permits easy management by surgical team
- Buffer PACU waiting list
- Eliminate PACU transport delay (18-> 3 min!!)
- All of these factors reduce non-operative time

Results of Process Changes

	ORF		Traditional OR		*p*
N	63		61		ns
Process Variable (minutes)	*Mean ± SE*				
Total wait time	55	3.2	80	3.2	< 0.01
Pre-anesthesia wait time	6.6	1.4	14.9	1.5	<0.001
Total pre-op anesthesia time	49	3	64	3	<0.001
OR pre-op anesthesia time	13.5	1.5	31.8	1.5	<0.01
OR emergence time	8.3	1.3	18.7	1.1	<0.01
N = 124 consented patients					

All of the times controlled by anesthesia are markedly reduced. This has translated into a substantial and reproducible improvement in OR throughput as compared to traditional ORs. The ORF can accomplish as many as 10 general surgery cases (laparoscopic and open) during *regular working hours*. (Sandberg et al, 2004)

Clash of technology …

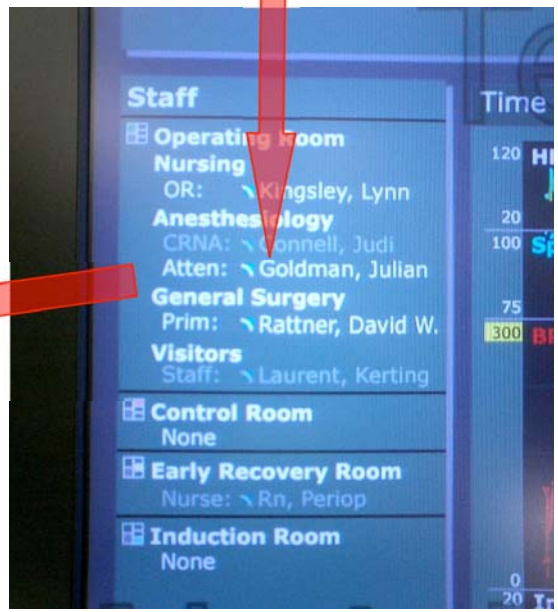
The joy of legacy systems …

Provides an excellent opportunity to introduce errors into the EMR!

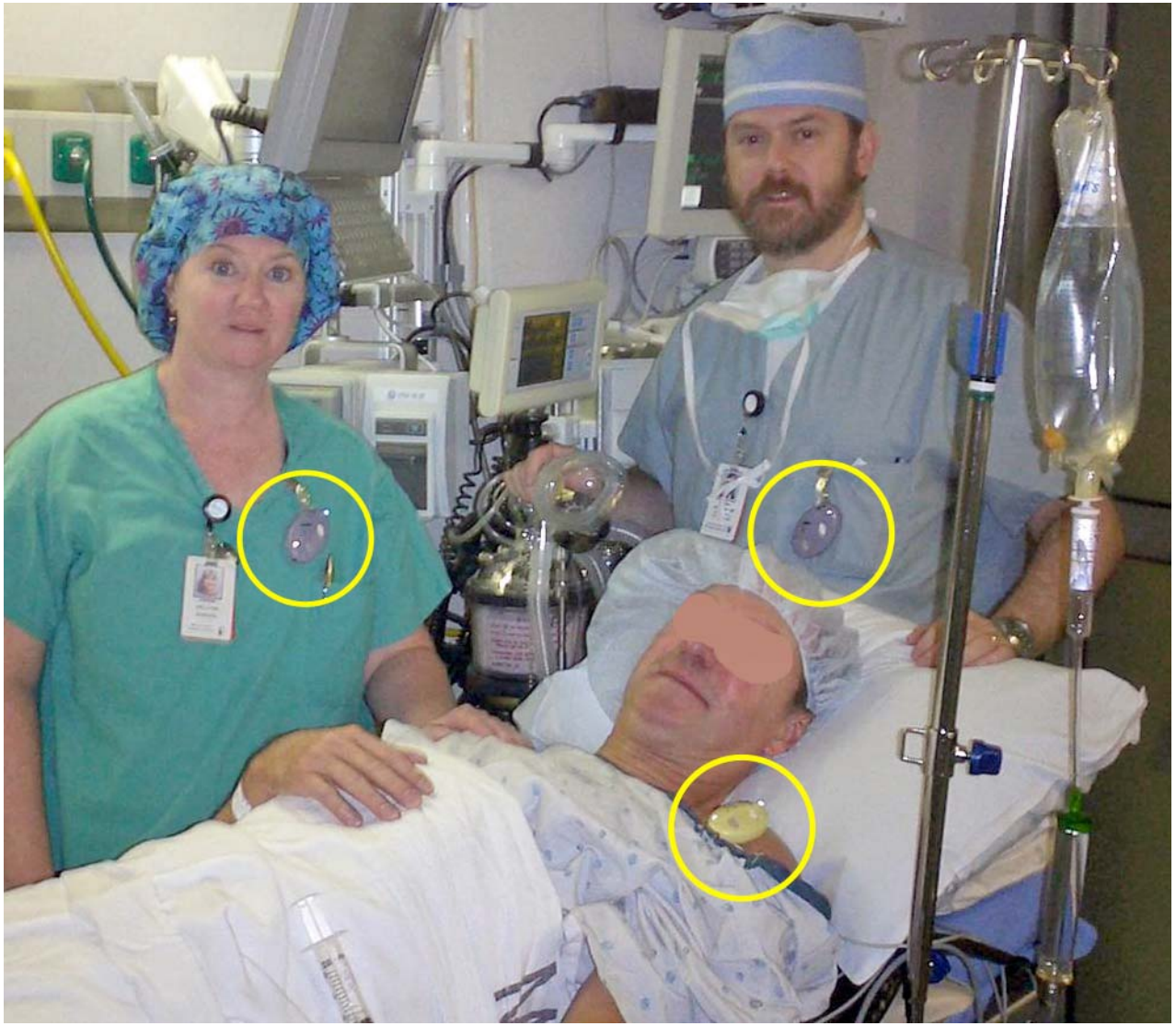
What is an “ORF”?

- The “Operating Room of the Future” (ORF) is not a specifically configured OR.
- “ORF” is shorthand for a constellation of emerging innovations in processes and technologies for perioperative care.
- These *may* include:
  - Surgical robots
  - Minimally invasive surgery suites
  - Innovative Health Information Technologies
  - Redesign of entire perioperative environment

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



ORF perspective on data integration

- Comprehensive integration of data from clinical and environmental systems, using the latest computer-science methodologies, will prevent errors and inefficiencies
  - Smart Alarms
  - Decision Support
  - Workflow support

MGH ORF

“I give up. Where’s the patient?”

Cables required for various monitors to connect to Anesthesia EMR

Lessons from the ORF

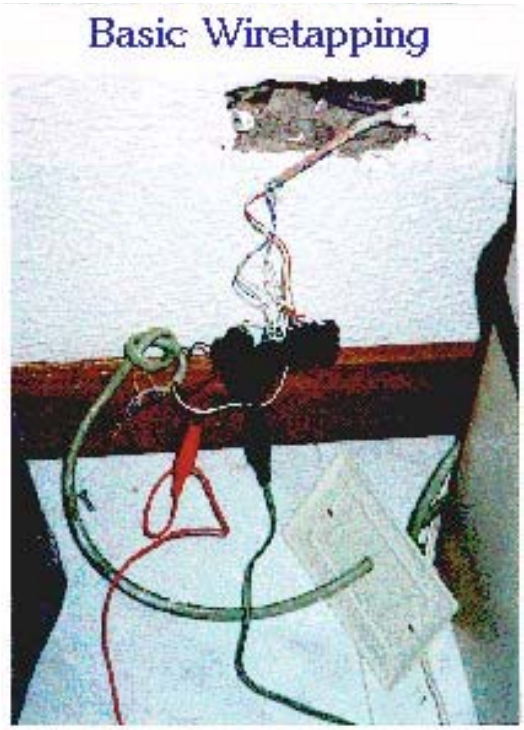
- Pushing the boundaries of “traditional” care and has revealed the limitations of current systems
- Advanced technology teases us with the promise of integrated and “error resistant” systems, but these latent opportunities have not been realized.
- Intractable problems:
  - “One off” solutions are not practical
  - Absence of medical device interoperability is a costly barrier to safety innovation

Iraq

Reality

Reality

Remember telephone plugs B.S.?



B.S. = Before Standardization

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

Monitors

Oximeter

Infusion Pumps

Bar Code Scanner

BP

Data Integration, Analysis, and Display

Cell / PDA

Tablet PC

Workstation

Medication Station

Electronic Medical Record

Interoperability is better now …

Ethernet, Internet, USB memory

Interoperability has become pervasive

- The Consumer Electronics Experience is changing expectations:
  - USB memory, printers, and other hardware may be connected connect by consumers to computers with no expensive programming required.
  - Standard data formats allow digital pictures and documents to emailed and viewed anywhere.

Connectivity is used to support “safety interlocks” at the system level in many potentially hazardous products.

  - Example: The cruise control is disengaged when the brake pedal is pressed.

WSJ.com THE WALL STREET JOURNAL. ONLINE

February 22, 2007

Apple, Cisco Reach Accord Over iPhone

By NICK WINGFIELD
February 22, 2007; Page B4

Apple Inc. and **Cisco Systems** Inc. agreed to resolve a trademark dispute over the term iPhone that had threatened to put a damper on the introduction of Apple's most eagerly anticipated electronics product in years.

Under their agreement, Cisco, of San Jose, Calif., and Apple, of Cupertino, Calif., are free to use the iPhone trademark on their respective products throughout the world. Cisco will drop a lawsuit it filed against Apple in federal court in San Francisco, accusing Apple of infringing on a Cisco trademark with a forthcoming cellphone called the iPhone, due out in June.

In a joint statement, Apple and Cisco said they will explore opportunities for making their products work better together "in the areas of security, and consumer and enterprise communications." The companies said other terms of the settlement are confidential, declining to comment further.

Everywhere* *but* Healthcare

- Healthcare has minimally benefited from standards based interoperability.
- Focus has been on the “xHR”. Successes have been at IT-level data transfer (HL7, DICOM), not at Biomedical Engineering level (patient connected devices)
- Advances in patient safety and healthcare efficiency cannot yet benefit from interoperability of medical technology.

*almost everywhere. DRM is a notable exception

HIT and the Medical Device "Last Mile" Problem

- Proposed Health Information Technology innovations address many critical problems in medical record-related data communication
- Patient and clinician interaction with medical devices has not received the same attention
- Diagnosis and therapy is usually performed with medical devices!

Problems with Discharge Summaries

"The current method of discharge summary production and distribution is unacceptable. The high number of errors (36.4%) and the low rate of receipt (27.1%), indicates that resources invested in the production of the discharge summary could be better utilized to improve information transfer." [NSW Australia]
General practitioner-hospital communications: a review of discharge summaries.
J Qual Clin Pract. 2001 Dec;21(4):104-8.

- We must improve quality of records (like the discharge summary) before we introduce systems to distribute them widely

Why interoperability?
The Acute-Care End-Game

- Create context for decision support using data from devices and databases
- Free clinicians to explain clinical needs, and free marketplace to deliver solutions
  - Improve patient safety
  - Improve workflow efficiency
- Decrease cost of ownership of medical devices and hospital networks.
  - KP CIS integration cost is ~ 40% TCO
  - Interoperability standards will save KP ~$40M annually for 10 years.

Example of Safety Interlock

Brake / Automatic Transmission

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

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

Planes, trains, automobile. Why not medical devices?

- Single-vendor device integration is easily achievable
- Devices from multiple vendors, assembled by end users or system integrators, run into interoperability barriers

5 examples of clinical procedures that could benefit from connected medical devices ->

Airway Laser-O_2 Interlock

- Measure inspired O_2during anesthesia
- Prevent activation of airway laser if O_2 > x

NOT AVAILABLE

- (Doctorate thesis project of Sem Lampotang, PhD, Univ. of Florida, Gainesville

Cardio-Pulmonary Bypass

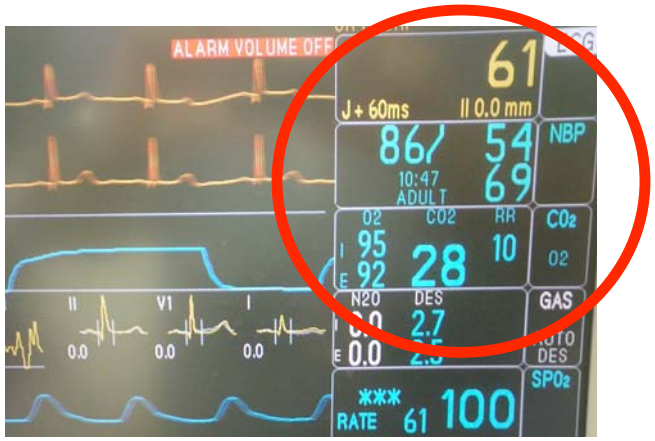
NOT AVAILABLE

Smart system would provide warning of ventilator off and CPB pump flow = 0.
I found <u>one</u> anesthesiologist who has NOT forgotten to ventilate after CPB

Insufflation-induced problems:
Opportunity for improving safety through interlocks

1	Start of Surgery
1	3011 Laparoscopy: abdomen insufflated
	3023 Bougie advanced into esophagus per surgec
	3024 Bougie removed from esophagus per surgec
	2181 Position: Trendelenberg
1	2182 Position: reverse Trendelenberg
	3012 Laparoscopy: abdomen deflated
	6001 Local anesthetic injected by surgeon:
	End of Surgical interaction

NOT AVAILABLE



Should insufflation be permitted if the NIBP isn't cycling?

Benefit of medical device interoperability:
Synchronization to mitigate hazard

Ventilation stopped
during intraoperative
cholangiography

Example: Cholecystectomy

"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/need more coffee?
- *At its root, this is a system problem*

Solution: “synchronization”

Synchronize or “gate” x-ray to expose image at end of expiration.
We are implementing this use-case in the MD PnP Lab

MD PnP Lab at CIMIT
Cambridge, MA
Opened May 2006

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

APSF Board Retreat
October 13, 2006
PCA pump scenario

A 49-year-old woman underwent an uneventful total abdominal hysterectomy. Postoperatively, the patient complained of severe pain and received intravenous morphine sulfate in small increments. .. 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 nursing staff called a “code” and the patient was resuscitated and transferred to the intensive care unit on a respirator... The patient ultimately died.

-AHRQ Morbidity and Mortality website

PCA = Patient-Controlled Analgesia

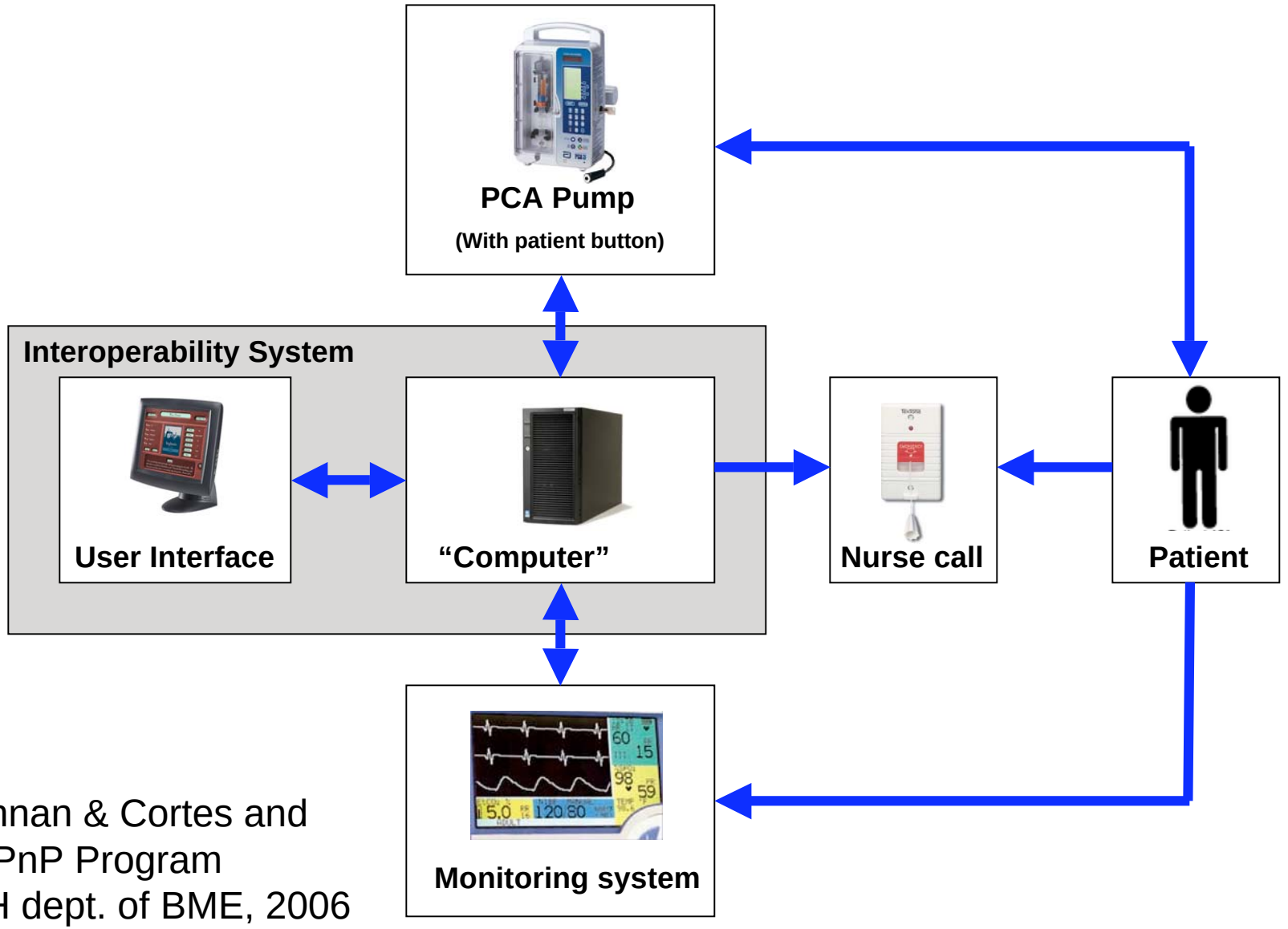
PCA Monitoring

- Treating pain can be hazardous
- Can we reduce the risk of pain management by using patient monitors already in our hospital inventory to monitor on patients PCA medications?
- Goal: Integrate monitors with an intelligent “controller” to:
  - Detect respiratory disturbance
  - Lock-out pain medication infusion
  - Activate nurse-call

NOT AVAILABLE

PCA = Patient-Controlled Analgesia

Proposed PCA Safety Monitoring



Krishnan & Cortes and
MD PnP Program
MGH dept. of BME, 2006

Challenges

- Algorithm development
  - Data to design PCA monitoring algorithms is limited, because hospitals cannot currently connect to devices!!
  - Don’t know which alarm strategies to implement. Simple alarm thresholds? Statistical limits? Pulse Oximetry? Capnography? Other monitors?
- Device integration
  - Today, cannot easily integrate monitors, infusion pump, and nurse call to implement safety interlock. Especially from multiple manufacturers.
- Liability
  - Is the system a new medical device? Who will be responsible for failures?
  - Solution: Record all alarms and data to support QA/forensic analysis and vendor cooperation

Are these good ideas?

- If so, then why don’t we have them available in our hospitals?
- Why not connect these devices and solve these problems?
- Because “one-off” solutions complicated and expensive, and there are concerns about regulations and liability.

MD MP3 ™
Medical Device Plug-and-Play Platform

- Key “ecosystem” functions for delivering point-of-care technologies:
  - Plug and play architecture
  - Data logging
  - Security (e.g. for HIPAA compliance)
  - Device authorization
- Support data acquisition, decision support, actuator control
- Share with other research groups for other applications

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

MGH and CIMIT (Center for Integration of Medicine and Innovative Technology) initiated a program in 2004 to lead the adoption of open standards for medical device interoperability to improve patient safety.

Three 2-day plenary sessions, smaller meetings, and clinical focus groups have elicited input to shape the mission and strategy and identify clinical requirements.

Over 65 institutions and > 500 experts (clinicians and engineers) are involved. Many support provider-mandated conformance to interoperability standards.

MD PnP
Getting connected for patient safety

What is the scope of effective medical device interoperability ?

There are two distinct – but closely related – capabilities of medical device interoperability:

1. Data communication capability will enable complete and accurate data acquisition by the EMR/AIMS from medical devices. Comprehensive data acquisition will support the development of remote monitoring, advanced clinical decision support systems, and intelligent alarms.

2. Medical device integration capability will permit the control of medical devices into networks to produce “error-resistant” systems with safety interlocks to decrease use-errors, closed-loop systems to regulate the delivery of medication and fluids, and remote patient management (e.g. remote ICU).

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.
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
   - model clinical use cases (in simulation environment)
   - develop and test medical device network safety and security systems
   - serve as a resource for medical device interoperability

MD PnP
Getting connected for patient safety

MD PnP Program collaborators

- and,
- NIST
- NSF
- American Society of Anesthesiologists
- Society for Technology in Anesthesia
- And others …

Clinical Requirements

- Clinical scenarios are being collected from clinicians and clinical engineers worldwide, to assure that interoperability standards and manufacturer-provided solutions will support clinical improvement in safety and efficiency.
- PHS ISRC grant to clarify concepts and systems for: “clinical scenarios”, “use cases”, “specifications”
- Example of clinical scenarios and proposed solutions (format provided by FDA)

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

New standard in preparation: “ICEMan”

- Integrated Clinical Environment Manager
- Risk management standard for MD PnP “ecosystem”
- Does not specificy technology

Kaiser Contract Language

- **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)

How might the functional layers “fit together”?

(MD PnP architecture working group)

Top layer: Loosely coupled Enterprise CISs and beyond

Local “patient centric” layer:
ICEMan with monitors, actuators etc. (e.g. Ethernet, IEEE 11073)

Sub-layers: tightly integrated systems to support Physiologic Closed Loop Control Systems (e.g. CAN technology)

Continua Health Alliance (Consortium announced June 2006)

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Imagine products so intelligent they help manage one's health at home. Imagine an alliance of the finest companies joining forces to improve the quality of people's lives. Imagine highly integrated systems that seamlessly work together. We are the Continua Health Alliance.

THE TIME FOR TECHNOLOGY-BASED HEALTH CARE SOLUTIONS IS NOW.

Health begins at home, but time pressure or a lack of motivation may keep generally healthy individuals from maintaining exercise and weight management programs. Individuals with a chronic disease, such as diabetes or heart disease, may experience trouble with treatment plans, and the elderly, who may be less able to physically or mentally maintain their own health, require greater access to in-home care and supervision.

CONTINUA HEALTH ALLIANCE

Fostering independence through establishing a system of interoperable personal telehealth solutions that empower people and organizations to better manage health and wellness.

LATEST NEWS

Press Release
June 6, 2006.
Leading health and technology

Adoption of medical device interoperability will support:

1. Clinical decision support systems
2. Smart clinical alarms
3. Medical device safety interlocks
4. Closed-loop control of ventilation, medication and fluid delivery
5. Support of remote healthcare delivery (home, battlefield, e-ICU)
6. Automated system readiness assessment (prior to starting invasive clinical procedures)
7. Complete, accurate electronic medical records
8. Increased quality and completeness of national research databases
9. Facilitation of disaster preparedness: real-time inventory of hospital equipment in-use and national stockpiles, and rapid deployment of devices in makeshift emergency care settings

MD PnP
Getting connected for patient safety

Achieving Success

- End-user demand (IHDNs, physicians, risk managers, patient safety advocates, CIOs)
- FDA and other government agencies can keep barriers low
- Phased implementation: connect -> interoperate
- Support meaningful use-cases
- Risk Mitigation for new MD PnP paradigm
  - ICEMan ecosystem standard
  - FDA MD PnP “experiments”
  - Vendor neutral lab evaluation
- Collaborate

MD PnP Challenges

- Proprietary medical device systems; long capital equipment cycles (12 years!)
- Limited comprehensive, vetted user requirements (clinically/safety based)
- Absence of proven standards matched to clinical requirements
- Tendency to silo standards that would limit interoperability across continuum of care
- Limited funding for development
- Limited recognition of complexity of challenges in IT-BME convergence and lack of system integrators to build the middleware
- Legal (liability) concerns
- Regulatory pathway questions

MD PnP
Getting connected for patient safety

Meeting Notification:
Joint Workshop On High Confidence Medical Devices, Software, and Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability

June 25-27, 2007
Cambridge, Mass

See http://rtg.cis.upenn.edu/hcmdss07/index.php3

HIMSS07 University Row 7806-7808

www.MDPnP.org www.jgoldman.info