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Update on Medical Device Interoperability

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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.
- 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.

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Conceptual framework for device and data integration

- Comprehensive integration of clinical and non-clinical data, devices, and systems can provide "error-resistance" and reduce inefficiencies:
  - Smart Alarms requires "contextual awareness"
    - Example: Vent data for PVR interpretation
  - Workflow Support requires "closing the workflow loop"
  - Safety Interlocks require tight system integration
  - Not limited to the OR: ICU, ER, home, etc.
- *These solutions require seamless cross-vendor connectivity, which is not currently available:*
  - STA members and individual companies cannot implement potentially important solutions
  - Therefore, many great ideas die on the vine

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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.

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

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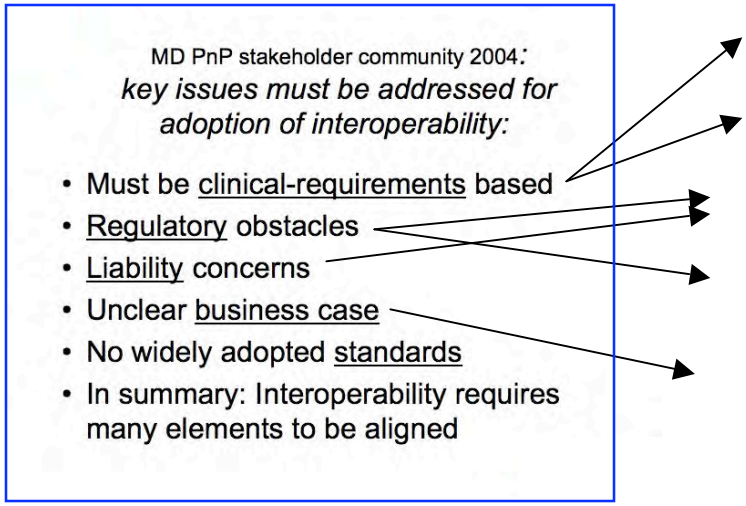
Goals of the MD PnP Program

1. Lead the adoption of open standards and related technology to support medical device interoperability 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

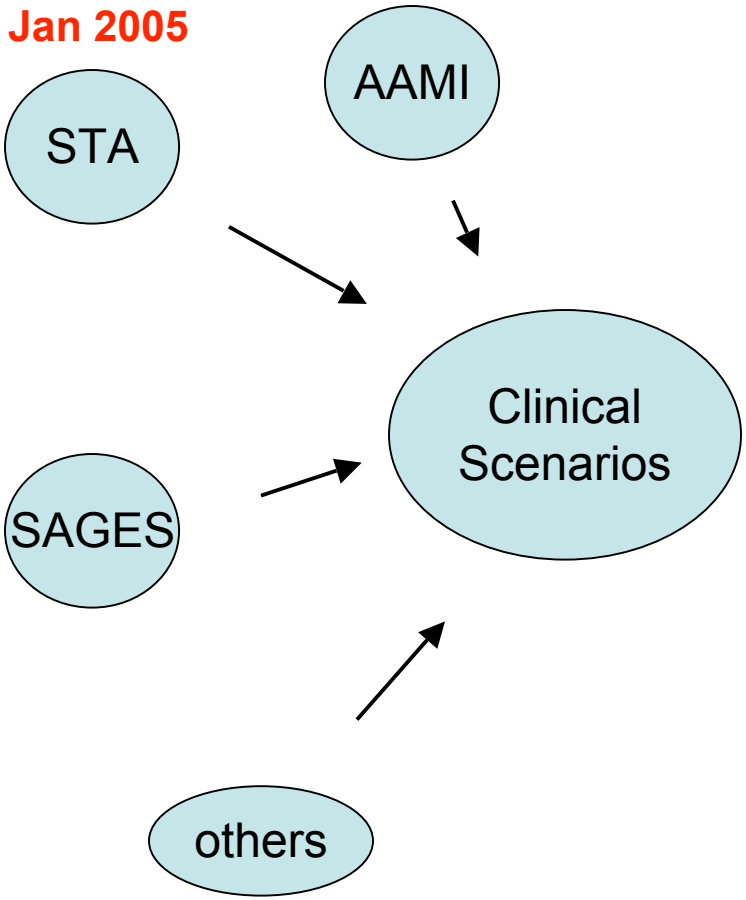
- NSF
- Philips Healthcare
- Lockheed Martin
- and others

MD PnP Program Projects



- 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 now or enable future innovations.
Assume no financial or technical limitation"

EXAMPLE Clinical Scenario worksheet

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

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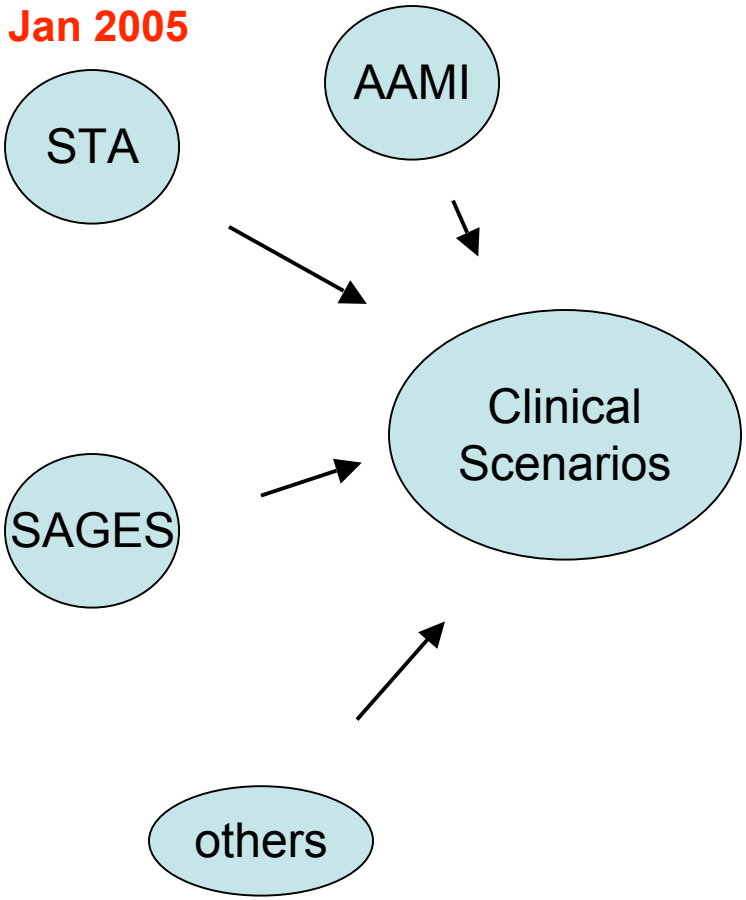
Clinical Requirements



Clinicians

Clinical Engineers

Design Engineers

Clinical Scenario

Clinical Workflow

Use Cases

Logic Map/Key

State Diagram

Technical Solution and Clinical Implementation

Clinical Scenarios included in draft ICE Standard

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

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

Medical Device Interoperability for Patient Safety: Driving Procurement Changes	October 2008

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.

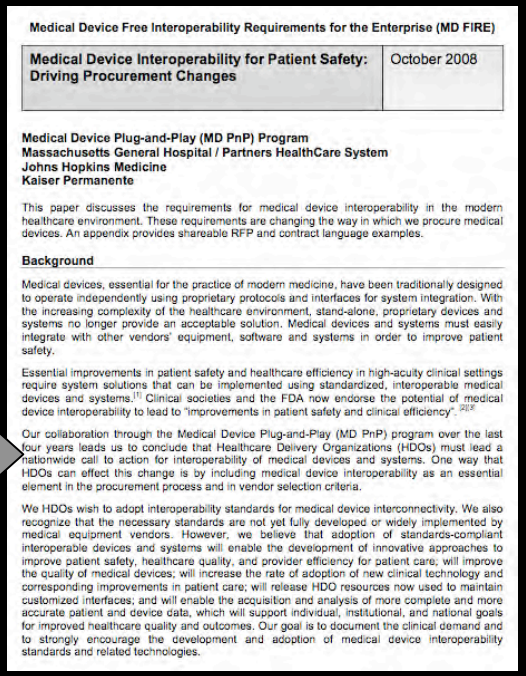
5 Stakeholders:
BME
IS
Clinical
Purchasing
Lawyers

Download MD FIRE from www.MDPnP.org

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



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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.[1] Clinical societies and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency".[2][3]

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.


Clinical Society "Requirements"

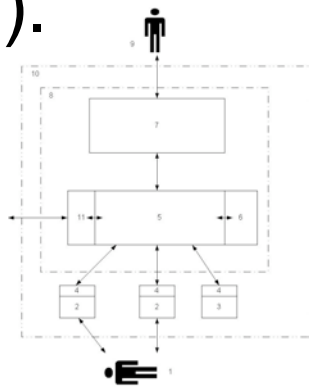
"We believe that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind…"

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

“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 MD PnP Program writing group convened under the authority of ASTM Committee F29*
- First draft: June 2006 (Draper Laboratory). ASTM Ballot Closes: January 26, 2009



*ASTM F29.21 Devices in the Integrated Clinical Environment

Scope of ICE Part I

"This International Standard … Integrated Clinical Environment (ICE) … is intended to facilitate the safe integration of medical devices and other equipment from different manufacturers into a medical system for the care of a single high acuity patient.

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

Functional Elements of the Integrated Clinical Environment

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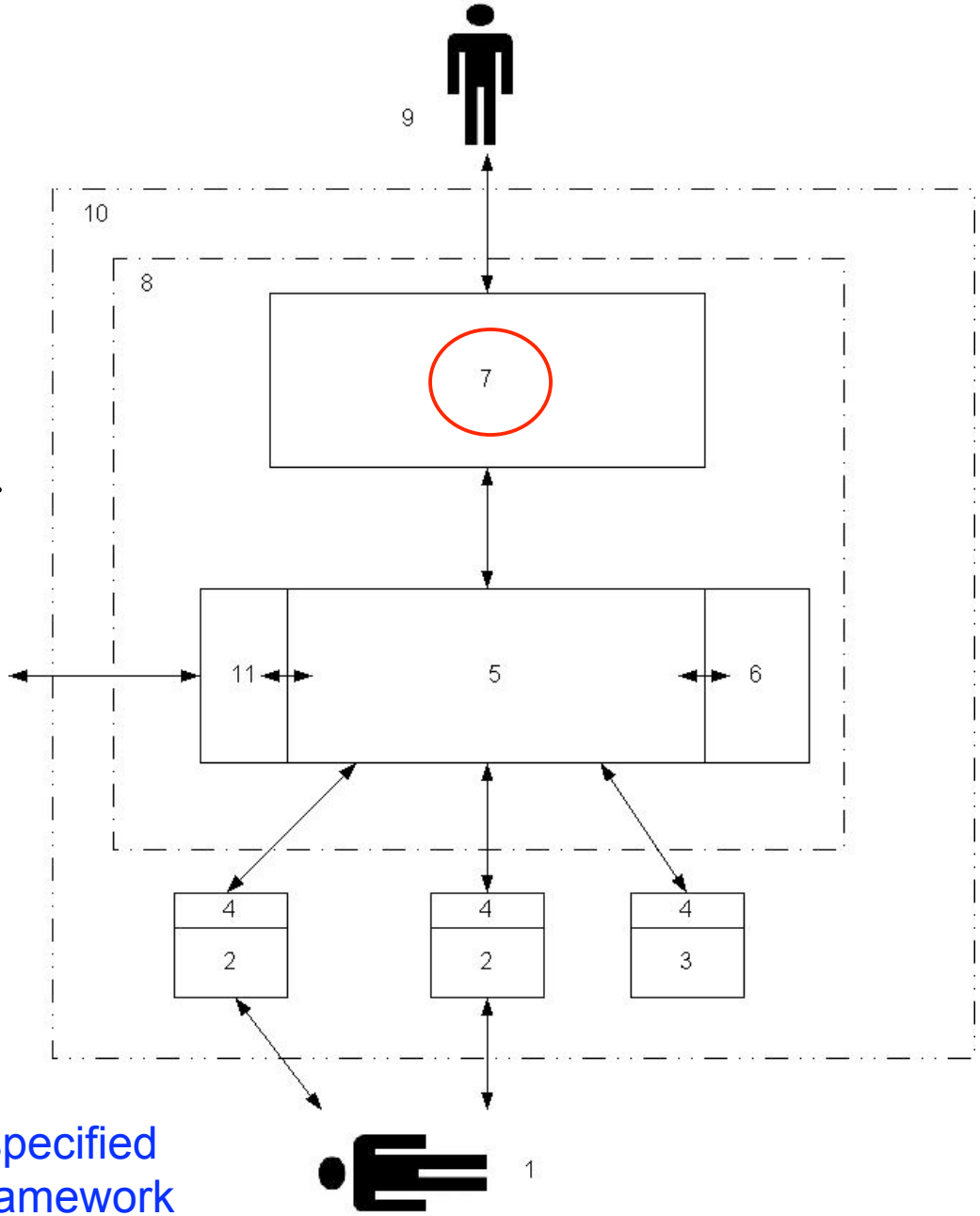
Key

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 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
- 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)

From draft ICE Part I

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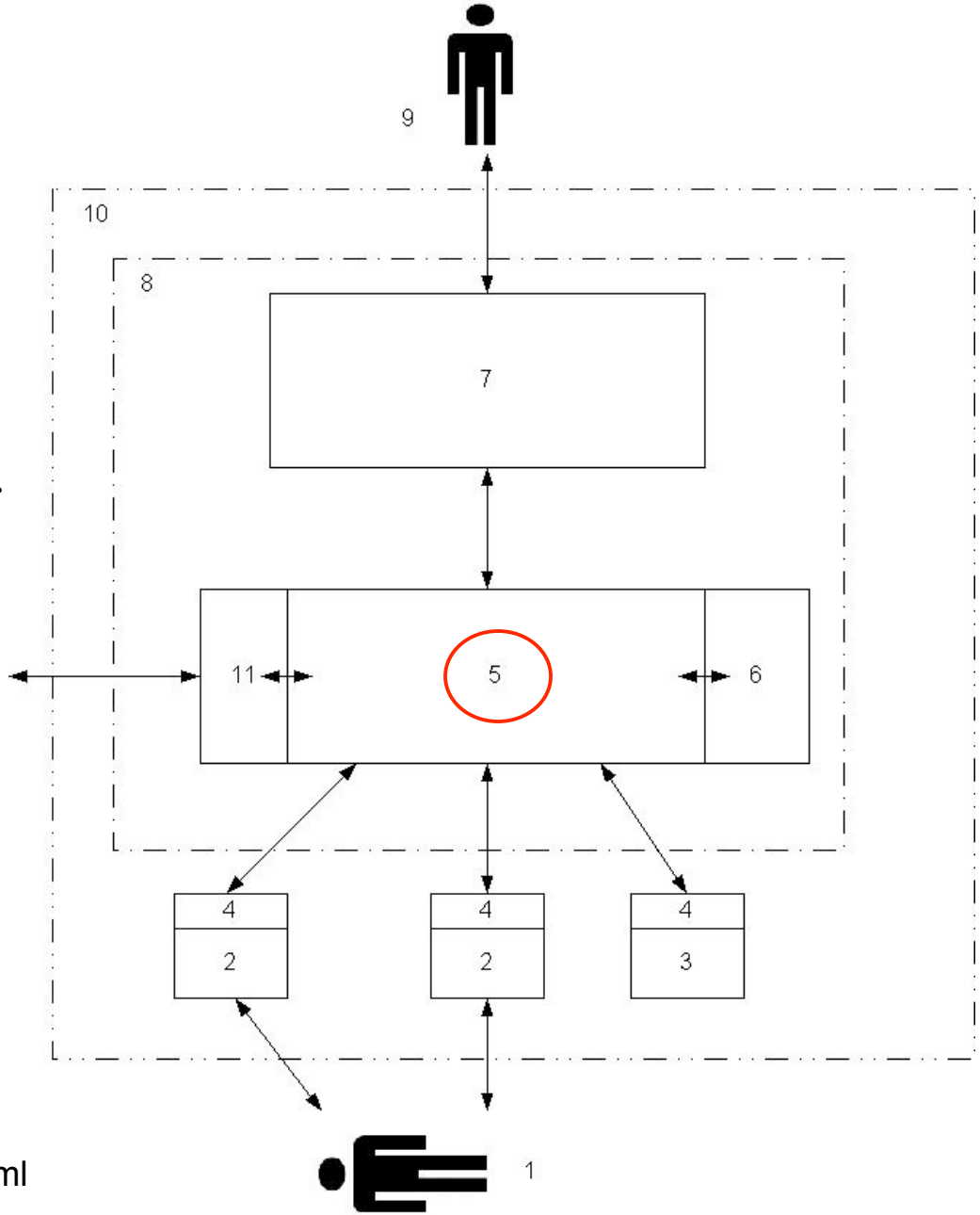
From draft ASTM ICE Part I



Current draft: http://mdpnp.org/ice.html

The ICE network controller 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)

From draft ICE Part I

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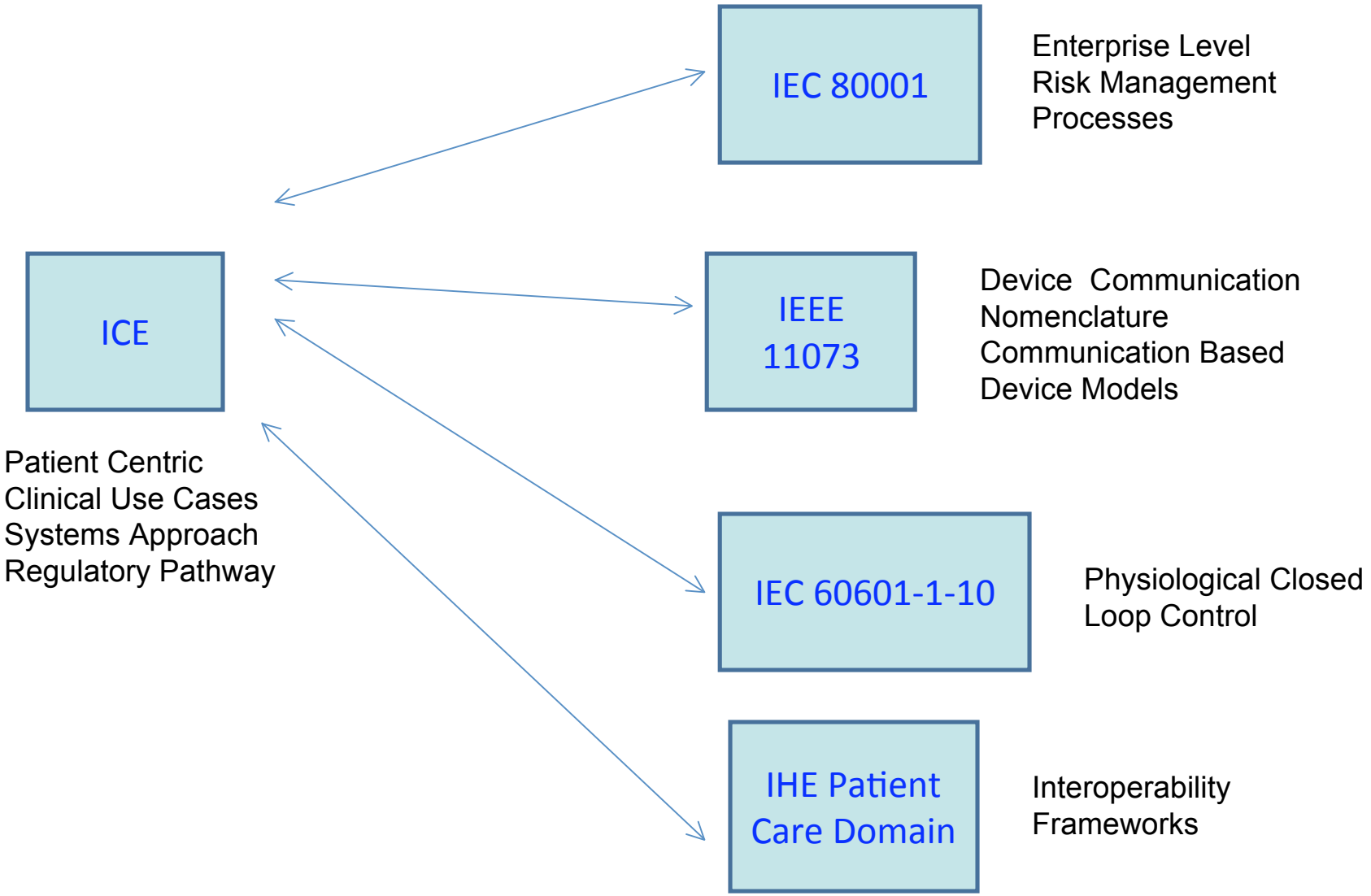
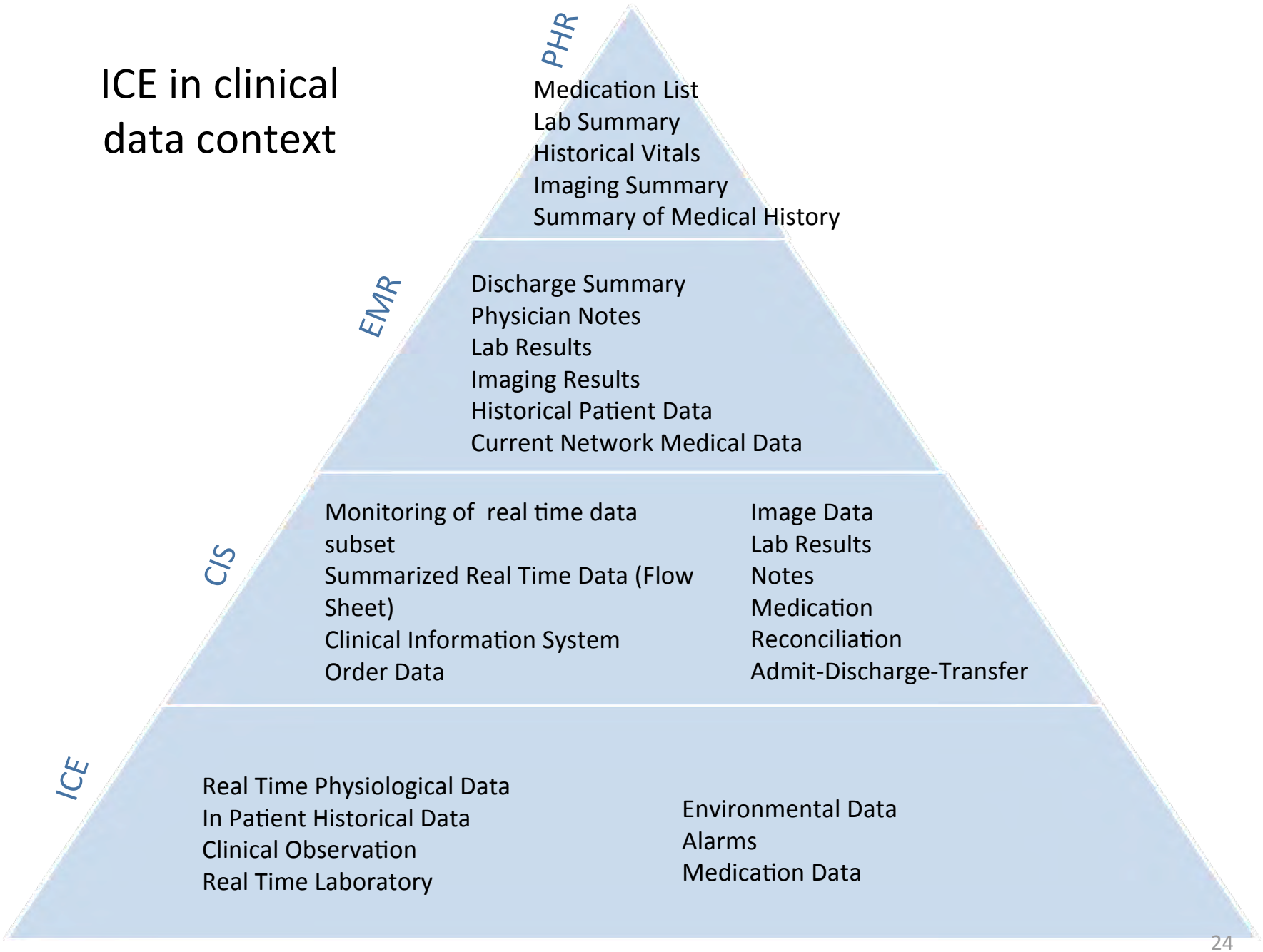
ICE - in a standards context



ICE in clinical data context



U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology

Common Device Connectivity

Draft AHIC Extension/Gap

August 15, 2008

2.2 Scope Common device connectivity is the means by which clinical device information such as settings, measurements, and monitoring values are communicated to an EHR. Examples of devices include hemodynamic monitors, ventilators, anesthesia monitors, and infusion pumps. Therefore, requirements for common device connectivity can be summarized as:

The ability to communicate clinical device information to an EHR.

The identification, development, and harmonization of standards to support communication of device information to EHRs still requires additional work. As mentioned in Section 1.0, these needs have not yet been fully addressed by the national health agenda's standardization efforts. Examples of gaps in industry standards are outlined in the upcoming sections of this extension/gap document.

Common Device Connectivity
Draft AHIC Extension/Gap 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.

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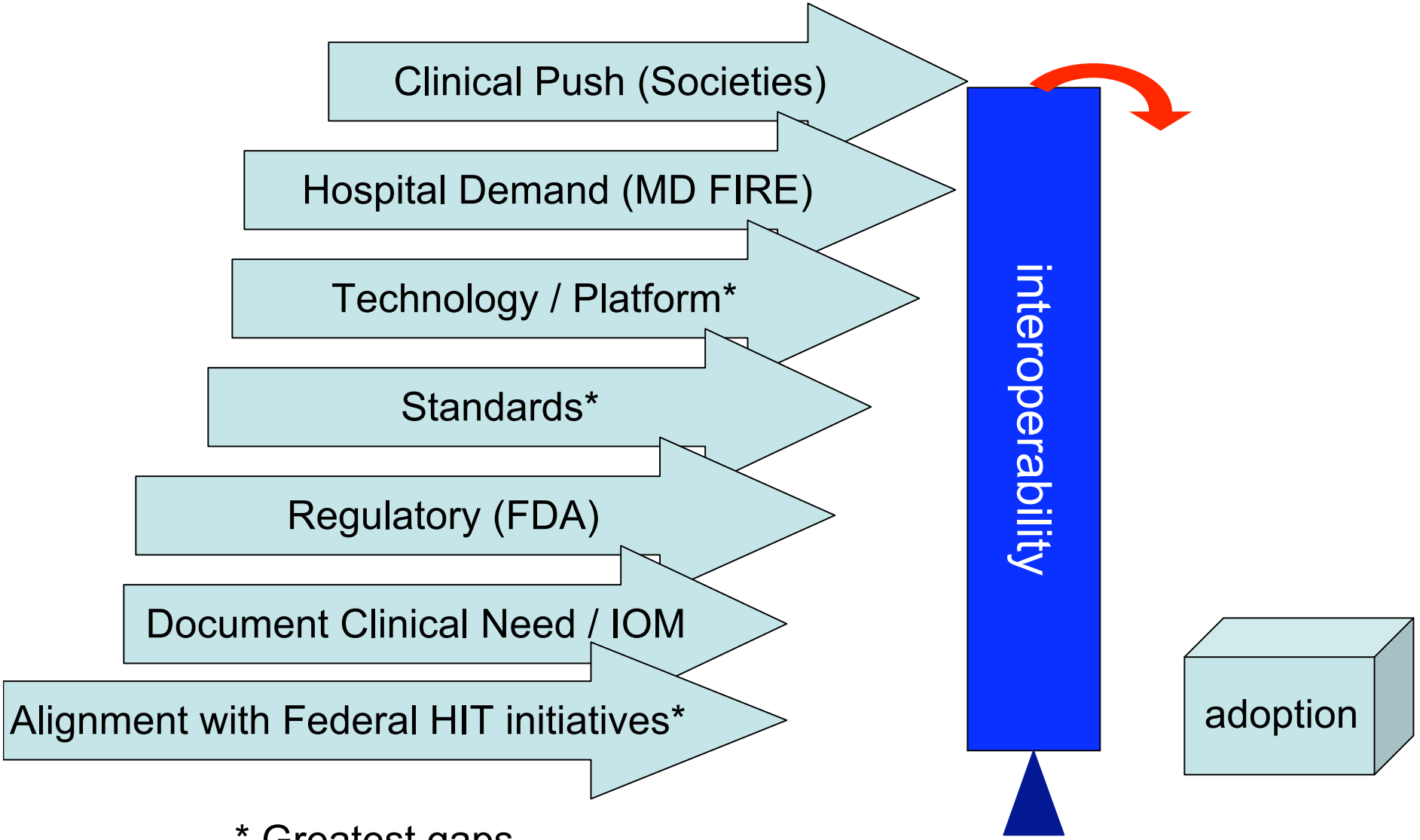
Will we reach the tipping point?



* Greatest gaps

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 (by STA members)

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What is needed?

- Development of an open research platform to facilitate:
  - Evaluation of proposed engineering solutions
  - Standards gap analysis and resolution
- More complete interop standards
- Trial implementation in innovative healthcare setting
- Alignment with Federal HIT initiatives
- Increase consumer demand (MD FIRE)
- Data to supplement anecdotal benefits of interop
- Broaden outreach : use slides, MD FIRE, society endorsements, etc.


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