CIMIT

MD PnP™
Getting connected for patient safety™

Cyber Physical Systems Briefing
902 Hart Senate Office Building
July 9, 2009

Medical Device Safety & Innovation

preparing for system integration at the sharp edge of healthcare

Julian M. Goldman, MD
Attending Anesthesiologist, Massachusetts General Hospital / Harvard Medical School
Medical Director, Partners HealthCare System Biomedical Engineering
Founding Director, CIMIT Program on Medical Device "Plug-and-Play" Interoperability (MD PnP)
Boston, Massachusetts

Contact information: www.jgoldman.info

Medical Device Safety & Innovation

"Integrating the clinical environment" is essential to create error-resistant systems to improve patient care and healthcare efficiency

Current state

… at the sharp edge of high-acuity patient care …

Clinical environments are crowded with complex, life-saving technology.

Forward-area Operating Room in Iraq

Critical Care Air Transport

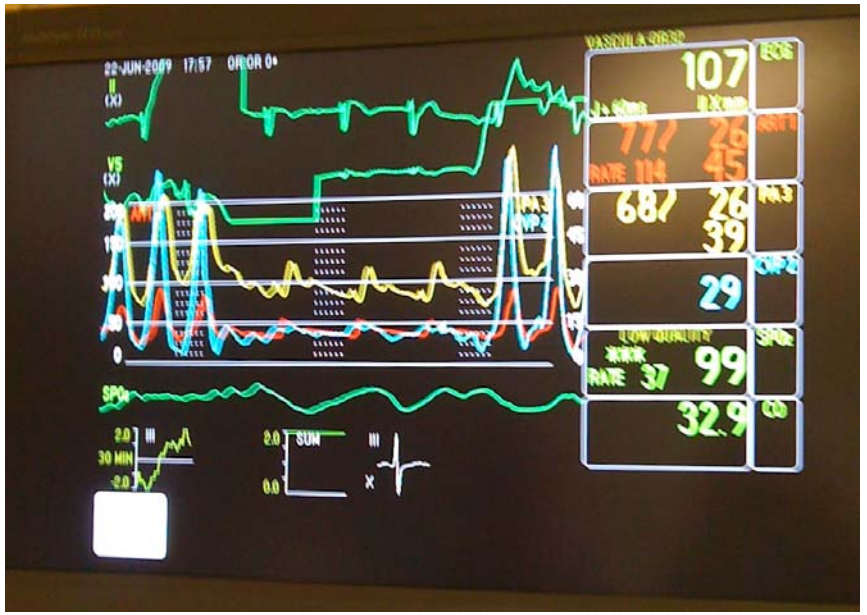
Intensive Care Unit

Credit: T. Rausch

How do we connect medical devices to the EMR?

Hint: it isn't "plug and play" like USB memory sticks

How will we interpret this electronic medical record?



Mass General Hospital
Operating Room of the Future (OR#49)

Lessons from the OR of the Future project

- Comprehensive integration of clinical and non-clinical devices and systems could provide:
  - Workflow Support require "closing the workflow loop"
  - Smart Alarms require "contextual awareness"
  - Safety Interlocks require tight system integration

  Not limited to the OR: ICU, ER, home, etc.

MD PnP™
Getting connected for patient safety™

Example of error resistant system:
Landing gear not down? -> Smart ALARM

Contextual awareness requires data from several device and systems.

“Hudson River Over-ride” - Augment awareness, not control

Examples of 2 clinical procedures and associated safety issues ->

(From our “Clinical Scenarios” Repository)

MD PnP™
Getting connected for patient safety™

Scenario: Surgical Fires

600 surgical fires each year

The most severe burns are internal – in the lungs
Caused by burning breathing tubes

Airway Laser Surgery + O_2 -> Fire

- O_2 in respiratory gas supports combustion.
- If laser hits breathing tube, could produce devastating burn.
- Surgical team must “remember” to minimize O_2

Breathing Tube with Oxygen

A Solution: Laser-O_2 Interlock

- Monitor breathing O_2 concentration. (This is already measured.)
- Safety interlock to prevent laser activation if O_2 > 25%

Proposed and published in 1999!

NOT Commercially available

Scenario:
Failure to ventilate

Heart-Lung (Cardio-Pulmonary) Bypass

or

Switch from anesthesia machine ventilator to heart-lung bypass machine and back.

Heart-Lung (Cardio-Pulmonary) Bypass

Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.

Anesthesiology. 87(4):741-748, October 1997

12 Years

"… the anesthesiologist forgot to resume ventilation after separation from cardiopulmonary bypass. The delayed detection … was attributed to the fact that the audible alarms … had been disabled during bypass... patient sustained permanent brain damage."

Almost every surgical team has experienced this error!

Heart-Lung (Cardio-Pulmonary) Bypass

Should alarm if both are off

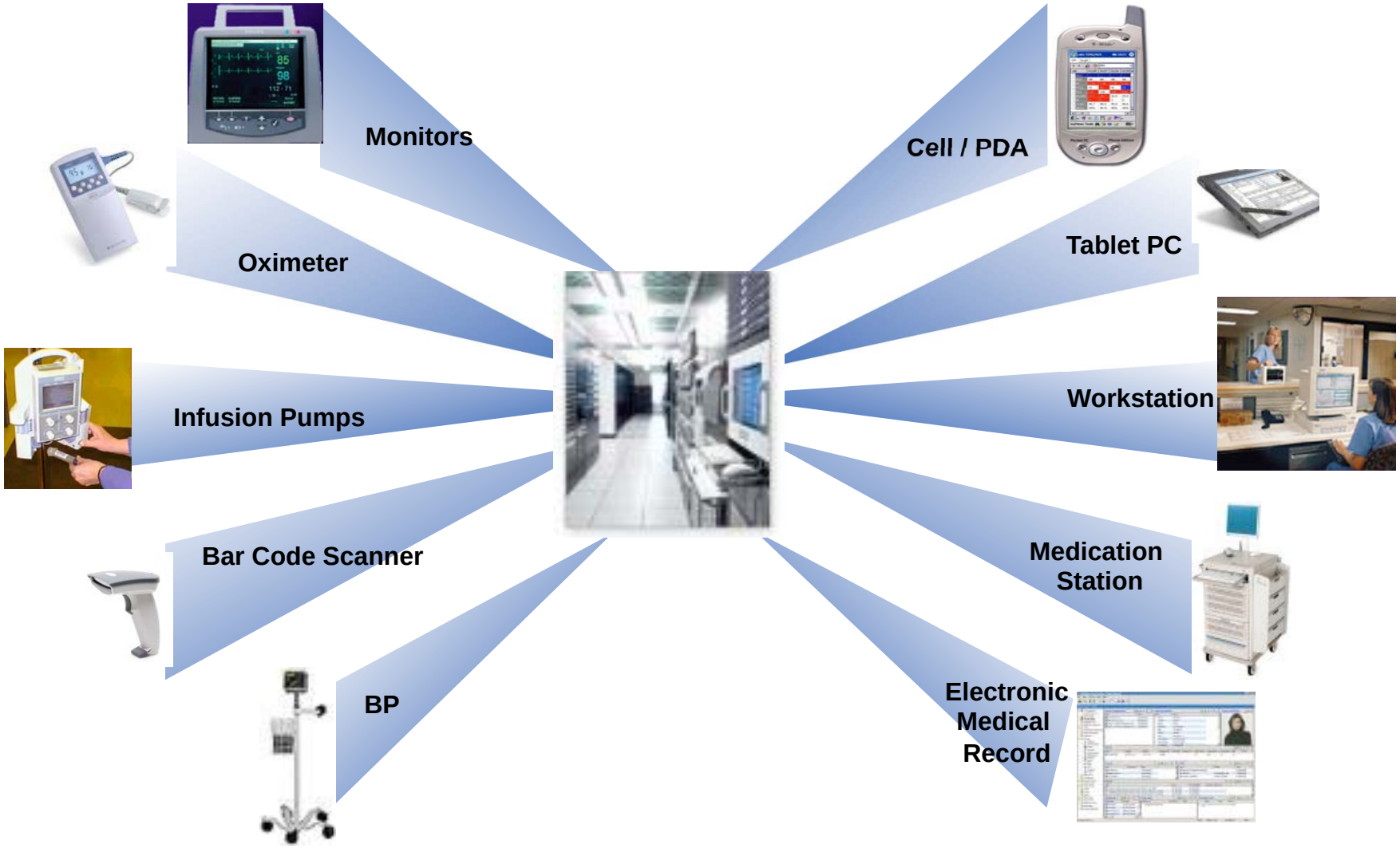
NOT Commercially available

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

Needs and complexity will only increase …

Point-of-Care Medical Devices (wired ⇒ wireless and mobile)

Data Integration, Analysis, and Display



Connectivity challenge extends beyond the OR

Credit: P. Carleton, RN

Unmet Clinical Needs:

many years of "great ideas" – no implementation pathway

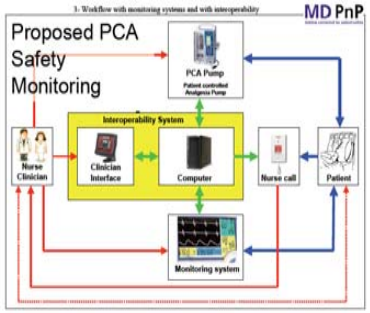
- "Integration of operating room monitors for development of a smart alarm system" (Navabi/Mylrea 1990)
- "A system for optimized design of fluid resuscitation in trauma" (1991)
- OR: 70% of anesthesiologists disable clinical alarms (Block, Nuutinen, Ballast 1995)
- ICU: 86% false alarms (Tsien, Fackler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

Medical device integration demonstrated at national medical conference

Lui Sha, PhD - UIUC

NSF CPS-funded Collaboration:

"Architecture for the Safe Composition of Complex Medical Systems"



Goal: Provide technology foundation for real time safety critical systems in healthcare

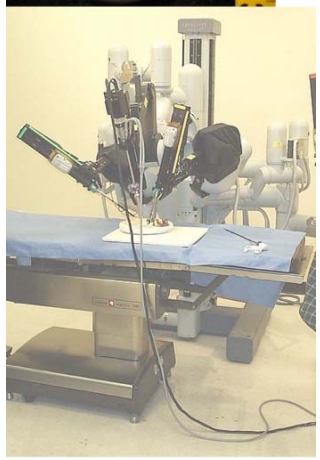
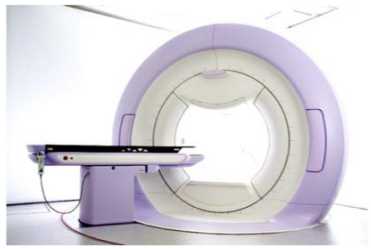
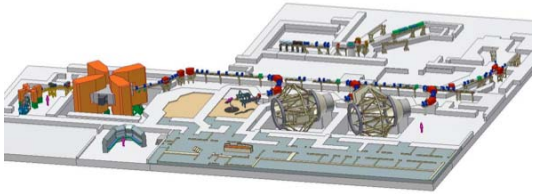
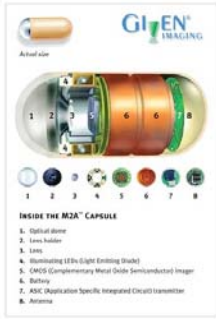
Specific Issue:

– Real-time safety analysis as multiple devices are integrated

Insup Lee, PhD – U Penn

NSF CPS-funded collaboration:
"Composition, Interoperability, and Robustness of CPS Components for MD PnP"

- Complex medical device hardware and software requires new methods to certify software prior to clinical use.
- New design and productivity technologies are needed

*"a computer interface problem between the CT scanner and the workstation containing the Variseed software occurred that prevented the precise calculation of doses of radiation … received by the patient"**

Dr. Gary Kao's statement to U.S. Senate Committee on Veterans' Affairs, June 29, 2009, regarding problems with prostate cancer radiation seed treatments in 92 veterans at Philadelphia VA Medical Center:

*Section 11c and 12e

MD PnP™
Getting connected for patient safety™

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

Massachusetts General Hospital and the CIMIT, with Army/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.

Voice of the MD PnP stakeholder community: Interoperability requires many elements to be aligned

- Focus on clinical needs
- Regulatory obstacles *(Lui Sha, UIUC)*
- Liability concerns *(Insup Lee, Penn)*
- Business case *(MD FIRE – Kaiser, Hopkins, Partners HealthCare)*
- Promote/develop/adopt suitable standards *(ASTM ICE)*

Non trivial technology challenges exist in each area

MD PnP™
Getting connected for patient safety™

MD PnP™
Getting connected for patient safety™

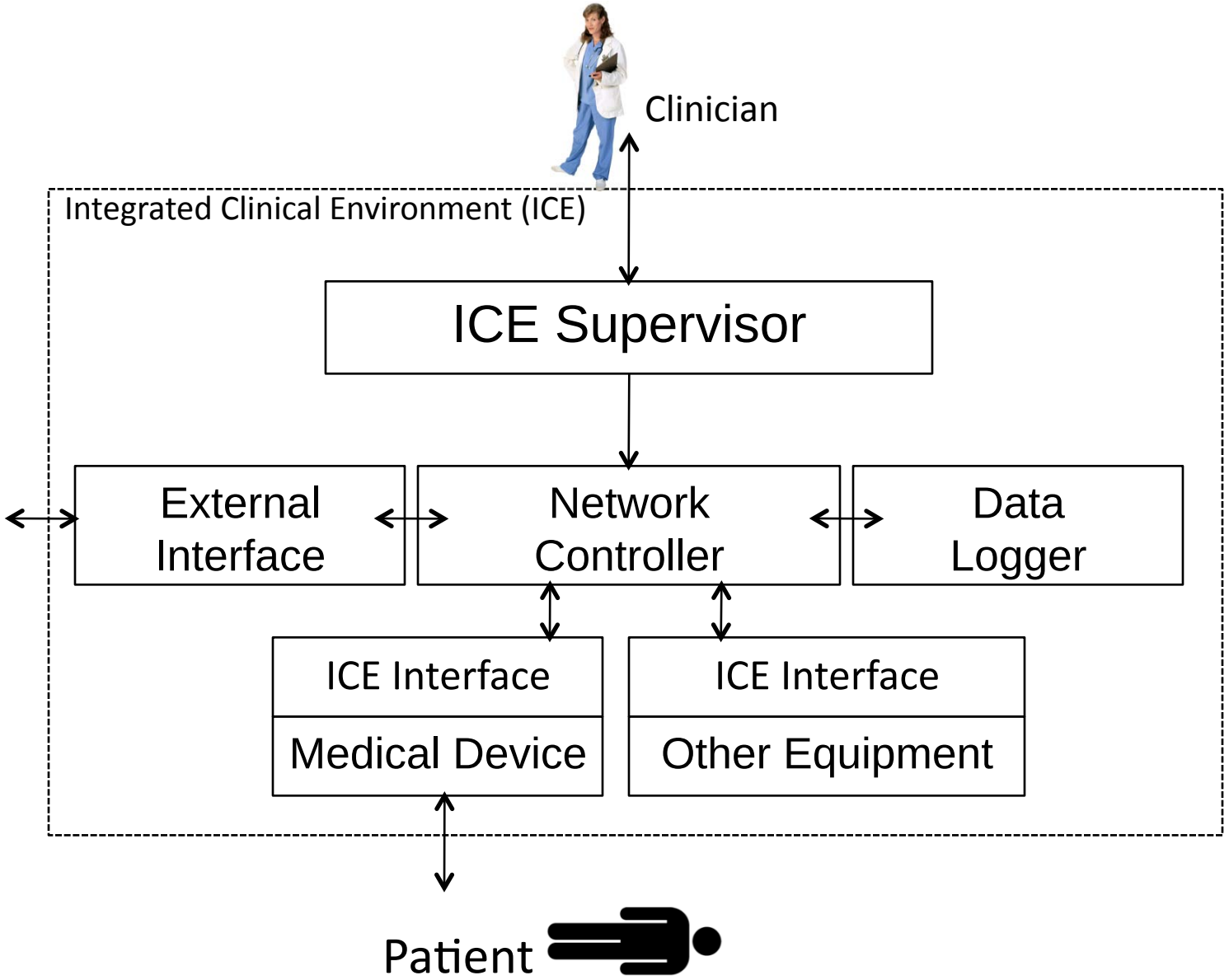
Goals of the MD PnP Program

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
3. Elicit clinical requirements for the proposed interoperable solutions
4. Use our vendor-neutral laboratory to:
   - evaluate interoperability standards and solutions
   - serve as a national resource
5. Investigate safety of proposed engineering solutions

CIMIT
Medical Device
Plug-and-Play
Interoperability Lab

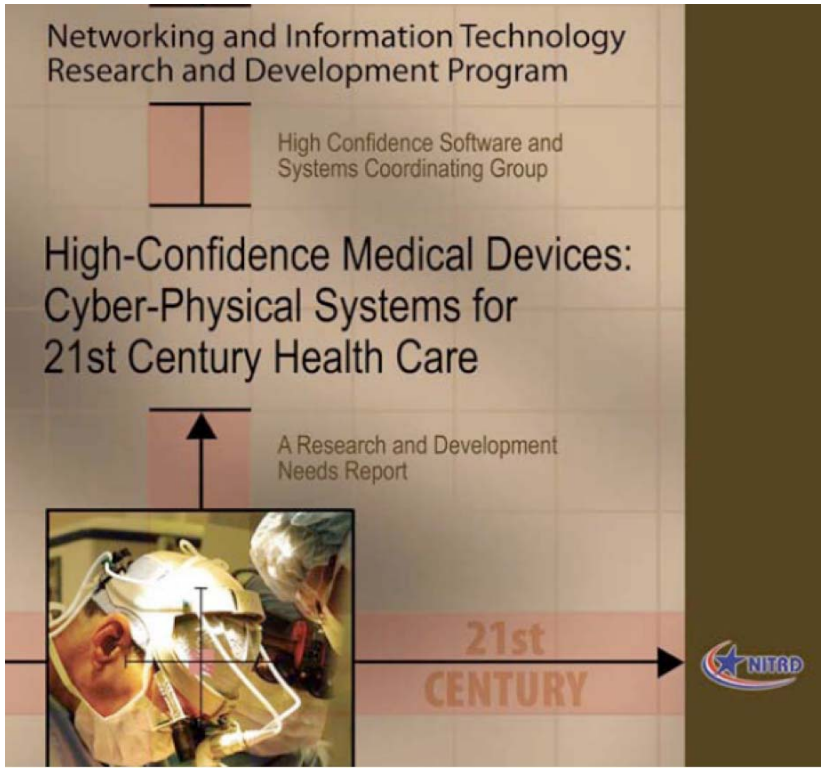
Developing Medical Device Software
ing the Model Driven Architecture

New ASTM standard for the Integrated Clinical Environment
For safe "plug-and-play" integration of medical devices



- April 2009: The 2nd Joint Workshop On High Confidence Medical Devices, Software, and Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability.
- 18 submitted papers - specific ICE standard-related implementation research

http://www.cpsweek.org/



Plug-and-Play Network Devices

Another enabling technology for the aforementioned vision is the development of plug-and-play networking technology for medical devices. Plug-and-play capability is needed to ease the setup of integrated point-of-care and extramural arrays of medical devices that communicate with a patient's electronic health record.

Devising the technology would require addressing concerns about privacy, security, safety, regulations, and technology. In hospital settings, for example, networks would form and reform frequently, as patients are admitted and discharged. Technology for the rapid formation of ad hoc networks needs developing. At the same time, authentication mechanisms would be needed to

MD FIRE

Medical Device Free Interoperability Requirements for the Enterprise

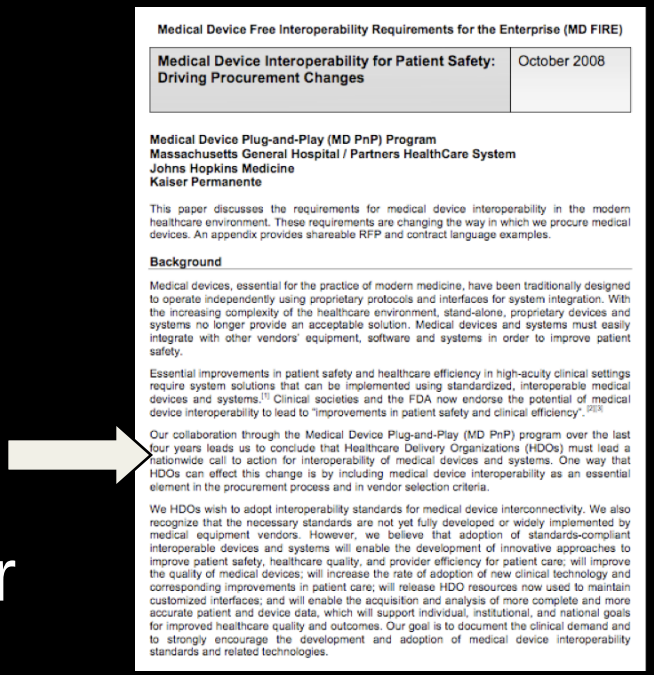
- Position Statement & Sample of Interoperability RFP and Contract language
- Developed by Mass General Hospital / Partners, Hopkins, Kaiser
- Conveys healthcare needs to industry, and simplify purchasing specifications
- Released Oct 17, 2008

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

Download MD FIRE from www.mdpnp.org

MD FIRE

"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."



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.

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.

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

RESOLVED, That our American Medical Association (AMA) believes 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. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well … ”

as of July 2009:

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

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

Financial Implications of standards-compliant medical device interoperability

- Kaiser Permanente: 2006 Analysis medical device-to-EMR integration costs with and without interoperability standards
- Devices: bedside monitors and ventilators
- Analysis excludes safety and workflow benefits
- Results: standard interfaces would reduce integration costs 30%
- Savings: ~ $12M annually

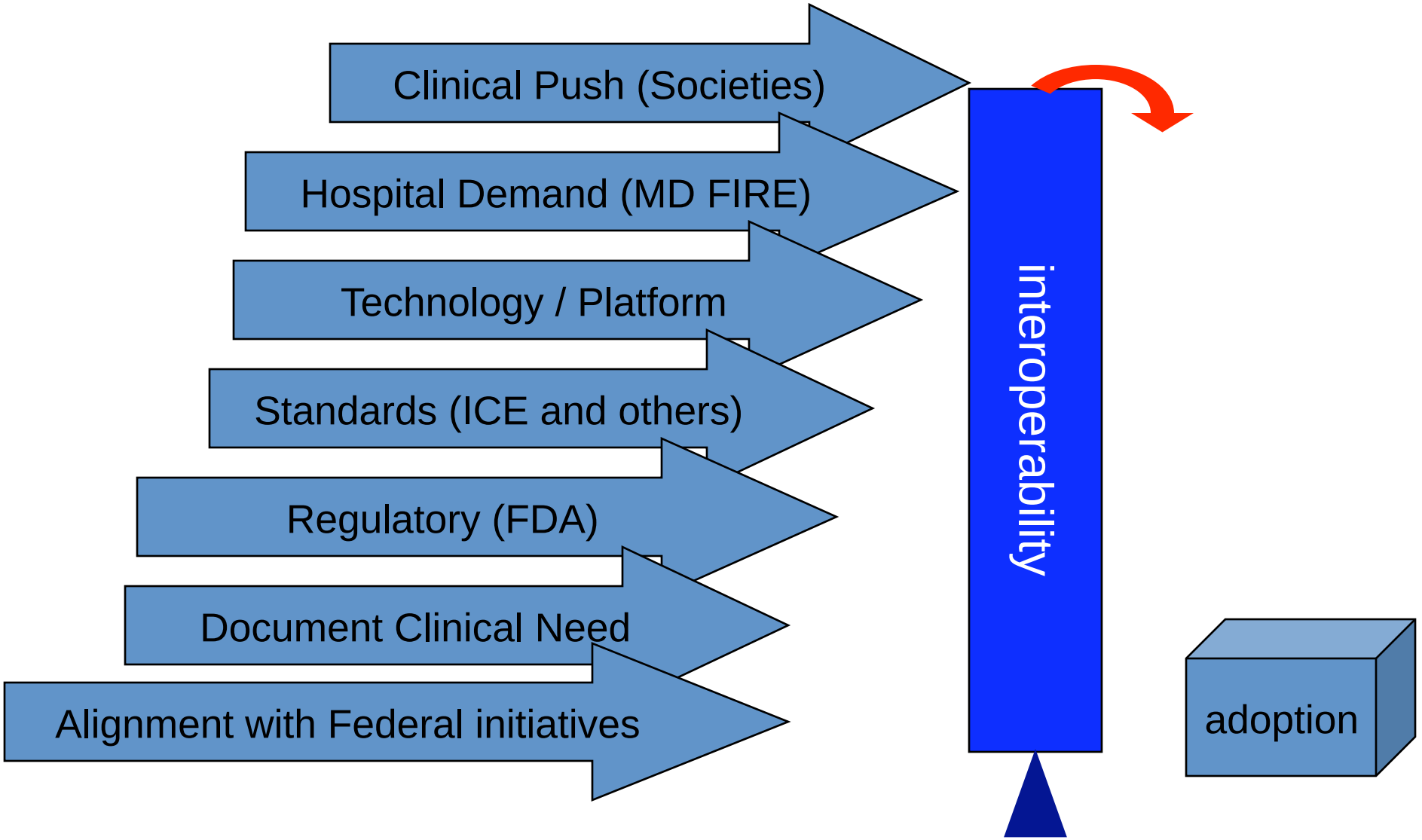
“Automation” in healthcare

- Automation has increased safety and efficiency in aviation, agriculture, manufacturing and some areas of healthcare (e.g. pharmacy).
- Example: Clinical workflow automation, dynamic smart checklists
- System integration and interoperability are necessary for automation

Attribution: L. Sha

MD PnP™
Getting connected for patient safety™

Will we reach the tipping point?



Our Vision

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

MD PnP™
Getting connected for patient safety™

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

MD PnP™
Getting connected for patient safety™

Contact info:
www.jgoldman.info

MD PnP Program:
www.mdpnp.org