Integrating the Clinical Environment to Improve Patient Safety at the sharp edge of healthcare delivery

Julian M. Goldman, MD
Medical Director, Partners HealthCare Biomedical Engineering Director, CIMIT/MGH Program on Medical Device “Plug-and-Play” Interoperability (MD PnP)
Attending Anesthesiologist, Massachusetts General Hospital
Let’s talk about problems, not solutions
Asystole (no cardiac activity). Really???

False/Nuisance Alarm problem: Single-signal analysis is not sufficient to create clinically meaningful alarms. Also, data is not captured for post-hoc analysis.
Peripheral Nerve Stimulator data -> AIMS

Interface was encrypted! Had to write software to connect PNS to EMR/AIMS (FDA MDDS regulatory implications)

Interface for data upload to PC (Fiber-Optic to RS232 line)
Problem – Alarm from pulse-rate counting error due to atypical waveform.

Issue #1: Should have option to suppress alarm if ECG HR, BP, SpO₂ are OK

Issue #2: Manufacturer cannot use data to improve SpO₂ algorithm. Because waveform data is not acquired

Result: False alarms, incorrect data in permanent record.
Interoperability could enable error resistance

Typical Patient Controlled Analgesia System

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

Why not monitor every patient? Alarm fatigue.

Solution: Smarter alarms + means to stop infusion prior to injury
• “A particularly attractive feature may be the ability to automatically terminate or reduce PCA (or PCEA) 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.

• 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.”

Problem was revisited at June 2011 workshop!
How do we prevent errors and injuries?

Cannot readily support complex workflow with available technology.

Cannot:
- Real-time allergy check
- Dynamic checklists
- Blood product checking
- App prototyping
Most ICU systems are not integrated ... but should be
You feel water dripping on your head!

What will you do?

- Look up?
- Go inside?
- Open umbrella?
- Call plumber?
- Join the water fight?
- Put on a hat?
- Stop the rain dance?
- Apply shampoo?
The HR is 64, what should the monitor do?

No alarm?
Low priority alarm?
High priority alarm?
Example of widely used smart alarm
Landing gear not down? -> Loud alarm

Contextual awareness requires data from several device and systems. Altitude, airspeed, etc.

Without context, landing gear alarm would be on at 30,000 feet!
You want accurate and complete data in the EMR?

What time is it?
ACT – appeared to have been checked 22 minutes after heparin administration (was actually 30 min). Could -> overdose. Cause – ACT device time incorrect (note - device does not use NTP).
EMR time stamp error

Blood gas analyzer in OR
Clock Times
Preliminary data (MGH, July 2011)

337 devices from 40 ORs and nearby storage/staging areas

• *Networked physiologic monitors*: 3-10 min errors (max one hour)
• *Infusion pumps*: 1-3 Hour errors (max 3.5 hours)
• *MetaVision EMR*: (hosted on PCs) some had 2-3 min errors
• *Wall clocks*: 5-10 min errors
• *Ultrasound machines*: 2-12 min error (max 3 hours)
• *Propaq transport monitors*: 7-30 min typical (max 90)
• *SEDLine*: 2-50 min (max 5 months)
Reference Date=07/11/11
Reference Time = 08:07:24
What is the cost of manual clock adjustment—twice /yr?

<table>
<thead>
<tr>
<th>MGH Data</th>
<th>MGH Hours/Year</th>
<th>National Projection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of person-hours</td>
<td>320</td>
<td>N/A</td>
</tr>
<tr>
<td>Number of devices</td>
<td>~1060</td>
<td></td>
</tr>
<tr>
<td>Total cost (Does not include overtime charges)</td>
<td>$16,160</td>
<td>$17,580,088 (from below)</td>
</tr>
<tr>
<td>Number of people involved</td>
<td>5 people * 2 days- 1 week</td>
<td></td>
</tr>
<tr>
<td>% Devices auto-timed on network</td>
<td>Less than 5%</td>
<td></td>
</tr>
</tbody>
</table>

| Hospital beds in USA*          | 944,277        |
| MGH + MGH OR Hours (2* 5 people*16 hours (2 days)*2 times a year) | (154*2) = 308 |
| MGH Beds**                     | 868            |
| Time/hosp bed                  | 0.35           |
| National time required (hours) | 3,35,066       |
| Cost: (may be underestimated)  |                |
| (MGH 5000+MGH OR 3080)* 2 times a year | $16,160         |
| Cost per Hospital Bed          | $18.62         |
| National Cost                  | $17,580,088    |

* Source: AHA
** Source: MGH Website

Preliminary data of study-in-progress by MD PnP program
MGH and BWH Ad-hoc Survey
Oct 2010

• “Smart monitors that look at multiple signals” from within a device and other devices to improve specificity & sensitivity
• Alarm priority and volume escalation by time, threshold(s), lack of response
• Remote/distributed alarms from isolation rooms
• Flag deviations from alarm default settings

• “Serial snapshots” of “important” data epochs (that did not cross alarm threshold) – e.g. arrhythmias
• More monitoring for more accurate and complete clinical picture – e.g. 24H BP monitoring
• Include more monitored data in EMR and d/c summary (alarm settings?)
MGH and BWH Ad-hoc Survey
Oct 2010

- Simplify setting of alarms. Implications of multiple settings (on/off) are confusing and resulting performance may not be as intended
- “synchronize” related alarm settings (e.g. arrhythmia processing level and alarms)
- Use historical data to help fine-tune alarm settings
- Configurable alarm tones

- Option to include waveform data in data log
Why have these been intractable problems?

• Multiple Parties: Physicians, Hospitals, Medical Device Manufacturers, FDA, SDOs
  – Not just a business problem
  – Not just a clinical problem
  – Not just a standards problem
  – Not just a software problem

• This is a healthcare systems problem and a formidable challenge
Network accesses latent capabilities

Connectivity, standard

- 1 Jetdirect inside 10/100 Base-T port
- 1 foreign interface harness (FiH) port
- 1 USB type A for adding accessories
- 1 USB type B for printing
- 1 open EIO slot
system integration should enable error-resistance

Example of a clinical procedure and associated safety issues ->

(From our “Clinical Scenarios” research repository)
Scenario: Surgical Fires

600 surgical fires each year in USA

Some of the most severe burns are caused by burning tracheal tubes
Airway Laser + O₂ -> Fire

- High inhaled O₂ concentration typically used for anesthesia
- But, O₂ enriched respiratory gas supports combustion, especially > 28% *
- Therefore, surgical team must “remember” to minimize O₂ prior to laser use in the airway

* ISO/TR 11991:1995
Airway Laser-O₂ Safety Interlock

1. Measure O₂ during anesthesia
2. Warn surgeon and prevent activation of airway laser if inspired O₂ > 28%

Solution requires connecting laser equipment and anesthetic equipment / O₂ monitor

App is NOT Commercially Available

(initially proposed in 1990s by Sem Lampotang, PhD, Univ. of Florida, Gainesville)
Scenario:
Failure to ventilate #1
Cardio-Pulmonary Bypass

Normal routine: Switch from anesthesia machine ventilator to cardiopulmonary bypass machine, and back to ventilator (after bypass)
Failure to Ventilate after Bypass

- Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.
- Anesthesiology. 87(4):741-748, October 1997
- “... 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.”

Almost every surgical team has experienced this error!
Cardio-Pulmonary Bypass

Smart system would provide warning if ventilator off and bypass pump flow = 0.

Solution is NOT AVAILABLE
Scenario:
Failure to ventilate #2
Example: Cholecystectomy (gall bladder removal) w/ intraop cholangiography (x-ray)

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

Breath hold -> improve x-ray quality.
“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.
Synchronize x-ray with ventilator:
@ expiration: cholangiogram, angiograms
@ inspiration: routine chest radiograph

Integration of devices into an integrated, networked system could improve safety by avoiding ventilator shut-off, improve image quality (especially on serial images), and decrease re-imaging.

Prototype solution has been demonstrated in MD PnP Lab
Application of novel devices and treatments

CCAT example: improving alarm sensitivity and specificity with “dual oximetry”
One SpO₂ probe on each hand
Urgent if both low. Send alarm to?
ICE facilitates novel strategies
Implementation:

• What is required to safely integrate these devices and implement a better, safer PCA system? Need ...
  
  • Combine devices from multiple vendors at the point of care (or 1 integrated product)
  
  • Reliable, effective plug-and-play connectivity
  
  • “App platform” to efficiently develop clinical decision support apps that can acquire data from, and control medical devices in real-time.
  
  • Device/network data log at system and device level forensic analysis
What could we accomplish in healthcare with open, interoperable platforms?

• Innovation
  – Rich contextual data (for clinical decision support)
  – Means for rapid prototyping of new sensors and algorithms
  – Facilitate validation for regulatory clearance
  – Swap devices as needed to optimize selection

• And what we have seen in other domains
  – Crowd-sourcing of “Apps”: If device platform is standardized, apps can be developed by global expert community
Essential Healthcare Needs

• **Needs:** Significant innovation in patient safety and healthcare efficiency require innovative, innovative system solutions.

• **Barriers:** Medical systems cannot be fully integrated due to the lack of effective interoperability of medical devices and Health IT systems. Even incomplete integration is expensive.

• **Solutions:**
  – “integrate the clinical environment” to create complete EHRs and error-resistant systems
  – Define a regulatory pathway in partnership with the FDA and other regulators
  – Investigate safety of proposed engineering solutions
Medical Device “Plug-and-Play” Interoperability Program (MD PnP)

Founded in 2004, the MD PnP research program is a multi-institutional community with Lab based at CIMIT, and supported by Massachusetts General Hospital (MGH), CIMIT, and Partners HealthCare.

Mission: lead the adoption of open standards and technologies for medical device interoperability to improve patient safety

Funding and Collaboration: DoD/TATRC, NSF, NIST, FDA, AHRQ, NIH, VAH
Standard for the “Integrated Clinical Environment”
ASTM F2761-09

“Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model”

Provides a standards-based system architecture intended to support safe medical system composition
Functional Elements of the Integrated Clinical Environment
ASTM standard F2761-09
Published January 2010
MD PnP NIH Quantum Grant

Development of a Prototype Healthcare Intranet for Improved Health Outcomes

Translation: The creation of an eco-system for interoperability of medical device and CISs in high-acuity environments to support innovation in patient safety and healthcare quality

Award: 5 Years: $10M

Collaborating Organizations:
CIMIT/Massachusetts General Hospital (Julian Goldman P.I.)
Anakena Solutions, California (Michael Robkin)
DocBox Inc, Waltham, MA (Tracy Rausch)
Penn (Insup Lee)
Kansas State University (J. Hatcliff)
Moberg Research, Ambler, PA (Dick Moberg)
University of Illinois at Urbana-Champaign (Lui Sha)
Tim Gee - Medical Device integration consultant

An HHS ONC Health IT SHARP affiliated program
“HealthCare Intranet”

To enable interoperable, reliable, private, secure, affordable, integration of medical devices and clinical information systems/EHRS to deliver innovative medical device “apps” to improve the safety, quality, efficacy, and efficiency of healthcare delivery.
Strategic Health IT Advanced Research Projects (SHARP) Program

SHARP Research Area Five/NIH Affiliate:
Medical Device Strategic HIT Advanced Research Project

Overview:
The MD SHARP project is led by the Medical Device Plug-and-Play (MD PnP) Interoperability Program based at CIMIT (Center for Integration of Medicine & Innovative Technology) and Massachusetts General Hospital (part of the Partners HealthCare System). MD PnP is an interdisciplinary, multi-institutional medical device informatics research program that seeks to improve patient safety and clinical efficiency by enabling standards-based integration of medical devices, and is developing a framework and capabilities for integrated clinical environments of the future. We have been working to accelerate the adoption of medical device interoperability by providing interoperability building blocks (use cases, standards, a neutral sandbox, and open research tools) and by changing clinical and market expectations of what can be achieved.

MD SHARP is a Quantum Project funded by the National Institute of Biomedical Imaging & Bioengineering at the NIH and adopted as an affiliate project of the SHARP program. The goal of the MD SHARP project is to develop a prototype healthcare infract for improved health outcomes, which includes an open platform and tools to enable clinical application development. Our platform is being designed to be compliant with the ICE standard (Integrated Clinical Environment, ASTM F2761) and will build on four core Clinical Scenarios, selected to represent common acute care devices and key device interoperability functionality.

The Main Themes Are:
- Safe integration of medical devices into patient-centric networked systems
- Synergy with current work on developing regulatory pathways for interoperable medical devices
- Development of testable clinical requirements for key aspects of medical device interoperability, including architecture and safety
- Development of safe hospital protocols for interoperable medical devices, including clinical decision support protocols with technical and process requirements
- Creation of validated, safe, reliable, secure, and re-usable software interfaces that are easily re-used by the medical device industry, Health IT vendors, academia, and government
- Updates and improvements to existing medical device interface standards
- Technical solutions to improve accuracy of medical device data time-stamps
- Creation of a simulated clinical environment and related tools where workflows, protocols, interactions, and technology can be tested and validated
Summary of Quantum Scenarios

1. PCA Safety Interlock, example of component-level medical device interoperability
2. ICU preparedness, example of in-hospital patient transfer and rich clinical context
3. Tele-health (TH) devices in hospital, example of transferring care from home to hospital and use of TH devices for high-acuity care
4. FDA regulatory – staged implementation of framework for levels of interoperability and associated levels of hazards and their mitigation
Clinical Scenario #1

PCA Infusion Pump Safety Interlock
**PCA INFUSION PUMP SAFETY INTERLOCK**

**Clinical Summary:** Hospitalized patient is receiving intravenous (IV) opioid medication by PCA. Patient is monitored with a pulse oximeter and respiratory CO$_2$ (capnography). An automated system monitors clinical data and IV pump status. If the medication depresses the patient’s respiration to an unsafe level, the supervisory system “app” detects the problem, stops the medication, and calls the nurse.

**Clinical Innovation:** Heterogeneous (multi-vendor) integration of monitors and actuators to improve PCA safety will be developed. Apps to improve the quality of real-time monitoring will be developed.

Scenario based on ASTM F2761-2009, Annex B PCA = Patient Controlled Analgesia
Quantum Clinical Scenario #1

**PCA INFUSION PUMP SAFETY INTERLOCK**

Technical Innovations:

“Component level” heterogeneous medical device plug-and-play interoperability, including rapid development of Clinical Apps that interact with devices in real-time

Scenario Extension: Use clinical data for real-time control of other medication infusions and devices
Mapping from ASTM ICE Standard to MD MP3

Diagram showing the network components:
- Caregiver
- Supervisor
- Network Controller
- Data Logger
- Adapter: PulseOx
- Adapter: Pump
- Adapter: PulseOx
- External Network
- Patient

The diagram illustrates the connections between these components.
Mapping from ICE to MD MP3
PCA Demonstration: Increased Alarm Specificity

Data fusion algorithm masks nuisance SpO$_2$ alarm (Context is adult PCA setting)

SpO$_2$ drops, but RR and PR are steady.

The pulse oximeter would typically alarm in this setting.

This is a nuisance alarm that can be masked, because more information is available.

Also implementing multiple trend analysis (RR, SpO$_2$) to increase sensitivity
Smart PCA monitoring system

- Plug-and-play integration of monitors/pump connected to patient.
- Hosts “apps” to detect respiratory problems -> stop IV pump
- Permits selection of “best” monitor and alarm algorithm at point of care

American Society of Anesthesiologists Scientific Exhibit October 2007

Exhibit recognized with First Place award
Clinical Scenario #2

Prepare ICU to Receive Post-OP Cardiac Patient
Quantum Clinical Scenario #2

PREPARE ICU TO RECEIVE POST-OP CARDIAC PATIENT

Clinical Summary: While patient undergoes CABG surgery in the OR, a decision support system reads, via medical device interfaces, medication infusions, lung ventilator settings, and medical devices/therapies being used. This information will guide ICU staff to prepare equipment and medication for the patient. ICU medical device settings are set automatically to OR settings (with clinician confirmation). Hospital protocol “checklists” will also be presented to the ICU team, and missing steps/data/devices will be automatically identified when possible.

Clinical Innovation: Intelligent device-related data transfer and setup, dynamic smart checklists, and reduction of nursing workload and errors related to complex patient transfers.

ICU: Intensive Care Unit; CABG: Coronary Artery Bypass Graft, or “bypass”
Quantum Clinical Scenario #2

PREPARE ICU TO RECEIVE POST-OP CARDIAC PATIENT

Technical Innovations:
• Querying complete status of medical devices in use (just as is routinely done with networked computers and printers)
• Configure medical devices. For example, read ventilator settings from OR brand X vent, translate to ICU brand Y ventilator terminology, and apply settings.
• “System readiness assessment” of clinical environment, prior to initiating care.
• Dynamic checklists for ICU staff: Alert to missing steps and devices, allergies
  • Example: Do not setup routine post-op medication or product (e.g. latex) if allergy (read remote allergy via NHIN)
Clinical Scenario #3

Use of Tele-health Devices in Hospital
Clinical Problem:
Data from home tele-health (TH) devices are typically monitored by a remote monitoring service. TH devices and their use paradigms are specialized. For example, patient identity is typically bound to data by a “home health hub”. Also, TH medical devices may not have clinical alarms, and even if they do, their standards/interfaces may not transmit alarms. When a patient wearing TH devices arrives in the Emergency Department (ED), how would the clinical data be accepted in the EMR? Will it be tagged as TH-sourced? How could the absence of device alarms be addressed?
Quantum Clinical Scenario #3

USE OF TELE-HEALTH DEVICES IN HOSPITAL

Clinical Summary:
Patient with chronic medical condition is wearing an array of tele-health (TH) sensors at home, and is monitored by a commercial remote disease monitoring service. The patient’s condition worsens, and in consultation with the medical team, the patient – still wearing the TH sensors – is transported by ambulance to the hospital Emergency Dept. On arrival in the ED, the TH devices are linked to the hospital IT network/EMR, enabling continuous monitoring of the patient on the hospital network. Clinical alarms are implemented with ICE Supervisor “apps”
Quantum Clinical Scenario #3

USE OF TELE-HEALTH DEVICES IN HOSPITAL

Technical Innovations:
• Hospital “grade” connectivity to TH devices
• Implementation of clinical alarms from TH devices (devices function as “thin sensors”)
• Use of hospital-located TH monitor data for real-time patient management:
  • TH device data provenance management
  • Patient ID-TH monitor data association in hospital environment
  • Time syncing of data from TH monitors
Scenario #3 Tele-health Devices in Hospital

Scenario extension:

Disaster Preparedness: TH devices in non-hospital setting to manage mass casualties. Uses TH sensors with high-acuity monitoring systems (e.g. nursing station monitors) designed for hospital use
Clinical Scenario #4

Increasing Levels of Interoperability of Medical Devices in Hospital (FDA PRS Scenario)
Quantum Clinical Scenario #4

INCREASING LEVELS OF INTEROPERABILITY OF MEDICAL DEVICES IN HOSPITAL (FDA PRS SCENARIO)

Regulatory Background:
Following the FDA workshop on medical device interoperability in January 2010, an interdisciplinary team formed the FDA Prototype Regulatory Submission Working Group (“PRS”) to analyze the hazards of, and risk mitigation strategies for, interoperable medical device systems, in order to inform future regulatory approaches. The PRS WG produced a “levels of interoperability” analysis which aligns risk with the complexity and clinical function of the system. This scenario is an implementation of the analysis developed by the PRS WG Jan 2010 – May 2011
Medical Device Interoperability, January 25, 2010

The public workshop was held on January 25 and 26, 2010, from 9 a.m. to 5 p.m. and on January 27, 2010, from 9 a.m. to 12 noon.

Location: The public workshop was held at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

FR Doc E9-30871

Related Document

- Transcript: Medical Device Interoperability, January 25, 2010 (PDF - 574KB)
- Transcript: Medical Device Interoperability, January 26, 2010 (PDF - 320KB)
- Transcript: Medical Device Interoperability, January 27, 2010 (PDF - 244KB)
Scenario #4 - Levels of Interoperability

• **1. Virtual Display**: Pulse Oximeter, ETCO$_2$ (end-tidal CO$_2$), and BIS (depth of anesthesia monitor) data are remotely displayed to monitor a patient during colonoscopy. Monitoring devices are exchanged to demonstrate interoperability.

• **2. Derived Alarms**: SpO$_2$ from pulse oximeter, and ETCO$_2$ and BIS signals are combined to create smart alarms (to detect medication-induced respiratory depression during procedure)

• **3. Virtual front panel**: manually control multi-parameter monitor and IV infusion pump through single integrated control panel to assist with patient management from outside of procedure room

• **4. Autonomous control**: use SpO$_2$, ETCO$_2$, BIS data for:
  – Safety interlock – e.g. Stop IV propofol pump if resp or BP low, or
  – Physiologic Closed Loop Control - Titrate infusion rate of IV propofol pump to target BIS value
  – And, create smart alarm and activate innovative alarm signal
Capabilities to consider

1. Collect “data” – consider accuracy, bandwidth, and completeness requirements
2. Decision support – consider quality, timeliness, and all of above
3. Tight integration/control – examples:
   - trigger NIBP cycle when PR changes 20%
   - Stop opioid infusion if respiratory deterioration
4. Safety/Performance/Security considerations – system properties based on requirements
   NOT bottom up based on communication standards (Wi-Fi, HL7, etc.) need system architecture
NITRD Report Feb 2009:

**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
Common Device Connectivity
AHIC Extension/Gap
December 31, 2008
Common Device Connectivity (CDC)

• HHS Office of National Coordinator for HIT Common Device Connectivity AHIC Extension/Gap Report:

  “Therefore, the requirements for 2009 Common Device Connectivity Extension/Gap can be summarized as … the ability to communicate high-acuity and inpatient multi and single parameter device information to and from an EHR and other specialized clinical information systems via direct network connections and wireless networking within an organization.”

Published December 2008
HITSP Device Connectivity Technical Note

HITSP/TN905

Submitted to:
Healthcare Information Technology Standards Panel

Submitted by:
Consumer Perspective Technical Committee
REPORT TO THE PRESIDENT
REALIZING THE FULL POTENTIAL OF
HEALTH INFORMATION TECHNOLOGY
TO IMPROVE HEALTHCARE
FOR AMERICANS:
THE PATH FORWARD

Executive Office of the President
President’s Council of Advisors
on Science and Technology

December 2010
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
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

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

Download MD FIRE from www.mdpnp.org
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.

Download: http://mdpnp.org/MD_FIRE.php
Reaching the tipping point

Clinical Push (Societies)

Hospital Demand (MD FIRE)

Technology / Platform

Standards

Regulatory (FDA)

Document Clinical Need

Alignment with Federal initiatives

interoperability

adoption
Integration of the clinical environment is required to:

• Acquire healthcare data comprehensively
• Support distributed healthcare workers in managing high-acuity patients
• Add error-resistance to patient care
• Enable compliance with data security, integrity, and privacy requirements
• Manage the connected devices
• Enable Apps for high-acuity healthcare

These needs are present across continuum of high-acuity healthcare: hospital, home, transport, etc.
The Commissioners' Plan of 1811 was the original design plan for the streets of Manhattan, which put in place the grid plan that has defined Manhattan to this day. It originated as a proposal by the New York State Legislature, adopted in 1811 for the orderly development and sale of the land of Manhattan between 14th Street and Washington Heights. The plan is arguably the most famous use of the grid plan and is considered by most historians to have been far-reaching and visionary.
When standardized clinical databases are populated via standardized data and system interfaces, Validated clinical “Business Rules” will be shared globally.
Contact info:
www.jgoldman.info

MD PnP Program:
www.mdpnpp.org