"Moving Toward Interoperability"
NIST October 18, 2006

Gaps in the System: Medical Device Interoperability

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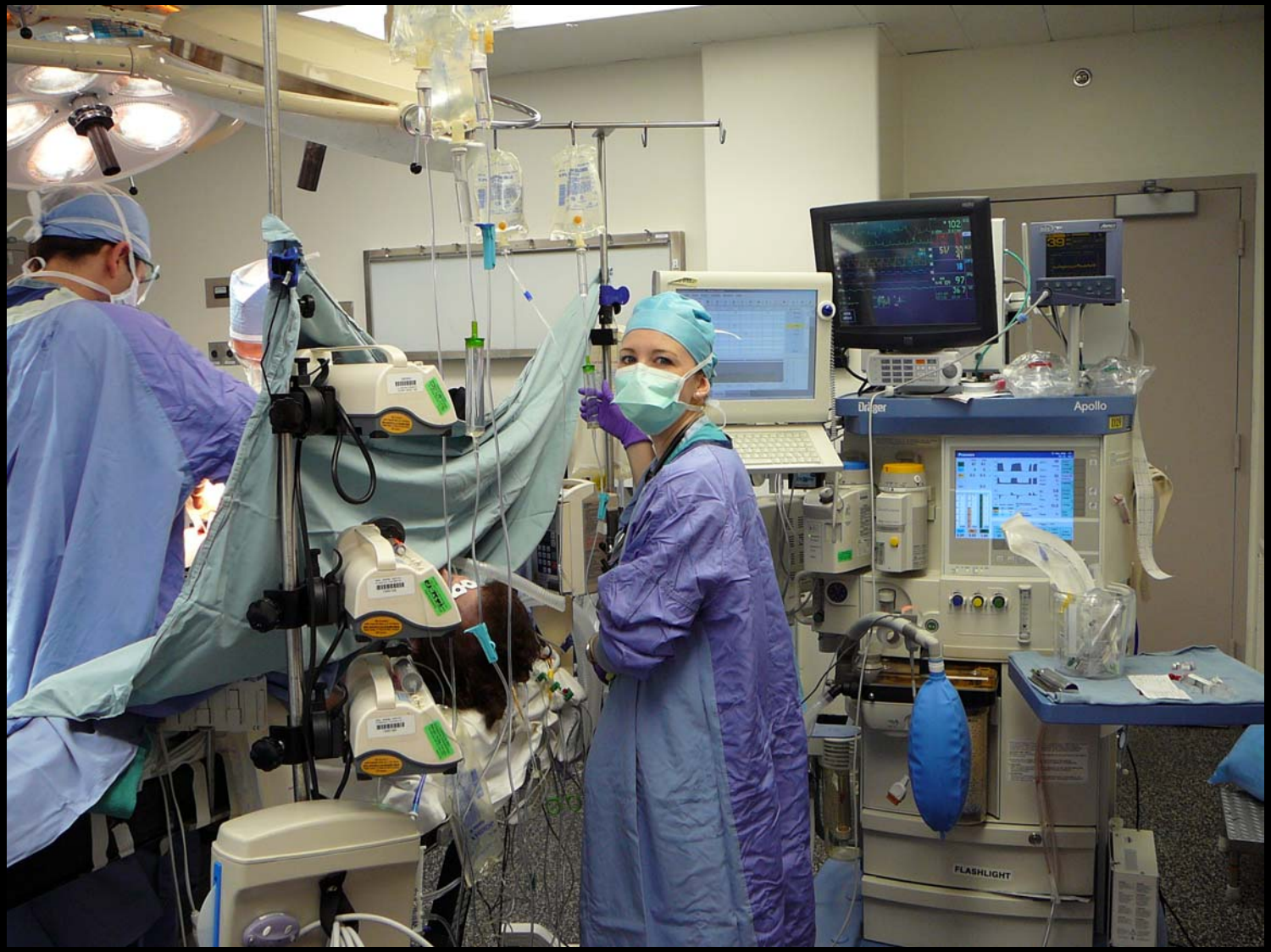
Clinical environment are crowded with technology
EMR integration is challenging



Lifesaving surgery using modern equipment in typical older OR

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

Our work with interoperability has been inspired by the

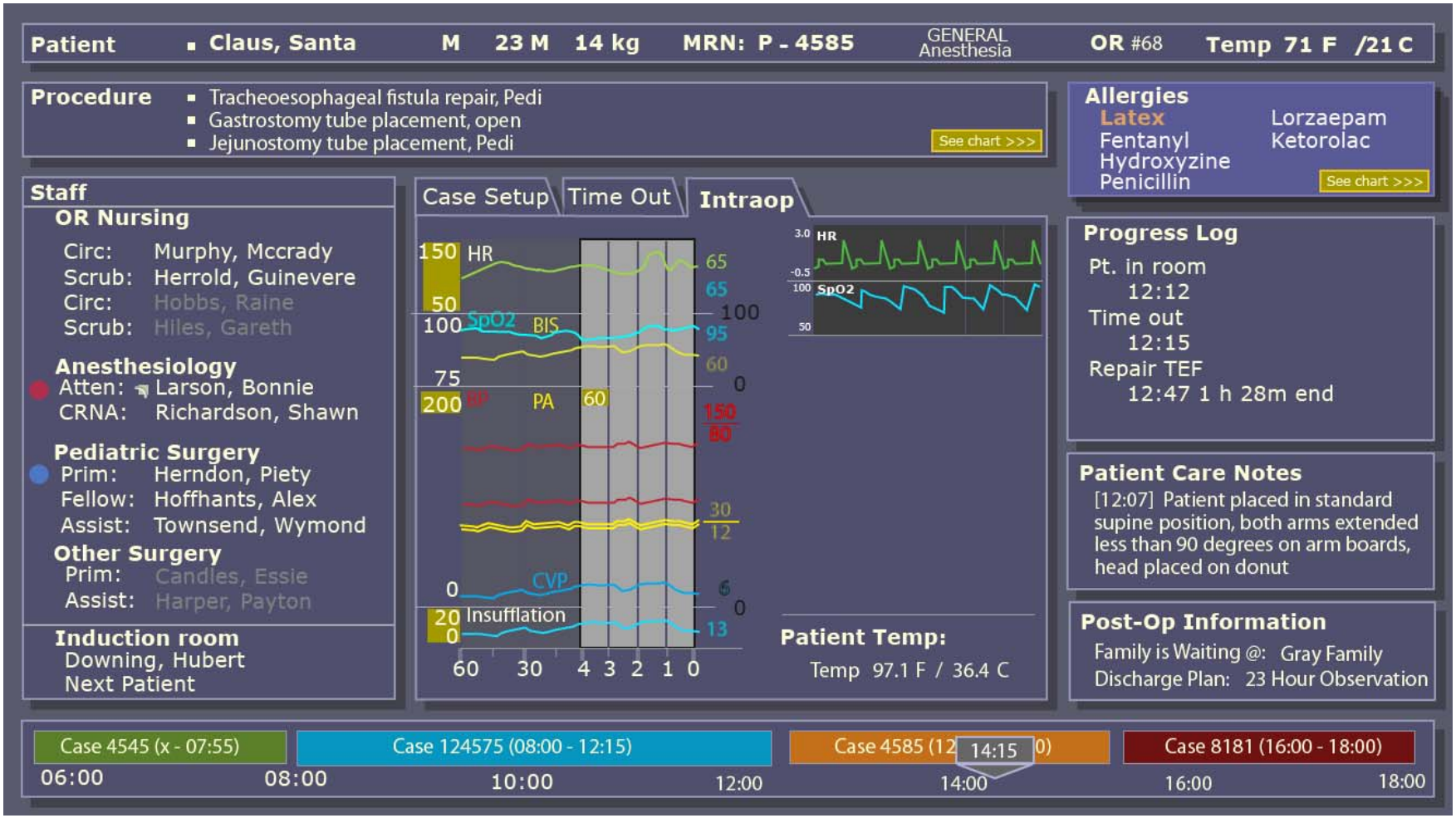
CIMIT/MGH OR of the Future Project

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.

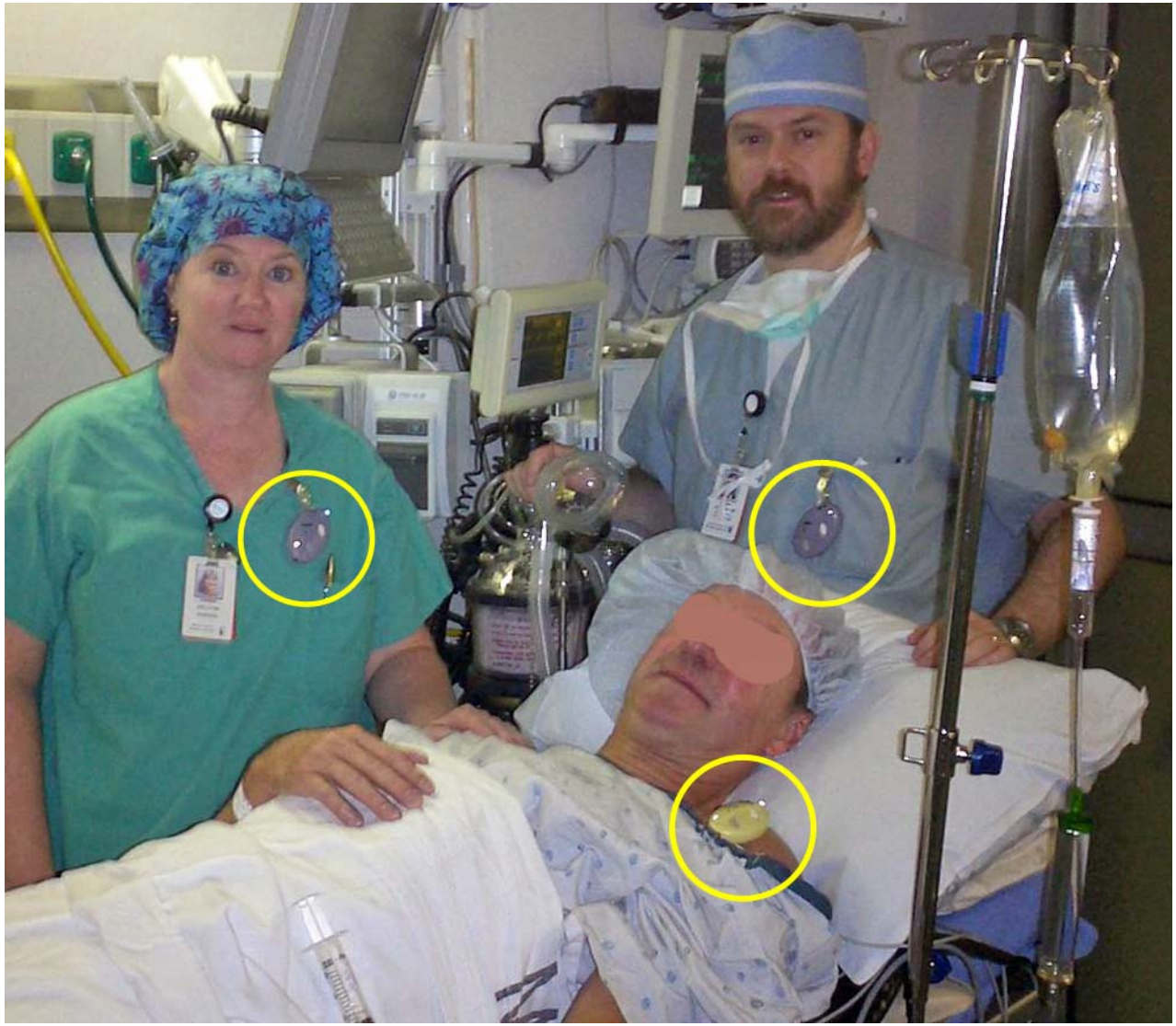
Massachusetts General Hospital ORF

LiveData OR-Dashboard



Radianse Indoor Positioning System (active RFID + IR)

<u>Association</u>: Using Indoor Positioning System used to automatically determine the time of “start of anesthesia care”



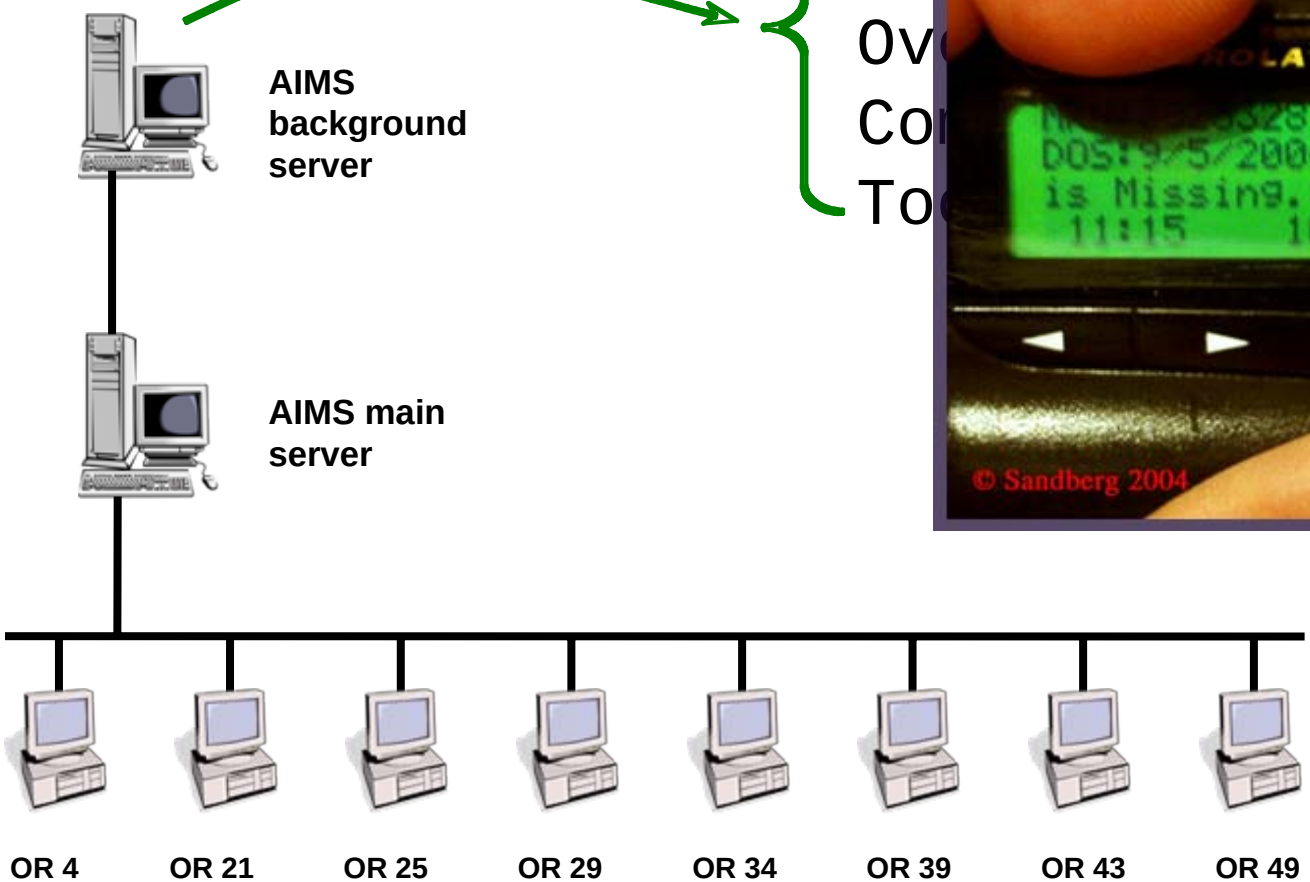
Data integration for decision support

- To obtain reimbursement, complete and error-free documentation is required.
- We installed an Anesthesia Information Management System in 2003:
- After implementation, significant numbers of records contained errors precluding billing.
- 1.3% of records could NEVER be billed.

(From S. Spring and W. Sandberg, MGH)

Proof of Concept Example

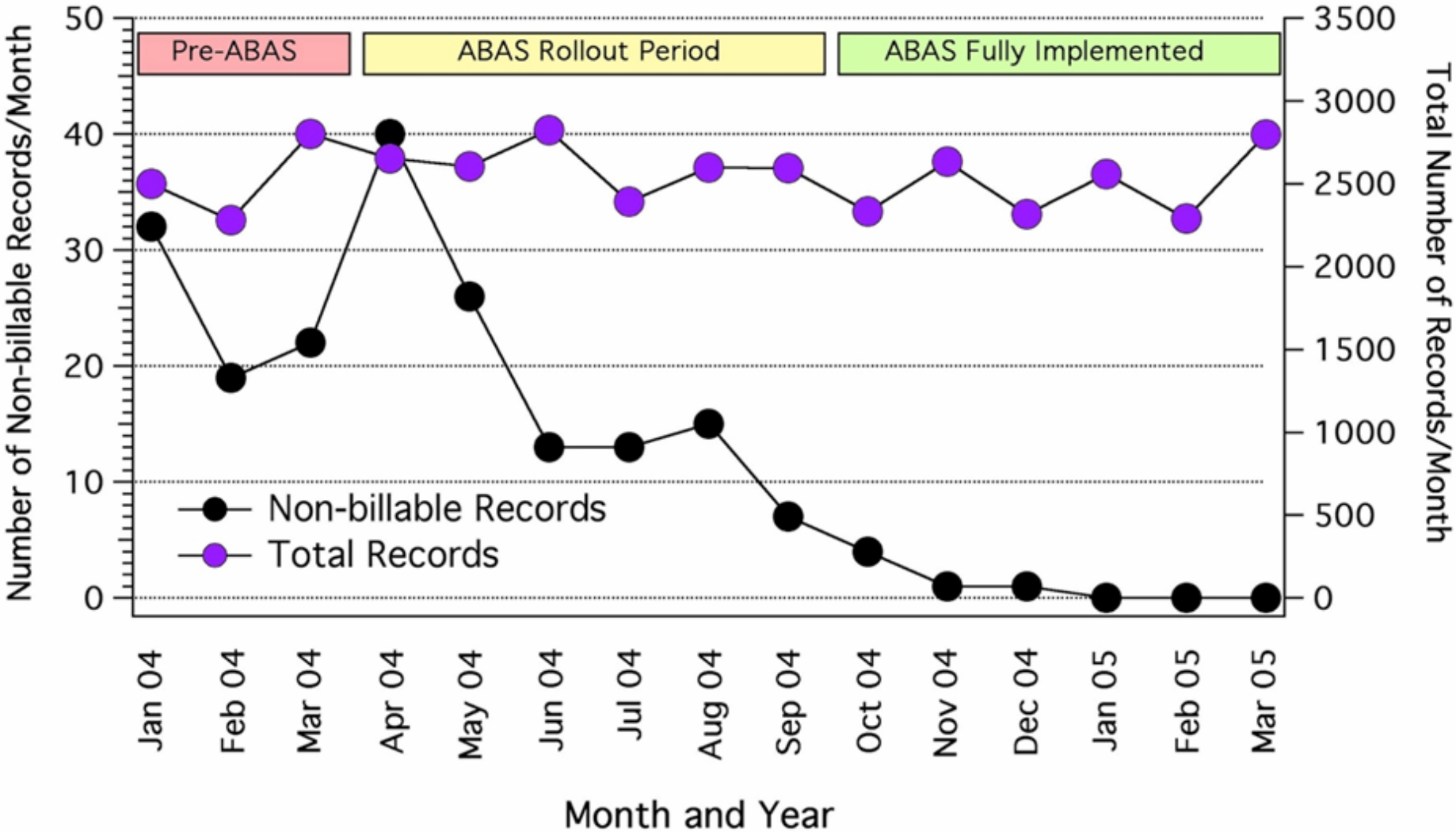
MGH AIMS Architecture



Key events documented?
Events in correct order?
Ov es?
Co d?
To es?

Spring, et.al., Anesthesiology, in press

More Charts ‘Correct’



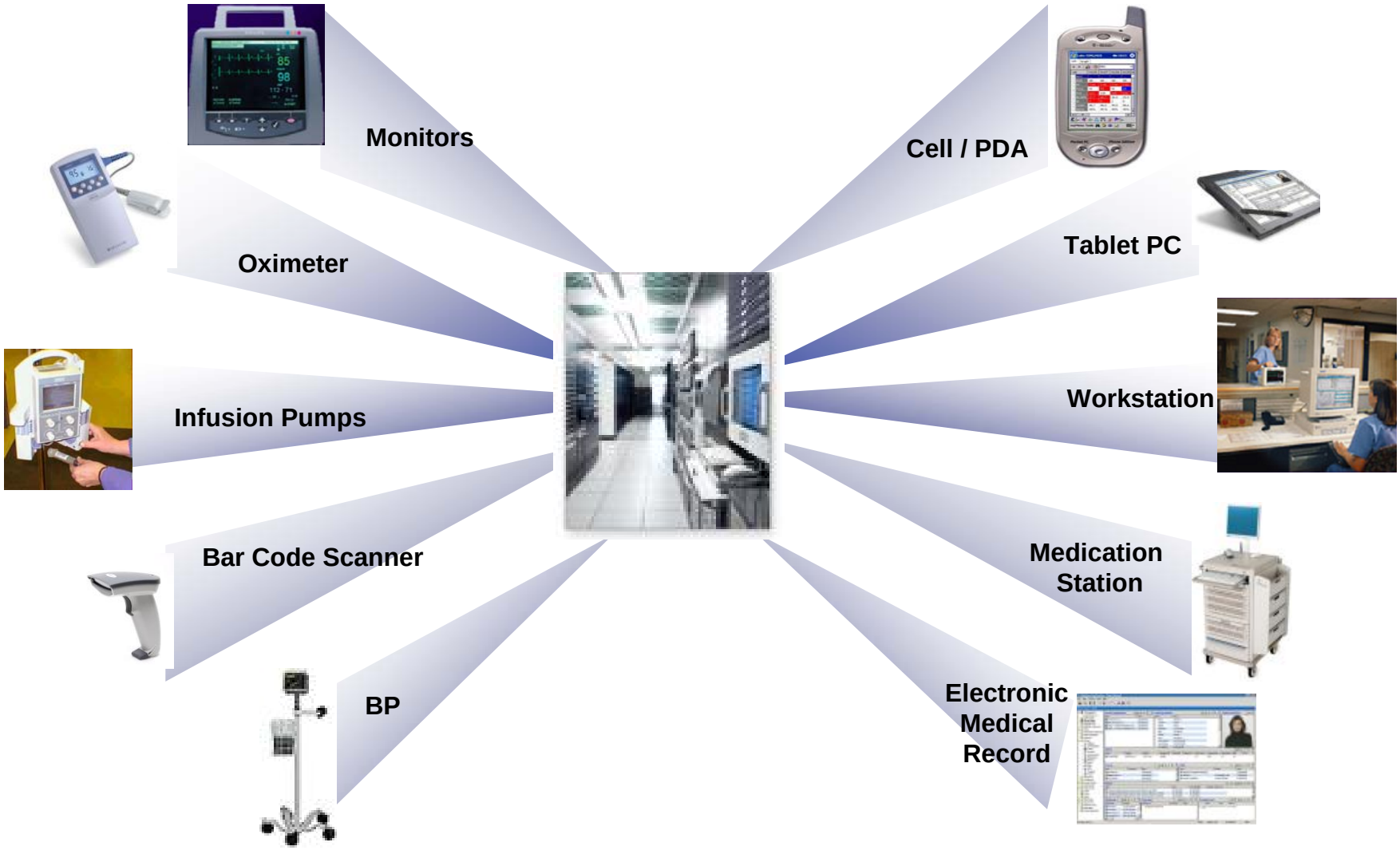
Spring, et.al., Anesthesiology, in press

Financial Impact

- Development cost (one time): $180,000.
- Maintenance: $37,500 per year.
- Based on
  - case volume,
  - contract rates
  - performance improvements
- Annual additional revenue is: **$390,000** per year.
- We were also able to redeploy administrative personnel.

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

Data Integration, Analysis, and Display



Interoperability has become pervasive

- We live in a “connected” plug-and-play world.
- Computers effortlessly attach to a networked world and securely deliver services to the point of need
- 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.

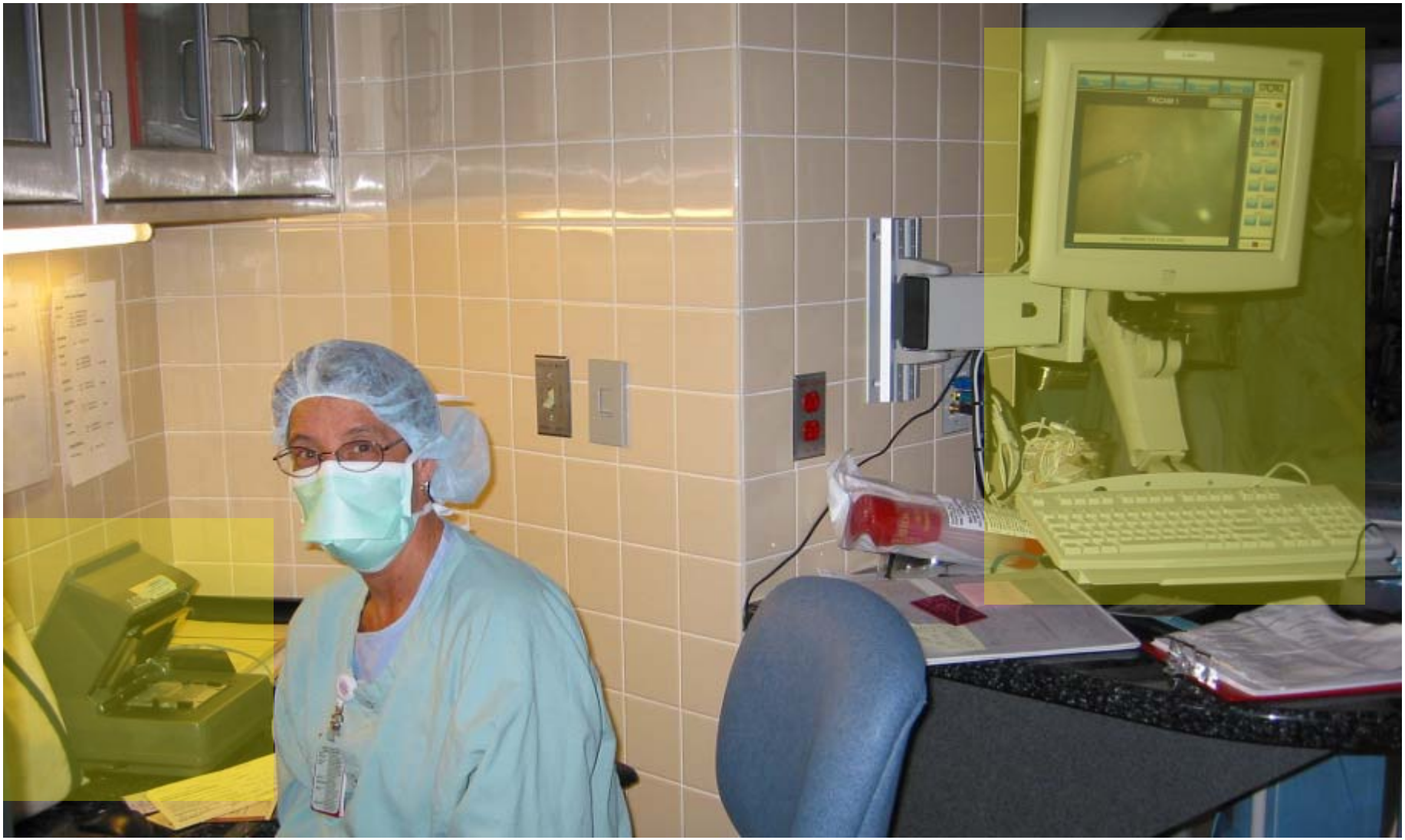
Everywhere* *but* Healthcare

- The technology backbone for the web, digital photography, and other pervasive services (like electrical power) supports standards-based interoperability.
- Healthcare has minimally benefited from standards based interoperability. Success has 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.
- Consider the current cost and complexity of connecting medical devices to the EMR or implementing safety interlocks

*almost everywhere. DRM is a notable exception

Cables required for various monitors to connect to Anesthesia EMR

Clash of technology …



Absence of Medical Device Interoperability is a Roadblock to Innovation

- Delivery of acute care is complex and potentially hazardous
- We rely on teamwork and a potpourri of systems to mitigate hazards instead of using automated safety systems and decision support.
- Clinicians are not empowered by information technology to achieve complete situational awareness, or to network and control medical devices in the environment
  - Absence of smart alarms, automated clinical decision support, and physiologic closed-loop control, etc.
  - Absence of technological infrastructure to implement the required solutions

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

Data integration

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

Why interoperability? The End-Game

- Create context for decision support using data from devices and databases
- Free clinicians to list clinical needs, and free marketplace to deliver solutions
- This will create barriers to accidents (a “fence around safety”) and improve workflow
- Decrease cost of ownership of medical devices and hospital networks.
  - KP integration cost is 40% TCO
  - Interoperability standards will save ~$40M annually for 10 years.

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

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. <u>The anesthesiologist stopped the ventilator for the film.</u> 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. <u>This patient ultimately expired</u>.

What are the “root causes”?

- Inadequate alarms?
- Poor vigilance?
- *At its root, this is a system problem*

Solution: “synchronization”

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

CIMIT
Medical Device
Plug-and-Play
Interoperability Lab
www.MDPnP.org
Apollo

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

PCA Monitoring

- Treating pain can be hazardous
- Can we use 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

PCA = Patient-Controlled Analgesia

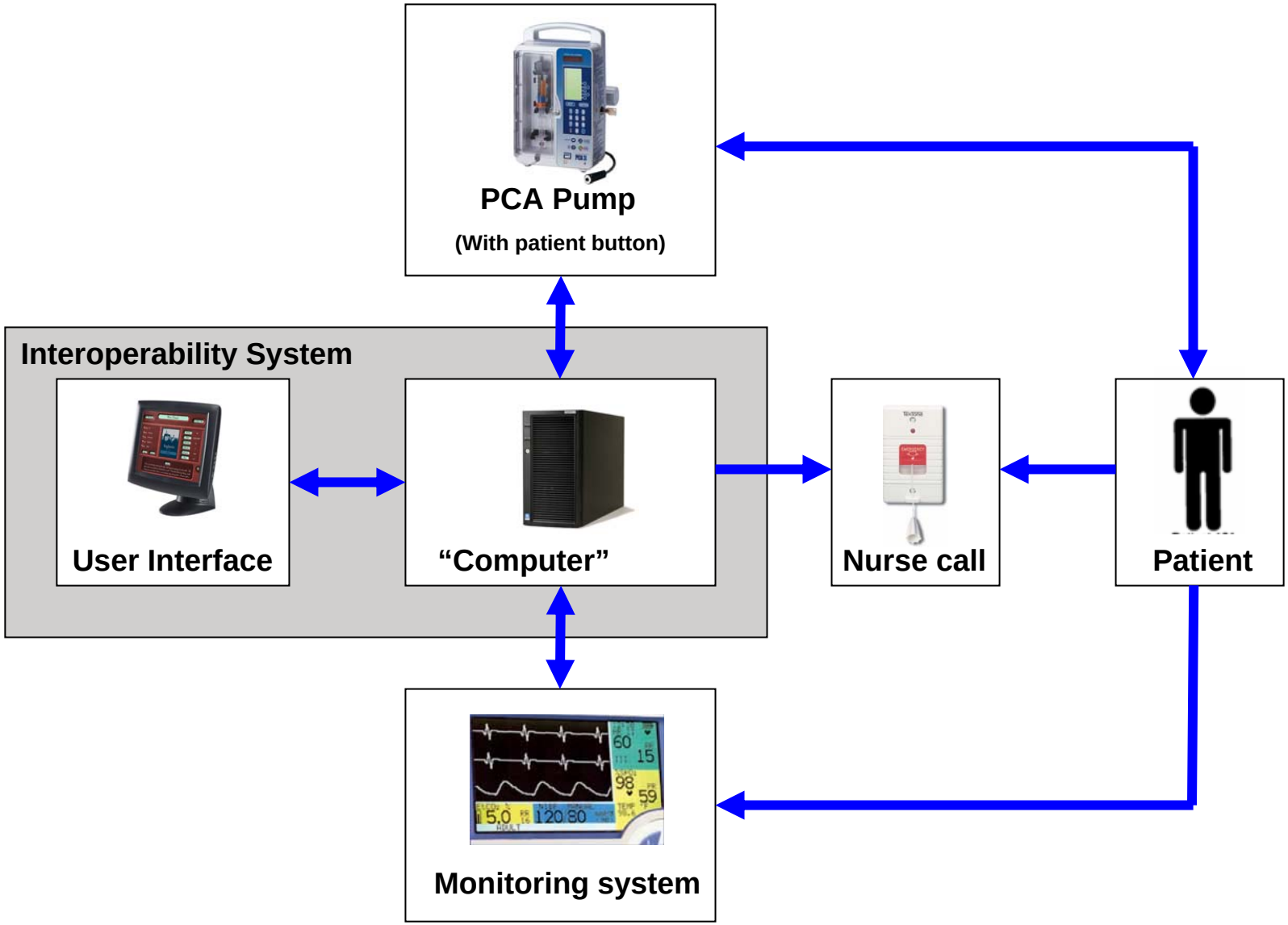
APSF Board Retreat
October 13, 2006
PCA pump scenario

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 Mortality and Morbidity Website

PCA = Patient-Controlled Analgesia

Proposed PCA Monitoring



Challenges

- Algorithm development
  - Data to design PCA monitoring algorithms does not exist, because hospitals cannot currently connect to devices!!
  - Don’t know which alarm strategies to implement to save lives. Which signals should be used? Simple alarm thresholds? Statistical limits?
- Device integration
  - Today, cannot integrate monitors, infusion pump, and nurse call to implement safety interlock. Especially difficult to integrate monitors from multiple manufacturers.
- Liability
  - Is the system a new medical device? Who is the manufacturer? Who will be responsible for failures?
  - Record all alarms and data to support QA/forensic analysis

Why not connect these devices and solve the problem?

- Yes, it is possible to create a custom system - a “one off” system - but it is complicated, expensive, and cannot be shared (or sold) by hospitals.

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 development and adoption of open standards for medical device interoperability.

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

Goals of the MD PnP Program

1. Lead the development and adoption of open standards 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 national resource for medical device interoperability

MD PnP
Getting connected for patient safety

MD PnP Program collaborating with..

- DoD (TATRC)
- FDA
- NIST (Sriram's group)
- NSF
- ASA
- STA

- Kaiser Permanente
- Medical device manufacturers
  - LiveData
  - Drager Medical
  - Philips Medical
- IT technology manufacturers
- Draper Labs
- Mitre

Clinical Requirements

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

US Goal: Portable e-health care records within 10 years

the White House
President George W. Bush

January 27, 200

Improving Care and Saving Lives Through Health IT

Today's Presidential Action

- Today, President Bush visited Cleveland, Ohio, to highlight the benefits of health care information technology in saving lives and improving health care for all Americans. Better health information technology is essential to improving America's health care system.
- **The President's Health Information Technology Plan is an important part of his overall health care agenda to make America's first- rate health care safer, more accessible, and more affordable.**
- The President's budget for FY 2006 continues to support the use of health information technology by increasing funding to $125 million for demonstration projects tha will help test the effectiveness of health IT and allow for widespread adoption in the health care industry. The Administration is also seeking an additional $50 million for FY 2005 (in addition to the $50 million already appropriated by Congress for FY 2005) to support the use of health IT.
- An important new step in the President's health information technology plan is today's announcement of the electronic prescribing (e-prescribing) proposed regulation by the Centers for Medicare and Medicaid Services (CMS) at the Department of Health and Human Services (HHS). This new E-prescribing regulation will improve the care seniors receive in Medicare by helping to bring electronic prescriptions to seniors when the prescription drug benefit takes effect in January 2006. It will also increase broader adoption of e-prescribing across the entire health care system.

Portable EHR Challenges
Example - Discharge summary

- Critically important record of hospital care
- Essential for follow-up care
- Created at time of discharge
- Should be available anywhere, anytime
- Should be accurate and comprehensive

Problems with Discharge Summaries

Ń 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.Ó [NSW Australia]
General practitioner-hospital communications: a review of discharge summaries.
J Qual Clin Pract. 2001 Dec;21(4):104-8.

Ń Electronic screening of discharge summaries for adverse events using keyword searches is feasible but thus far has poor specificityÓ [USA]
Electronically screening discharge summaries for adverse medical events.
J Am Med Inform Assoc. 2003 Jul-Aug;10(4):339-50. Epub 2003 Mar 28.

Ń Overall, 2 per cent of consultant discharge summaries contained errors compared with 7 per cent for the senior registrar, 10 per cent for registrars and 17 per cent for senior house officers.Ó [UKÓ
Prospective audit of discharge summary errors.
Br J Surg. 1996 Jun;83(6):788-90.

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

Adoption of medical device interoperability standards will support:

1. Clinical decision support systems
2. Smart clinical alarms
3. Medical device safety interlocks
4. Closed-loop control of medication delivery
5. Remote healthcare delivery (home, battlefield, e-ICU, etc)
6. Complete, accurate electronic medical records
7. Hospital emergency preparedness
8. Increased quality and completeness of national research databases.

MD PnP
Getting connected for patient safety

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
- 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

Achieving Success

- End-user demand (IHDNs, physicians, risk managers, patient safety advocates, CIOs)
- Two-stage implementation: connect -> interoperate
- Support meaningful use-cases
- Risk Mitigation for new MD PnP paradigm
  - ICEMan ecosystem standard
  - FDA MD PnP “experiment”
- More resources are needed (we need your help!)

- www.jgoldman.info
- www.mdpnp.org