

CIMIT

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Medical Device Interoperability:

to Enable System Solutions at the Sharp Edge of Healthcare Delivery

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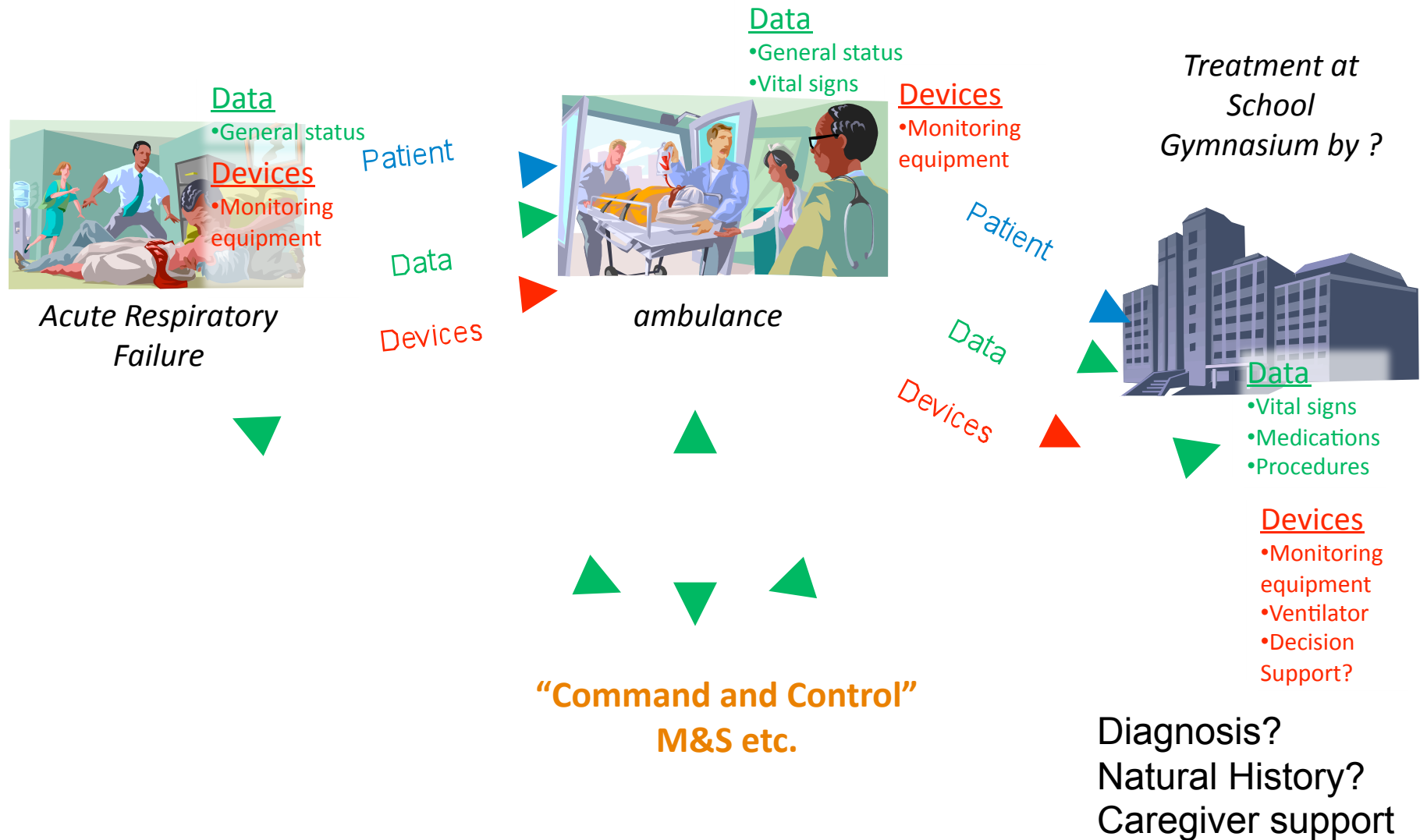
Scenario

- Population exposure to CBW or H5N1 pandemic
- May produce large numbers affected civilians in severe acute respiratory failure
- Mass respiratory support with mechanical ventilation
- Could require care by minimally skilled individuals in non-healthcare settings (e.g. high school gymnasiums)

Current Plans

- BARDA - Biomedical Advanced Research and Development Authority is working on Non-Pharmacologic Respiratory Countermeasures
- RFP* for low-cost ventilators < \$2000/each for Strategic National Stockpile, with ability to ramp-up to 10,000 units in 6 months
- Other early planning may be addressing less expensive devices and far greater quantities

Use Case: Flu/CBW -> Respiratory Failure



Needs

- Connecting ventilators, monitors, etc. in local networks would support above and enable local care of patients, for decision support, alarms, etc.
- Also need for resource management
- Development of an open platform approach could support or automate some of these needs.

Proximity Tiers I-II (Local and regional)

- Local (gymnasium, field): Decision support, smart alarms, closed loop control (O₂, infusion, etc.), resource management
- Regional (town, etc) : Resource allocation, regional data analysis, data reduction

Proximity Tier III (remote)

- Remote: Means to permit population surveillance
 - connectivity of devices and monitors at local level for remote data access
- Remote: Means to monitor natural history of disease and to assess treatment efficacy in near real-time
 - Improve?
 - Deteriorate?
 - Management Problems? (with secretions, pulmonary barotraumas, or hypoxemia?)
 - Is therapy effective?

High-Level Problem statement

- Improvements in patient safety, patient care, and healthcare efficiency require systems solutions
 - cannot be implemented due to the lack of interoperability of medical devices and systems, especially in high-acuity clinical settings.
- Need for interoperable systems will increase with distributed/remote care and innovative care models
- Ability to “integrate the clinical environment” is an essential step to create error-resistant systems
- Requirement: medical device system integration.
 - Medical device interoperability is a key enabling capability.



Forward-area OR in Iraq

ICU



This is the current state

OR

How do we prevent errors and
Injuries?



How do we connect medical devices to the EMR?
Hint: We don't use TCP/IP over Ethernet ...



Examples of 4 clinical procedures
and associated safety issues ->

(From the MD PnP “Clinical Scenarios” Repository)

Scenario: Surgical Fires

Airway Laser + O₂ -> Fire

- O₂ enriched respiratory gas supports combustion
- Surgical team must “remember” to minimize O₂ prior to airway laser use (dependent upon teamwork and communication)

Tracheal
Tube



Airway Laser-O₂ Interlock

- Measure O₂ during anesthesia
- Prevent activation of airway laser if inspired O₂ > ~25%

Tracheal
Tube



Solution requires connecting laser equipment and anesthetic equipment / O₂ monitor

**NOT Commercially
AVAILABLE**

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

Scenario:

Failure to ventilate #1

Cardio-Pulmonary Bypass



or



Normal routine: Switch from anesthesia machine ventilator to cardiopulmonary (heart-lung) 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 12 Years
- “... 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.”

clinicians report problem, but solutions are not proposed or developed

Cardio-Pulmonary Bypass



NOT AVAILABLE

Should
alarm if
both off



Smart system would provide warning if both ventilator and bypass pump are off.

Almost every surgical team has experienced this error!

Scenario:

Failure to ventilate #2

Example: Cholecystectomy (gall bladder removal) w/ intraop cholangiography (bile duct x-ray)

Workflow:

1. Ventilation is stopped
2. Intraoperative cholangiogram is performed with contrast to identify internal structures.

Breath pause -> 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. 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 medical device system problem, because the ventilator never should have been turned off... it should have been synchronized with the x-ray*

■

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



NOT COMMERCIALY AVAILABLE

Integration of imaging 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

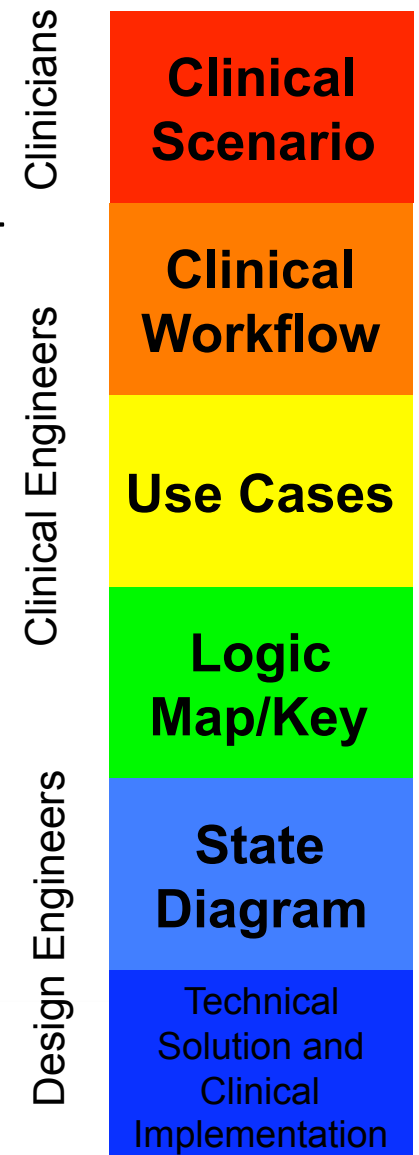
10 years

24

Solution has been demonstrated in MD PnP Lab

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

1. Elicited clinical scenario (STA 2005 conference)
2. Analyzed requirements and workflow (MD PnP multi-institutional interdisciplinary team)
3. Vetted by vendor, engineers
4. Use Case development / UML
5. Rapid prototype in lab
6. Iterate

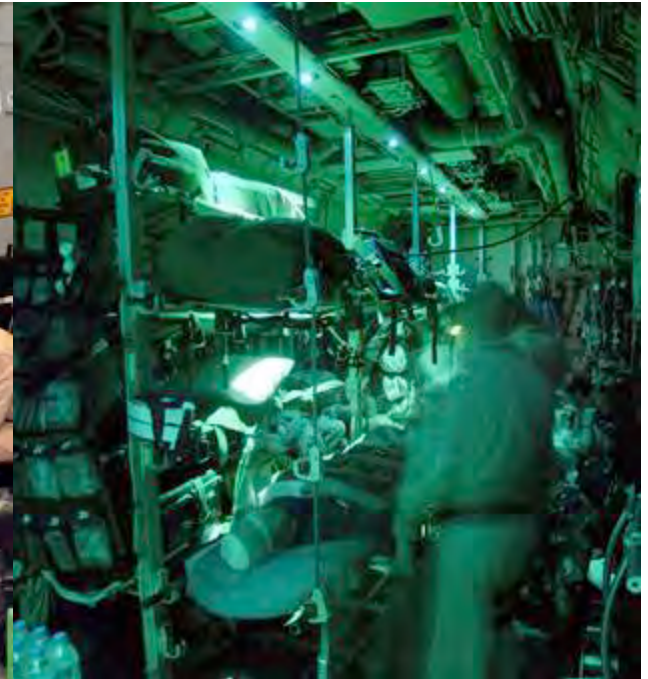


Ventilator - Xray Simulation at ASA Scientific Exhibit October 15, 2006



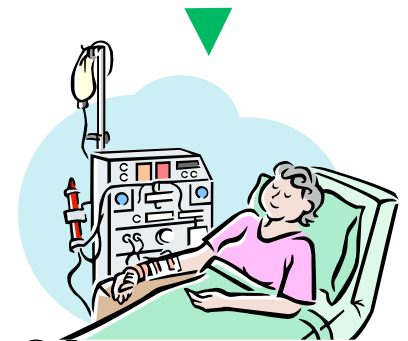
Implications of unmet needs

- “Integration of operating room monitors for development of a smart alarm system” (Navabi/Mylrea 1990)
- “A system for optimized design of fluid resuscitation in trauma” (1991)
- OR: 70% of anesthesiologists disable clinical alarms (Block, Nuutinen, Ballast 1995)
- ICU: 86% false alarms (Tsien, Fackler CCM 1997)



Application of
novel devices
and treatments

CCAT example: improving alarm sensitivity
and specificity with “dual oximetry”
ICE facilitates novel annunciation strategies





NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Volume 21, No. 4, 61-88

Circulation 80,350

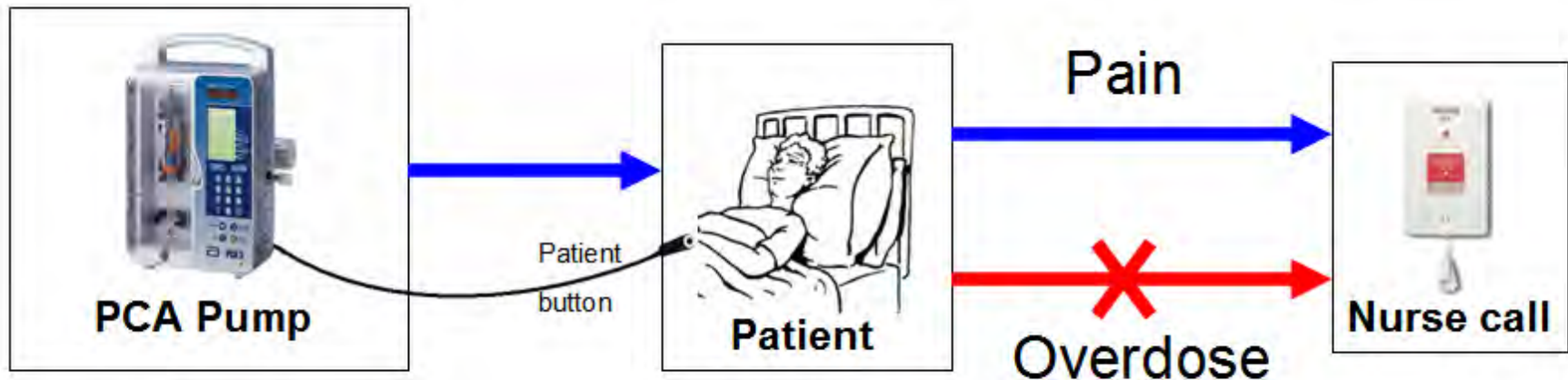
Winter 2006-2007

Dangers of Postoperative Opioids

APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications

Typical PCA System

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



PCA = Patient-Controlled Analgesia

APSF PCA Recommendations

- “A particularly attractive feature may be the ability to automatically terminate or reduce PCA ... 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...”

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” supervisory algorithm at point of care*



Exhibit recognized with First Place award

How urgent is the problem?

- “To Err is Human” IOM 1999
 - 98,000 preventable hospital deaths annually
- *HealthGrades* “Patient Safety in American Hospitals”
 - 2000-2002
 - 195,000 preventable deaths annually
- These studies only address current practice models

The “sharp edge” of acute health care delivery: Why Focus on Medical Device Interoperability?

- The national focus has been on one-way data transfer to the EMR, but Medical Devices have a unique place in the “interoperability ecosystem”
 - 1. DATA - Medical Devices are key data sources (to EMR). Data obtained via current interfaces may not be complete or accurate
 - 2. CARE DELIVERY - Medical devices can be better utilized to improve health care delivery (fluid, medication, energy, measurement)
 - 3. INJURIES - Adverse Events/Near Misses that involve medical devices can be mitigated using medical devices as part of system solutions

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.

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 stakeholder community 2004:
*key issues must be addressed for adoption of
interoperability:*

- Must be clinical-requirements based
- Regulatory obstacles
- Liability concerns
- Unclear 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 and system solutions
2. Define a regulatory pathway in partnership with the FDA and other regulatory agencies
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
5. Investigate safety of proposed engineering solutions

MD PnP Program collaborators 2004-2009



- NSF
- Philips Healthcare
- Lockheed Martin
- and others

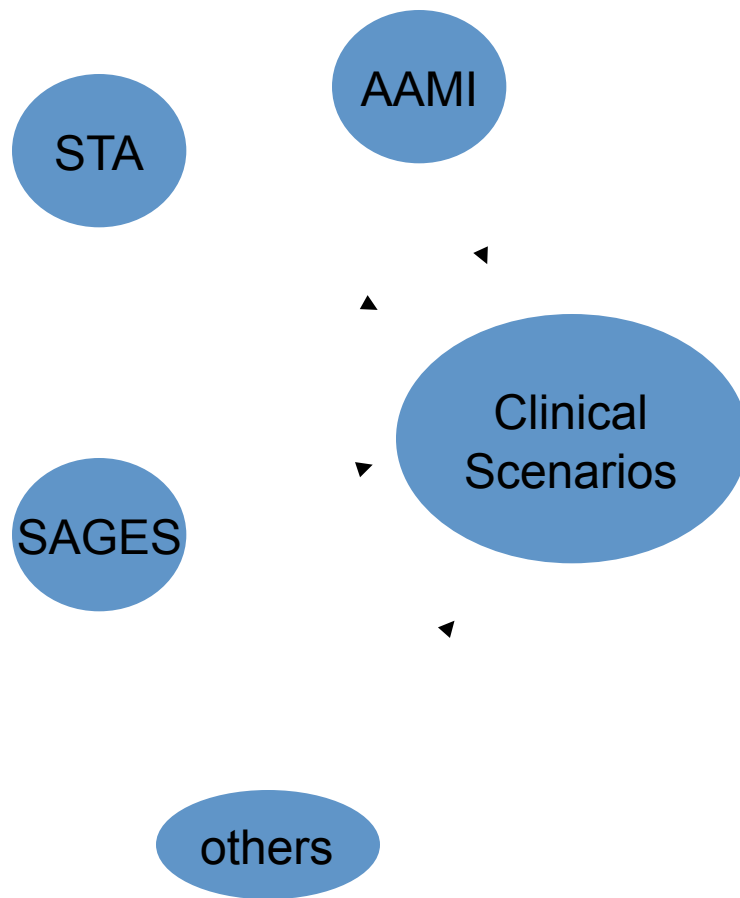
MD PnP Program Projects

MD PnP stakeholder community 2004:
*key issues must be addressed for
adoption of interoperability:*

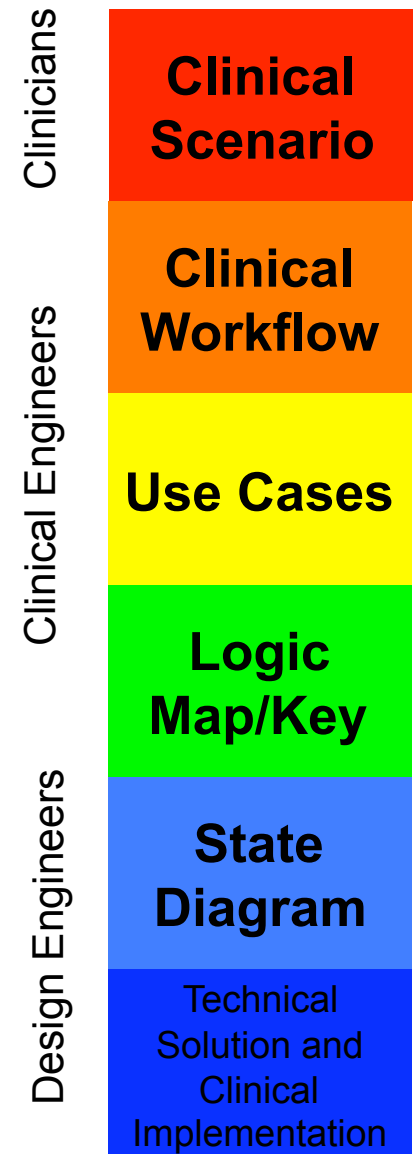
- Must be clinical-requirements based
- Regulatory obstacles
- Liability concerns
- Unclear business case
- No widely adopted standards
- In summary: Interoperability requires many elements to be aligned

- ▼ • Clinical Scenarios/Use Cases
- ▼ • Society Endorsements
- • Standards - “ICE” and others
- ▶ • FDA position/projects
- ▶ • Healthcare provider purchasing language - MD FIRE

Clinical Requirements



Focus groups: "Provide examples of how interoperability could improve safety or efficiency."



MD FIRE

Medical Device Free Interoperability Requirements for the Enterprise

- Interoperability RFP and Contract samples
- Developed by MGH, Partners, Hopkins, Kaiser
- Conveys healthcare needs to industry, and simplify purchasing specifications
- Released for public use Oct 17, 2008

5 Stakeholder groups from each organization:
Purchasing/materials management, BME, IS,
Clinical, Legal

MD FIRE

“Our collaboration through the Medical Device Plug-and-Play (MD PnP) program over the last four years leads us to conclude that Healthcare Delivery Organizations (HDOs) must lead a **nationwide call to action for interoperability of medical devices and systems**. One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria.”

Signed: MGH, PHS, Hopkins, Kaiser
October 2008

Download: http://mdpnp.org/MD_FIRE.php

Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE)

Medical Device Interoperability for Patient Safety: Driving Procurement Changes	October 2008
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Medical Device Plug-and-Play (MD PnP) Program
Massachusetts General Hospital / Partners HealthCare System
Johns Hopkins Medicine
Kaiser Permanente

This paper discusses the requirements for medical device interoperability in the modern healthcare environment. These requirements are changing the way in which we procure medical devices. An appendix provides shareable RFP and contract language examples.

Background

Medical devices, essential for the practice of modern medicine, have been traditionally designed to operate independently using proprietary protocols and interfaces for system integration. With the increasing complexity of the healthcare environment, stand-alone, proprietary devices and systems no longer provide an acceptable solution. Medical devices and systems must easily integrate with other vendors' equipment, software and systems in order to improve patient safety.

Essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and systems.¹¹ Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency."¹²

Our collaboration through the Medical Device Plug-and-Play (MD PnP) program over the last four years leads us to conclude that Healthcare Delivery Organizations (HDOs) must lead a nationwide call to action for interoperability of medical devices and systems. One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria.

We HDOs wish to adopt interoperability standards for medical device interconnectivity. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. However, we believe that adoption of standards-compliant interoperable devices and systems will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency for patient care; will improve the quality of medical devices; will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; will release HDO resources now used to maintain customized interfaces; and will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual, institutional, and national goals for improved healthcare quality and outcomes. Our goal is to document the clinical demand and to strongly encourage the development and adoption of medical device interoperability standards and related technologies.

MD FIRE Recommendations: (from page 2)

“We strongly encourage HDOs to adopt medical device interoperability as an essential element of their procurement process.

We have drafted sample medical device interoperability requirements and would encourage HDOs and vendors to use such requirements in their procurement process, including their requests for proposals (RFPs) and contracts. You can find the sample language attached as an Appendix to this document and available at http://www.mdpnp.org/MD_FIRE.html. We expect that the sample requirements and contracting language will evolve over time based on use.

We believe that changing the way in which we procure medical devices to integrate requirements for interoperability will provide a way for us to ensure patient safety, improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information”

MD FIRE RFP Examples (MD FIRE pages 4-5)

A. Request for Specific Functionality and Interoperability Capabilities

Note: Requests a complete description of specific functionality and interoperability capabilities. The text shown is an example only, and should be greatly expanded by the HDO. This may be used if the HDO knows what interoperability capabilities it is seeking, what product functions support that interoperability, and which standards are to be implemented.

B. Description of All Interoperability Capabilities and Related Functionality

Note: Requests a complete description of the Product interoperability, but does not call for any particular function or standard.

C. Description of Technology Supporting Interoperability

Note: Requests a complete description of the Product technology. This should be used only if the Customer intends to evaluate the Product's technology and implementation

D. Description of Vendor's Past Support for Interoperability

Note: Requests a complete description of the vendor's corporate activities related to interoperability but not directly related to the Product itself. This should be used only if the Customer intends to evaluate vendors' past commitment and contributions to interoperability.

MD FIRE: CONTRACT TERMS EXAMPLES (MD FIRE pages 6-8)

(section headings and excerpts)

Option 1: Complete Interoperability

Note: The purpose of this section is to provide an example of terms for complete interoperability. Language in square brackets [this or that] should be selected as appropriate by the Healthcare Delivery Organization (referred to herein as “Customer” or “HDO”).

Option 2: Independent lab testing of interfaces

Supplier agrees to have each interface tested and verified by an independent lab approved by Supplier and Customer. All costs from the Supplier and other third parties for independent lab testing and certification shall be listed separately [and paid by Supplier]. Supplier also agrees to obtain any applicable consortia certification for Product interfaces, including without limitation, USB, WiFi, ZigBee, Bluetooth, HL7 and Continua.

Option 3: Connectivity by Clinical Domain

Note: This section provides a means to add requirements by clinical domain. Customer should consider selecting a specific domain if needed.

MD FIRE: CONTRACT TERMS EXAMPLES pages (6-8)

Option 4: Request for Conformance to Specific Standards

Note: This section provides a means to add conformance to specific standards if not required by other sections.

Option 5: Commitment to Work towards Interoperability

Purpose: This section is to be used when the Supplier is expected to make a best effort to achieve interoperability, and at the same time to inform the Customer of any issues, barriers, or problems with the current set of standards.

Option 6: Customer Requirements-Gathering Example

This is a placeholder for the Customer to define its program/project timeline with respect to gathering requirements for interoperable interfaces. It is referenced in the Agreement terms

VHA Presentation on MD FIRE

- Presented March 18, 2009 to supply chain management via webinar (VHA Dallas studio)
- VHA serves more than 1,400 not-for-profit hospital and more than 21,000 non-acute health care facilities in 47 states and the District of Columbia. VHA's membership includes approximately 28 percent of the nation's community-owned, not-for-profit hospitals.
- 140 hospitals connected to webinar

Financial Implications of Med Dev Interop

- Kaiser Permanente
- 2006 Analysis med device -> EMR integration costs with and without interoperability standards
- Analysis excludes safety and workflow benefits
- Results: standard interfaces would reduce integration costs 30%
- Savings: \$12M annually



Clinical Society “Requirements”

“We believe that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind...”

as of Nov 2008:

*Anesthesia Patient Safety Foundation
Society for Technology in Anesthesia
Society of American Gastrointestinal Endoscopic Surgeons*

*World Federation of Societies of Anesthesiologists
American Society of Anesthesiologists
Massachusetts Medical Society*

Scope of ASTM ICE Part I

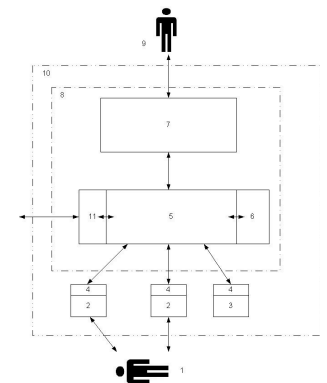
“This standard specifies general requirements... for integrating equipment to create a Integrated Clinical Environment (ICE), as defined in 3.6. This standard specifies the characteristics necessary for the safe integration of medical devices and other equipment, via an electronic interface, from different manufacturers into a single medical system for the care of a single high acuity patient.

This standard establishes requirements for a medical system that is intended to have greater error resistance and improved patient safety, treatment efficacy and workflow efficiency than can be achieved with independently used medical devices.”

“ICE” Standard - Integrated Clinical Environment ASTM F-2761

- New medical device standard describes requirements for safe and effective “plug-and-play” integration of devices in high-acuity environments
- Developed by CIMIT/MGH MD PnP Program writing group convened under the authority of ASTM International Committee F29*
- First draft 2006 prepared for ISO/IEC
- ASTM version initiated 2007
- Publication expected April 2009.

*ASTM F29.21 Devices in the Integrated Clinical Environment



Annex B -Clinical context and clinical scenarios

1. Safety Interlock (PCA)*
2. Synchronization with safety interlock (X-ray - ventilator synchronization)*
3. Process control/workflow (Heparin monitoring via PTT testing)
4. Smart alarm system (annunciate alarm when ventilator not re-started after cardiopulmonary bypass)*
5. Decision support (integrate bedside data and observations to activate Rapid Response Team)
6. Physiological Closed Loop Control (artificial pancreas via intravenous infusions)

Definition 3.6 INTEGRATED CLINICAL ENVIRONMENT (ICE)

An Integrated Clinical Environment is an environment where monitoring, treatment or diagnosis is performed on a single PATIENT, with interconnected medical devices and other equipment ... While many of the elements of a clinical environment exist in a bounded physical space containing the patient (e.g., an operating room, intensive care unit, field hospital, ambulance, or other acute care environments), they need not all be within that physical space. Some of the operators, some pieces of equipment (e.g., control consoles), or databases can be located at remote locations.

An Integrated Clinical Environment is patient-centric. As a patient moves among different venues (e.g., operating room, ICU, emergency department, transport, home) the ICE moves with the patient; however some of the elements of the ICE ... can change.

ICE Part I - Clinical Scenarios

- Listed in Annex B
- Six scenarios - all high-acuity care / documented preventable adverse events
- ICE-based solution pathway aligned with HHS “Common Device Connectivity” requirements

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

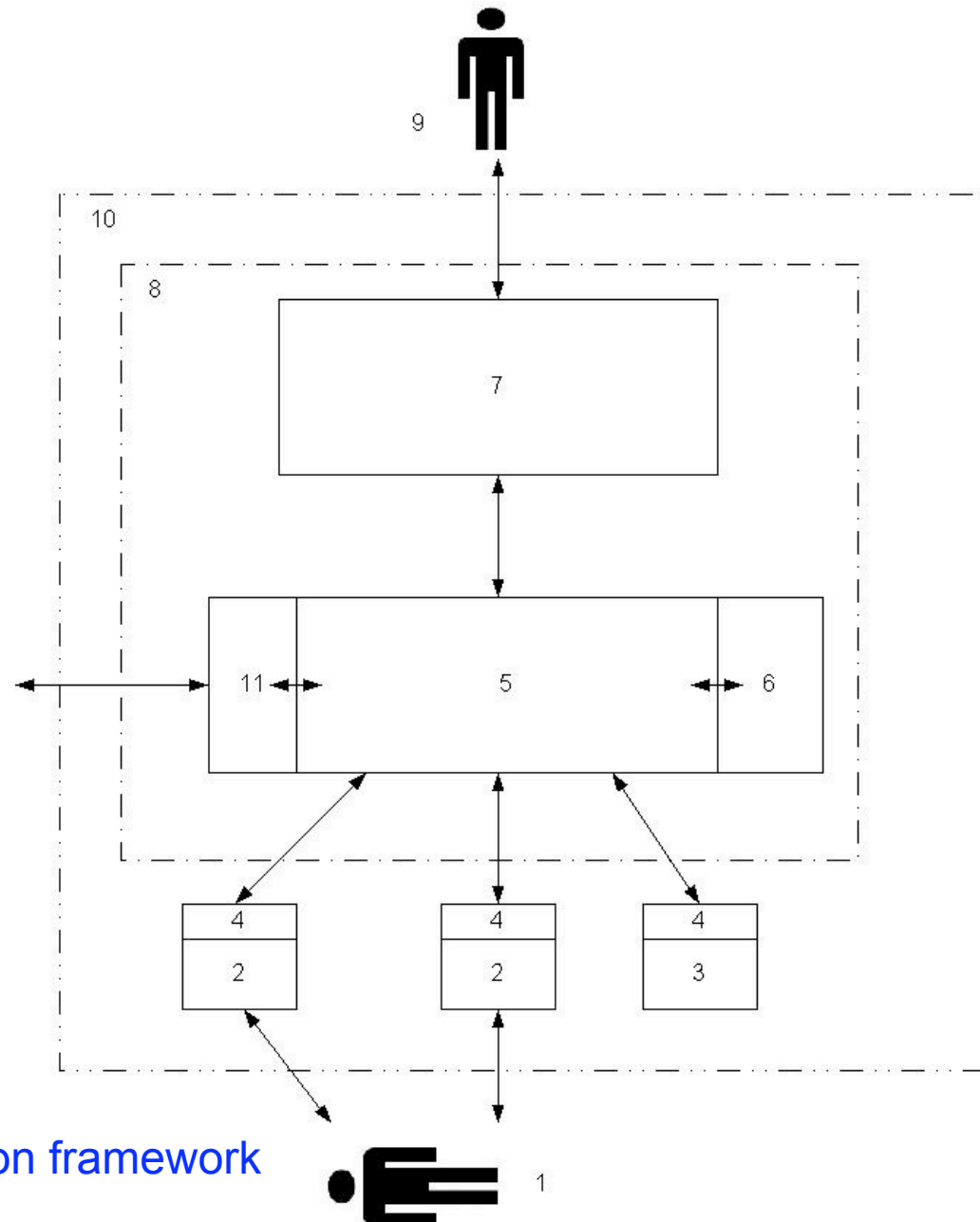
9 operator (clinician)

10 ICE

11 external interface

From ASTM Draft ICE Part I

ICE can serve as a collaboration framework



The ICE supervisor supports the following 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
- Perform data reduction with pointers for EMR

•Control of those features made available through the ICE interface (box #4)

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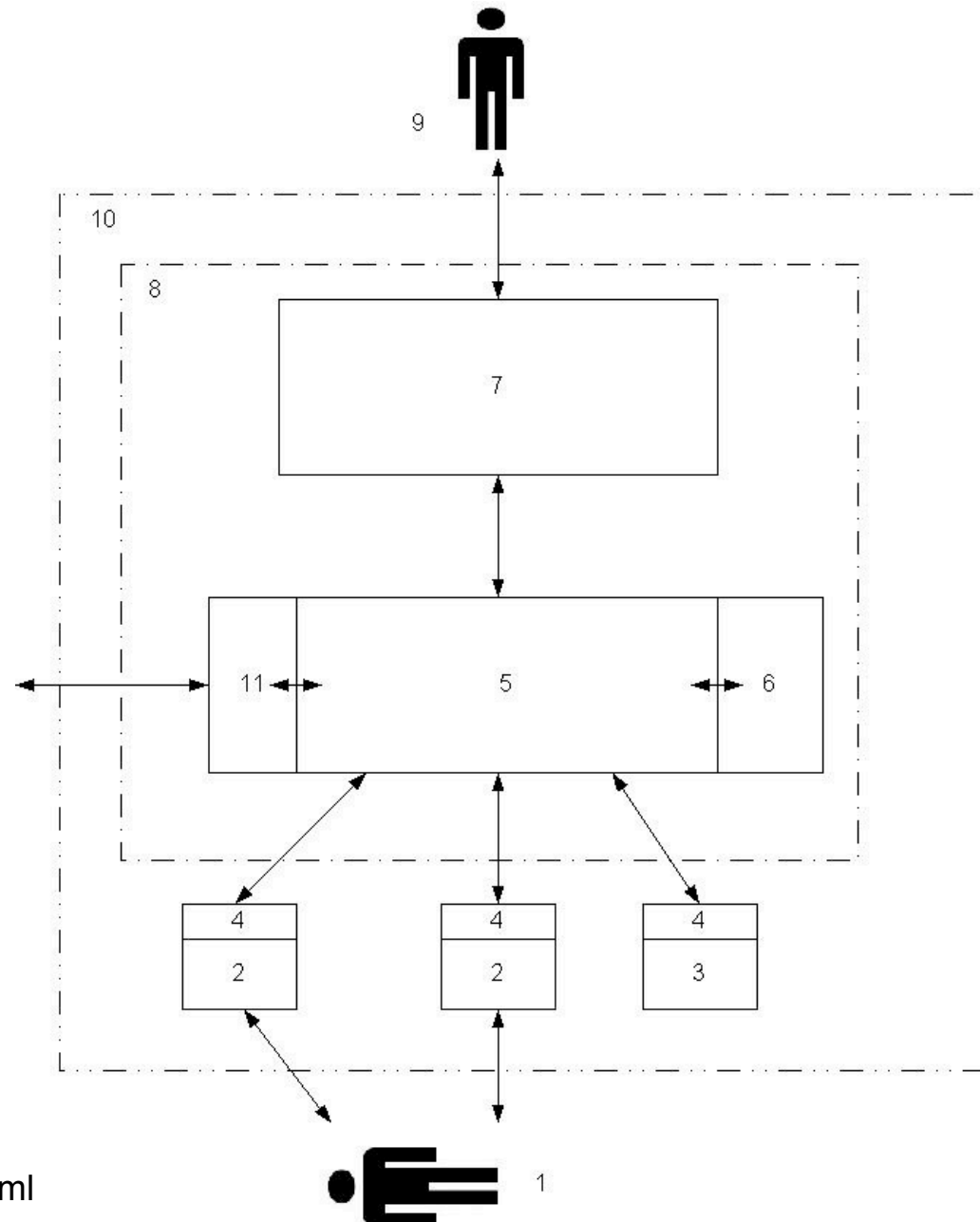
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9 operator (clinician)

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11 external interface

From draft ASTM ICE Part I



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

- Provide “Plug and Play” 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)

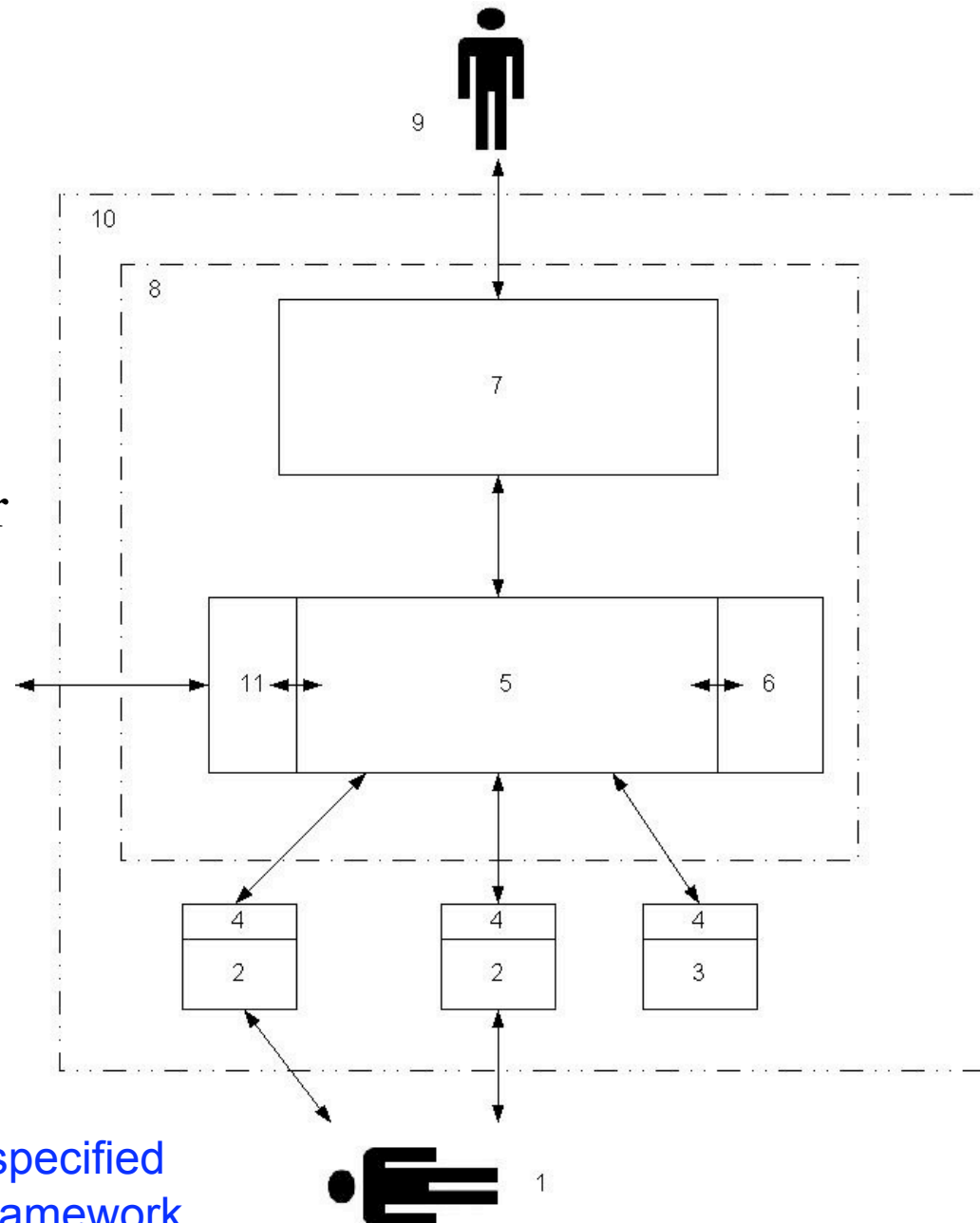
Functional Elements of the Integrated Clinical Environment

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- 7 ice network controller
- 8 data logger
- 9 ice supervisor
- 10 ice manager
- 11 operator** (clinician)
- 12 ICE
- 13 external interface

From ASTM Draft ICE Part I

ICE leaves many elements unspecified
Can serve as a collaboration framework



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
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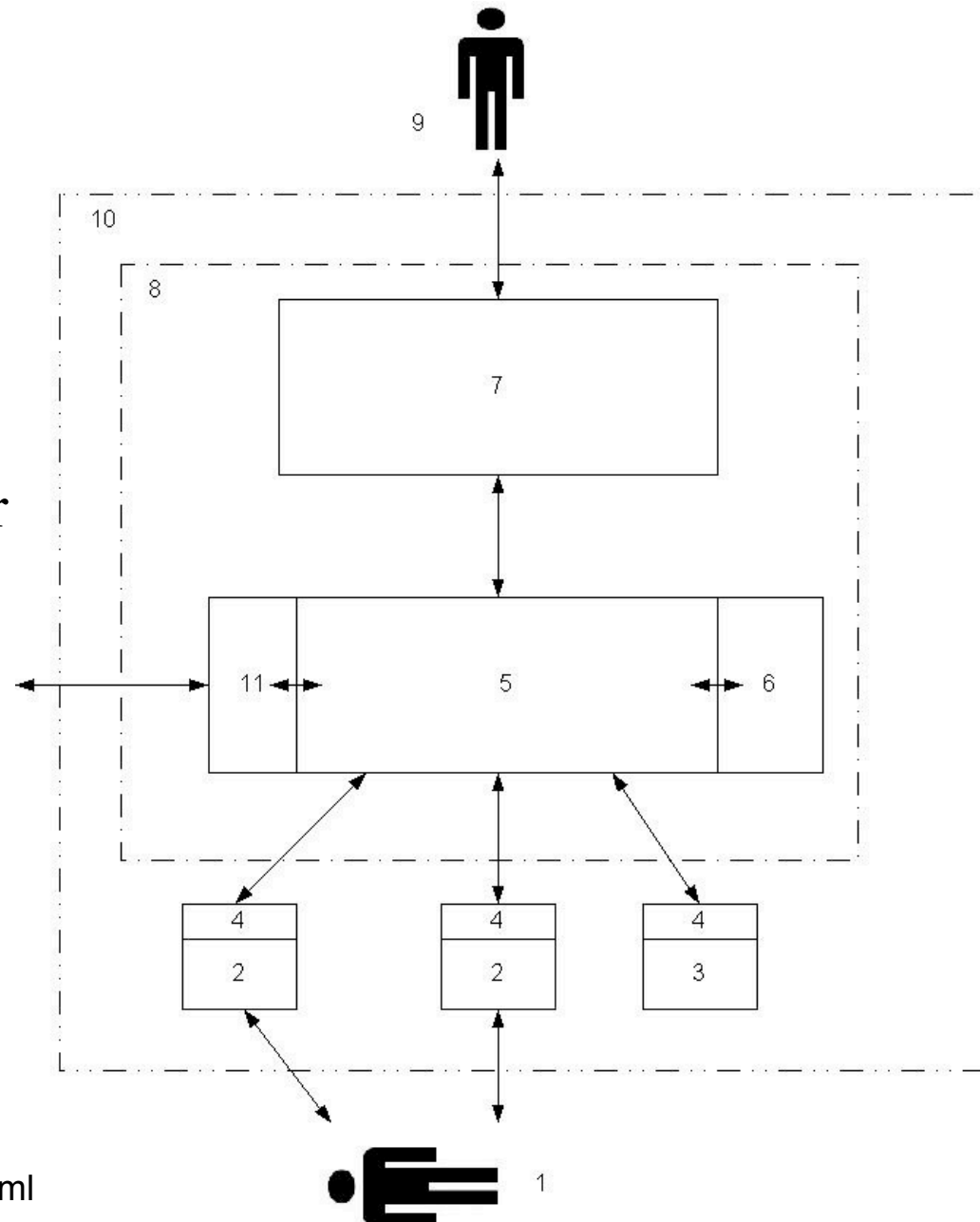
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Functional Elements of the Integrated Clinical Environment

Key

- 1 **patient**
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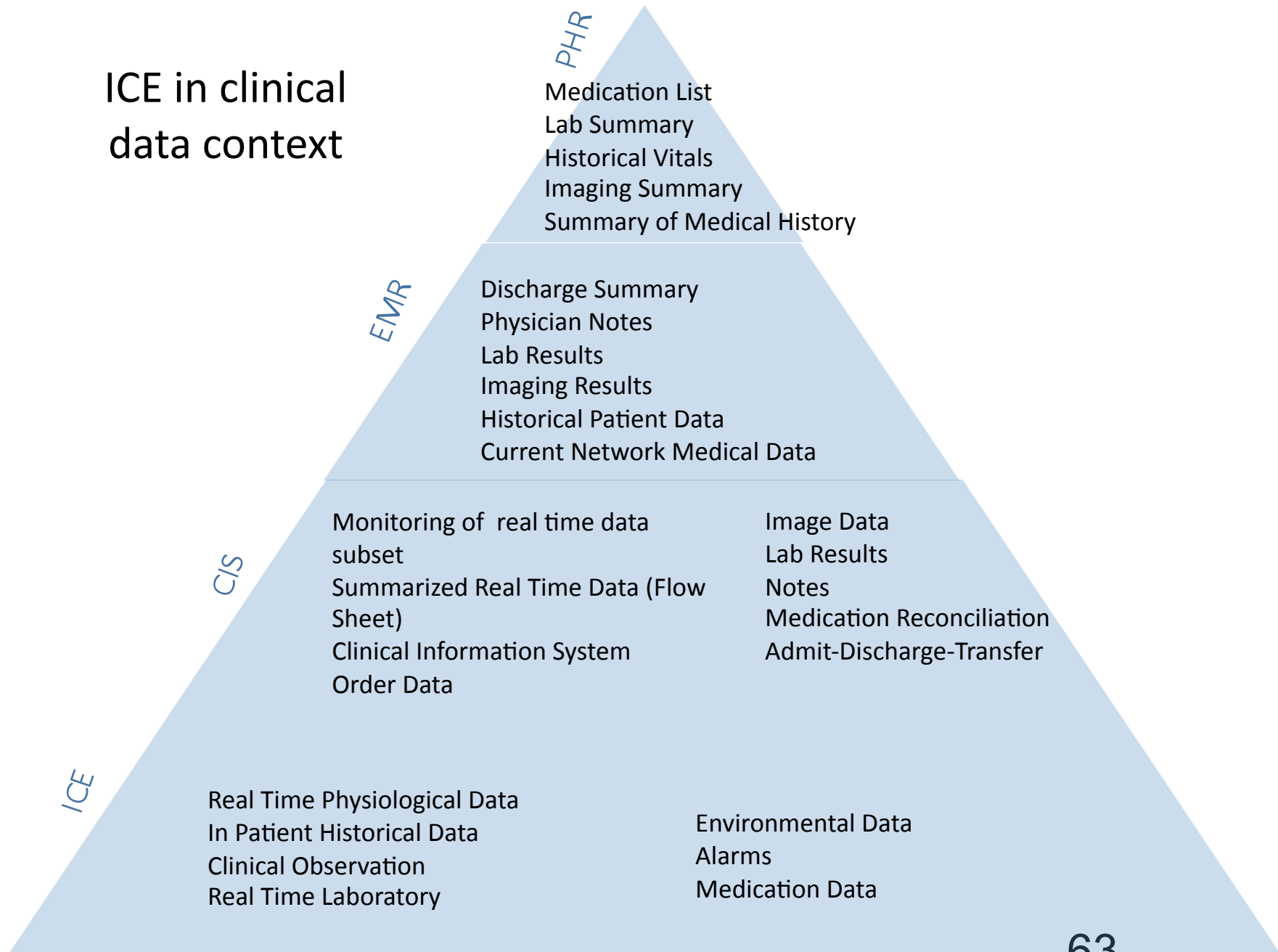
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ICE in clinical data context



Common Device Connectivity

Draft AHIC Extension/Gap Dec 2008

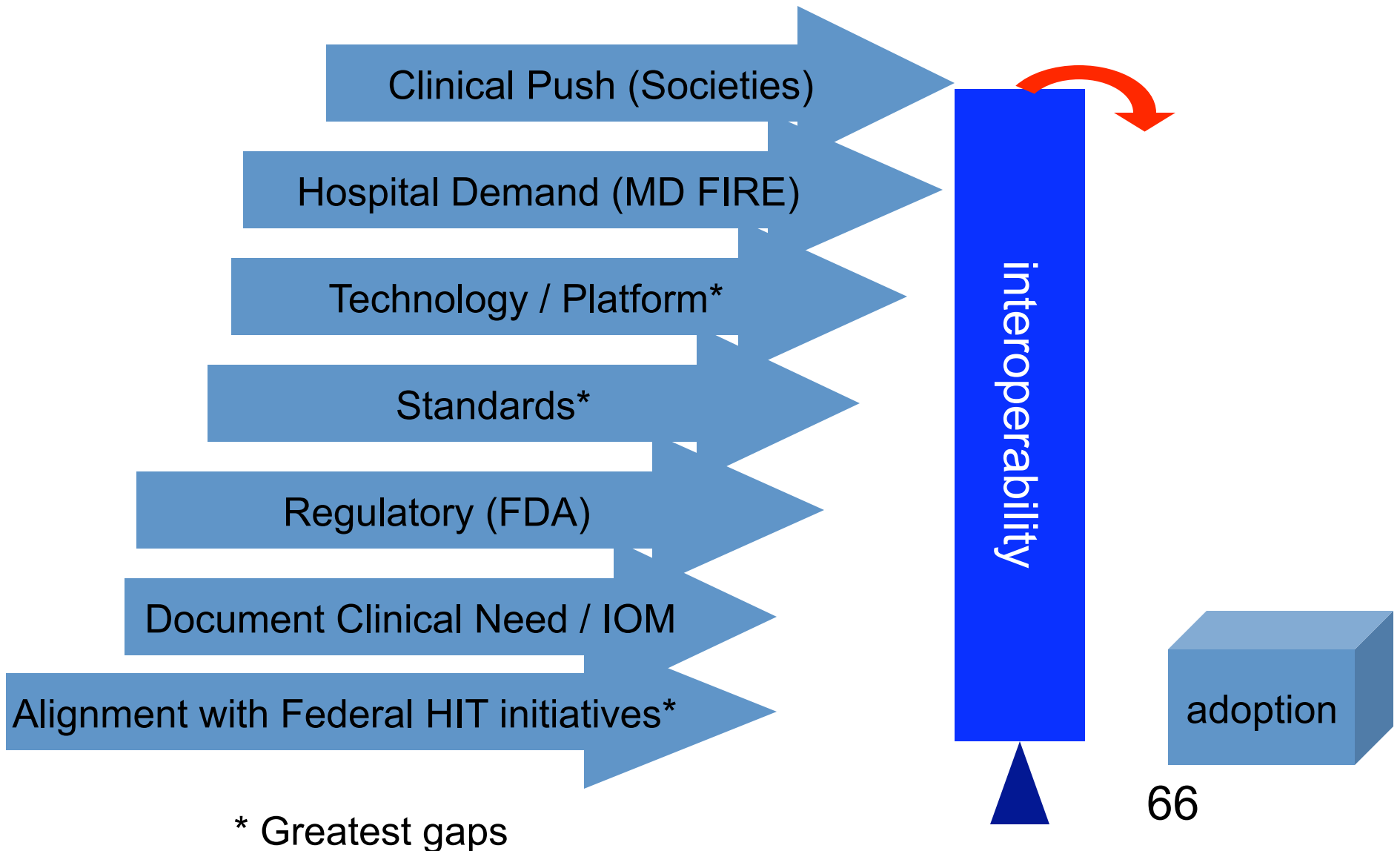
- c. The ability to communicate measurement information to the EHR for effective patient monitoring and management.
- D. The ability to uniquely identify a device and related components, communicate device setting and detailed device information associated with each measurement value, to the EHR.
- E. The ability to communicate and manage measurement intervals and device setting information within the EHR.
- F. The ability to query for additional device information captured by the device that may not have been communicated to the EHR.
- I. The ability to set and communicate limits and safeguards for device settings from the EHR to a device.



Adoption of medical device interoperability (standards and technologies) will support:

1. Complete, accurate electronic medical records
2. Rapid deployment of devices in makeshift emergency care settings
3. Clinical decision support systems and smart clinical alarms
4. Support of remote healthcare delivery
5. “flight data recorder” to facilitate adverse events analysis
6. Automated system readiness assessment (prior to starting invasive clinical procedures or critical care transport)
7. Reduce cost of devices and their integration, and reduce EMR-adoption costs
8. Closed-loop control of therapeutic devices and safety interlocks (e.g. ventilation, medication and fluid delivery)
9. Pathway for innovative medical applications

Will we reach the tipping point?





The MD PnP Vision

Improve safety and efficiency by
changing expectations;
changing technology;
changing healthcare



Contact info:
www.jgoldman.info

MD PnP Program:
www.mdnpn.org