Malignant Spaghetti
Wireless Technologies in Hospital Health Care
November 14, 2008

The “Operating Room of the Future”
and medical device interoperability:
preparing for system solutions at the sharp edge of healthcare

Julian M. Goldman, MD
Massachusetts General Hospital Depts. of Anesthesia and Biomedical Engineering
Director, CIMIT Program on Interoperability and the
Medical Device Plug-and-Play (MD PnP) Program
Boston, Massachusetts

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Contact information: www.jgoldman.info
Overview

1. Clinical Scenarios (Use Cases)
2. MD PnP Program scope and activities
3. Clinical society endorsements
4. Contracting Language
5. ICE Standard
Current state

… at the sharp edge of high-acuity patient care …
This is the current state
Reality
Clinical environments are crowded with advanced, life-saving technology
High-acuity care today:
How do we prevent errors?
How do we keep track of all this?
Demand 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
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.

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OR of the Future Suite at MGH

Self contained OR suite
Mass General Hospital/CIMIT
Operating Room of the Future
CIMIT “Center for Integration of Medicine and Innovative Technology”
an Engine for Inter-Disciplinary, Inter-Institutional Innovation

CIMIT Mission

To improve patient care by bringing scientists, engineers and clinicians together to catalyze development of innovative technology, emphasizing minimally invasive diagnostics and therapy.

- **Major Supporters & Collaborators:**
  - Partners HealthCare System
  - Department of Defense
- **Academic Medical Centers:**
  - Massachusetts General Hospital
  - Brigham and Women’s Hospital
  - Beth Israel Deaconess Medical Center
  - Children’s Hospital Boston
  - Newton-Wellesley Hospital
  - Boston Medical Center
- **Universities:**
  - Massachusetts Institute of Technology
  - Boston University
  - Harvard Medical School
- **Engineering/Research Laboratory:**
  - Charles Stark Draper Laboratory
- **Private Sector Companies:** 60+

“Program on Interoperability”

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LiveData OR-Dashboard

Patient: Claus, Santa
- M 23 M 14 kg
- MRN: P - 4585
- General Anesthesia
- OR #68
- Temp 71 F / 21 C

Procedure:
- Tracheoesophageal fistula repair, Pedi
- Gastrostomy tube placement, open
- Jejunostomy tube placement, Pedi

Staff:
- OR Nursing
  - Circ: Murphy, Mccrady
  - Scrub: Herrold, Guinevere
  - Circ: Hobbs, Raine
  - Scrub: Hiles, Gareth
- Anesthesiology
  - Attent: Larson, Bonnie
  - CRNA: Richardson, Shawn
- Pediatric Surgery
  - Prim: Herndon, Piety
  - Fellow: Hoffharts, Alex
  - Assist: Townsend, Wymond
- Other Surgery
  - Prim: Candies, Essie
  - Assist: Harper, Payton

Allergies:
- Latex
- Fentanyl
- Hydroxyzine
- Penicillin
- Lorzaepam
- Ketorolac

Progress Log:
- Pt. in room:
  - 12:12
- Time out:
  - 12:15
- Repair TEF:
  - 12:47 1 h 28m end

Patient Care Notes:
[12:07] Patient placed in standard supine position, both arms extended less than 90 degrees on arm boards, head placed on donut

Post-Op Information:
- Family is Waiting:
  - Gray Family
- Discharge Plan:
  - 23 Hour Observation
Confidential Information - Please dispose of this document in the appropriate bin for shredding.

MGH OR Schedule from 02/02/2007 thru 02/02/2007

<table>
<thead>
<tr>
<th>Room</th>
<th>Date</th>
<th>Time</th>
<th>Duration</th>
<th>Unit</th>
<th>Patient Name</th>
<th>Age</th>
<th>Procedure</th>
<th>Category</th>
<th>Anesthesia</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>49</td>
<td>02/02/2007</td>
<td>08:30</td>
<td>1:15</td>
<td>Unit</td>
<td></td>
<td></td>
<td>LAPEACHYLIOTOMY + OPEN</td>
<td>TRANSPORT</td>
<td>GENERAL</td>
<td>SCHEDULED</td>
</tr>
<tr>
<td>49</td>
<td>02/02/2007</td>
<td>11:45</td>
<td>1:15</td>
<td>Unit</td>
<td></td>
<td></td>
<td>LAPEACHYLIOTOMY</td>
<td>TRANSPORT</td>
<td>GENERAL</td>
<td>SCHEDULED</td>
</tr>
<tr>
<td>49</td>
<td>02/02/2007</td>
<td>14:00</td>
<td>1:00</td>
<td>Unit</td>
<td></td>
<td></td>
<td>PNEUMONAL HEMORRHAGE REPAIR</td>
<td>TRANSPORT</td>
<td>GENERAL</td>
<td>SCHEDULED</td>
</tr>
<tr>
<td>49</td>
<td>02/02/2007</td>
<td>15:45</td>
<td>2:15</td>
<td>Unit</td>
<td></td>
<td></td>
<td>LAPEACHYLIOTOMY</td>
<td>SAME DAY ADMIT</td>
<td>GENERAL</td>
<td>SCHEDULED</td>
</tr>
<tr>
<td>49</td>
<td>02/02/2007</td>
<td>16:00</td>
<td>2:15</td>
<td>Unit</td>
<td></td>
<td></td>
<td>LOW ANTERIOR RESECTION - AVAIL #1 MB 49</td>
<td>SAME DAY ADMIT</td>
<td>GENERAL</td>
<td>SCHEDULED</td>
</tr>
</tbody>
</table>

http://ppd.partners.org/ORWebSched/schedmain.html

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Real-time data integration
Using indoor positioning system
**Association**: Indoor Positioning System used to automatically determine the time of “start of anesthesia care” for documentation.
OR of the Future project perspective on device and data integration

• Comprehensive integration of data from clinical and environmental systems, can provide “error-resistance” and reduce inefficiencies across the continuum of care:
  – Smart Alarms requires “contextual awareness”
  – Workflow Support requires “closing the loop”
  – Safety Interlocks require system integration
  – Not limited to the OR: in the ICU, ER, home, etc.

• These solutions require seamless cross-vendor connectivity, which currently can only be provided by vertically integrated companies
  – Hospitals, researchers, and small companies cannot implement potentially important solutions

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Value of data integration:
Landing gear not down? -> Smart ALARM

Contextual awareness and safety interlocks require data from several device and systems
Interoperability => Empowerment

• We need to provide an infrastructure for innovation to create error resistant systems

• Medical Devices have a unique place in the “interoperability ecosystem”
  – 1. DATA - Medical Devices are key data sources (to EMR/CIS etc.)
  – 2. CARE DELIVERY - Medical devices can be better utilized to deliver care
  – 3. INJURIES - Medical Devices are at the sharp end of patient care. Adverse Events/Near Misses that involve medical devices must be mitigated using medical devices as part of system solutions
Examples of clinical procedures that could benefit from interconnected medical devices (system solutions) to address safety issues ->

(From the MD PnP “Clinical Requirements Repository”)

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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)

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Failure to Ventilate

- 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.”
Cardio-Pulmonary Bypass

Smart system would provide warning if ventilator off and bypass pump flow = 0.
Almost every surgical team has experienced this error!
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.
What are the “root causes”?

• Inadequate alarms?
• Inadequate vigilance?
• At its root, this is a system problem, because the ventilator never should have been turned off…
Synchronize x-ray with ventilator:
@ expiration: cholangiogram, CVP, CO
@ inspiration: routine chest radiograph

In this case, integration of devices into a networked, smarter system can improve safety by avoiding ventilator shut-off, improve image quality (especially on serial images), and decrease re-imaging.

Synchronization of Radiograph Film Exposure with the Inspiratory Pause
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Solution has been demonstrated in MD PnP Lab
Medical Device “Plug-and-Play” Interoperability Lab at CIMIT
Cambridge, MA
Opened May 2006
Photos includes collaborators from MGH, U Penn, and LiveData)
Ventilator - Xray Simulation at ASA Scientific Exhibit
October 15, 2006
End-to-End Approach of analyzing and prototyping X-Ray Ventilator Use Case

1. Elicited use case (STA conference in 2004)
2. Analyzed requirements and workflow (MD PnP multi-institutional interdisciplinary team)
3. Vetted by clinicians, vendor, engineers
4. Rapid prototype in lab
5. Public presentations, publication
6. Refinement with clinical data and clinical engineers
7. Inform change to existing ventilator standards (OR and ICU) and functions of “ICE” standard

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Based on APSF Board of Directors Workshop
October 2006

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Typical PCA System

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

PCA = Patient-Controlled Analgesia
APSF PCA Recommendations

• “A particularly attractive feature may be the ability to automatically terminate or reduce PCA … 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…”
Proposed PCA Safety Monitoring

Interoperability System

PCA Pump
Patient controlled Analgesia Pump

Clinician Interface

Computer

Nurse call

Patient

Monitoring system

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3- Workflow with monitoring systems and with interoperability
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

Exhibit recognized with First Place award
Clinical Requirements

- Clinical scenarios must be collected from clinicians and clinical engineers to assure that interoperability standards and manufacturer-provided solutions will support clinical improvements in safety and efficiency.
<table>
<thead>
<tr>
<th>Req #</th>
<th>Clinical Scenario</th>
<th>Current Hazards</th>
<th>Proposed State</th>
<th>Future Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLN-050</td>
<td>ESU causes interference on ECG</td>
<td>Risks to patient safety due to poor diagnostics</td>
<td>Notify devices of ESU activity to eliminate/reduce ESU interference, or flag bad data</td>
<td>none</td>
</tr>
<tr>
<td>CLN-011</td>
<td>Difficult to reposition patient, cables, devices due to cluttered physical environment (&quot;malignant spaghetti&quot;)</td>
<td>Devices could get disconnected, causing patient harm; it is difficult to maintain a clean environment with cables; visual paths of clinicians can be obstructed</td>
<td>Uncluttered environment, allowing appropriate communication between devices, information system, and patient; ease of movement of desired resources without barriers (NOT WIRELESS)</td>
<td>Possible interference of communication paths</td>
</tr>
<tr>
<td>CLN-052</td>
<td>Operating room lights and anesthesia task lights are not coordinated</td>
<td>Can end up in total darkness</td>
<td>Interconnect lighting, such that when room lights go off, anesthesia machine task light goes on</td>
<td>May want to work in the dark. Must permit override</td>
</tr>
<tr>
<td>CLN-048</td>
<td>Electronic medical record is missing medical device-generated data</td>
<td>Lack of adequate data for clinical decision-making</td>
<td>Comprehensive medical record, with capture of all medical device-related data in EMR: patient ID, personnel, equipment IDs, &quot;ESU on&quot; vs. &quot;ESU off&quot; (especially for later analysis)</td>
<td>EMR may become &quot;bloated&quot;, overly complex</td>
</tr>
<tr>
<td>CLN-017</td>
<td>Laser, x-ray use in the OR</td>
<td>Unprotected personnel may enter OR unknowingly</td>
<td>Laser/x-ray outputs network message for automatic notification within environment during laser use</td>
<td>Failure of notification system; wrong room, wrong device activated</td>
</tr>
</tbody>
</table>
Data integration is hard!
Example of cables required to connect devices to the Anesthesia EMR (AIMS)

The cables represent one aspect of the “interoperability barrier”
Medical Device Connectivity for Improving Safety and Efficiency

Julian M. Goldman, M.D.
Committee on Electronic Media and Information Technology

“Use wireless technologies to eliminate the ‘malignant spaghetti’ of cable clutter that interferes with patient care, creates hazards for the clinical staff and delays positioning and transport.”

“Synchronize the respiratory cycle of the anesthesia machine ventilator with portable X-ray exposure so that an X-ray will be triggered at end-expiration, thus avoiding the need to turn-off the ventilator for an intraoperative cholangiogram.”

“Trigger the portable X-ray at end-inspiration by synchronizing with the ICU ventilator.”

“Why can’t a pulse oximeter be connected to a PCA infusion and automatically interrupt the infusion and activate an alarm when a patient is hypoxic?”

“Support the recording of infusion pump data in the electronic anesthesia information system and permit control of the infusion rate at the anesthesia machine.”
these clinical scenarios represent ongoing system problems

• Isn’t it concerning that adverse events that can be predicted from clinical workflow analysis, may be reported in focus groups, and are documented in the literature, but solutions to mitigate these clinical hazards have not been adopted?
• Why are solutions not being implemented?
What is interoperability?

"The capability to communicate, execute programs, or transfer data among various functional units in a manner that requires the user to have little or no knowledge of the unique characteristics of those units”

*Definition of interoperability from ISO/IEC 2382-01, Information Technology Vocabulary, Fundamental Terms*
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.

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MD PnP Program collaborators 2004-2008

- NSF (National Science Foundation)
- Philips Healthcare
- and others

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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
2. Define a regulatory pathway in partnership with the FDA and other regulators.
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
What are we doing?

- Requirements
- Researching safe design
- Standards - ICE and others
- Education/Outreach
  - Clinical user - what is possible
  - Manufacturer - what is needed
Workshop/ Lab Demos: June 2007

Videos from June conference agenda available at http://www.cimit.org/mdpnjpjune07/start.htm

Insup Lee, Rob Kolodner, Julian Goldman
What is the scope of effective high-acuity medical device interoperability?
There are two distinct – but closely related – capabilities of medical device interoperability that are required

1. Bidirectional medical device data communication

2. Medical device control capability to permit the integration of medical devices into networks to produce “error-resistant” systems.

“Control” should be defined as exposure of selected features or device functions over the network, to enable classes of clinical scenarios cases. (Example: “activate pre-set ventilatory pause to enable an x-ray”).

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The ultimate goal of the MD PnP Program is to **improve patient safety** by enabling the integration of automated oversight and intervention into clinical systems, and managing the emerging complexity of networked medical devices and IT systems.

**Current Practice**

- Care team is *solely* responsible for patient safety & risk mitigation

**MD PnP Vision**

- Implement redundant safety mechanisms in a smart clinical system
- Leverage the power of system integration

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MD PnP Program leads initial development process by
• Defining system function and architecture
• Driving market creation
• Identify and analyze requirements
• Engaging industry, advising

Industry can lead implementation and deployment based on the framework developed by the MD PnP Program

Regulatory Agencies Provide guidance and implement regulatory processes
“with great power comes great responsibility” - SM

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Clinical Society Support of Interoperability

“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.

We also recognize that, as in all technological advances, interoperability poses safety and medico legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit.”

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Medical Device Free Interoperability Requirements for the Enterprise

• “MD FIRE”
• Developed by MGH, Partners, Hopkins, Kaiser
• To convey healthcare needs to industry, and simplify purchasing specifications
• RFP and Contract samples
• Standards-based
• Released for public use Oct 17, 2008
  – See www.mdpnp.org

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“ICE” Standard - Integrated Clinical Environment

- New draft 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:
  - Will be completed Q3 2009 by ASTM International
  - http://www.astm.org/DATABASE.CART/WORKITEMS/WK19878.htm

Additional information available at www.MDPnP.org
ICE Functional Diagram
Scope of ICE Part I

“This International Standard specifies requirements for integrating equipment to create the Integrated Clinical Environment (ICE). It 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.”

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Figure 1: Functional Elements of the Integrated Clinical Environment

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 ICE Part I NWIP
September 2007

Current draft: http://mdpnp.org/ICE.html
The ICE supervisor supports i.a. 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 ICE Part I NWIP September 2007
Figure 1: Functional Elements of the Integrated Clinical Environment

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11 external interface

From ICE Part I NWIP
September 2007

Current draft: http://mdpnp.org/ICE.html
The ICE network controller supports i.a. 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 mechanism
- 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 ICE Part I NWIP September 2007
Adoption of medical device interoperability (standards and technologies) will support:

1. Complete, accurate electronic medical records
2. Reduce errors caused by manually entered data, and provide single “source of truth” for patient ID and other key data
3. “flight data recorder” to facilitate adverse events analysis
4. Rapid deployment of devices in makeshift emergency care settings
5. Clinical decision support systems and smart clinical alarms
6. Support of remote healthcare delivery
7. Automated system readiness assessment (prior to starting invasive clinical procedures or critical care transport)
8. Reduce cost of devices and their integration, and reduce accelerating EMR-adoption costs
9. Closed-loop control of therapeutic devices and safety interlocks (e.g. ventilation, medication and fluid delivery)
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 Alarms.”

This technology will change the world.

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Contact info:
www.jgoldman.info

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