The Medical Device Interoperability Program
Overview and Updates Oct 23, 2008

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

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Mass General Hospital/CIMIT
Operating Room of the Future

Lessons from the OR of the Future project: perspective on device and data integration

- Comprehensive integration of data from clinical and environmental systems, can provide "error-resistance" and reduce 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.
- *These solutions require seamless cross-vendor connectivity, which currently can only be provided by vertically integrated companies*

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3 Examples of 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   11 Years

- "… 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>."

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Cardio-Pulmonary Bypass

NOT AVAILABLE

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

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Scenario:
Failure to ventilate #2

Example: Cholecystectomy w/ intraop cholangiography

Workflow: 1) Ventilation is stopped. 2) Intraoperative cholangeogram is performed with contrast to identify internal structures.

Apnea -> improve 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…*

Synchronize x-ray with ventilator:
@ expiration: cholangiogram, CVP, CO
@inspiration: routine chest radiograph

NOT COMMERCIALLY AVAILABLE

In this case, integration of devices into a networked, smarter system can improve safety by avoiding ventilator shut-off, improve image quality (especially on serial images), and decrease re-imaging.

Synchronization of Radiograph Film Exposure with the Inspiratory Pause
Am. J. Respir. Crit. Care Med., Volume 160, Number 6, December 1999, 2067-2071

9 years

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Solution has been demonstrated in 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

End-to-End Approach of analyzing and prototyping X-Ray Ventilator Use Case

1. Elicited use case (STA conference in 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 clinical engineers

7. Inform change to existing ventilator standards (OR and ICU) and functions of "ICE" standard

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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.

PCA Pump — Patient button — Patient — Pain — Nurse call — Overdose
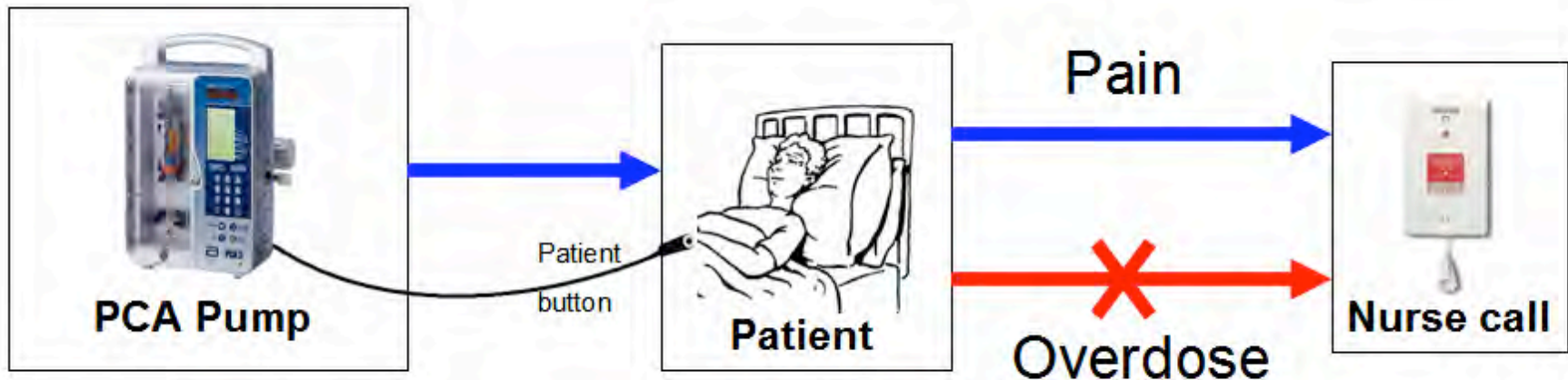
PCA = Patient-Controlled Analgesia

APSF PCA Recommendations

- "A particularly attractive feature may be the ability to <u>automatically terminate or reduce PCA … 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…"

Proposed PCA Safety Monitoring
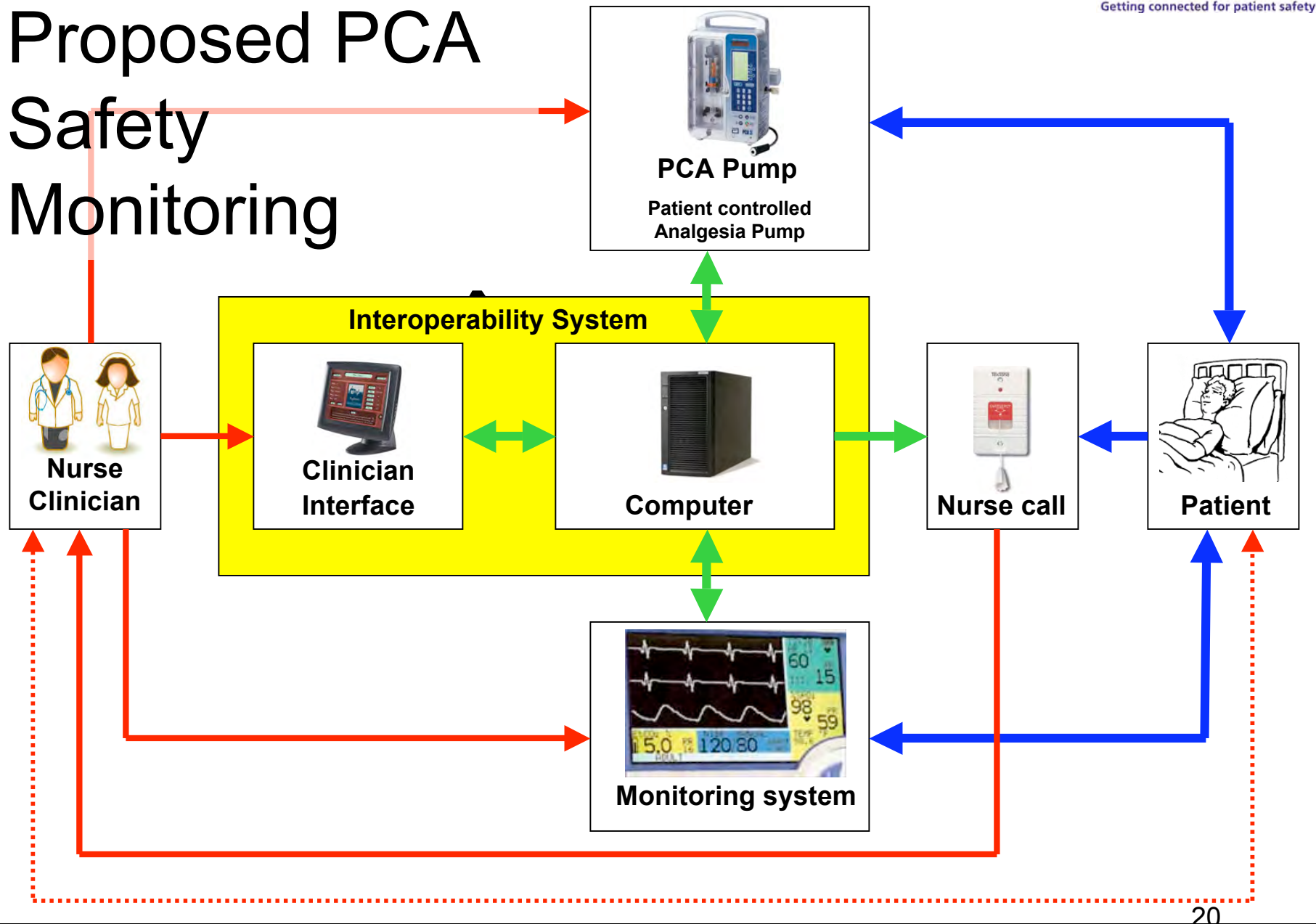
Smart PCA monitoring system
American Society of Anesthesiologists
Scientific Exhibit October 2007

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 clinical scenarios represent ongoing system problems

- Isn't it 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?

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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>.

More than 85 companies and institutions and > 700 experts (clinicians and engineers) have participated in four plenary conferences, working group meetings, and clinical focus groups to shape the mission and strategy and identify clinical requirements.

MD PnP Program collaborators 2004-2008

- NSF (National Science Foundation)
- Society for Technology in Anesthesia
- DocBox, Inc.
- Philips Healthcare
- and others

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

5. Investigate safety of proposed engineering solutions

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What are we doing?

- Requirements
- Researching safe design
- Input to Standards - ICE and others
- Education/Outreach
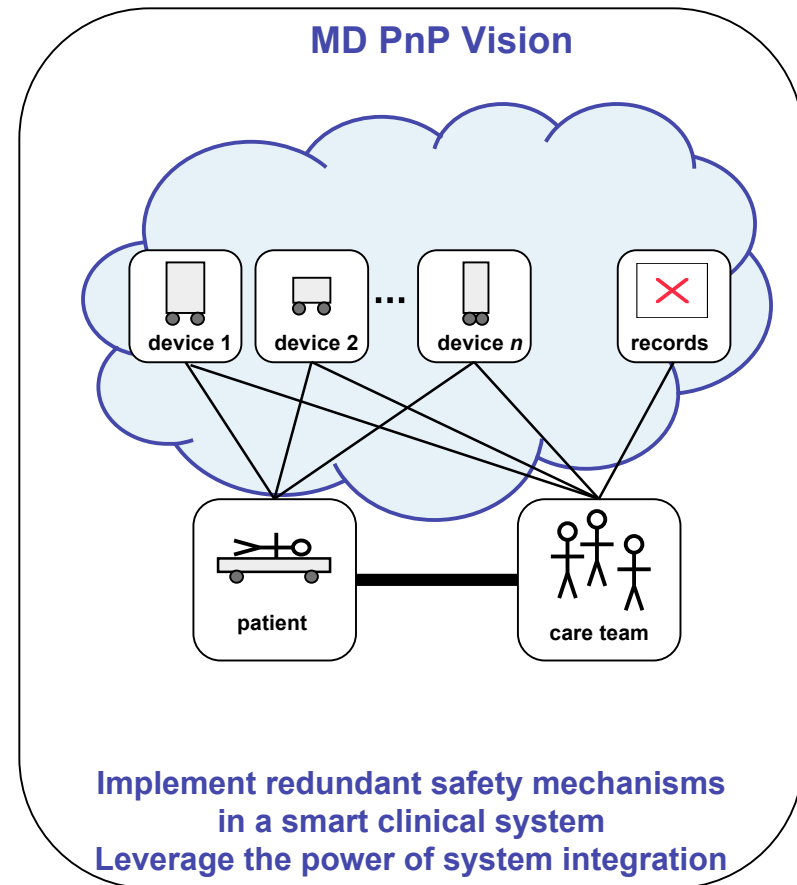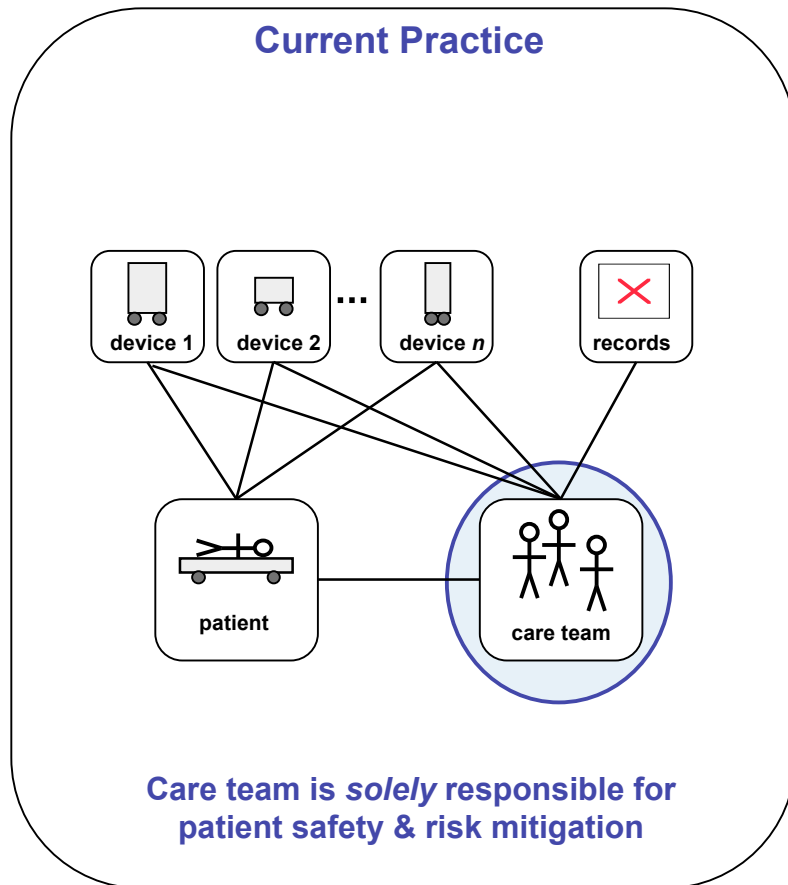 - Clinical user - what is possible
  - Manufacturer - what is needed

What is the scope of effective high-acuity medical device interoperability?

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

1.   Bidirectional medical device data communication

2.   Medical device control capability to permit the integration of medical devices into networks to produce "error-resistant" systems.

"Control" should be defined as exposure of selected features or device functions over the network, to enable classes of clinical scenarios cases. (Example: "activate pre-set ventilatory pause to enable an x-ray").

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The ultimate goal of the MD PnP Program is to **improve patient safety** by enabling the integration of automated oversight and intervention into clinical systems, and managing the emerging complexity of networked medical devices and IT systems.

Current Practice

device 1   device 2   ···   device *n*   records

patient

care team

Care team is *solely* responsible for patient safety & risk mitigation

MD PnP Vision

device 1   device 2   ···   device *n*   records

patient

care team

**Implement redundant safety mechanisms in a smart clinical system
Leverage the power of system integration**

What functions are necessary to achieve this vision?

Safety Logic
Need to encode safety rules and procedural knowledge.

Device Access
Safety Logic needs to know medical device status & patient physiological parameters

Device Control
Safety logic needs to be able to control devices to successfully intervene

Interoperability
Every device needs to be able to communicate/interoperate

CIS/ Records Access
Safety Logic must access patient data in Clin Info System, and add device clinical and technical data as relevant.

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Implementing these functions not only improves safety, but also enables additional clinical systems efficiencies.
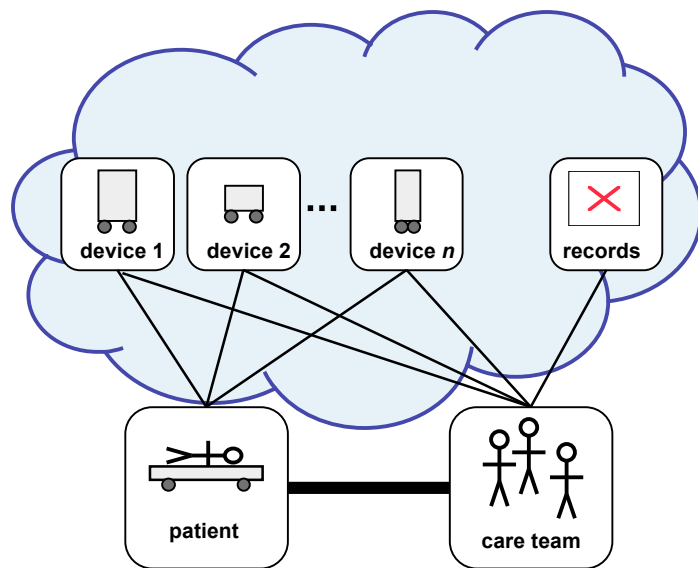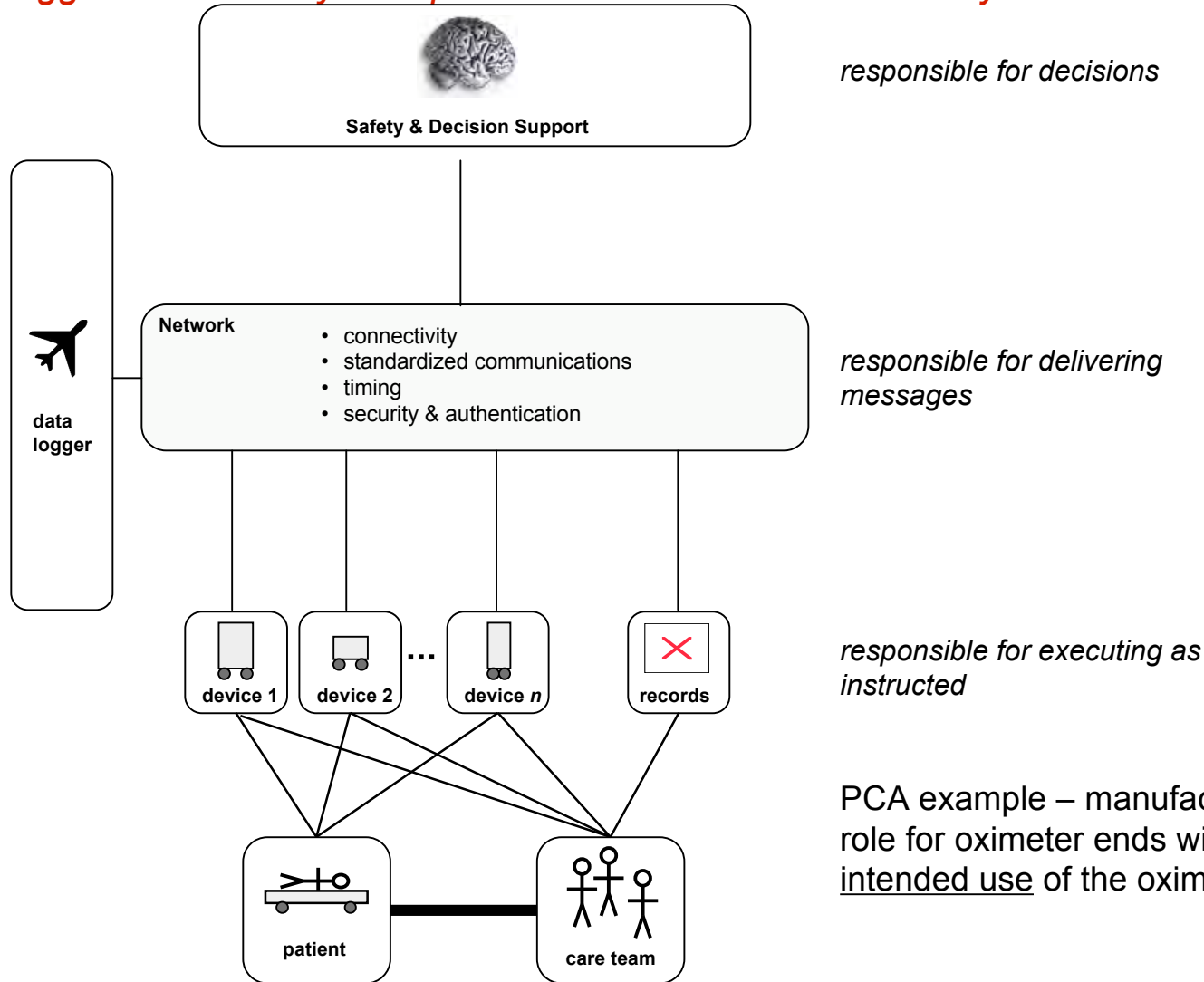

Safety

- safety interlocks
- smart, adaptive alarms
- clinical decision support/pathways
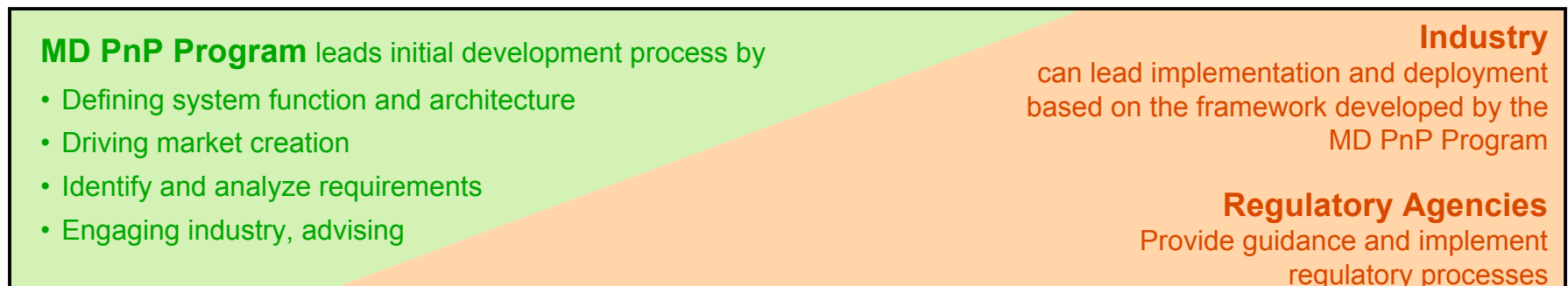- system readiness assessment prior to procedures

Efficiency

- automated equipment inventory
- improved ability to *manage* and *demonstrate* continuous quality improvement
- greater equipment purchasing freedom – best of breed instead of what fits
- automated patient records
- clinical decision support
- push patches / upgrades

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Clear parsing of roles and responsibilities helps to address liability and regulatory concerns.
Example: Pulse oximeter manufacturer is only responsible for the device and interface;
Closed-loop control software manufacturer is responsible for added functionality
And, Data Logger facilitates system problems / adverse events analysis.

responsible for decisions

Safety & Decision Support

Network
- connectivity
- standardized communications
- timing
- security & authentication

data logger

responsible for delivering messages

device 1   device 2   ...   device *n*   records

responsible for executing as instructed

patient   care team

PCA example – manufacturer's role for oximeter ends with the intended use of the oximeter

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Standards encode actionable definition of roles and responsibilities to product developers.

The implementation plan follows a staged approach with the MD PnP program establishing a framework for successful implementation.

Phase I	Phase II	Phase III	Phase IV	Phase V	Phase VI
Concept Definition and Preliminary Requirements	Detailed Function & Requirements Definition	Preliminary Implementation & Testing	"Final Design" Validation & Release	Adoption / Roll-out	Steady State

MD PnP Program leads initial development process by

- Defining system function and architecture
- Driving market creation
- Identify and analyze requirements
- Engaging industry, advising

Industry
can lead implementation and deployment based on the framework developed by the MD PnP Program

Regulatory Agencies
Provide guidance and implement regulatory processes

Clinical Society Support of Interoperability

"[Society] 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.

[Society] 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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<u>M</u>edical <u>D</u>evice <u>F</u>ree <u>I</u>nteroperability Requirements for the <u>E</u>nterprise

- "MD FIRE"
- Developed by MGH, Partners, Hopkins, Kaiser
- RFP and Contract samples
- Standards-based
- Released for public use Oct 17, 2008
  - See www.mdpnp.org/MD_FIRE.html

"ICE" Standard - Integrated Clinical Environment

- New draft standard describes requirements for safe and effective "plug-and-play" integration of devices in high-acuity environments

- Developed in ASTM Committee F29.21
  - http://www.astm.org/DATABASE.CART/WORKITEMS/WK19878.htm

Scope of ICE Part I

"*This International Standard specifies requirements for integrating equipment to create the Integrated Clinical Environment (ICE). It is intended to facilitate the safe <u>integration of medical devices and other equipment from different manufacturers</u> into a medical system for the care of a single high acuity patient.

ICE <u>is a medical system that has greater capability</u> to support error resistance and improvements in patient safety, treatment efficacy and workflow efficiency than that achievable from independently used individual medical devices."
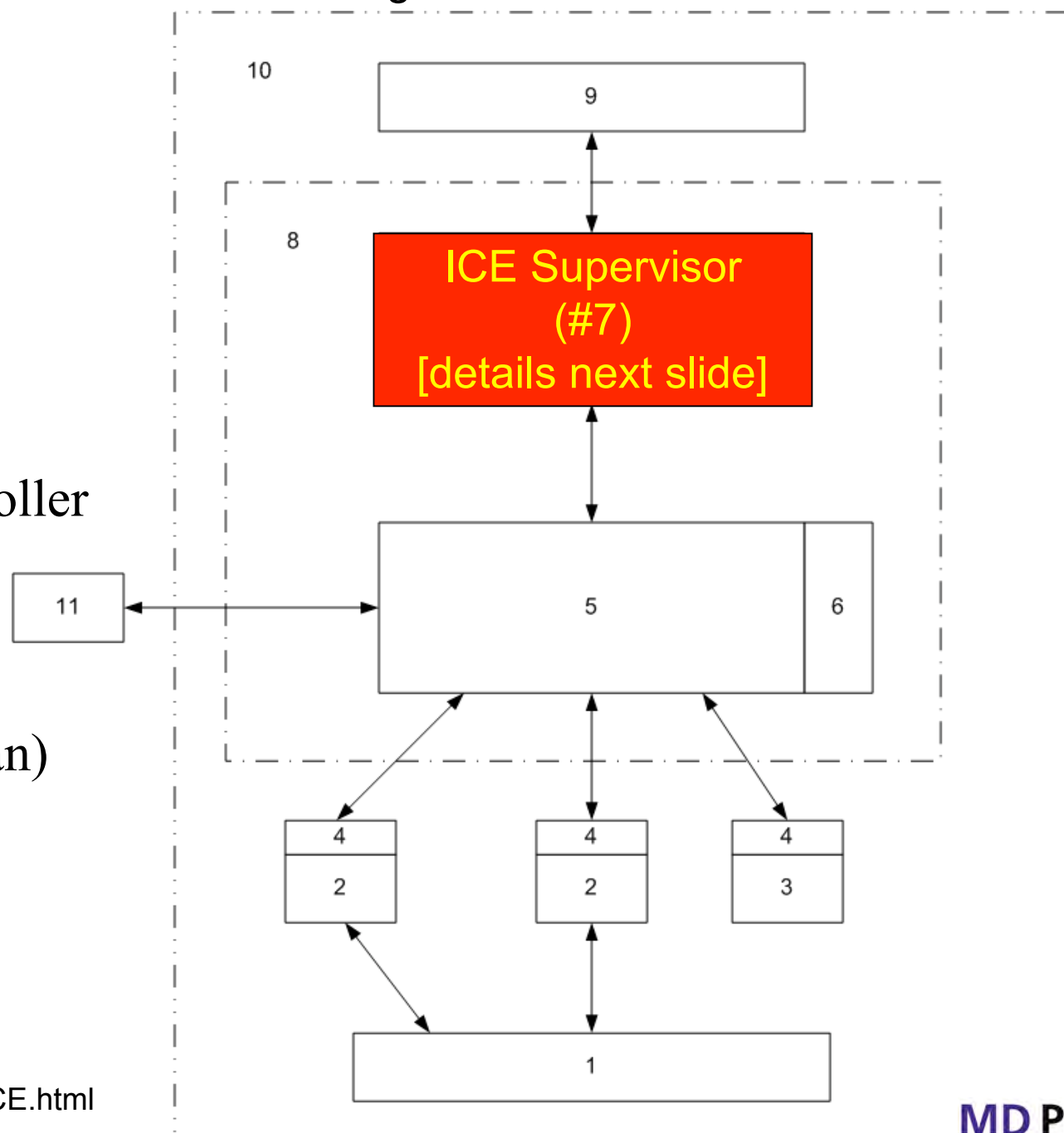
* Draft

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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 ICE Part I NWIP
September 2007

The ICE <u>supervisor</u> supports i.a. 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 (box #4)

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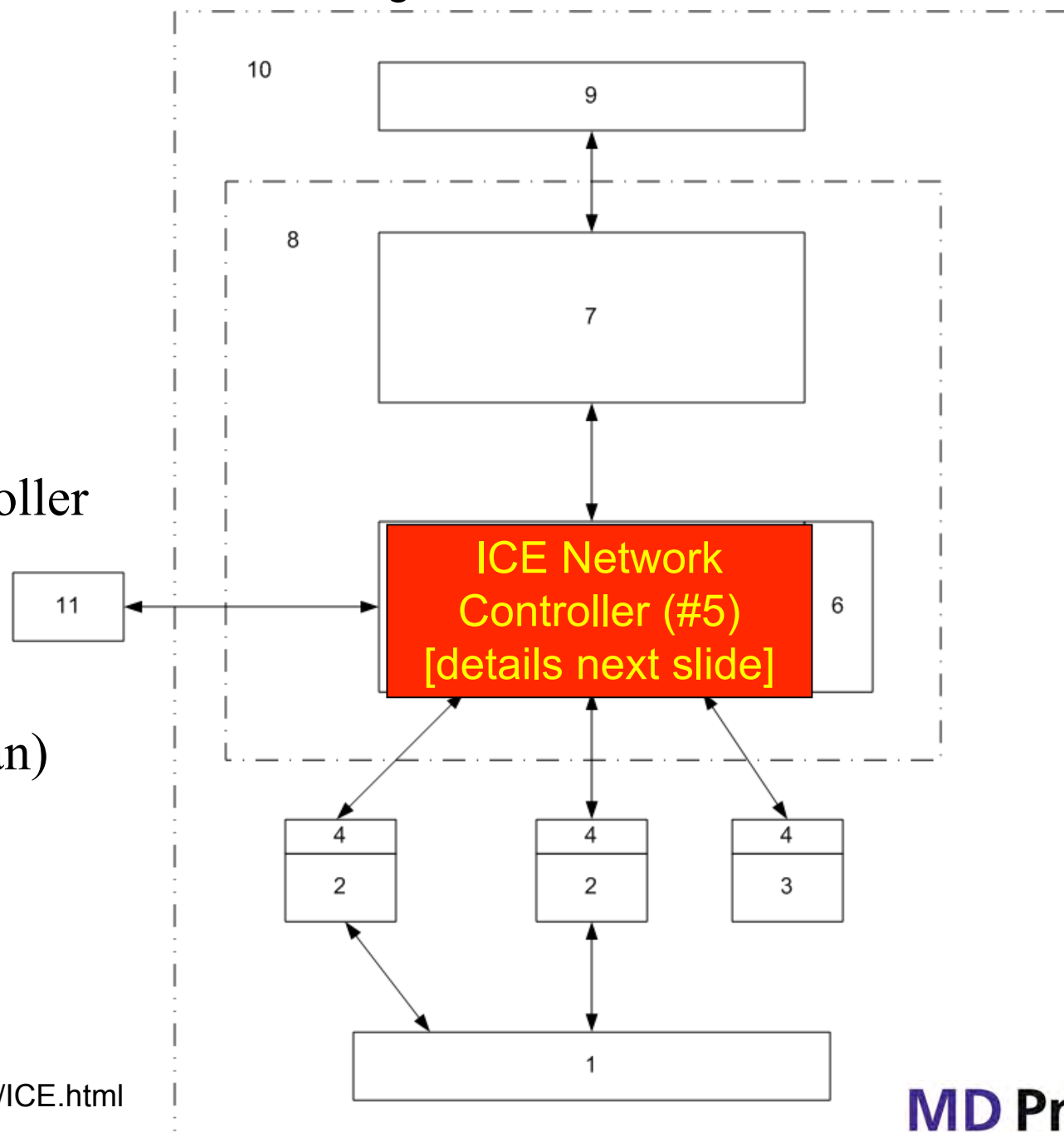
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From ICE Part I NWIP
September 2007

Current draft: http://mdpnp.org/ICE.html
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The ICE <u>network controller</u> supports i.a. 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)

From ICE Part I NWIP September 2007

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