ICE Meeting at FDA
March 25, 2008

Integrated Clinical Environment (ICE): Background, Rationale, and Clinical Scenarios

Julian M. Goldman, MD
Depts. Of Anesthesia and Biomedical Engineering
Massachusetts General Hospital / Harvard Medical School
Director, CIMIT Program on Interoperability and the
Medical Device Plug-and-Play (MD PnP) Program

Problem statement

- It is becoming increasingly clear that many improvements in patient safety, patient care, and healthcare efficiency require systems solutions which <u>cannot be implemented due to the barriers of integrating medical devices and systems,</u> especially in high-acuity clinical settings

- The ability to "integrate the clinical environment" is an essential step to address these issues and create <u>error-resistant systems</u>

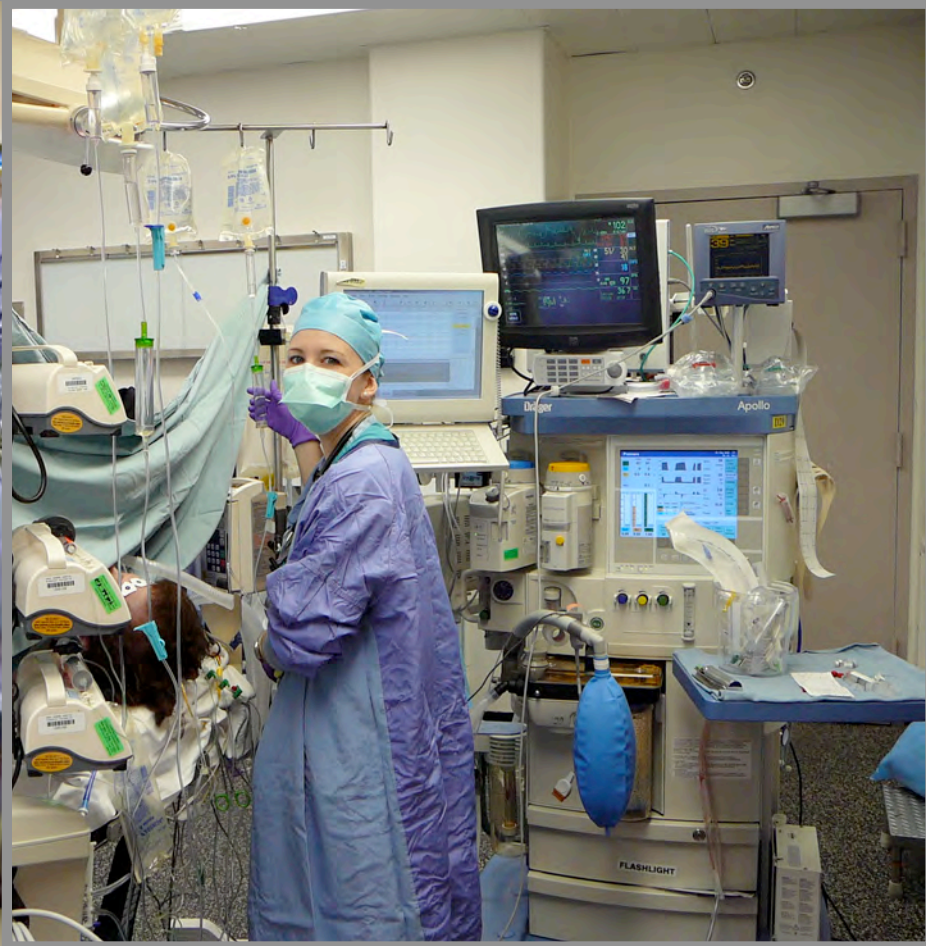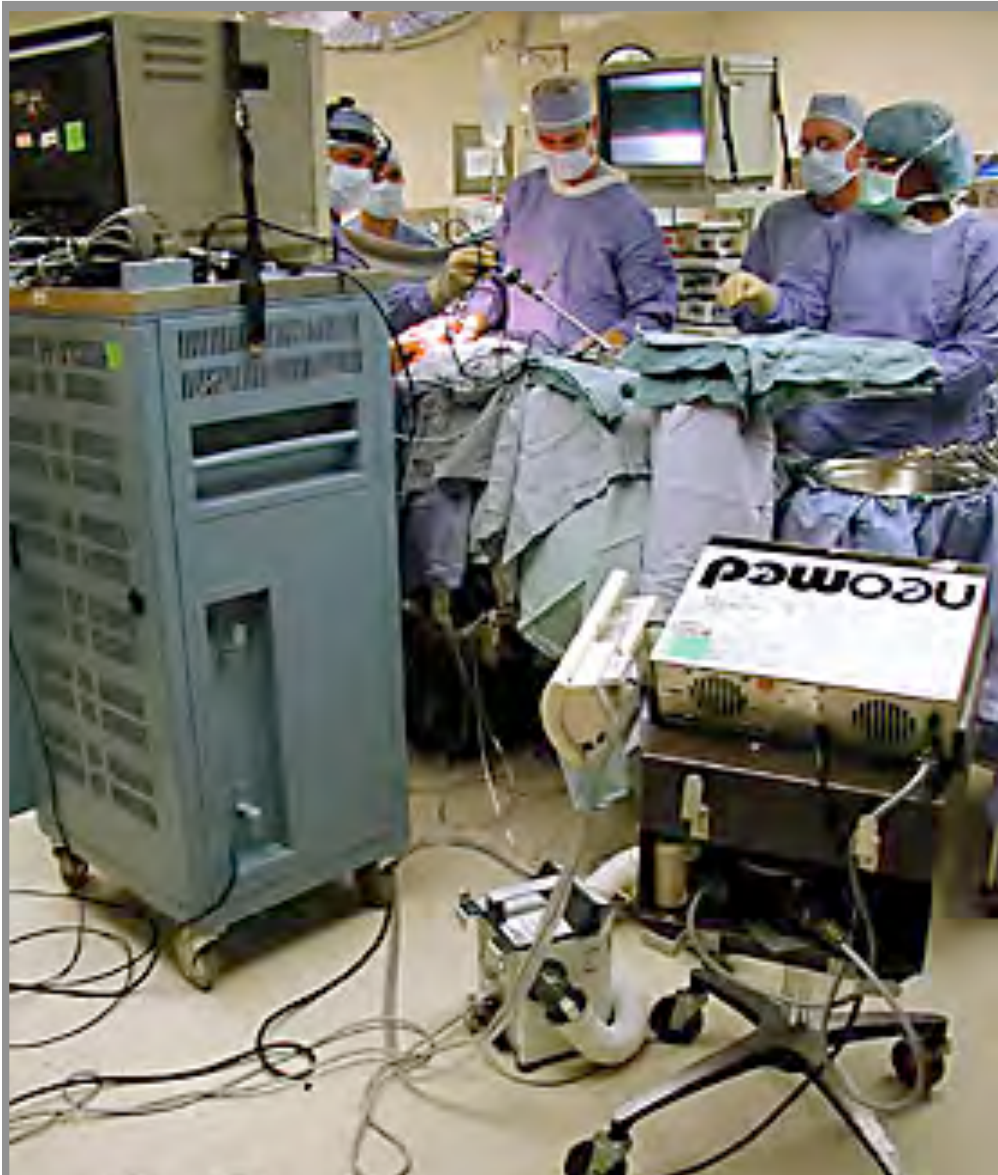*98,000 annual deaths attributable to medical errors
http://www.iom.edu/Object.File/Master/4/117/0.pdf
Ref. IOM/NAE Report 2005: "Building a Better Delivery System"

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Current state

… at the sharp edge of high acuity patient care …

Typical ORs of "today"

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

Mass General Hospital/CIMIT
Operating Room of the Future

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.

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
- <u>Not limited to the OR</u>: 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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6 Examples of clinical procedures that could benefit from integration of medical devices to address system safety issues ->

## (From the MD PnP Program's "Clinical Scenario Database")

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Scenario: Surgical Fires

- ASA Closed Claims Analysis of Burn Injury in the OR

Source: ASA Newsletter, June 2004

Airway Laser + O_2 -> Fire

- High inhaled O_2 concentration typically used for anesthesia

- But, O_2 enriched respiratory gas supports combustion, especially > 28% *

- Therefore, surgical team must "remember" to minimize O_2 prior to laser use in the airway

Tracheal
Tube

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* ISO/TR 11991:1995
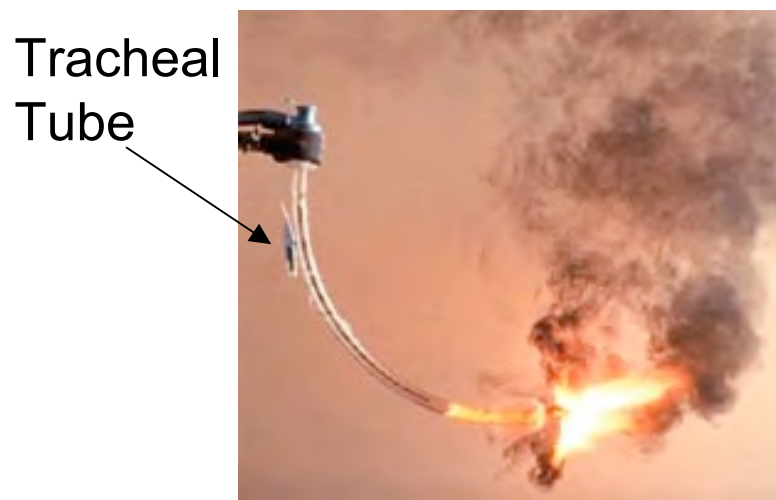
Airway Laser-O$_2$ <u>Interlock</u>

- Measure O$_2$ during anesthesia
- Warn surgeon and prevent activation of airway laser if inspired O$_2$ > 28%

Tracheal Tube

Solution requires connecting laser equipment and anesthetic equipment / O$_2$ monitor

NOT Commercially AVAILABLE

(initially proposed in 1990s by Sem Lampotang, PhD, Univ. of Florida, Gainesville

Scenario:
Failure to ventilate #1

Cardio-Pulmonary Bypass (heart-lung 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 <u>1997</u>

- "… In the second case, the <u>anesthesiologist forgot to resume ventilation after separation from cardiopulmonary bypass</u>. 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. <u>Both patients sustained permanent brain damage</u>."

Cardio-Pulmonary Bypass

NOT AVAILABLE

and

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

Scenario:
Failure to ventilate #2

Example: Cholecystectomy (Gall Bladder removal) w/ intraop cholangiography

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

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

X-ray

Ventilator

"With the advent of sophisticated anesthesia machines incorporating comprehensive monitoring, it is easy to forget that serious anesthesia mishaps still can and do occur."
APSF Newsletter Winter 2005

A 32-year-old woman had a laparoscopic cholecystectomy performed under general anesthesia. At the surgeon's request, a plane film x-ray was shot during a cholangiogram. <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?
- Inadequate vigilance?
- *At its root, this is a system problem, because the ventilator never should have been turned off…*

Solution - don't turn off ventilator: <u>synchronize x-ray with ventilator</u>

NOT COMMERCIALLY AVAILABLE

Synchronize or "gate" x-ray to expose image at end of expiration. May require integration of x-ray and ventilator to briefly pause ventilator (under operator control) if respiratory rate is too high to sync. (Similar approach useful for CO and CVP measurement.) Discussion: Is it safer to add pause capability or to maintain the status quo (reliance on operator memory)?

Solution has been demonstrated in MD PnP Lab

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Medical Device "Plug-and-Play"
Interoperability Lab at CIMIT
Cambridge, MA
Opened May 2006
Photos includes collaborators from
MGH, U Penn, and LiveData)

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

Scenario:
Detect/Prevent Hemodynamic Instability from Pneumoperitoneum (Insufflation) during Minimally Invasive Abdominal Surgery

The Problem: Insufflation-induced hemodynamic instability:
Initial insufflation of CO_2 into the abdomen (peritoneal cavity),
especially combined with head-up table tilt ("reverse Trendelenburg
Position"), may severely decrease blood pressure and heart rate.

Surprisingly, the occurrence of insufflation-induced bradycardia (low heart rate) and hypotension (low blood pressure) are well known:

Cardiopulmonary complications during laparoscopy: two case reports

South Med J. 1995 Oct;88(10):1072-5

"The first case describes a patient who developed bradycardia and asystole [cardiac arrest] during insufflation for a laparoscopic hernia repair."

Laparoscopic Gall Bladder Surgery:
What can we do to improve safety?

- Integrate surgical and anesthetic devices to provide:
  - 1. Safety interlock: "can't insufflate if BP and ECG not actively monitoring"
  - 2. Smart alarms: Contextual information permits high sensitivity and specificity of clinical alarms (to detect HR and BP changes)
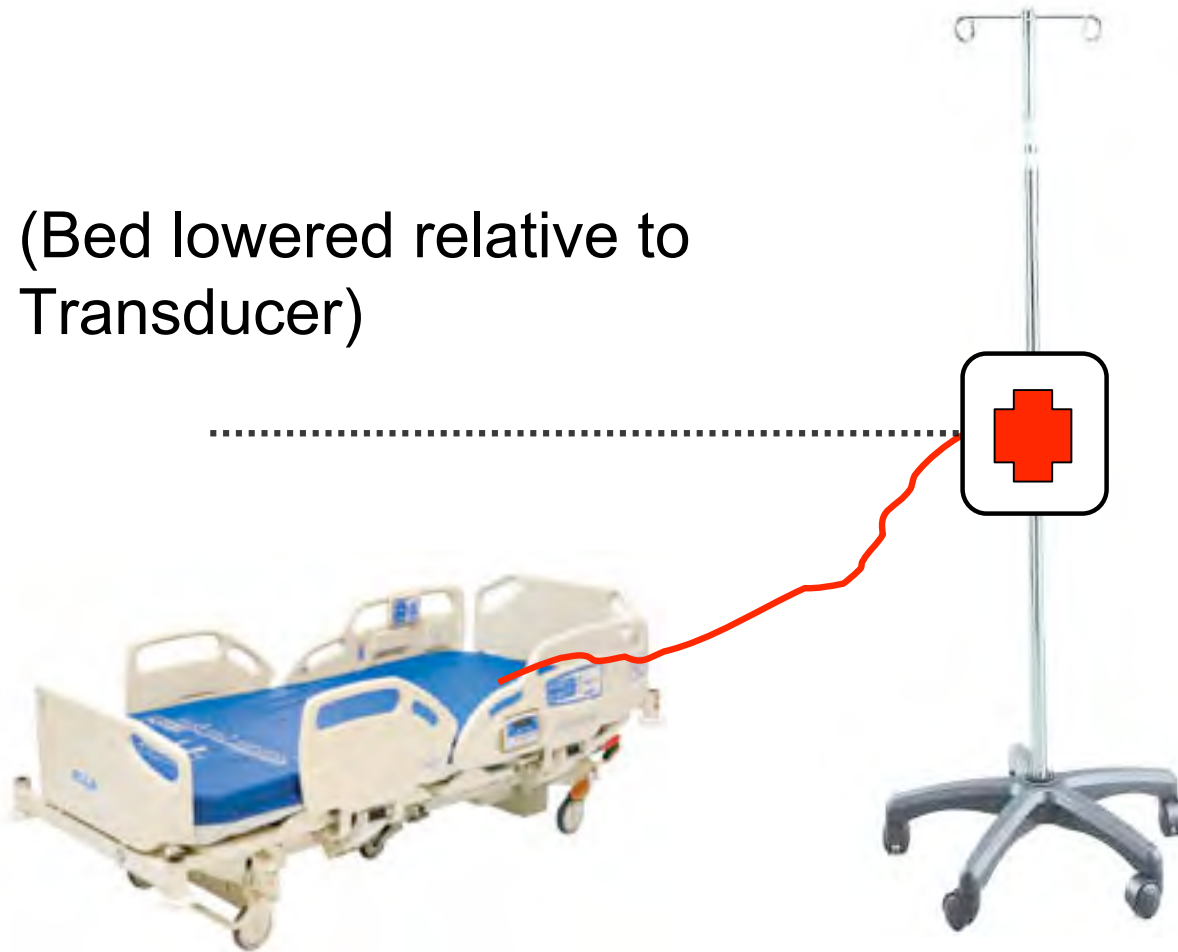 - 3. Activate NIBP measurement: Trigger BP measurement upon insufflation + table tilt

Scenario: Blood Pressure Measurement Errors

Invasive BP Measurement

Transducer

Level

Correct value
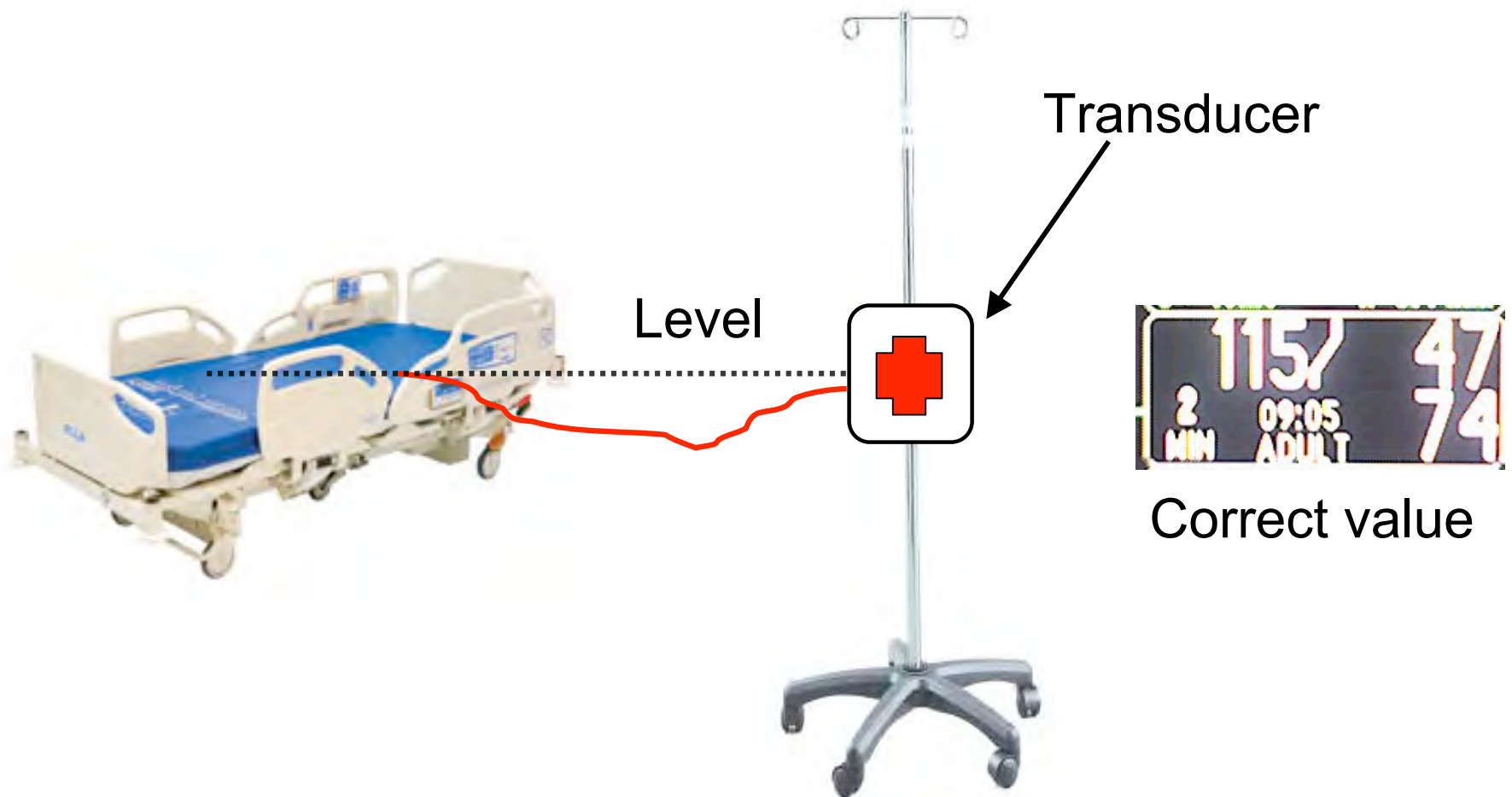
Invasive BP display error

(Bed lowered relative to
Transducer)

Error: too low

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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 <u>median differences from the reference PAOP values</u> were 2 mmHg (<u>-6 to 9</u> mmHg) for physicians and 2 mmHg (<u>-6 to 16 mmHg</u>) for nurses"

Automatic BP display correction <u>is possible</u> with currently available bed network data
(bed reports changes to height and angle)

NOT COMMERCIALLY AVAILABLE
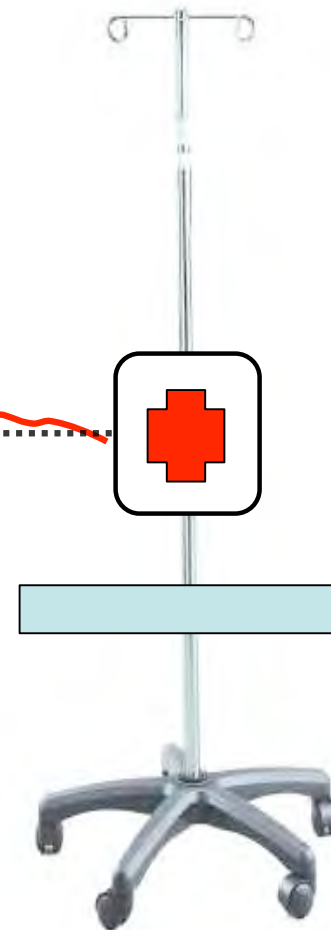
Solution requires connecting bed and blood pressure monitor

Offset Corrected

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Solution demonstrated in MD PnP Lab

HIMSS 2007 New Orleans, USA:
two clinical scenarios demonstrated

Dangers of Postoperative Opioids

APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications

Based on APSF Board of Directors Workshop
October 2006

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Typical PCA System

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

Pain

PCA Pump

Patient
button

Patient

Overdose

Nurse call
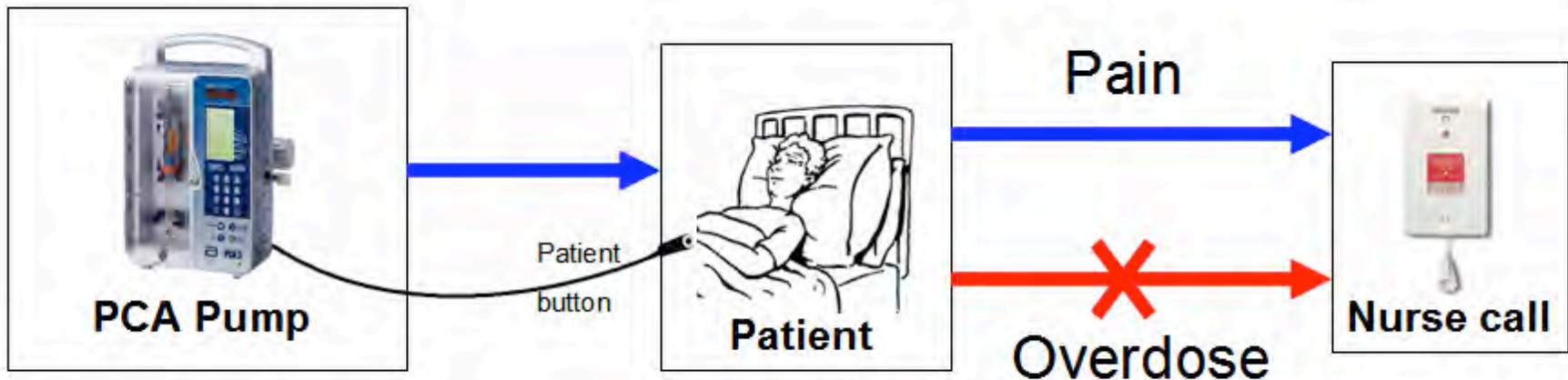
PCA = Patient-Controlled Analgesia

"Not Uncommon" PCA pump scenario

A 49-year-old woman underwent an uneventful 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 patient ultimately died.

-AHRQ Morbidity and Mortality website

PCA = Patient-Controlled Analgesia

APSF PCA Recommendations
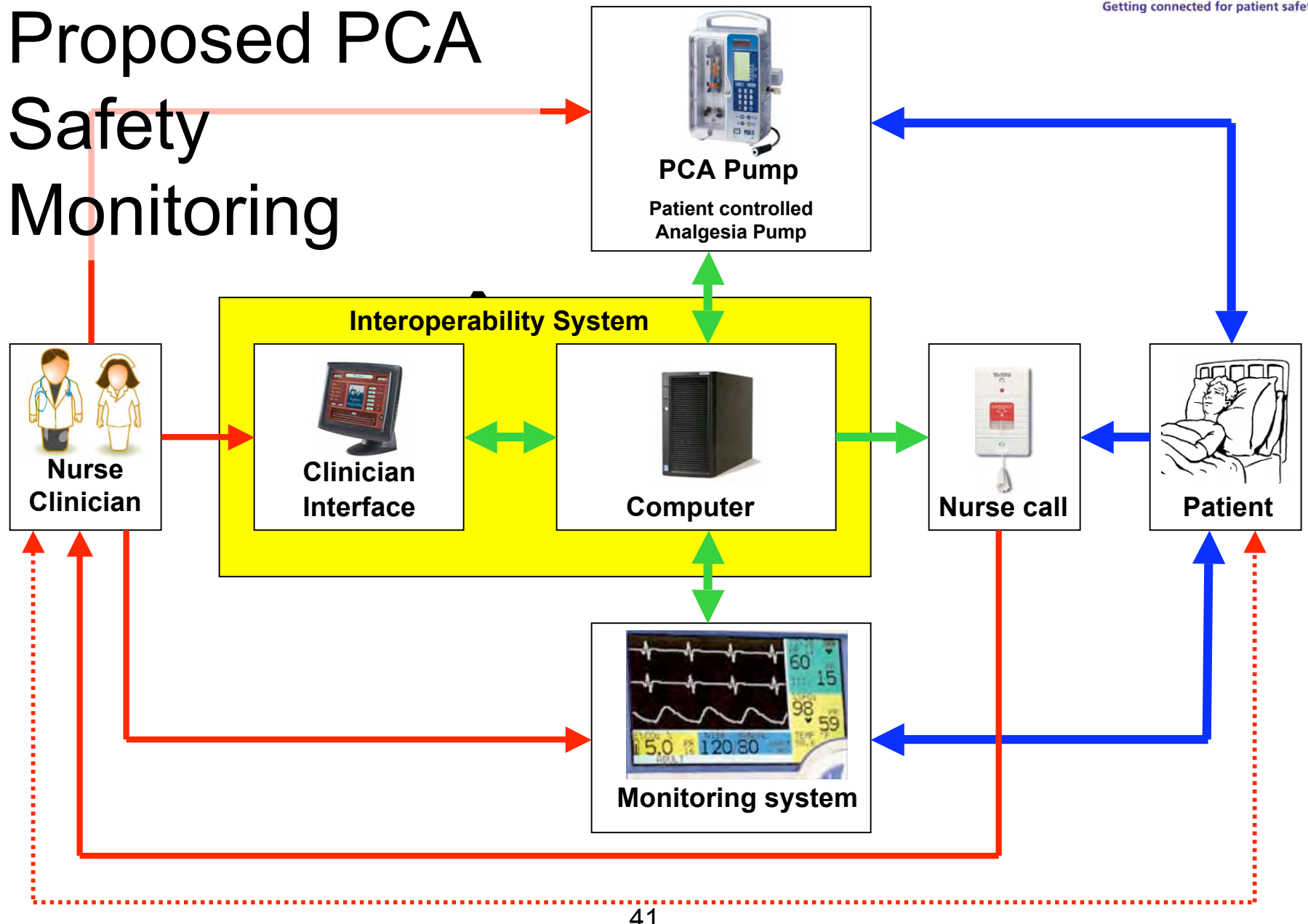
- "We advocate widespread acceptance of the goal that no patient shall be harmed by opioid-induced respiratory depression in the postoperative period.

- 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 <u>automatically terminate or reduce PCA (or PCEA) infusions</u> when monitoring technology suggests the presence of opioid-induced respiratory depression. To facilitate such capabilities, <u>we strongly endorse the efforts to develop international standards for device interoperability</u> 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

PCA Pump

Patient controlled Analgesia Pump

Interoperability System

Nurse Clinician

Clinician Interface

Computer

Nurse call

Patient

Monitoring system

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Smart PCA monitoring system
American Society of Anesthesiologists
Scientific Exhibit October 2007
Plug-and-play detection of monitors connected to patient,
Permits selection of "best" monitor and alarm algorithm at point of care

Exhibit recognized with First Place award

These are elegant solutions!

- Isn't concerning that adverse events that can be predicted from clinical workflow analysis, may be reported in focus groups, and are documented in the literature, but <u>solutions to mitigate these clinical hazards have not been adopted</u>?

- Why are solutions not being implemented?

- Because hospital-implemented "one-off" solutions - especially when integrating medical devices - are frequently complicated and expensive, and there are concerns about safety, regulatory compliance, and liability.

- <u>We need a standardized means to deliver these - and similar -safety-enhancing innovative solutions.</u>

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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 <u>improve patient safety</u>.

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.

We learned from the 2004 MD PnP kick-off meeting that key issues must be addressed for adoption of interoperability:

- Must be <u>clinical-requirements</u> based
- <u>Regulatory</u> obstacles were perceived
- <u>Legal</u> concerns were deal-breakers
- What is the <u>business case</u>?
- No widely adopted integration <u>standards</u>
- 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 <u>clinical requirements</u> 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

- <u>May 24-25, 2004 Kick-Off Symposium</u>: sponsored by TATRC & CIMIT, Cambridge, MA – 84 attendees: 37 from industry, 43 from academic and healthcare institutions, 4 from government agencies
- <u>Nov 15-16, 2004 Second Meeting, hosted by FDA</u>, Rockville, MD – 75 attendees: 31 from industry, 29 from academic and healthcare institutions, 15 from government agencies
- <u>June 6-7, 2005 Symposium: Third Meeting</u>, 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
- <u>June 25-27, 2007 Joint Workshop</u> 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. Proceedings published Feb 2008.
- (Presentations are freely available on www.MDPnP.org)

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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 <u>clinical improvements</u> in safety and efficiency.

Req #	Clinical Scenario	Current Hazards	Proposed State	Future Hazards
CLN-050	ESU causes interference on ECG	Risks to patient safety due to poor diagnostics	Notify devices of ESU activity to eliminate/reduce ESU interference, or flag bad data	none
CLN-011	Difficult to reposition patient, cables, devices due to cluttered physical environment ("malignant spaghetti")	Devices could get disconnected, causing patient harm; it is difficult to maintain a clean environment with cables; visual paths of clinicians can be obstructed	Uncluttered environment, allowing appropriate communication between devices, information system, and patient; ease of movement of desired resources without barriers (NOT WIRELESS)	Possible interference of communication paths
CLN-052	Operating room lights and anesthesia task lights are not coordinated	Can end up in total darkness	Interconnect lighting, such that when room lights go off, anesthesia machine task light goes on	May want to work in the dark. Must permit override
CLN-048	Electronic medical record is missing medical device-generated data	Lack of adequate data for clinical decision-making	Comprehensive medical record, with capture of all medical device-related data in EMR: patient ID, personnel, equipment IDs, "ESU on" vs. "ESU off" (especially for later analysis)	EMR may become "bloated", overly complex
CLN-017	Laser, x-ray use in the OR	Unprotected personnel may enter OR unknowingly	Laser/xray outputs network message for automatic notification outside clinical environment during laser use	Failure of notification system; wrong room, wrong device activated

EXAMPLE Clinical Scenario worksheet

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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
- Proceedings published in IEEE Feb 2008

HCMDSS - High Confidence Medical Devices, Software, and Systems

Conference: June 2007

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

Insup Lee, Rob Kolodner, Julian Goldman

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These limitations are being recognized and addressed …

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The Anesthesia Patient Safety Foundation endorsement of interoperability
March 2007

"APSF believes that intercommunication and <u>interoperability of devices</u> <u>could lead to important advances in patient safety</u>, 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."

ASA BOD STATEMENT ON THE INTEROPERABILITY OF MEDICAL DEVICES

"ASA believes that intercommunication and <u>interoperability of electronic medical devices could lead to important advances in patient safety and patient care</u>, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind.

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

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February 2008

Kaiser Procurement Contract Language
(24 new hospitals planned in USA)
(in use <u>now</u>)

- **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)   55

"ICE" - Integrated Clinical Environment

- ICE describes requirements for safe and effective "plug-and-play" integration of devices in high-acuity patient-centric environments to provide an infrastructure for innovation

- ICE incorporates many of the requirements identified by participants in MD PnP program workshops, to support deployment of error-resistant systems capable of mitigating long-standing clinical hazards and improving AE analysis

Scope of ICE (excerpt)

- "This International Standard is … 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 <u>intended to facilitate cross-manufacturer medical device integration</u>..."

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

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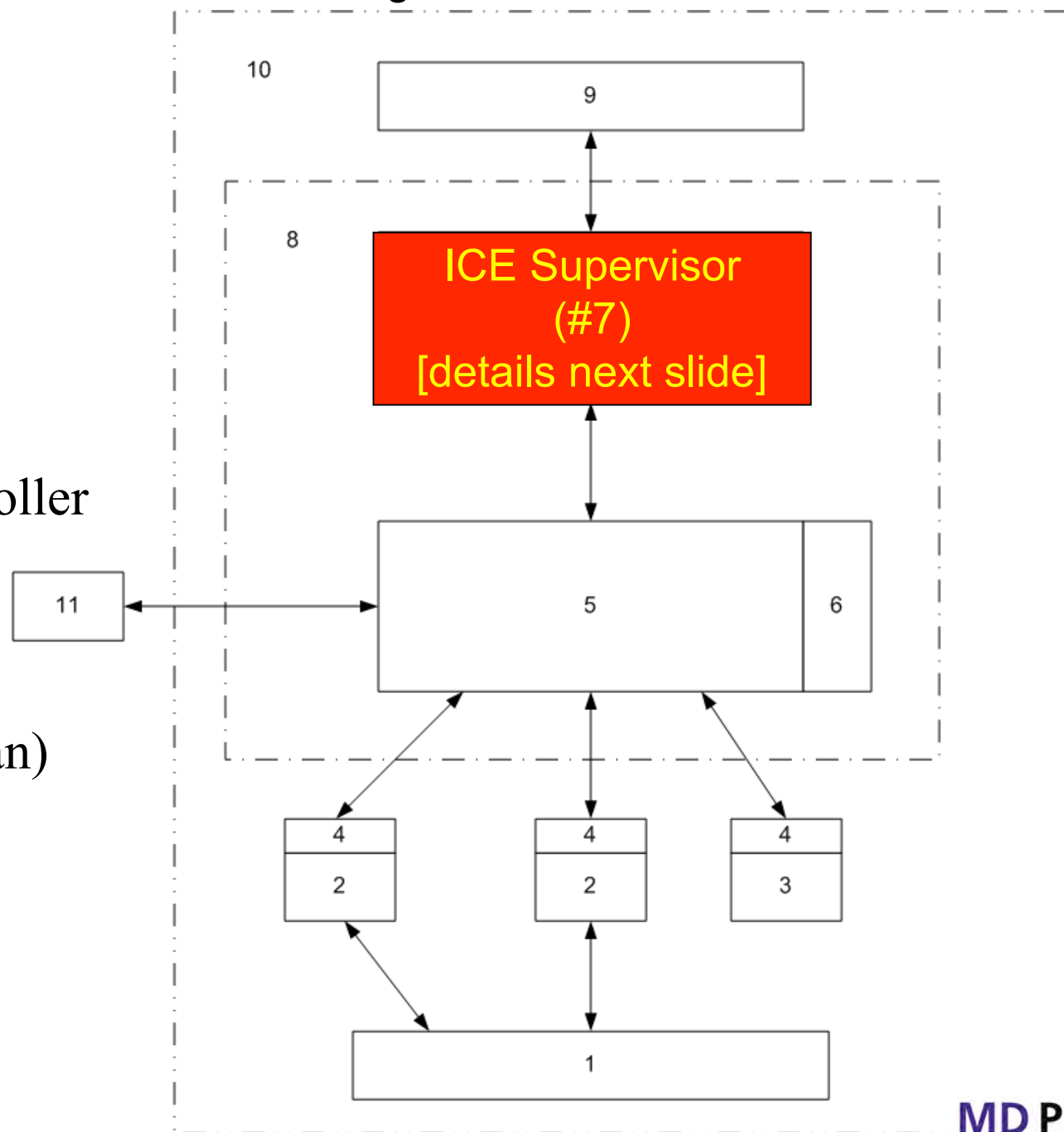
The ICE <u>supervisor</u> supports the following patient-centric capabilities of the integrated clinical environment

- 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 (e.g. change NIBP cycle interval)
- Assess the readiness of medical devices in a clinical environment to support specified functions or clinical workflow
- Perform integration of alarm conditions from multiple medical devices
- Perform automated record keeping
- Support integrated control* of devices

•Control of those features made available through the ICE interface (Fig 1, #4)

From ICE Part I NWIP September 2007

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Figure 1: Functional Elements of the Integrated Clinical Environment

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From ICE Part I NWIP
September 2007

ICE Network Controller (#5) [details next slide]

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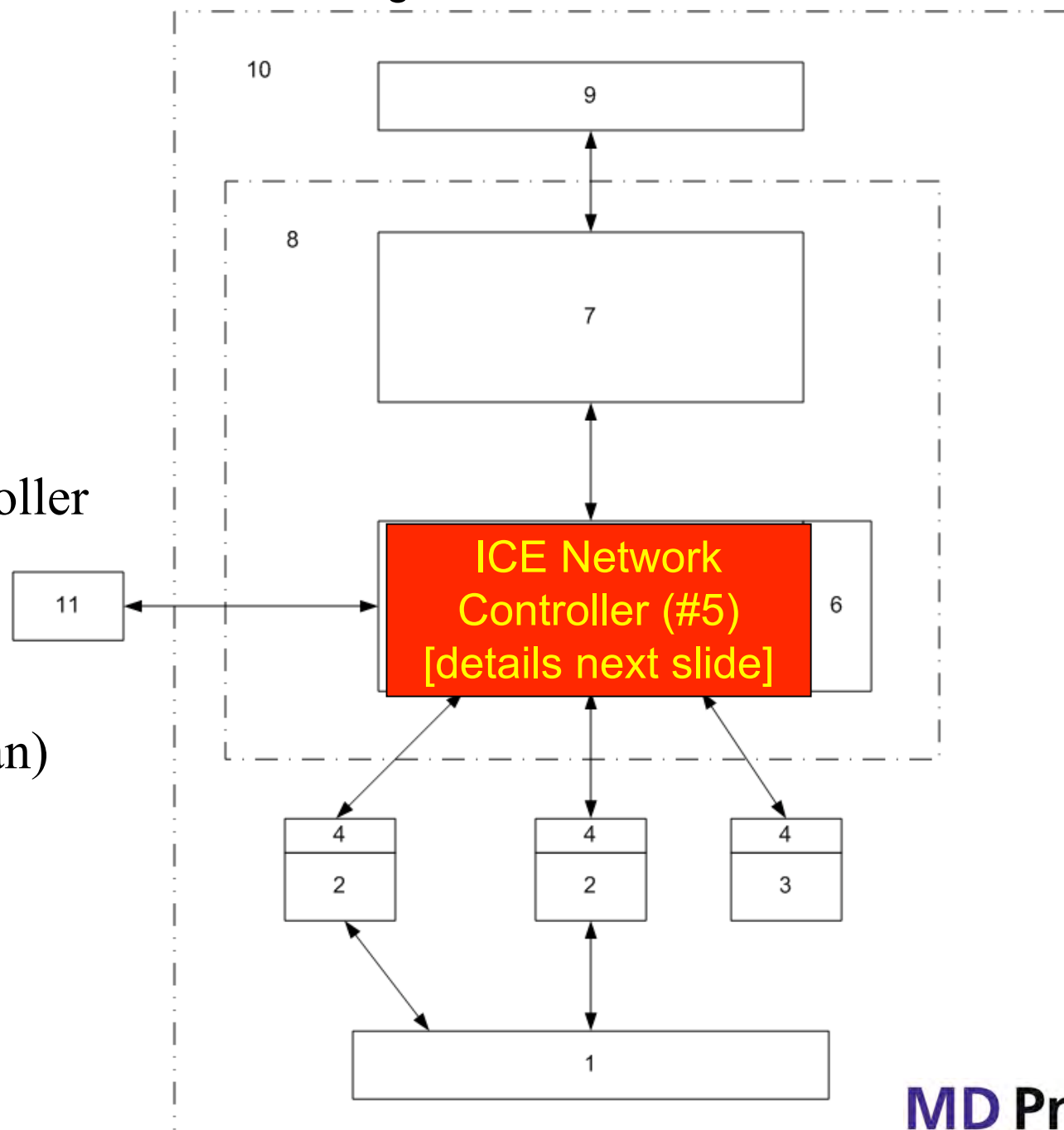
The ICE <u>network controller</u> supports the following patient-centric capabilities of the integrated clinical environment

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

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Some benefits of medical device interoperability for muti-vendor system integration in the"Hospital of the Future"

- Network-based inventory of
  - Devices (tens of thousands)
  - Device status, including software/firmware
  - Push device patches/upgrades
  - Could significantly reduce TCO of devices (per Kaiser data)
  - Leverage FDA-promoted UDI (Unique Device ID)
- Enable system solutions at the "sharp edge" of healthcare delivery

Conclusions:

1. There is "opportunity for improvement"

2. Medical Devices have a unique place in the "interoperability ecosystem"

    A. Medical Devices are key data sources (to EMR/CIS etc.)

    B. Medical Devices are at the sharp end of patient care. Adverse Events/Near Misses that involve medical devices must be mitigated using medical devices as part of system solutions

3. Healthcare providers need a pathway to build error-resistant systems by implementing and managing solutions that leverage patient-centric medical device systems integration

Thank you

MD PnP Program: www.MDPnP.org

CIMIT: www.cimit.org

My e-card: www.jgoldman.info