Medical Device Interoperability
to enable innovation at the sharp edge of healthcare delivery

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Current state

... at the sharp edge of high-acuity patient care ...
Forward-area Operating Room in Iraq

Critical Care Air Transport
Typical Operating Room
Clinical environments are crowded with complex, life-saving technology.
CIMIT/MGH OR of the Future Project

Center for Integration of Medicine and Innovative Technology

The ORF is a “living laboratory” to study the impact of process change, technology, and team work, on safety and productivity.
OR of the Future Suite at MGH

Self contained OR suite
Simulation courtesy of Dr. James Stahl, MGH
Real-time data integration
Using indoor positioning system
ORF Insights: “Close the Loop” (3 levels)

• Effective integration of devices and clinical systems could add error resistance and improve workflow – in the OR and beyond:
  
  ➢ close the workflow loop – provide notification of skipped steps, missing data. Example – blood sample not arrived in lab, dynamic checklists
  
  ➢ Smart Alarms require “contextual awareness” – alarms without context are a nuisance. Example – BP drops 20%. Is that OK?
  
  ➢ Safety Interlocks - require tight system integration. Example - Sync x-ray and ventilator, lockout PCA if O₂ < 90%
2005: Begann focus on HIT -> 2009 ARRA

January 27, 2005

Improving Care and Saving Lives Through Health IT

Today’s Presidential Action

- Today, President Bush visited Cleveland, Ohio, to highlight the benefits of health care information technology in saving lives and improving health care for all Americans. Better health information technology is essential to improving America’s health care system.

- The President’s Health Information Technology Plan is an important part of his overall health care agenda to make America’s first-rate health care safer, more accessible, and more affordable.

- The President’s budget for FY 2006 continues to support the use of health information technology by increasing funding to $125 million for demonstration projects that will help test the effectiveness of health IT and allow for widespread adoption in the health care industry. The Administration is also seeking an additional $50 million for FY 2005 (in addition to the $50 million already appropriated by Congress for FY 2005) to support the use of health IT.

- An important new step in the President’s health information technology plan is today’s announcement of the electronic prescribing (e-prescribing) proposed regulation by the Centers for Medicare and Medicaid Services (CMS) at the Department of Health and Human Services (HHS). This new E-prescribing regulation will improve the care seniors receive in Medicare by helping to bring electronic prescriptions to seniors when the prescription drug benefit takes effect in January 2006. It will also increase broader adoption of e-prescribing across the entire health care system.

But, exclusive focus on EMR is misplaced
• With expanding use of EMRS and increasing expectations, we are seeing limitations and latent problems emerging:
  – Different data on different system screens
  – Questionable time stamps for point-of-care data
  – Erroneous data in permanent record
Challenge – Accurate documentation and analysis of clinical data in EMR
Pulse Oximeter data in EMR and bedside monitor display.
Intermittent error counting pulse rate due atypical waveform.

Result: False alarms, incorrect permanent record.
Since no waveforms recorded, no possibility of algorithm refinement.
How would we interpret this electronic medical record?
“Protocol Watch: severe sepsis screening”

Nuisance alarm ... all night long!
Algorithm was missing data: temp, wbc, glucose, ...
Innovative algorithm, but requires connectivity and context to personalize

Sleep-deprived patient
Surprise! Pacemaker activity data is NOT part of EMR

System could not be personalized for this patient
ACT – appeared to be checked too soon after heparin administration

Cause – Time not synchronized to server (device does not use NTP)
Asystole (no heart beat). Really???

Clinicians/Engineers/Researchers/Innovators could make this better – if they could
MGH death spurs review of patient monitors

Heart alarm was off; device issues spotlight a growing national problem

By Liz Kowalczyk, Globe Staff | February 21, 2010

A Massachusetts General Hospital patient died last month after the alarm on a heart monitor was inadvertently left off, delaying the response of nurses and doctors to the patient’s medical crisis.

Hospital administrators said they immediately began an investigation, which led them to inspect and disable the off switch on alarms on all 1,100 of Mass. General’s heart monitors within a day of the death. The hospital also has temporarily assigned a nurse in each unit to specifically listen for alarms, out of concern that sometimes even functioning alarms can’t be heard over the din of a busy ward.

Patient safety officials said the tragedy at Mass. General shines a spotlight on a national problem with heart sensors and other ubiquitous patient monitoring devices. Numerous deaths have been reported because alarms malfunctioned or were turned off, ignored, or unheard.

“This is one of the most frequent and serious problems we see,” said Jim Keller, a vice president for ECRI Institute, a nonprofit research and consulting organization based in Pennsylvania that specializes in medical devices. On its top 10 list of health technology hazards last year, it listed alarms on patient monitoring devices as number two.

The Joint Commission, an Illinois-based organization that inspects and accredits hospitals, said it also has seen a surge in alarm-related incidents.
Keller, of ECRI, said the number of patients who have died or been injured because of problems with alarms is uncertain. Kathryn Pelczarski, director of ECRI’s applied solutions group, said a search of the US Food and Drug Administration database of adverse events found 237 reports of alarm-related deaths between 2002 and 2004. Of the 2,200 medical device problems hospitals reported to ECRI between 2000 and 2006, 12 percent involved alarms, said Pelczarski, whom hospitals often hire to help them fix technology problems.

“Alarm fatigue” is one of the most common problems she sees, where nurses and doctors are besieged with so many alarms that they lose their urgency.

Alarms have multiplied in hospitals as technology has become more sophisticated. A very sick patient could be hooked up to a heart monitor, a ventilator that assists breathing, infusion pumps that dispense medications, and a pulse oximeter that measures the oxygen level in blood. Each is equipped with alarms sensitive to small changes in a patient’s physiology.

“There may be so many alarms going off it sort of becomes the background noise,” Pelczarski said. “We have seen situations where all the nurses are responsible for all alarms within that unit and there is the assumption that someone else will get that alarm. I frequently see alarms turned down to the point of being inaudible.”

George Mills, a senior engineer at the Joint Commission, said early in the past decade, inspectors sometimes found that hospital staffers were so overwhelmed by alarms, they were muzzling them with gauze and tape and otherwise blunting the noise. After an educational effort by the organization in 2005, employees stopped overriding alarms and manufacturers improved new machines, in part by making them harder to turn off, he said.
Urgent Clinical Needs

• Needs: Improvements in patient safety and healthcare efficiency require systems solutions.
  – Medical systems cannot be fully integrated due to the lack of interoperability of medical devices and HIT systems, especially in high-acuity clinical settings.

• Solutions:
  – Ability to “integrate the clinical environment” is an essential step to create complete EMRS and innovative error-resistant systems, and requires medical device interoperability
  – Interop-> Integration -> Innovative System Solutions
Other industries have elegant and effective system solutions. Wouldn’t these capabilities be useful for patient care?
Consumer electronics have raised expectations
Real-time status

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Platforms enable innovation ...

**An iPhone gets Zipcar drivers on their way**

SAN FRANCISCO — The iPhone can do many things. Now it can even lock and unlock a car and start the engine.

Cambridge, Mass.-based car-sharing service Zipcar this week launched an app that lets you locate and reserve one of its vehicles, unlock it using the iPhone’s touch-screen and drive it off the lot.

"The iPhone is a pipeline for almost one-third of our members," says Luke Schneider, Zipcar’s chief technology officer. "This is something they have been asking for."

While there are many iPhone apps for autos, most are focused on directions, traffic, roadside assistance and games. Zipcar’s app is the first to control the operation of a car, which is why David Cole, chairman of the Ann Arbor, Mich.-based Center for Auto Research, calls it a "breakthrough."

"Once you have this kind of electronic ability in a cellphone, there’s no end to the type of technology you could bring to cars," he says.
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
3 Examples of clinical procedures and associated safety issues ->

(From our “Clinical Scenarios” research repository)
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 + O₂ -> Fire

• O₂ in respiratory gas supports combustion.
• If laser hits breathing tube, could produce devastating burn.
• Surgical team must “remember” to minimize O₂
A Solution: Laser-O\textsubscript{2} Interlock or smart alarm

- Monitor ventilator O\textsubscript{2} concentration. (This is already measured.)
- “Smart” safety interlock to prevent laser activation if O\textsubscript{2} > 25%

Proposed and published in 1999!

NOT Commercially available
Scenario:
Failure to ventilate
Heart-Lung (Cardio-Pulmonary) Bypass

Switch from anesthesia machine ventilator to heart-lung bypass machine and back.
“... 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!
Smart alarm system would provide warning if both ventilator and bypass pump are off.

NOT Commercially available

Should alarm if both are off
Typical PCA System

PCA = Patient-Controlled Analgesia

Patient can call to request more analgesia, but, cannot call for help when over-medicated.
Based on APSF Board of Directors Workshop
October 2006
APSF PCA Recommendations

• “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.”
Medical Device “Plug-and-Play” Interoperability Lab at CIMIT
Cambridge, MA
Opened May 2006
Photos includes collaborators from MGH, U Penn, and LiveData)
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” monitor and alarm algorithm at point of care
Absence of Interoperability is a Roadblock to Innovation

• Medical device interface requirements have not been fully elucidated
  – Important data is not transmitted via device interfaces
    • Contrast: Printer status can be read from personal computer
  – Devices do not expose control and other key functions over the network, so they are not available for use by other devices
    • Cannot lock-out PCA, trigger x-ray, pause ventilator
    • Contrast: Printer can be paused, paper tray selected via interface

• Safety and technology requirements to build systems of systems have not been well defined
Medical Device “Plug-and-Play”
Interoperability Program (MD PnP)

Massachusetts General Hospital and the CIMIT, with Army/TATRC and PHS IS 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
- **Liability** concerns
- **Business** case
- Promote/develop/adopt suitable **standards**
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
Selected initiatives and outcomes
FDA Workshop

- FDA Workshop on Medical Device Interoperability
- Co-sponsors: CIMIT and Continua Health Alliance
- January 25-27, 2010
- Dr. Chuck Friedman (ONC) presented crosswalk of medical device interop and M.U.
- Slides, Video available on www.mdpnp.org
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 (rev 2 in prep)

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

Download MD FIRE from www.mdppnp.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
Clinical Requirements

• Clinical scenarios are being collected from clinicians and clinical engineers to assure that interoperability standards and manufacturer-provided solutions will support clinical improvements in safety and efficiency. Scenario (or “requirements”) repository is used by collaborators, SDOs.
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
NSF: Cyber-Physical Systems Program (CPS) supporting research in medical device integration

NITRD Report:

**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
Functional Elements of the Integrated Clinical Environment
ASTM standard F2761-2009
Published January 2010

Integrated Clinical Environment (ICE)

ICE Supervisor

- External Interface
- Network Controller
- Data Logger

- ICE Interface
- Medical Device
- ICE Interface
- Other Equipment

Clinician

Patient
“ICE” Standard - Integrated Clinical Environment

- “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model”
- New standard describes requirements for safe and effective “plug-and-play” integration of devices in high-acuity environments
- Draft produced by MD PnP Program writing group convened under the authority of ASTM Committee F29: Published as F2761-2009 by ASTM International*
Scope of ASTM ICE Part I

“This standard specifies general requirements... for integrating equipment to create a Integrated Clinical Environment (ICE) ...

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 Annex B - Clinical context and clinical scenarios

1. Safety Interlock (PCA infusion)
2. Synchronization of equipment (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)
“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
Reaching the tipping point

Clinical Push (Societies)
Hospital Demand (MD FIRE)
Technology / Platform
Standards (ICE and others)
Regulatory (FDA)
Document Clinical Need
Alignment with Federal initiatives

Interoperability
Adoption
Our Vision

Improve safety and efficiency by changing expectations; changing technology; changing healthcare
When standardized clinical databases are populated via standardized data and system interfaces, validated clinical “business rules” will be shared globally.

Coupled with tools like “VB for HealthCare” or “LabView for Clinical Care.” This technology will change medical practice.
Contact info:
www.jgoldman.info

MD PnP Program:
www.mdpnp.org
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