



CIMIT

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Medical Device Interoperability for Improving Safety and Efficiency *A Multi-faceted Challenge*

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Overview

- The current state: limited, non-standardized connectivity in the Operating Room (OR)
- Absence of interoperability interferes with improving patient safety and healthcare efficiency
- Our efforts to accelerate the adoption interoperability
- Implications for the future of healthcare

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



Data integration is hard!
Example of cables required to connect devices to
the Anesthesia EMR



The cables represent one aspect of the “interoperability barrier”



Mass General Hospital/CIMIT
Operating Room of the Future

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

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

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

- Comprehensive integration of data from clinical and environmental systems, using the latest computer-science methodologies, 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*

Seamless Connectivity has become pervasive

- The Consumer Electronics Experience has changed expectations of patients AND providers:
 - USB memory, HDTV, and other hardware is plug-and-play - no expensive system integration required.
 - Standard data formats allow digital pictures and documents to be emailed and viewed anywhere, on any platform.
- Safety Benefits: Connectivity is used to support “safety interlocks” in many potentially hazardous products.
 - Example: The cruise control is disengaged when the brake pedal is pressed. This solution requires a “systems approach” to mitigating the risks of cruise control.



Example of Safety Interlock



Message: Simple interlock can be very effective

Brake / Automatic Transmission

When engine is running, children at play have accidentally shifted the car into Drive, injuring parents

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



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

Examples of 4 clinical procedures
that could benefit from
interconnected medical devices ->

(From the MD PnP “Clinical
Requirements Database”)

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
- “... 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

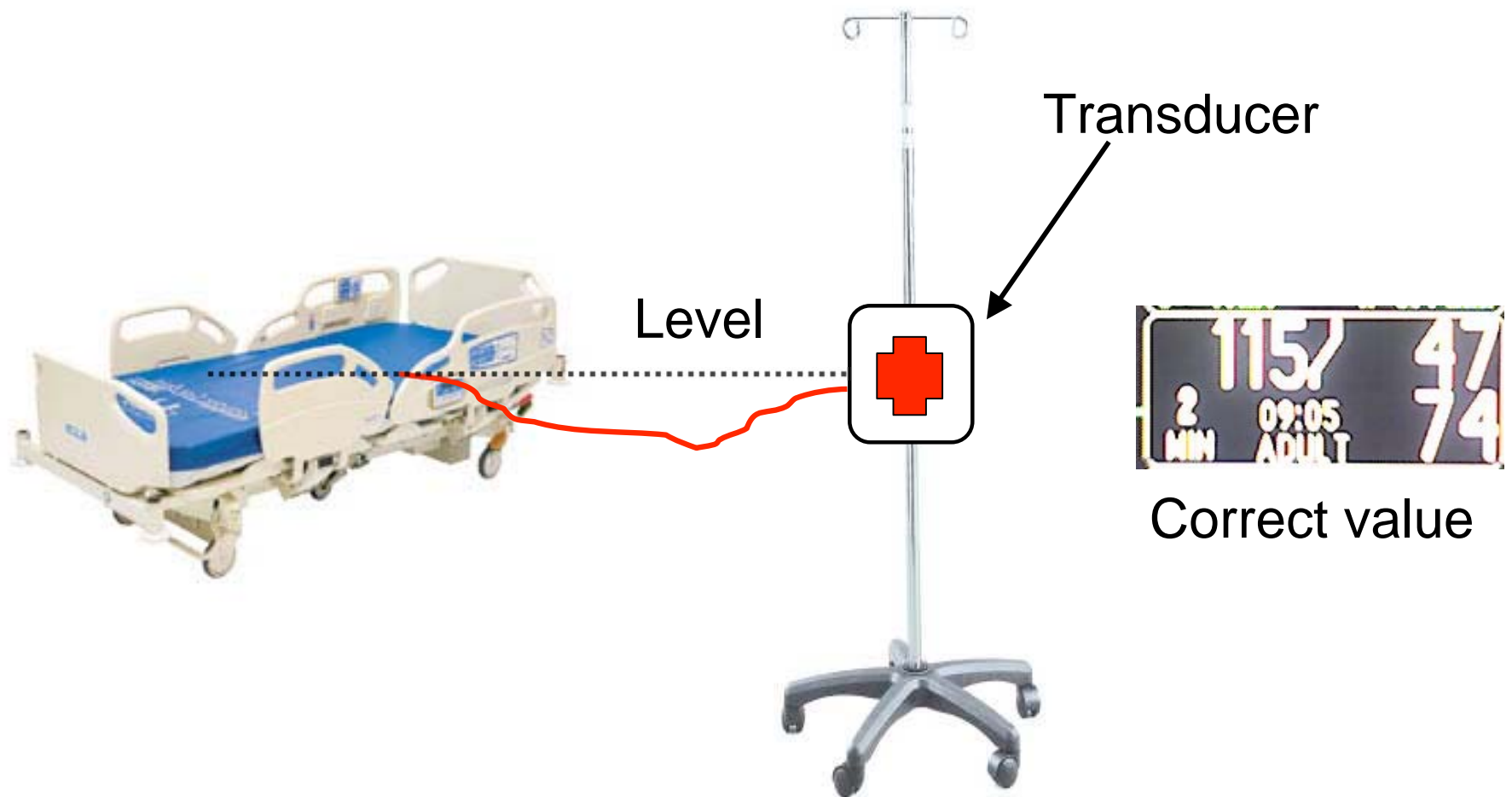
← and →



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

Scenario: Blood Pressure Measurement Errors

Invasive BP Measurement

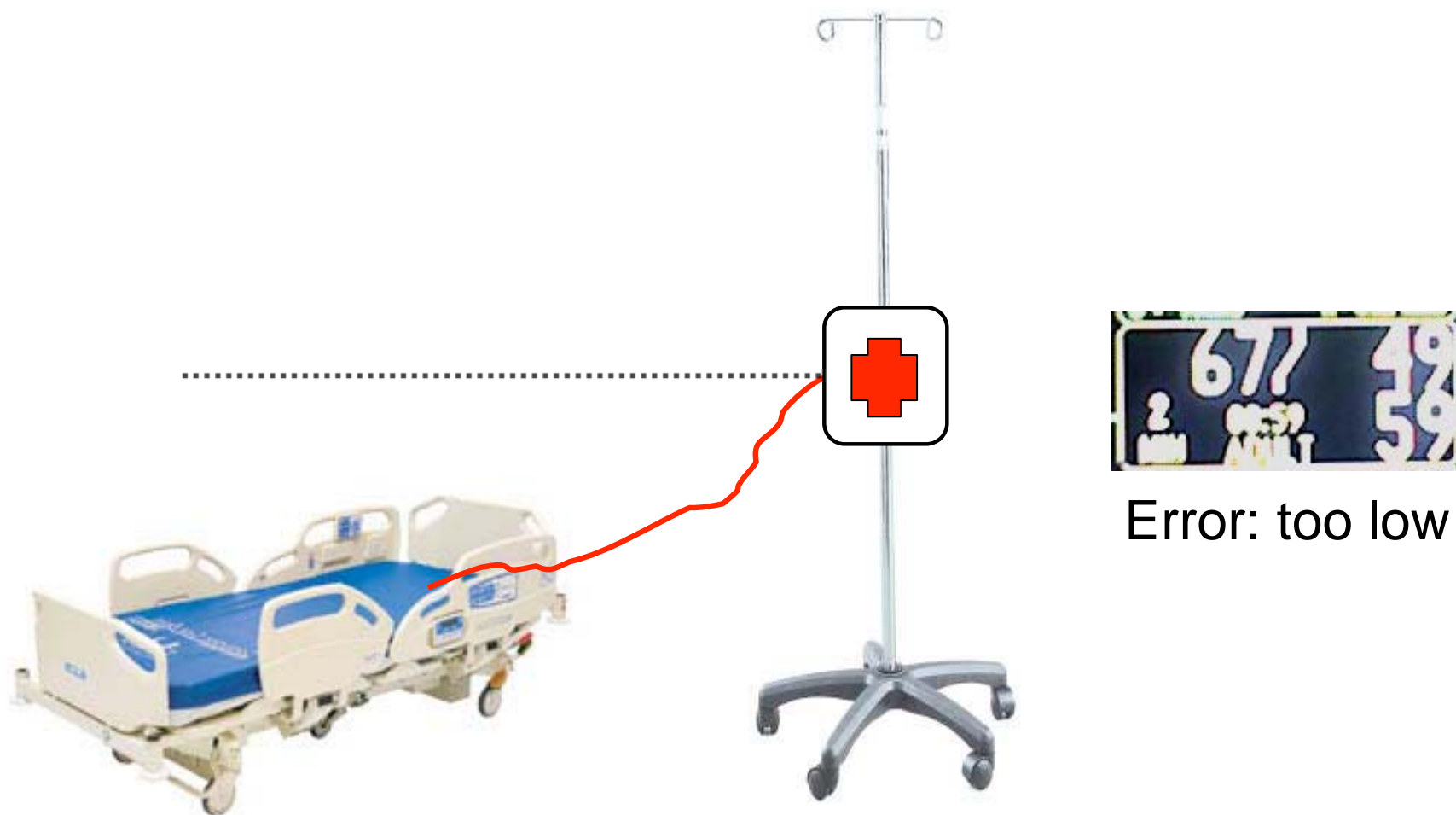


This offset can introduce > 50% measurement error!

BP Measurement Error

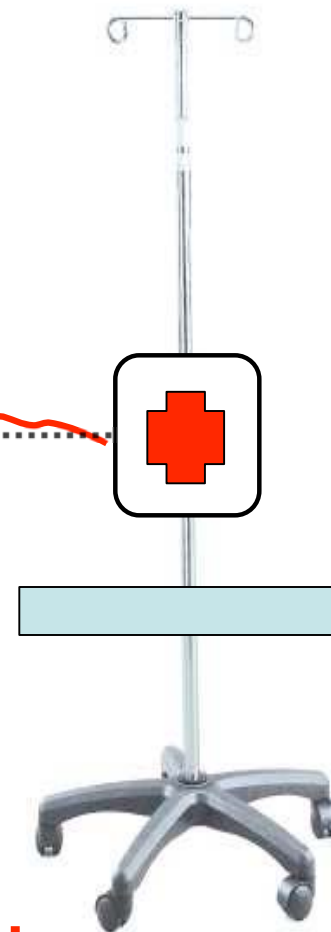
- Acta Anaesthesiol Scand. 2006 May;50(5):600-3: “Practical sources of error in measuring pulmonary artery occlusion pressure (PAOP): a study in participants of a special intensivist training program of The Scandinavian Society of Anaesthesiology and Intensive Care Medicine”
- “When PAOP values were 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”

Invasive BP display error



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

**NOT
COMMERCIALY
AVAILABLE**



*Solution requires connecting bed
and blood pressure monitor*

Offset
Corrected

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

Scenario: Surgical Fires

- ASA Closed Claims Analysis of Burn Injury in the OR
- Laser airway burns n=3, 1 death
- Largest claims were for airway fires (median \$167,500)

Source: ASA Newsletter, June 2004

Airway Laser + O₂ -> Fire

- O₂ enriched respiratory gas supports combustion
- Surgical team must “remember” to minimize O₂ prior to airway laser use



Why don't we rely on pilot to “remember” to deploy landing gear?

Airway Laser-O₂ Interlock

- Measure O₂ during anesthesia
- Prevent activation of airway laser if inspired O₂ > 30%



Solution requires connecting laser equipment and anesthetic equipment / O₂ monitor

**NOT Commercially
AVAILABLE**

Proposed by Sem Lampotang, PhD, Univ. of Florida, Gainesville

Scenario: Failure to ventilate

Benefit of medical device interoperability:

Equipment Synchronization to mitigate hazard

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

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



X-ray



Ventilator

Example: Cholecystectomy w/ intraop cholangiography

“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*

Solution - don't turn off ventilator: synchronize x-ray with ventilator *(analogous to synchronizing flash with shutter)*



NOT AVAILABLE



Synchronize or “gate” x-ray to expose image at end of expiration.
May require ventilator to briefly pause (automatically)
We are implementing this use-case in the MD PnP Lab



MD PnP
Getting connected for patient safety

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



MD PnP program: End-to-End Approach

1. Elicited use case (STA 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 BME
7. Informed new ISO/IEC standards language
8. Informed new anesthesia machine feature set
9. Awareness identified new adverse event



NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Volume 21, No. 4, 61-88

Circulation 80,350

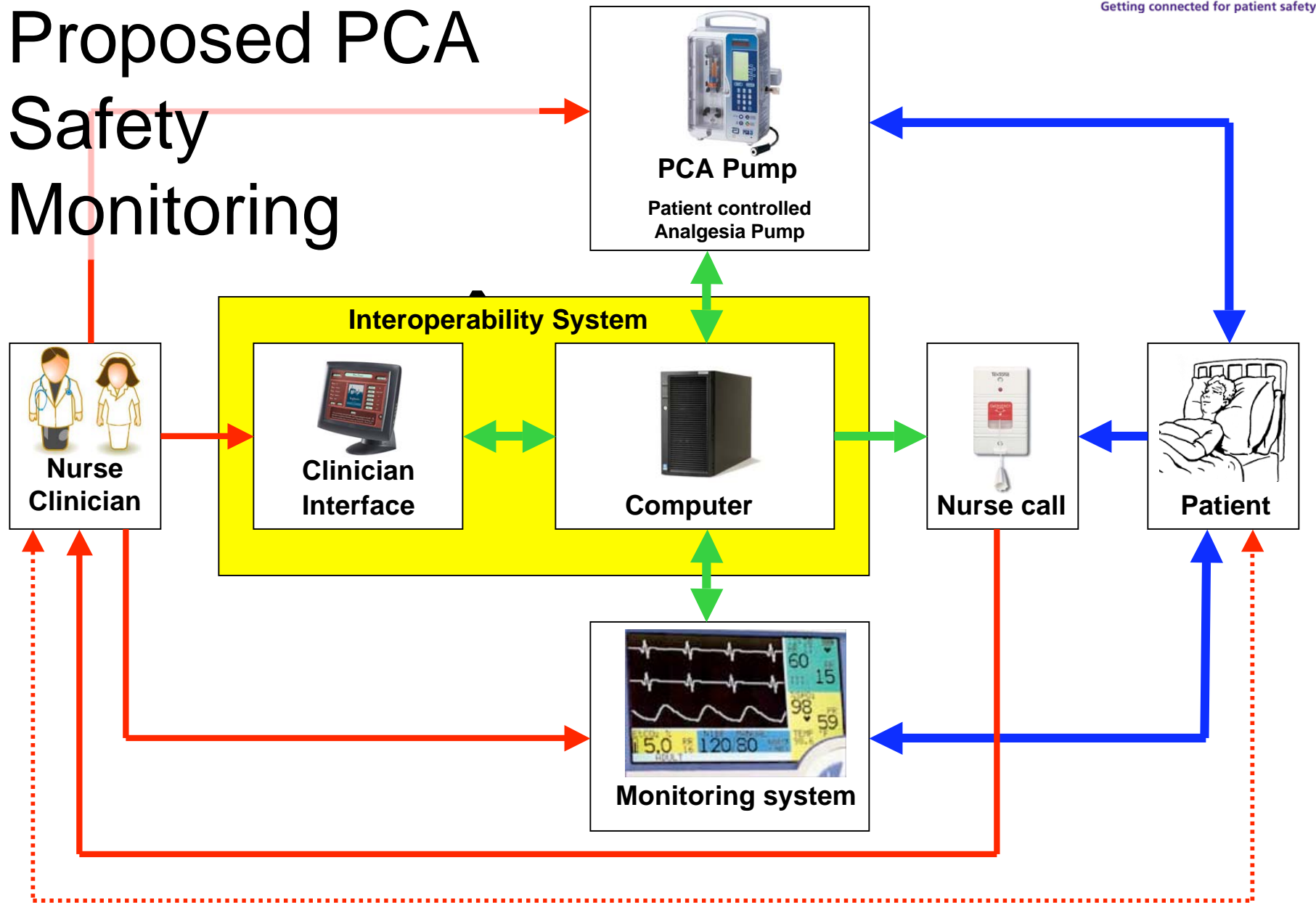
Winter 2006-2007

Dangers of Postoperative Opioids

APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications

Based on APSF Board of Directors Workshop
October 2006

Proposed PCA Safety Monitoring

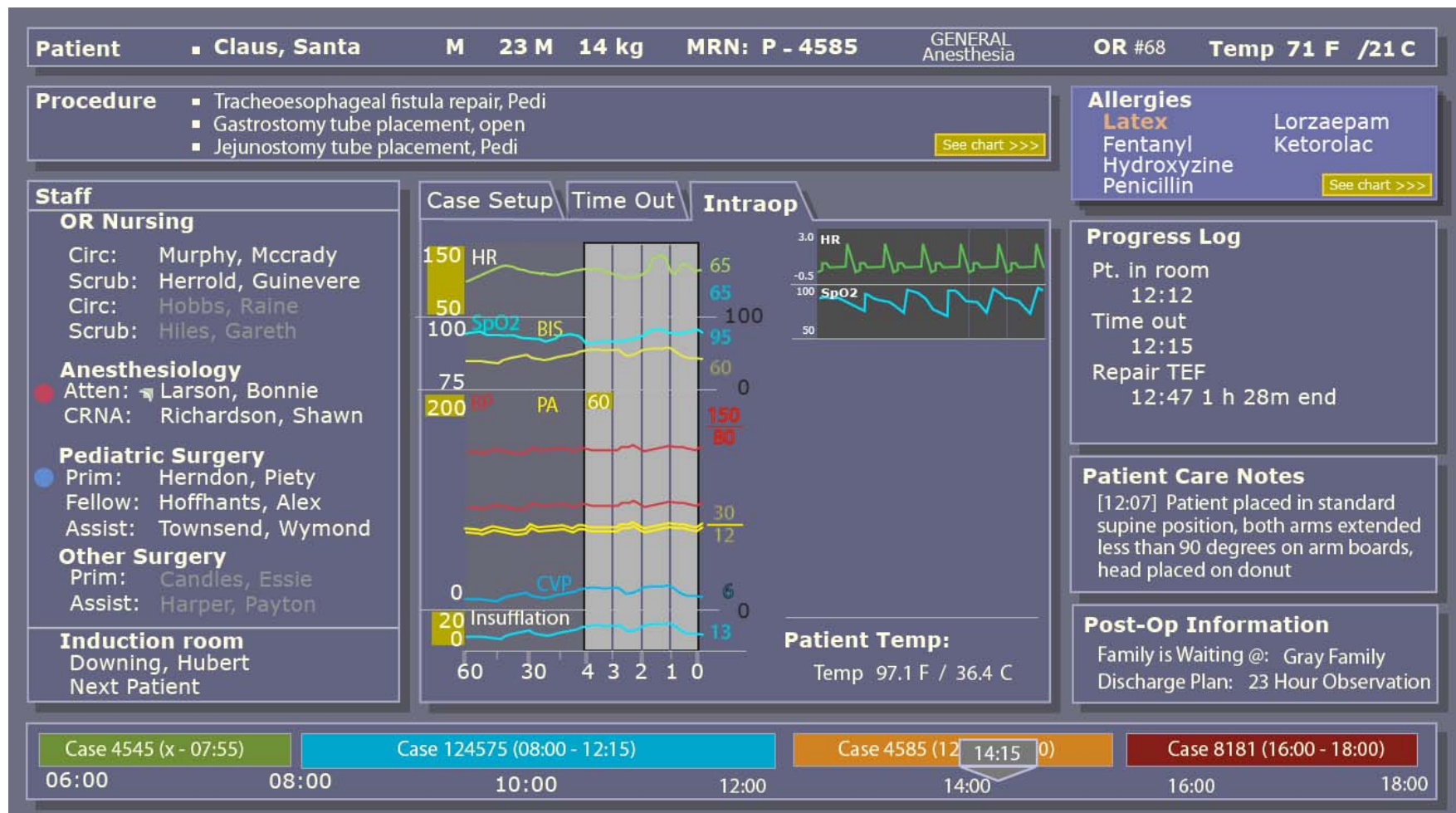


Aren't these great ideas?

- 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 - especially when controlling a medical device - are frequently complicated and expensive, and there are concerns about regulatory compliance and liability.

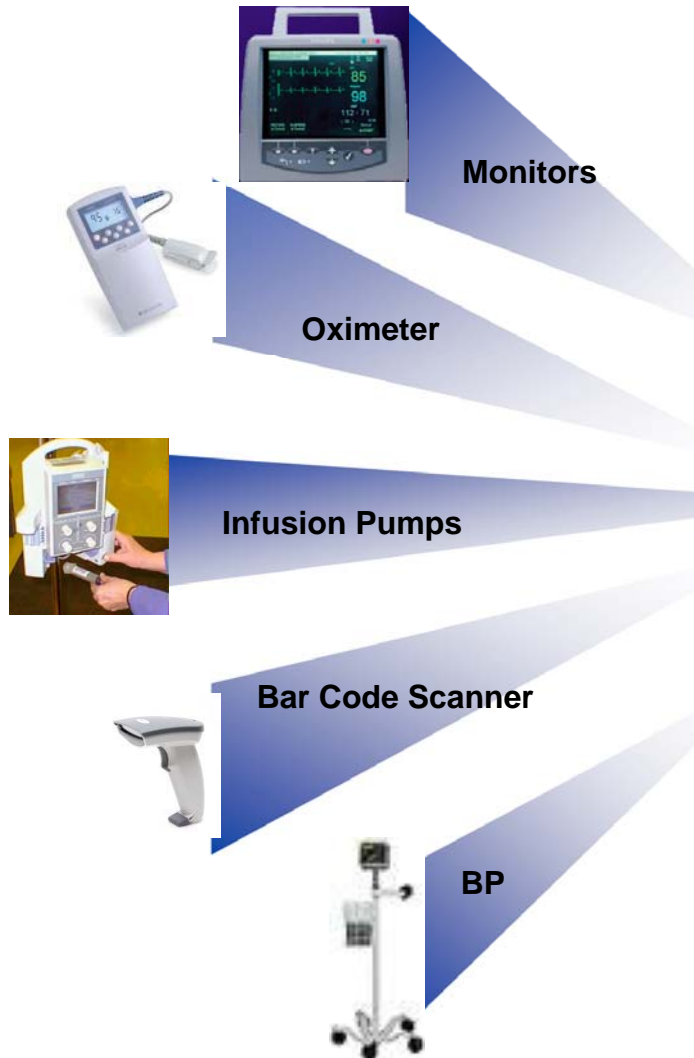
Despite challenges, data integration is possible and useful to deliver solutions NOW, and inform a “gap analysis” of technology and standards

LiveData OR-Dashboard

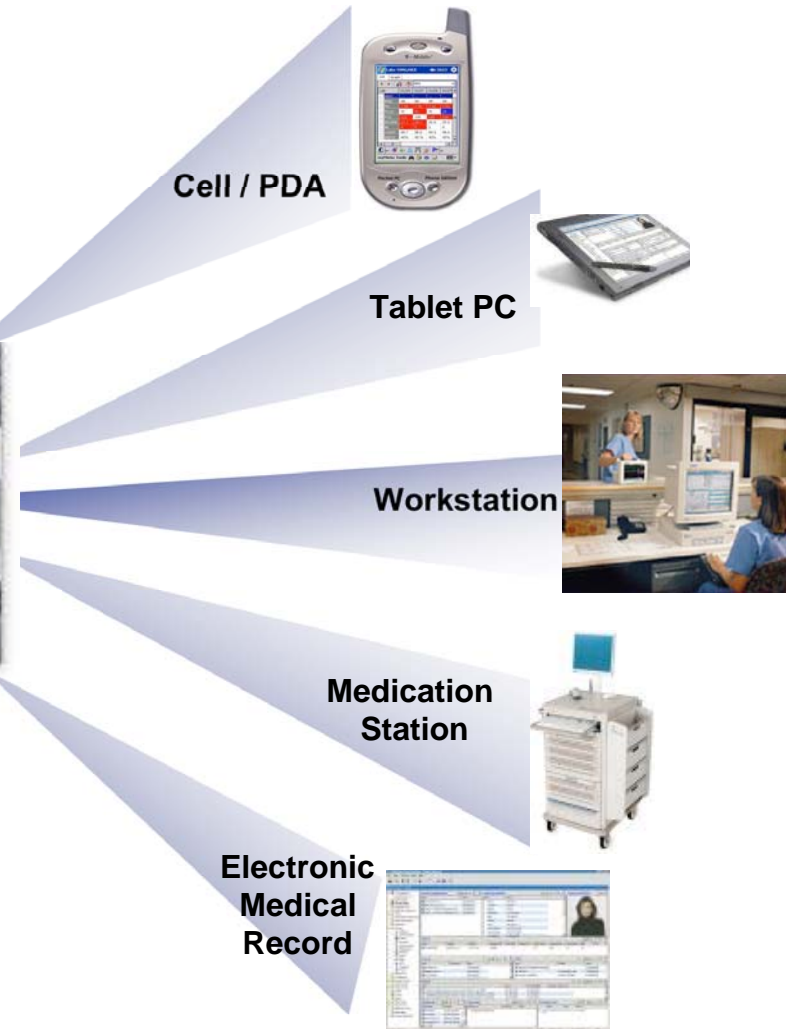


Demand and complexity will only increase ...

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



Data Integration, Analysis, and Display



What is interoperability?

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

"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"

Source: Wikipedia "Interoperability"

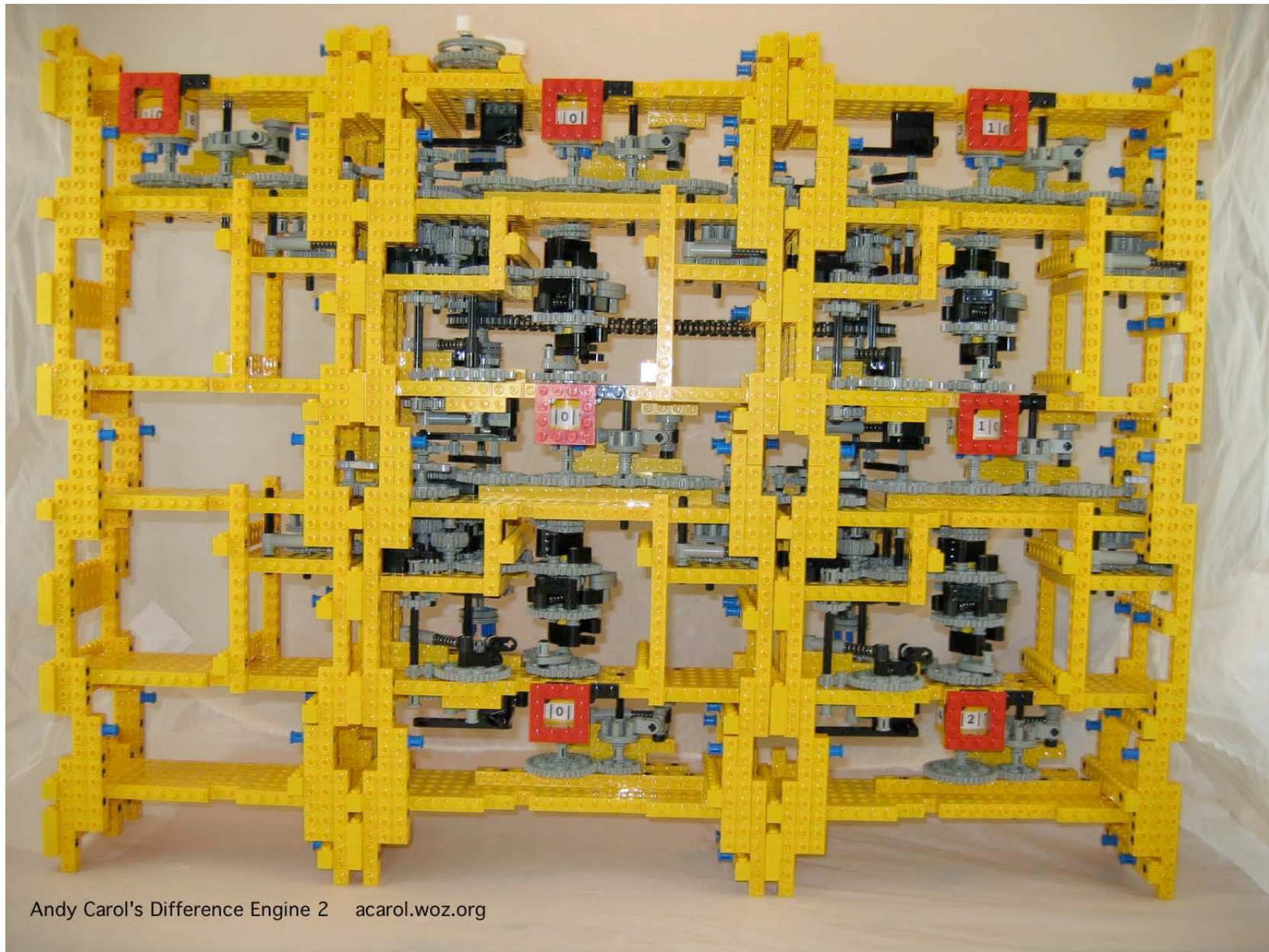
The power of standardized building blocks



(COURTESY BRICKARTIST.COM)



© 2007 Julian M. Goldman, MD
Babbage's Calculating Machine using LEGO® Pieces ... can compute 2nd or 3rd order polynomials to 3 digits



Andy Carol's Difference Engine 2 acarol.woz.org

Why interoperability?

The Acute-Care End-Game

- Free health care providers to explain clinical needs, and free marketplace to deliver solutions
- Decrease cost of ownership of medical devices and hospital networks.
 - According to Kaiser Permanente, CIS integration cost is ~ 40% TCO
 - Interoperability standards will save KP ~\$40M annually for 10 years.

Kaiser 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)

Interoperability is better now ...



Ethernet, Internet, USB memory

Healthcare is lagging

- Patient-centric healthcare has minimally benefited from standards based interoperability.
- Successes have been primarily at IT-level data transfer (HL7, DICOM, IHE), not at Biomedical Engineering level (patient connected devices) ... the “Sharp Edge” of patient care
- There are NO medical device interoperability standards that have been widely adopted by industry!
- Therefore, healthcare providers have been unable to specify “interoperability” in purchase orders ... but that is changing

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/EHR/CIS from medical devices. (“xHR”)
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

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.

Isn't this an old "quest"?

- Yes, several historical efforts to achieve interoperability
- "Kickoff" conference in May 2004 asked "is this the right time to re-consider medical device interoperability?"
- If we agree to proceed, what can be learned from prior efforts?

We learned that 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

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 and solutions
 - model clinical use cases (in simulation environment)
 - serve as a resource for medical device interoperability

MD PnP Program Plenary Meetings

2004-2007

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

MD PnP collaborators



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

MD PnP Program Working Groups

2004-2007

Other working groups – 60 participants from industry, healthcare, government

- Strategic Planning: Apr, Oct, Nov, Dec 2006, Jan 2007
- Clinical Requirements: Jan, Apr, May, Aug 2005, Jan, June 2006
- MD PnP Architecture: Jan, Feb 2007
- MD PnP PCA Platform Planning: April 2007 kick-off for Oct 2007
ASA Scientific Exhibit

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

- June 25-27, 2007
- Cambridge, Mass. USA
- Combined MD PnP and HCMDSS
- 145 attendees: Federal agencies, FDA, clinical researchers, CE/BMEs, manufacturers

June 2007



Selected MD PnP Program Initiatives

- Clinical Requirements
- Standards
- Liaison with other initiatives
- Facilitation of clinical society leadership

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 improvements in safety and efficiency.

New standard in preparation: ICE the “Integrated Clinical Environment”

- “Integrated Clinical Environment” of patient-centric networked medical devices, especially for high-acuity environments
- Risk management standard for MD PnP “ecosystem”
 - Data logging
 - Data Security
 - Connection to hospital network
 - Plug and play device “discovery”
 - User-interface
 - Enable decision support, closed-loop controls, etc
- Technology and other-standards agnostic
- Draft submitted as a “New Work Item Proposal by U.S.A. to ISO TC/121 in September 2007



©dman, MD

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."



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Imagine products so intelligent they help manage one's health at home.

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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.

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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 and smart clinical alarms
2. Medical device safety interlocks
3. Closed-loop control of ventilation, medication and fluid delivery
4. Support of remote healthcare delivery (home, battlefield, e-ICU)
5. Automated system readiness assessment (prior to starting invasive clinical procedures)
6. Complete, accurate electronic medical records
7. Increased quality and completeness of national research databases
8. 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
9. Understanding key issues at the heart of Biomedical Engineering (BME) - IT “convergence”

Conclusion:

Interoperability = Empowerment

- Consumer Electronics -> Consumer Empowerment
 - Digital photography
 - Personal computer peripherals
 - USB memory
- Medical System Interoperability -> Healthcare Provider Empowerment
 - Allow clinicians and biomedical engineers to leverage medical devices and IT systems to solve clinical problems, improve patient safety, and improve efficiency



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