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www.MD PnP.org

Massachusetts Health Data Consortium
Clinical Networking Forum November 6, 2007

Update on the Medical Device Interoperability Program

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Medical Device Plug-and-Play (MD PnP) Program

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Interoperability = Empowerment

- Cross-vendor standards-based interoperable Consumer Electronics Empowered Consumers
  - Created markets and solutions
  - Internet standards brought interoperability to PCs
    - Result -> Google!
  - Digital photography: SD cards, jpeg image format
  - USB memory

- Medical System Interoperability Can Create Healthcare Provider Empowerment
  - **Allow healthcare providers to leverage medical devices and IT systems to solve clinical problems, improve patient safety, and improve efficiency … by providing an infrastructure for innovation**

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

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

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

- Comprehensive integration of data from clinical and environmental systems, can prevent errors and inefficiencies across the continuum of care:
  - Smart Alarms requires “contextual awareness”
  - Workflow Support requires “closing the loop”
  - Safety Interlocks require system integration
- Not limited to the OR: in the ICU, ER, home, etc.
- *All require seamless connectivity*

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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 international 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”

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What is the scope of effective medical device interoperability ?

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

1. Bidirectional data communication to enable complete and accurate data population of the EMR/EHR/CIS from medical devices, and uploading of patient profiles, drug libraries, alarm limits, etc.

2. Medical device control capability to permit the integration of medical devices into networks to produce "error-resistant" systems with safety interlocks to decrease use-errors, and to enable closed-loop systems to regulate the delivery of medication and fluids and remote patient management

Examples of 3 clinical procedures that could benefit from interconnected medical devices to address system safety issues ->

(From the MD PnP “Clinical Requirements Database”)

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Scenario:
Failure to ventilate #1

Cardio-Pulmonary Bypass

or

Normal routine: Switch from anesthesia machine ventilator to cardiopulmonary bypass machine, and back to ventilator (after bypass)

Failure to Ventilate

- Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.
- Anesthesiology. 87(4):741-748, October 1997
- "… 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

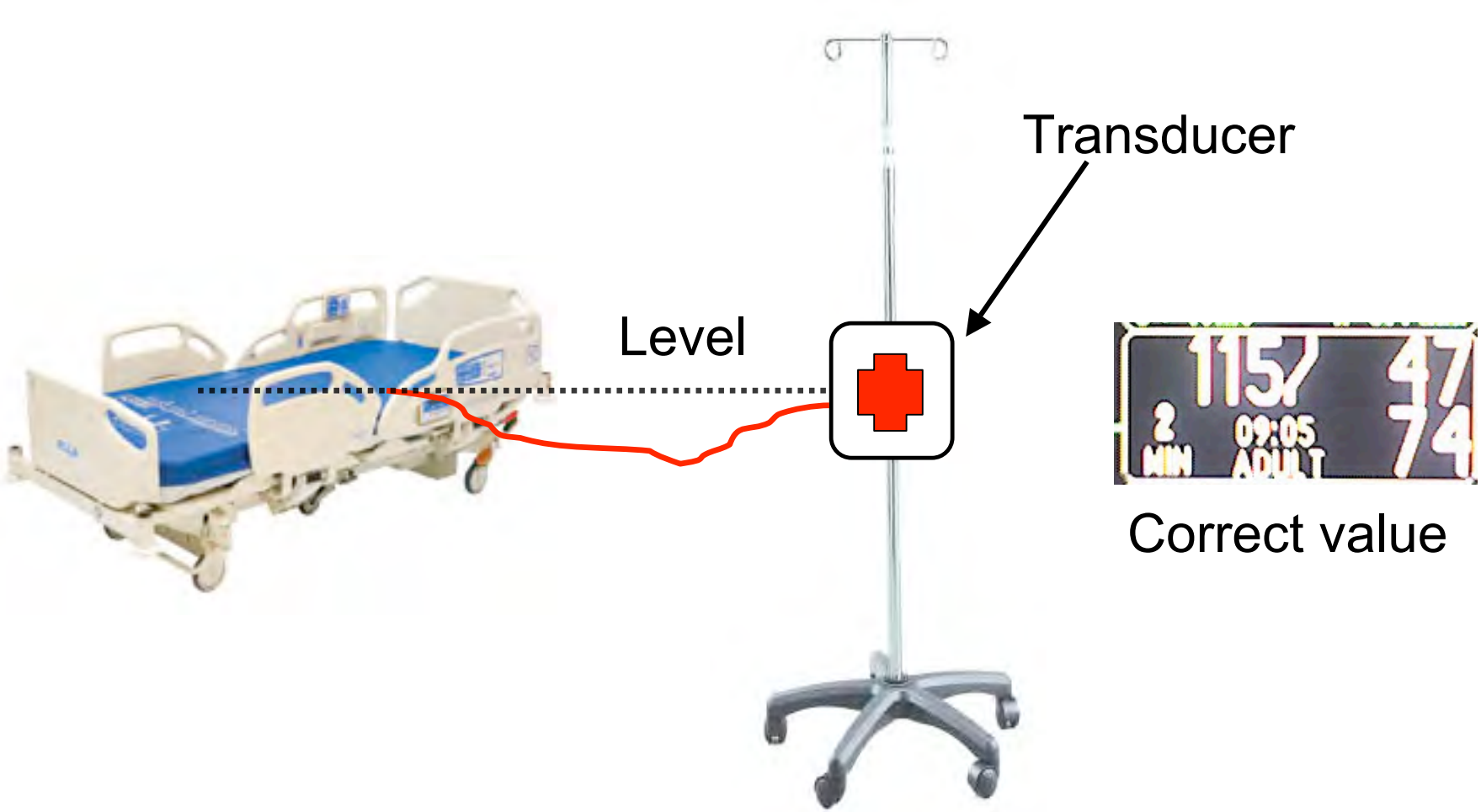
NOT AVAILABLE

← and →

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

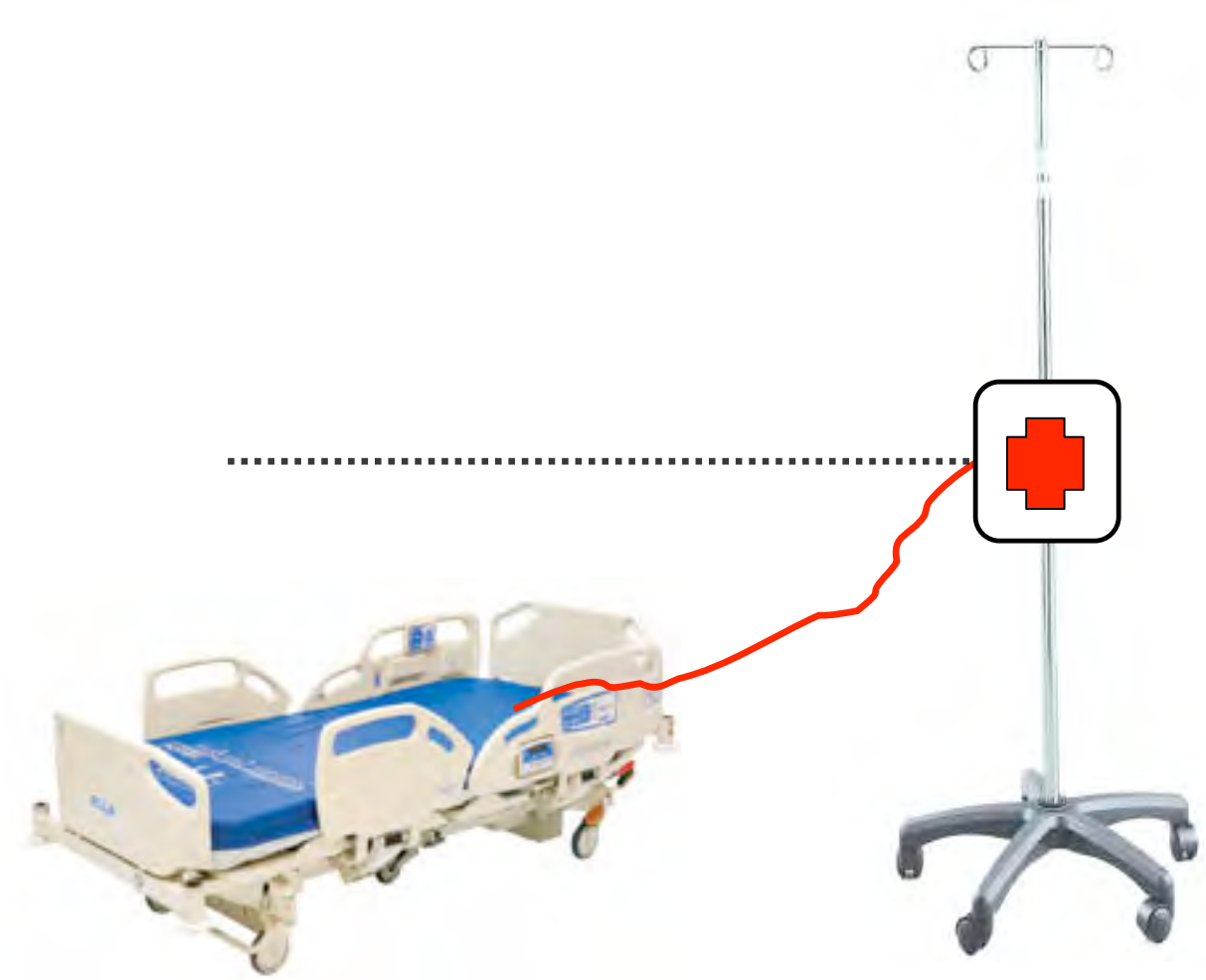
Scenario: Blood Pressure Measurement Errors

Invasive BP Measurement



Correct value

Invasive BP display error



Error: too low

This offset can introduce > 50% measurement error!

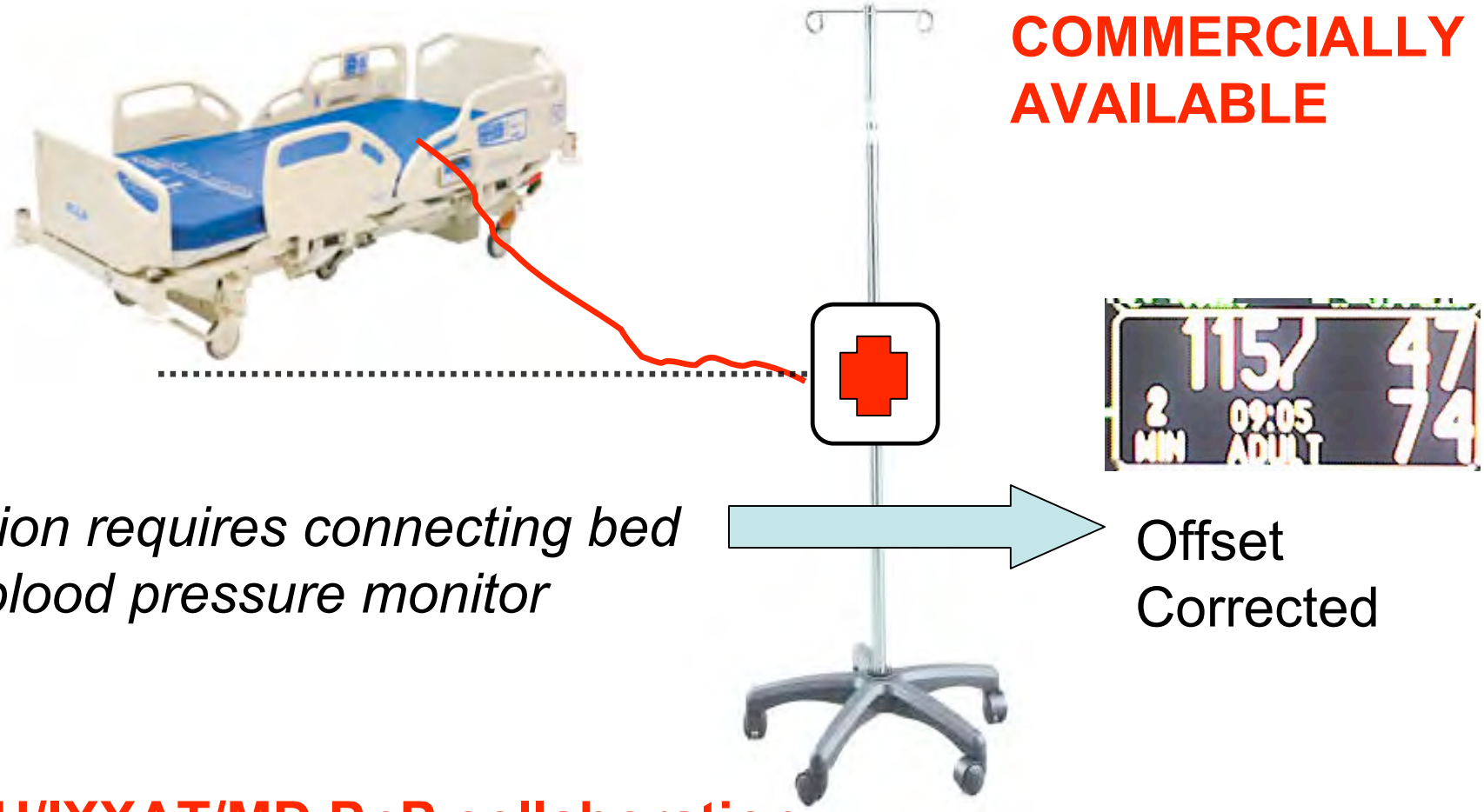
BP Measurement Error

- Acta Anaesthesiol Scand. 2006 May;50(5):600-3: "Practical sources of error in measuring pulmonary artery occlusion pressure (PAOP"

- "When PAOP values were adjusted for the differences from the reference transducer level, the median differences from the reference PAOP values were 2 mmHg (-6 to 9 mmHg) for physicians and 2 mmHg (-6 to 16 mmHg) for nurses"

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

NOT COMMERCIALLY AVAILABLE



Solution requires connecting bed and blood pressure monitor

Offset Corrected

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

HIMSS 2007 New Orleans: two use-cases demonstrated

NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Volume 21, No. 4, 61-88 Circulation 80,350 Winter 2006-2007

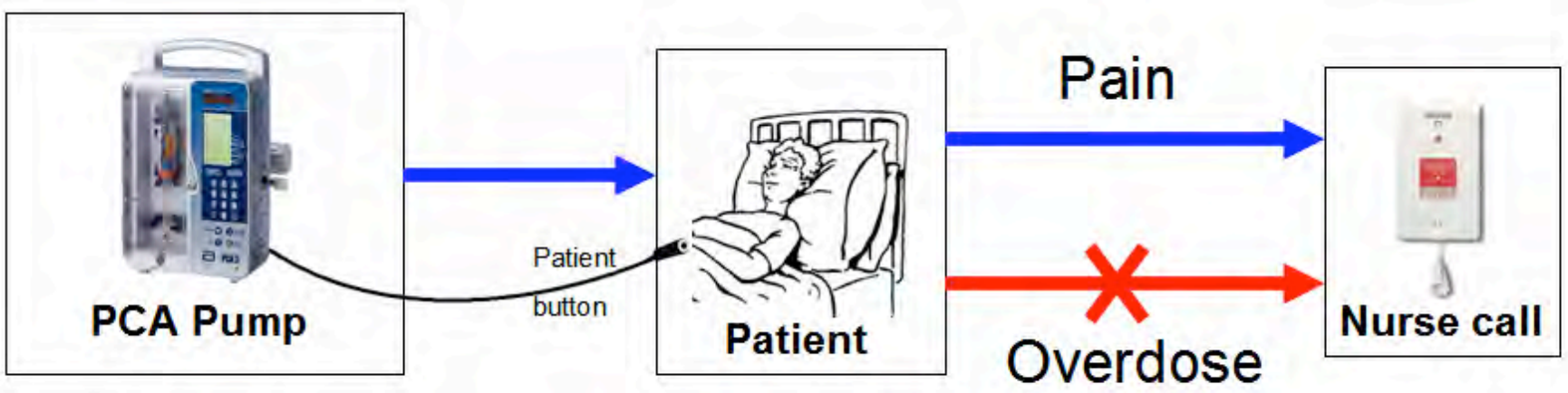
Dangers of Postoperative Opioids

APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications

Based on APSF Board of Directors Workshop
October 2006

Typical PCA System

Patient can call to request more analgesia, but, cannot call for help when over-medicated.



PCA = Patient-Controlled Analgesia

“Not Uncommon” PCA pump scenario

A 49-year-old woman underwent an uneventful total abdominal hysterectomy... 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

APSF PCA Recommendations

- “We advocate widespread acceptance of the goal that no patient shall be harmed by opioid-induced respiratory depression in the postoperative period.
- Thus, immediately, we urge health care professionals to consider the potential safety value of continuous monitoring of oxygenation (pulse oximetry) and ventilation in patients receiving PCA or neuraxial opioids in the postoperative period.”

APSF PCA Recommendations

- “A particularly attractive feature may be the ability to automatically terminate or reduce PCA (or PCEA) infusions when monitoring technology suggests the presence of opioid-induced respiratory depression. To facilitate such capabilities, we strongly endorse the efforts to develop international standards for device interoperability and device-device communication.
- It is critical that any monitoring system be linked to a reliable process to summon a competent health care professional to the patient's bedside in a timely manner.”

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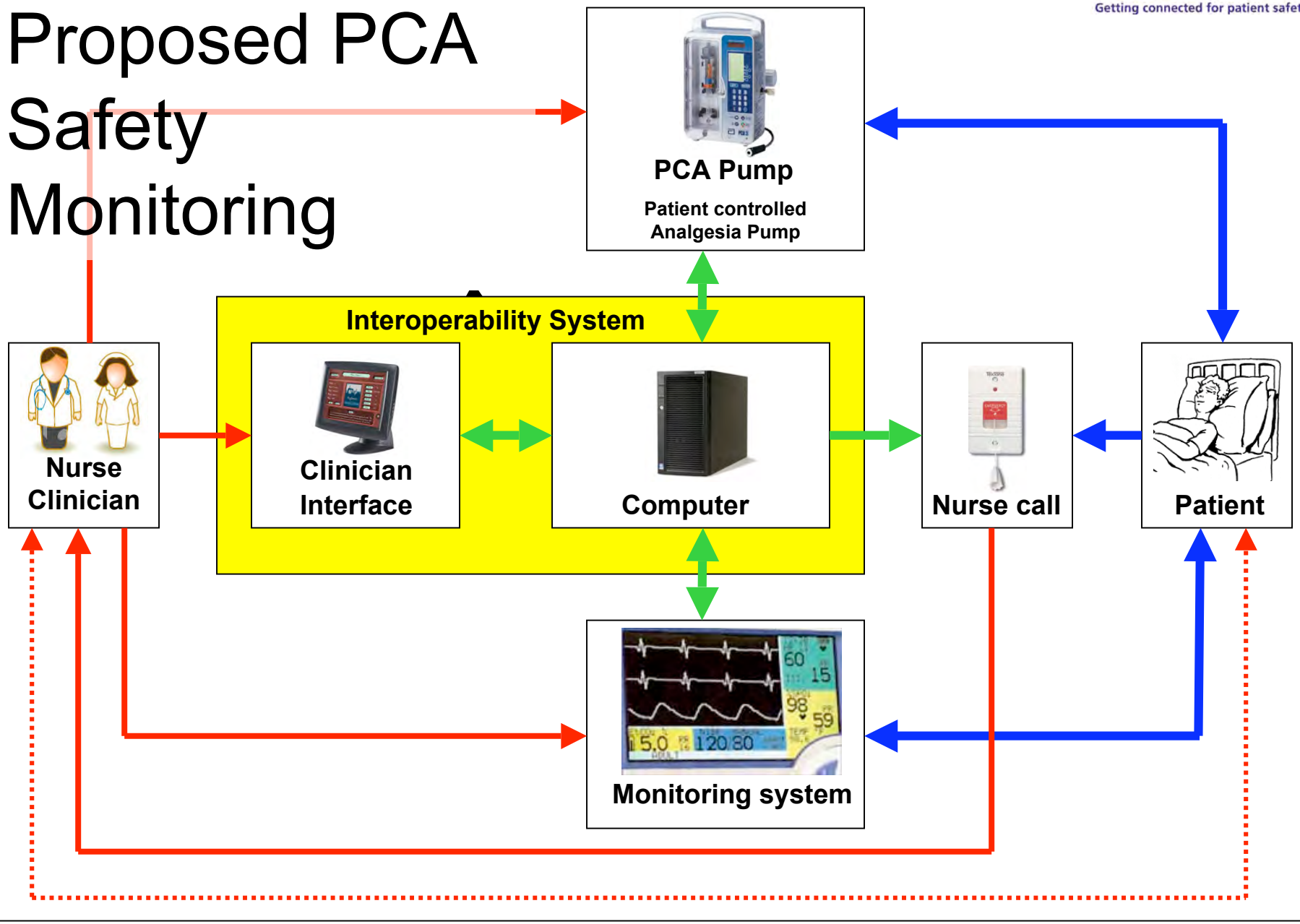
Proposed PCA Safety Monitoring



American Society of Anesthesiologists Scientific Exhibit October 2007

American Society of Anesthesiologists Scientific Exhibit October 2007

These are elegant solutions!

- Then aren't they available?
- Why not connect these devices and solve these problems?
- Because "one-off" or "home-made" solutions - especially when integrating medical devices - are frequently complicated and expensive, and there are concerns about safety, regulatory compliance, and liability.

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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”

Interoperability is better now …

Interoperability in healthcare is lagging …

- Patient-centric high-acuity 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)
- 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

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

MGH and CIMIT, with TATRC support, initiated the MD PnP program in 2004 to lead the adoption of open standards and technology for medical device interoperability to improve patient safety.

Four plenary conferences, working group meetings, and clinical focus groups have elicited input to shape the mission and strategy and identify clinical requirements.

Over 70 institutions and > 600 experts (clinicians and engineers) have participated. Many support provider-mandated conformance to interoperability standards.

Isn’t this an old challenge?

- Yes, several historical efforts to achieve interoperability
- “Kick-off” 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

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Goals of the MD PnP Program

1. Lead the adoption of open standards and related technology to support medical device interoperability
2. Define a regulatory pathway in partnership with the FDA and other regulators.
3. Elicit clinical requirements for the proposed interoperable solutions to maintain focus on patient safety.
4. Use our vendor-neutral laboratory to:
   - evaluate interoperability standards and solutions
   - model clinical use cases (in simulation environment)
   - serve as a resource for medical device interoperability

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MD PnP Program Plenary Meetings
2004-2007

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

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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

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

- Co-Chairs: Drs. Insup Lee (Penn) and Julian Goldman (MGH/CIMIT)
- June 25-27, 2007
- Cambridge, Mass. USA
- Combined MD PnP and HCMDSS
- 145 attendees: Federal agencies, FDA, clinical researchers, CE/BMEs, manufacturers

Conference: June 2007

Insup Lee, Rob Kolodner, Julian Goldman

Selected MD PnP Program Initiatives

- Clinical Requirements repository/ methodology
- Standards support
- MD MP3
- Interop contract language
- Use-case implementations and analysis
- FDA interoperability projects

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Clinical Requirements

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

“ICE” - Integrated Clinical Environment

- US TAG to ISO/TC 121 authorized writing group to prepare draft standard to be used for New Work Item Proposal
- NWIP for “ICE Part I - Network Control” submitted by US to ISO/TC 121/SC3 and IEC 62A in September 2007; closing date for NWIP ballot is 21 December 2007.
- Proposed liaison with ISO/TC 215/WG7 (Devices) and ISO/TC 121/SC1
- Included draft of “ICE Part I, Network Control” proposed as CD.
- Proposed meeting: 25-28 March 2008, Lubeck, DE

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Scope of ICE Part I

- “This International Standard is applicable to the basic safety and essential performance of an ice network controller .. and ICE equipment interface … for managing a network of medical devices in a medical system in support of a single patient in the integrated clinical environment, (ICE)...
- This standard series establishes the general principles for the design, verification, and validation of a model- based integration system that enables the creation of an integrated clinical environment intended to facilitate cross-manufacturer medical device integration...”

Next slides -> draft functional architecture

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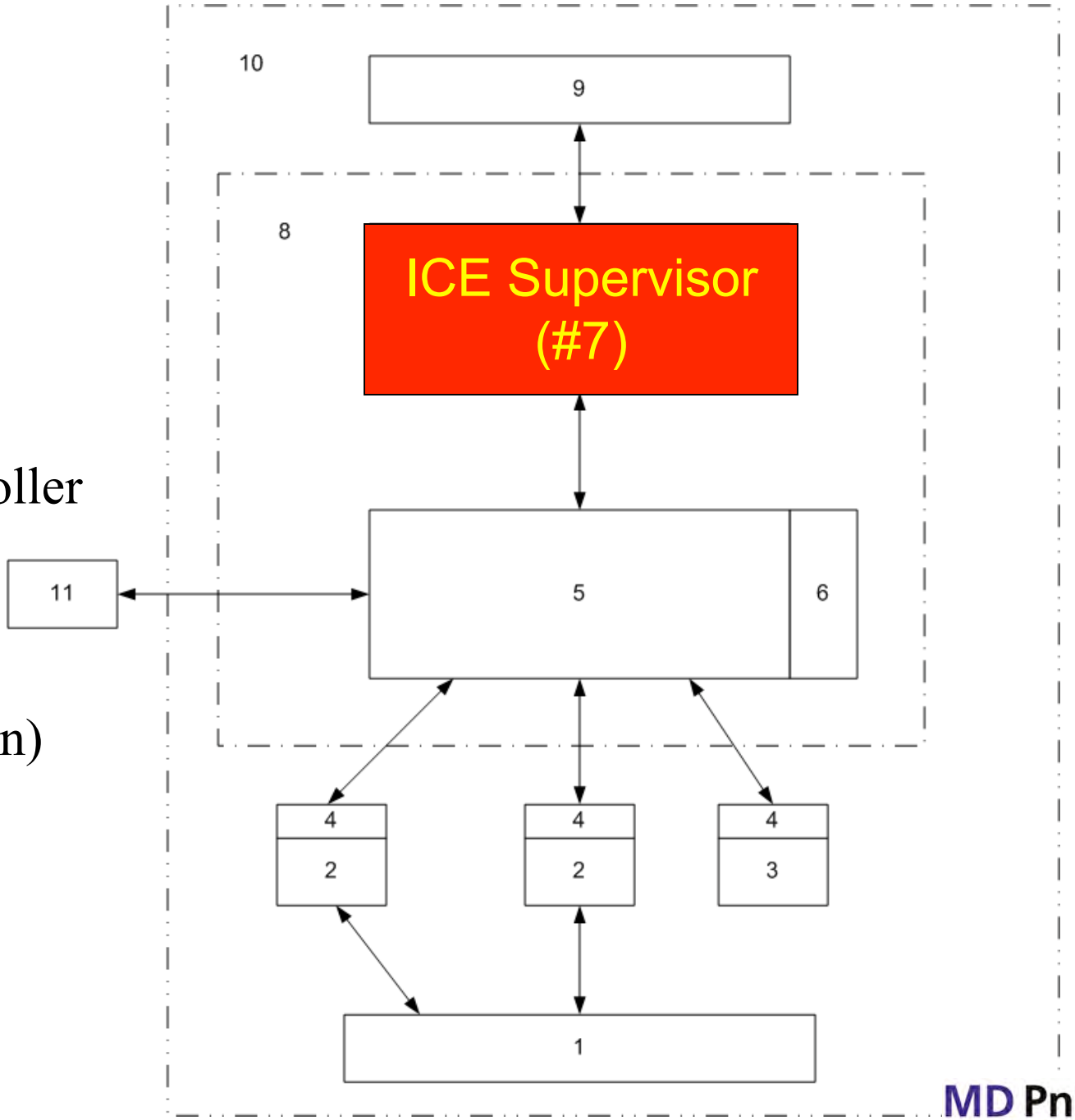
Figure 1: Functional Elements of the Integrated Clinical Environment

Key

1 **patient**
2 medical device
3 Equipment
4 ice interface
5 ice network controller
6 data logger
7 ice supervisor
8 ice manager
9 **operator** (clinician)
10 ICE
11 external interface



From proposed draft standard "ICE Part I"

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

- Provide safety interlocks
- Distribute integrated alarm conditions to relevant operators
- Provide context-aware clinical decision support
- Set command input variables of other medical devices, per operator-defined, context-appropriate rules in order to manage their operation
- 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 remote access and control of medical devices

From proposed draft standard "ICE Part I"

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Figure 1: Functional Elements of the Integrated Clinical Environment

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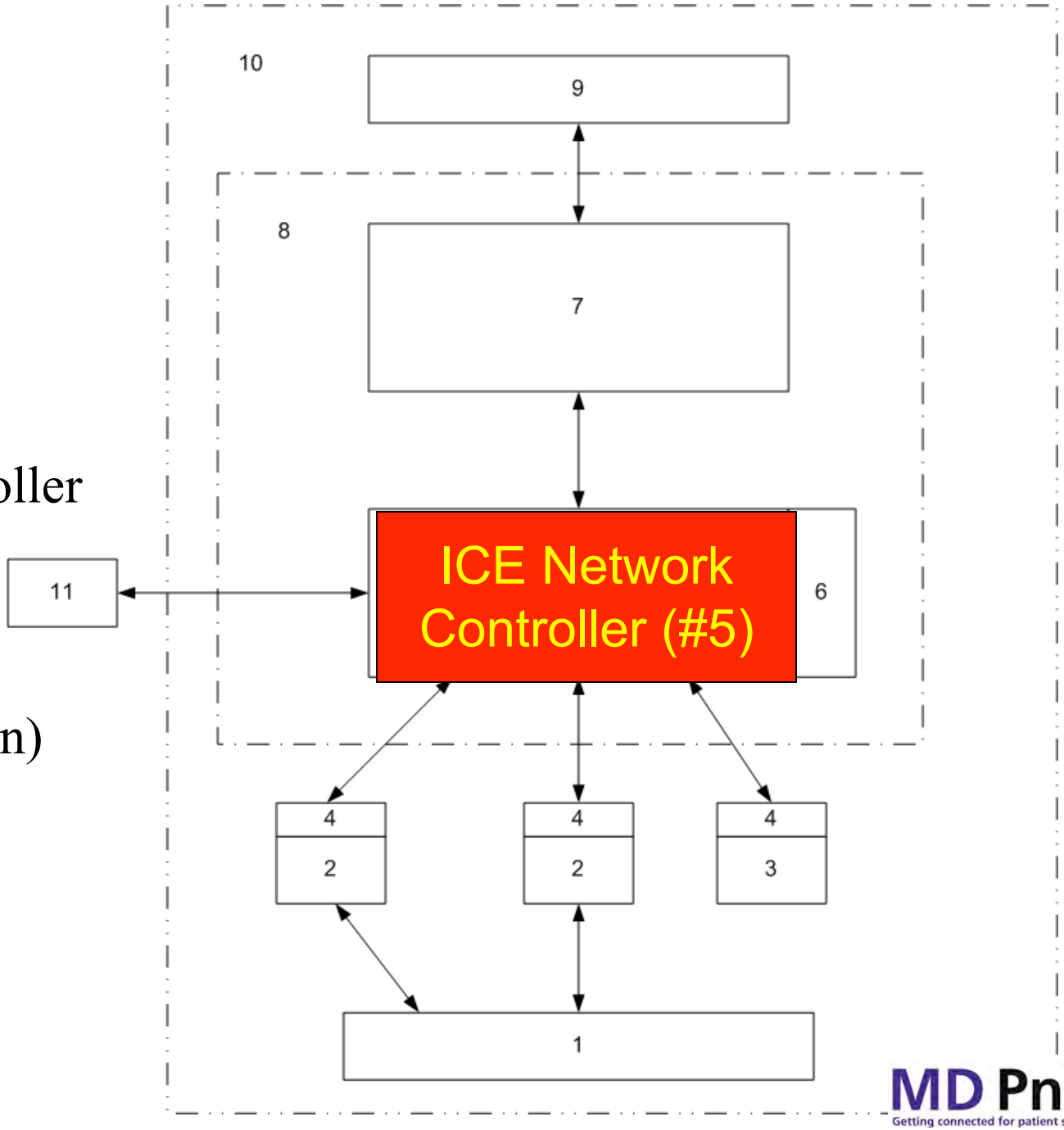

From proposed draft standard "ICE Part I"

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

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

From proposed draft standard “ICE Part I”

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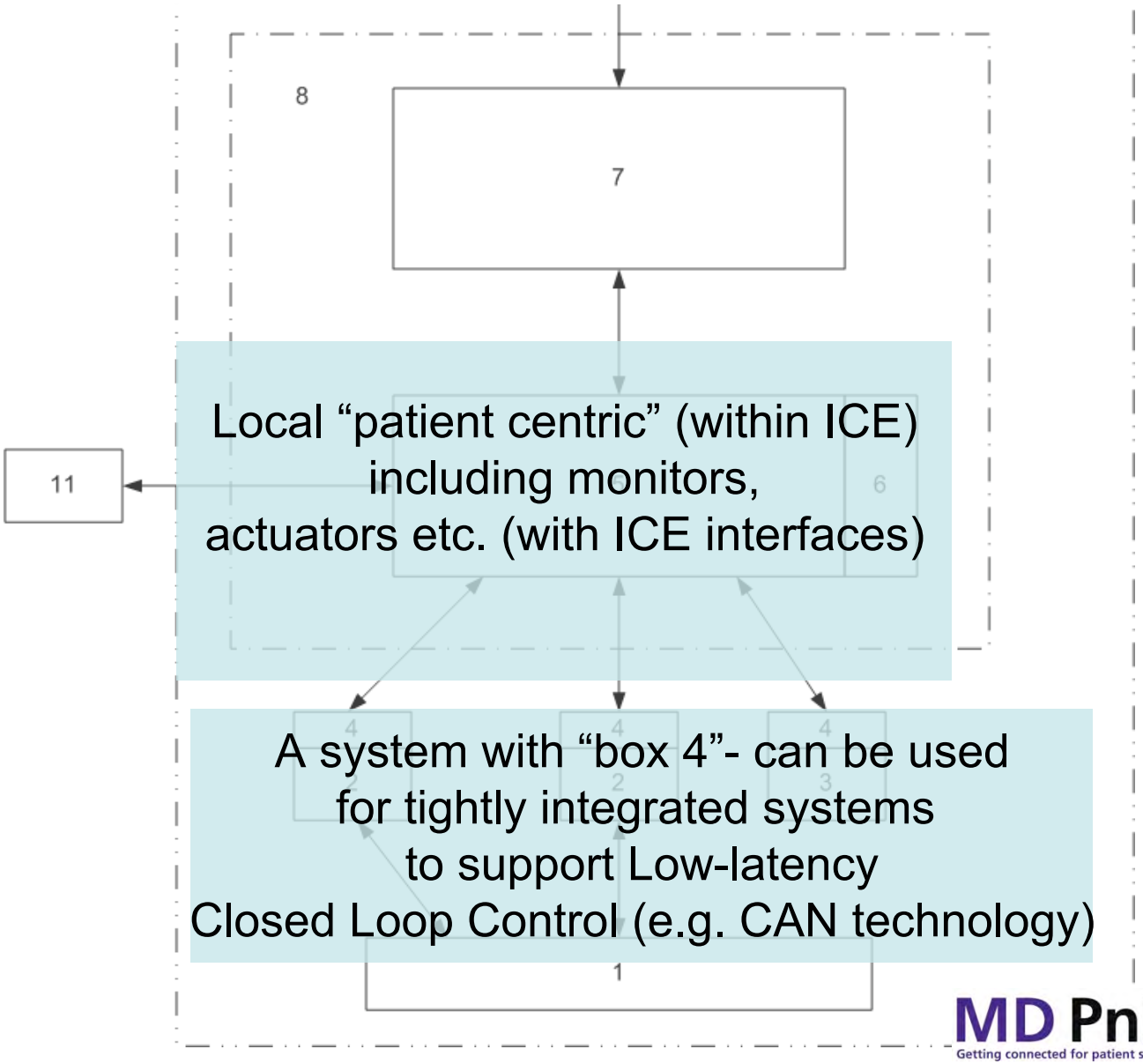
How might the interfaces “fit together”? (from MD PnP architecture working group)



“External interface” loosely coupled: Hospital network, enterprise CISs, internet

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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)

MD MP3™
Medical Device Mobile Plug-and-Play Platform

- Platform to deliver emerging interoperable solutions from Lab to clinical environments
- Support data acquisition, decision support, actuator control
- Disseminate as a national resource
- Collaborate with other groups for other applications

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The Anesthesia Patient Safety Foundation endorsement of interoperability March 2007

"APSF believes that intercommunication and interoperability of devices could lead to important advances in patient safety, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind.

APSF also recognizes that as in all technologies for patient safety, interoperability poses safety and medicolegal challenges as well. Development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety and outcome benefit."

Continua Health Alliance (Consortium announced June 2006) > 140 Member Companies

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ALLIANCE PARTNERS

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

Remote Device Interaction

- Is is safe?
- How will you know?
- HCMDSS community is applying methodology from safety critical systems

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MD PnP Lab

- Located at 65 Landsdowne St.
- Outfitted by CIMIT and PHS IS
- Virtual “Medical” Network
- Patch panel, sniffer ports
- What can we do?
  - Interoperability Development and Testing
  - Use Case Implementation
    - Continua Health Alliance
    - IHE PD

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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)

Example: Use Cases

- “Completely wireless alerting and alarms”
  - Sounds great!
  - But, the devil is in the details
- Must understand:
  - Workflow
  - Risks, especially system failure-modes

Requirements Engineering Practices in Support of the Medical Device Plug-and-Play Program

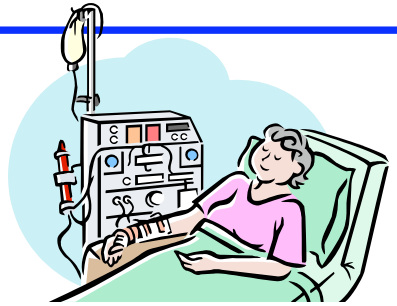
Project funded by PHS IS Research Council

P.I. - Rick Schrenker
Systems Engineering Manager
CIMIT MD PnP Program
www.mdpnp.org
MGH Biomedical Engineering

Conclusion:

Interoperability = Empowerment

- Consumer Electronics -> Consumer Empowerment
- Medical System Interoperability -> Healthcare Provider Empowerment
  - Need at least internet/digital photography performance
  - The “Blue Screen of Death” cannot be tolerated
  - Clinical requirements should dictate specific performance
  - If all devices in the medical network are are treated as “safety critical”, cost and complexity may block adoption



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A Challenge:

- How do we plan for interoperability in a 2010 facility, assuming a blank slate and unlimited budget?
- What could we expect?
  - IT systems
  - Medical devices
- What is the ultimate device integration engine and technology?
- Do we have use cases?
- Standards-based?
- How do we future-proof?


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