Medical Device Interoperability: "a wicked problem"

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DISCLAIMER: The views and opinions expressed in this presentation are those of the author and do not necessarily represent official policy or position of HIMSS.
Conflict of Interest Disclosure
Julian M. Goldman, MD

Has no real or apparent conflicts of interest to report.
Learning Objectives

• Recognize that broad patient safety and clinical care benefits could be achieved through the integration of medical devices and HIT systems in clinical environments

• Categorize and re-frame medical device interoperability barriers as “wicked problems” in which there is little agreement about “the problem”, no agreement on a solution, and problem solving is complex because of external constraints

• Using this framework, identify the barriers to medical device interoperability including technical, business, liability, standards, and regulatory factors
Essential Healthcare Needs …
Intractable Challenges

• **Needs:** Improvements in patient safety and healthcare efficiency require innovative technology and system solutions. Ability to integrate the clinical environment is an essential ingredient to create complete EHRs and error-resistant systems.

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

• **Solutions:** Understand and remove the barriers to interoperability.
How many minutes are remaining in this presentation?
How old is the data?

EMR time stamp error

Blood gas analyzer in OR
## Consolidated 4 Hospital Summary (Draft)

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<tr>
<th>Device Type</th>
<th>Count</th>
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<th>Average Offset</th>
<th>Maximum Offset</th>
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<td>0:00:53</td>
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## Incorrect dates

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<th>Device Location (Room)</th>
<th>Device Type</th>
<th>Manufacturer/Model</th>
<th>Date Picture Taken</th>
<th>Date on Device</th>
<th>Device Offset (DAYS)</th>
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<td>Patient Tower</td>
<td>Bladder Scanner</td>
<td>BVI 3000</td>
<td>11/7/2011</td>
<td>1/8/2012</td>
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<td>Adult ER</td>
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<td>OR</td>
<td>Hallway 1</td>
<td>Imaging System</td>
<td>Volcano S5 Cart Monitor</td>
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<td>Drager/ Evita XL</td>
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Note + and – offset
Time & Clock Errors

- Many medical devices do not set their clock using a network time reference (e.g. NTP)
- Manually set twice a year – Daylight Saving Time change
- No adopted standard for medical device time management
- EMR time stamping is configurable:
  - time stamp from medical device
  - time stamp when the data is acquired
- No method to maintain consistency among all time stamps contained in the patient’s EMR, correct clock errors, etc.
Why is “time” so hard to solve?

- Legacy medical device inventory
- Regulatory concerns impede product updates
- Lack of “customer demand”
- Limited documentation of problem
- Lack of alignment of needs and solutions
- Weak manufacturer incentives
- Lack of standards*

*JK
“Wicked Problem*” Definition

• Resistant to solutions
• Incomplete, contradictory, and changing requirements that are often difficult to recognize
• Due to complex interdependencies, the effort to solve one aspect of a wicked problem may reveal or create other problems

*C. West Churchman introduced the concept of wicked problems in a "Guest Editorial" of Management Science (Vol. 14, No. 4, December 1967 [Source – Wikipedia]
Patients can call to request more analgesia, but, cannot call for help when over-medicated.

Over-medication can cause respiratory and cardiac arrest.

Comprehensive monitoring is not typically used due to high false/nuisance alarm rate.

How can we improve safety of this system?

Solution: Smarter alarms with sensor fusion + capability to stop medication infusion prior to injury.
PCA Safety Issues are Pervasive …

http://ppahs.wordpress.com/2012/02/01/guest-post-yes-real-time-monitoring-would-have.saved.leah-2/
This is the story of an 11 year old who died from narcotic-induced respiratory depression. "Ten years after my daughter's death, nothing has changed in the codes of monitoring post-op patients continuously, until they leave the hospital. Alive."  

This is a statement from a multi-hospital coalition frustrated by ongoing adverse patient events: "A closed-loop system, which stops or pauses opioid dosing if respiratory depression is detected, is desirable. Systems are most ideally centrally monitored. In any case, alarms should be audible or otherwise available to the primary caregiver, and a mechanism for prompt response should be in place."

http://ppahs.wordpress.com/about/
"Carly Ann Pritchard … suffered an ankle injury and then underwent surgery to reduce lingering pain from her ankle injury. Unfortunately, although she survived surgery, she suffered brain damage because of an accidental overdose from a morphine-filled pain pump - after surgery. A California appeals court recently upheld a jury's award of about $9.9 million in damages."
PCA System needs the equivalent of smart cockpit alarm
Landing gear not down? ALARM

Contextual awareness requires data from several devices and systems. e.g. altitude, attitude, flap position, etc. And, we must respect the complexity of these safety critical systems
• “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!
Challenge of nuisance alarms and obtaining accurate data to stop PCA pump

Pulse oximeter shows oxygen saturation drop that is erroneous. Due to BP cuff inflation...
PCA Example: If devices could interoperate, smart PCA “App” could
A) increase alarm specificity (reduce nuisance alarms) & sensitivity (earlier warning)
B) stop the pump, and call nurse

Greater specificity
SpO₂ drops transiently, but Respiratory Rate and Pulse Rate are steady, therefore SpO₂ alarm is not activated.
This potential nuisance alarm has been prevented, because more information is available from other devices.

Greater Sensitivity: Respiratory depression may be detected earlier by monitoring trend of RR AND SpO₂. For example, detect small, gradual decrease in SpO₂ and RR that would not trigger current, conventional alarms.
Smart PCA monitoring system prototypes

- 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

Research prototype 2007
CANNOT IMPLEMENT due to Interoperability Barriers

2011 Version
Based on ASTM F2761 “ICE” architecture
Proposed 2014 National Patient Safety Goal on Alarm Management

Critical Access Hospital (CAH) and Hospital (HAP) Accreditation Programs

NPSG.06.01.01

1. CAH Improve the safety of clinical alarm systems.

Rationale:

2. Alarms are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety. This is a multi-faceted problem. In some situations, individual alarms are difficult to detect. At the same time, many patient care areas have numerous alarms and the resulting noise tends to desensitize staff and cause them to ignore alarms or even disable them. Other issues associated with effective alarm management include too many devices with alarms, default settings that are not at an actionable level, and alarm limits that are too narrow. These issues vary greatly among critical access hospitals and even within different units in a single critical access hospital.

11. There is general agreement that this is an important safety issue. Universal solutions have yet to be identified, but it is important for a critical access hospital to understand its own situation and to develop a systematic, coordinated approach to alarms. This NPSG focuses on managing alarms that have the most direct relationship to patient safety. As alarm management solutions are identified, this NPSG will be updated to reflect best practices. *

* Footnote: Additional information on alarm safety can be found on the AAMI website http://www.aami.org/htsi/alarms/index.html. ECRI has identified alarm hazards as one of the top technology hazards for 2013; more information can be found at www.ecri.org/2013hazards.
A system perspective is needed
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 interoperable medical systems
Integrated Clinical Environment - Simplified Architecture
From ASTM F2761-09

ICE System

ICE Manager
- Apps for PCA Safety, Smart Alarms, Remote Notification, Team coordination

ICE Supervisor (runs apps)

ICE Network Controller

ICE Data Logger

Medical Device or other equipment

EMR

ICE External Interface

Patient and Family

Clinicians
Mapping from ASTM “ICE” Standard
Improving the Quality of Clinical Alarms (requires interoperability)

1. Use “integrated platform” to create “smarter” alarms by using multiple data sources for earlier detection of events and more meaningful alarms by improving alarm sensitivity and specificity. (e.g. detect repeat small \( O_2 \) desats that would not currently trigger a conventional alarm). Crowd-source this activity.

2. Set “wider” alarm limits to decrease nuisance and false alarms on each monitor/device. (e.g. \( SpO_2 \) alarm at 80%). This maintains “device level” alarms.


4. Implement smart alarms and use capabilities to … (e.g. stop/adjust PCA)
Why has these been intractable problems?

- Solution Involves Multiple Parties: Physicians, Hospitals, Medical Device Manufacturers, FDA, Standards Development Organizations, Payers
  - Not just a business problem
  - Not just a clinical problem
  - Not just a standards problem
  - Not just a software problem
- This is a **medical systems problem** and a formidable challenge … or a “Wicked Problem”
Rittel and Webber's 1973 formulation of wicked problems in social policy planning specified ten characteristics:

1. There is no definitive formulation of a wicked problem (defining wicked problems is itself a wicked problem).
2. Wicked problems have no stopping rule.
3. Solutions to wicked problems are not true-or-false, but better or worse.
4. There is no immediate and no ultimate test of a solution to a wicked problem.
5. Every solution to a wicked problem is a "one-shot operation"; because there is no opportunity to learn by trial and error, every attempt counts significantly.
6. Wicked problems do not have an enumerable (or an exhaustively describable) set of potential solutions, nor is there a well-described set of permissible operations that may be incorporated into the plan.
7. Every wicked problem is essentially unique.
8. Every wicked problem can be considered to be a symptom of another problem.
9. The existence of a discrepancy representing a wicked problem can be explained in numerous ways. The choice of explanation determines the nature of the problem's resolution.
10. The planner has no right to be wrong (planners are liable for the consequences of the actions they generate).
Conklin later generalized the concept of problem wickedness to areas other than planning and policy:

1. The problem is not understood until after the formulation of a solution.
2. Wicked problems have no “stopping rule”.
3. Solutions to wicked problems are not right or wrong.
4. Every wicked problem is essentially novel and unique.
5. Every solution to a wicked problem is a 'one shot operation.'
6. Wicked problems have no given alternative solutions.

Why Innovation in Health Care Is So Hard?
Regina Herzlinger HBS 2006

**Players** - The friends and foes lurking in the health care system that can destroy or bolster an innovation’s chance of success.

**Funding** - The processes for generating revenue and acquiring capital, both of which differ from those in most other industries.

**Policy** - The regulations that pervade the industry, because incompetent or fraudulent suppliers can do irreversible human damage.

**Technology** - The foundation for advances in treatment and for innovations that can make health care delivery more efficient and convenient.

**Customers** - The increasingly engaged consumers of health care, for whom the passive term “patient” seems outdated.

**Accountability** - The demand from vigilant consumers and cost-pressured payers that innovative health care products be not only safe and effective but also cost-effective relative to competing products.
Barriers to PCA Safety as Example Wicked Nature of Interoperability

• Technology:
  – Infusion pump interface – pump cannot be stopped
  – Full physiological and clinical data not accessible
  – Connectivity infrastructure difficult to assure/assess

• Requires ecosystem of other devices
• Regulatory Concerns
• Liability Concerns
• Incomplete standards, limited 3rd party certification
What is “interoperability” – wicked definitions

• HIT systems
• Medical device – HIT
• Medical device – medical device
• Human-device; human-human
• Device Electronic Data Interface (EDI) direct connectivity vs gateway/sever port
  – Implications for clinical care; manufacturers
• Consumer electronics and computing – their definition?
When we – as a community - talk about interoperability, are we talking about the same thing?

- Can we create a common vision of the transformative capabilities of effective and “meaningful” interoperability.
- Context may be essential to understand data and create information.

The Big Bang Theory, Season 2 Episode 3 “AFK” 30s clip
How can we interpret ("validate") this desaturation episode in the EHR without BP device data or SpO₂ QoS data or waveforms?

Erroneous data in EHR

J Goldman, MGH, 2012
Problem – EHR documents incorrect Pulse Rate due to atypical pulse ox waveform. Other monitor data could be used to detect and reject this error. Waveforms should be recorded to improve device algorithms.

Result: False alarms, incorrect data in EHR.
False/Nuisance Alarm problem: Including pulse oximeter and BP data could be used to suppress the false “asystole” alarm
Pulse Ox set to:  
16 sec averaging time  
2 sec averaging time  
8 sec averaging time  

Simulator is set to create transient desaturation  
99%->70%->99%  

Pulse Oximeter averaging time must be known to interpret transient desaturations (e.g. Apnea Hypopnea Index)  
There may be recognizable pattern of transient desaturations before terminal desat
What are approaches to maintain medical device safety: 3 regulatory pillars

- **Pre-market**: Various means (standards, studies, etc.) to assess safety and effectiveness. May be a high bar (e.g. PMA)
- **Quality Systems** – used by manufacturers to support high integrity in development and manufacturing (tongue depressor won’t have splinters; ECG won’t electrocute patient)
- **Vigilance Systems (post-market)** – Track product performance in the marketplace*

*Problematic
Vigilance Systems: Medical Device Data Logging

- Medical device data logs are essential, but
  - Are not universally implemented
  - Are incomplete
  - May be in a proprietary format or encrypted
  - Usually have incorrect time reference
  - Difficult to align with data from other devices and clinical interventions
We have come a long way ... in some areas ...

But people still use Post-it notes for equipment problems!
Data Gaps

Example of data gaps today:
Physiological data is not recorded or is purged upon d/c
- Minimum HR?
- Reverse p waves?
- No BP recorded?

<table>
<thead>
<tr>
<th>Date Sent</th>
<th>11/20/2012 15:49:36</th>
</tr>
</thead>
<tbody>
<tr>
<td>Callback#</td>
<td>OR35, just brady to 30, went into junctional escape with reverse p waves. gave glyco</td>
</tr>
</tbody>
</table>

J Goldman
MGH, 2012
System Data Logging

• Is logging of one device that is independent of the “system” sufficient for our needs?
  – A device may function correctly, but can still have AE; analysis requires system data to address “device is OK, but patient is not”
  – How can one assess the clinical impact of a ventilator problem without complete data from
    • Ventilator – airway pressure, flow, etc.
    • Oxygenation monitor / pulse oximeter
    • Hemodynamic data (blood pressure etc.)
  – Planes, trains, and automobiles log data
What could we accomplish in healthcare with open, interoperable medical device app 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**
  - If device platform is standardized, apps can be developed by global expert community (analogous to crowd-sourcing)
Mostashari calls on vendors to play fair

Says some of their actions are "beyond the pale," and that if need be, ONC will issue more regulations

WASHINGTON | February 7, 2013

At a Feb. 6 meeting of the Health IT Policy Committee, National Coordinator for Health Information Technology Farzad Mostashari, MD, said that, by and large, electronic health record vendors have their customers' best interests at heart. But to the few who don’t, he gave a stern warning: Abide by what is "moral and right," or face more regulation.
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

US Federal Funding and Collaboration: DoD/TATRC, NSF, NIST, FDA, NIH, VAH
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 regulators
3. Elicit clinical requirements for the proposed interoperable solutions
4. Use our vendor-neutral laboratory to:
   • evaluate interoperability standards and solutions
   • serve as a community resource
5. Investigate safety of proposed engineering solutions
Voice of the MD PnP stakeholder community:
Interoperability requires many elements to be aligned

• Focus on **clinical needs** (patient & clinician)
• **Regulatory** obstacles
• **Liability** concerns
• **Business case for adoption**
• **Promote/develop/adopt suitable standards**
NIH/NIBIB Grant – 5yr/ $10M

Development of a Prototype Healthcare Intranet for Improved Health Outcomes

The creation of an eco-system for interoperability of medical devices and CISs to support innovation in patient safety and healthcare quality. Developing open platform, test-bed, standardized interfaces, verification and validation tools. App platform for smart alarms. WWW.MDPNP.ORG

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
FDA – CDRH/OSEL/DESE
VA – OHI/Office of JIV

An HHS ONC Health IT
SHARP affiliated program
MD PnP LAB

Center for Integration of Medicine and Innovative Technology (CIMIT)

65 Landsdowne St., Cambridge, MA
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, Johns Hopkins, Kaiser Permanente via MD PnP program
- Conveys healthcare needs to industry, and simplify purchasing specifications
- V 2.0 August 2012 – added VA
- Creative Commons License

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 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: mdpnp.org/MD_FIRE.php
RFP Text Example L: RFP Example for Implementation of a Specific Technical Standard: Network Time Protocol

Requests a complete description of specific functionality and interoperability capabilities. The text shown is only an example and would be expanded by the HDO in a detailed specification.

Current Interoperability Functionality: The Product must have the following capabilities:

- A reliable system clock in UTC that includes a full implementation of either Network Time Protocol version 4 (NTPv4) or Simple Network Time Protocol version 4 (SNTPv4) as specified by IETF RFC 5905 (see [http://www.ntp.org/rfc.html](http://www.ntp.org/rfc.html)).
- If the product supports manual or automatic local time zones, then the local time shall be based on an algorithm that utilizes UTC.
- If the product utilizes automatic or manual daylight savings time, then the local time shall be based on an algorithm that utilizes UTC.
- The product shall use local time or UTC for all user and electronic interfaces.
- If the product is unable to synchronize on UTC though the implementation of NTPv4 or SNTPv4, then the product will inform the user in an appropriate manner.
Transfer patient data and device settings using Connect, IEEE 11073, and ASTM F2761 “ICE”
ICE 2761-09 ICE Architecture

- Clinician
- ICE Supervisor - presents information and accepts operator controls to operate an ICE Device Suite
- Forensic Data Logger
- ICE Network Controller – Manages external Interfaces, and device controllers
- External interface (e.g. EMR)
- ICE Equipment Interface – Abstract devices and present a consistent interface
- Equipment
- Medical Devices
- Patient
A proposal to align national patient safety interests and break through “wicked” problems “HITSA”

- Need a national systems approach. What is the system? (healthcare related technologies)
- Health IT Safety Administration (HITSA) modeled on NHTSA
  - Adverse event reporting (expanded definition)
  - Regulated and non-regulated devices
  - Multi-stakeholder
  - Regulators, clinical representatives, manufacturers, etc.
PSQH
PATIENT SAFETY & QUALITY HEALTHCARE

MEDICAL DEVICE INTEROPERABILITY

NURSE LEADERSHIP
ELECTRONIC DOCUMENTATION
HOSPITAL ENGAGEMENT NETWORKS
POPULATION HEALTH MANAGEMENT
When standardized clinical databases are populated with standardized data, validated clinical rules or “Apps” will be shared globally.

Crowdsourcing of clinical apps could transform healthcare

J. Goldman, MD 2005-2012
It all began with a new way of thinking.
Thank You!

My contact info:
www.jgoldman.info

Medical Device Interoperability Program:
www.mdpnp.org