Plug-and-Play Medical Device Interoperability (for the Operating Rooms of the Future)

A multidisciplinary program to standardize communication and control of medical devices to improve patient safety and healthcare efficiency

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Hello from Boston!
Standards that Work

Ethernet, Internet, USB memory
From This

Farnam Operating Amphitheatre, Yale New Haven

http://www.ynhh.org/general/history/oldsur.html
To This (next slide)
“minimally invasive surgery” yields “maximally invasive” technology!
Typical OR: Advanced surgery, modern equipment, “legacy” supporting systems
Problem

• The Health Care industry is facing demands to improve efficiency, clinical outcomes and safety against a backdrop of escalating costs.

• Haphazard introduction of new technology into a complex environment may lead to increased cost and increased risk of adverse events.
What is an “operating room” today?

• The convergence of
  – advances in computing (hardware and software)
  – imaging (optics, illumination, image capture and storage)
  – surgical instrumentation
  – energy delivery systems
  – (and, economic pressure,)

  has lead to the introduction of new surgical techniques and the blurring of traditional distinctions between “surgery” and “Interventional Medicine”.

What is an “OR of the Future”?

- The “Operating Room of the Future” (ORF) is not a specifically configured OR.
- “ORF” is shorthand for a constellation of emerging innovations in processes and technologies for perioperative care.
- The “ORF” may include:
  - Surgical robots
  - Minimally invasive surgery suites
  - Redesign of the perioperative environment
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.
Massachusetts General Hospital

- 875 bed quaternary care center
- 50 Operating Rooms
- Roughly 30,000+ operations per year
  - 14,000 ambulatory
  - 16,000 inpatient
  - 2.4 cases per OR-day
CIMIT: Center for Integration of Medicine and Innovative Technology
Re-engineering the perioperative process: The ORF

- Improve processes
- Improve ergonomics
- Integrate technologies
- Optimize patient safety
- Increase throughput
- Improve staff satisfaction
- Maintain protected research environment
ORF development process...

2000 Discovery
- Assemble Team
- Visit other sites
- Identify technology needs and industry partners

2001 Model-Design
- Built discrete event simulation model
- Validated concept of 3 rooms and parallel processing
- Computer Animated Model

2002 Construction
- Full Size Mock up
- Est. new model for multi-industry collaboration
- Industry: 9 Partners > $2m
- Installation of IPS

2003 Implementation
- Final revision for positioning equipment
- Training: Multiple dry runs
- Room opened Aug 2002
- 150 Cases 9/1-12/31
- 50% reduction in turnover
- Education-Outreach: Live post grad course
- Won Healthcare Design Team Award

2004-2005 Measure - Iterate
- Outcome Measurement:
  - Built discrete event simulation model that validated concept of 3 rooms and parallel processing
  - Computer Animated Model
  - Final revision for positioning equipment
  - Training: Multiple dry runs
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Outcome Measurement:
- Validated IPS and expanded to comparable OR.
- Industry: Collaborated on 4 SBIRs with small businesses.
- Team training: Designed 1st interdisciplinary OR team simulation
- Education-Outreach: >25 publications
- Part of DOD ORF Nat'l Initiative
- Won Healthcare Design Team Award

Outcome Measure:
- Refine analysis by modeling, predicting and then measuring effect of different patient flow schemes, staffing and technology
- Technology: Application of RFID and other sensors to develop new generation "smart devices" and integrated software applications to improve OR flow and resource utilization and patient centric Zone of Safety
- Convened consensus conference on PnP

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Self contained suite of rooms
Induction Room

Courtesy of Dr. W. Sandberg
Entering OR
Perioperative patient transport
Click and go
Optimized monitor placement

Can placement be automated?
Bedside surgical interface
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.
The President is “…committed to his goal of assuring that most Americans have electronic health records within the next 10 years”

“Adopting Uniform Health Information Standards to allow medical information to be stored and easily shared electronically … standards for transmitting X-rays over the Internet; electronic lab results transmitted to physicians …”
Daily News - June 16, 2005 - Thursday

Frist, Clinton unveil healthcare IT bill
Source: Healthcare IT News / Author: Caroline Broder, Senior editor

Frist, Clinton to introduce healthcare IT bill
Senate bill offers incentives for healthcare IT investment
Dodd healthcare IT legislation (S. 1223)
Email the writer
Email the editor

WASHINGTON — Senate Majority Leader Bill Frist (R-Tenn.) and Hillary Rodham Clinton (D-N.Y.) today introduced bipartisan legislation designed to create a healthcare information technology system where data can be easily exchanged over a secure network. The bill, which tracks closely with projects already under way within HHS, offers $125 million annually during a five-year period for local or regional health IT infrastructure projects.

Speaking at a news conference at George Washington University Hospital in Washington, D.C., Clinton and Frist touted IT's use in healthcare as a way to eliminate inefficiency, reduce costs and improve care.

"We ultimately will be saving lives and saving dollars," said Frist, who is a licensed physician.

What’s missing?
"I GIVE UP. WHERE'S THE PATIENT?"
Reality
Reality
Iraq

Reality
Cables required for MGH EMR
Battle of the foot pedals
HIT and the Medical Device “Last Mile” Problem

• Proposed Health Information Technology innovations address many critical problems in medical record-related data communication

• Patient and clinician interaction with medical devices is not receiving the same attention

• Diagnosis and therapy is usually performed with medical devices!
The Roadblock to Innovation

• The OR is a complex and potentially hazardous environment

• We rely on teamwork and a patchwork of systems to mitigate hazards instead of using automated safety systems (e.g. “interlocks”) and exception error notification.

• **Clinicians are not empowered** by information technology to achieve complete situational awareness, or to network and control medical devices in the environment
  - **Absence** of smart alarms and automated clinical decision support
  - **Absence** of technological infrastructure to implement the required solutions
Would you fly without landing-gear position indicators?
Safety Interlock

Safety interlock at 100° F (38° C).
Interlocks

- Motels
- Individual devices
- Generally, NOT across medical device systems
Insufflation-induced problems:
Opportunity for improving safety through interlocks

Should insufflation be permitted if the NIBP isn’t cycling?
Benefit of medical device interoperability: Synchronization to mitigate hazard

Ventilation stopped during intraoperative cholangiography
Clinical Hazard Mitigation: Examples of Proposed Safety “Interlocks”

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Description</th>
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<tbody>
<tr>
<td>(example: Inadvertent car movement when engaging gear)</td>
<td>Abdominal CO2 insufflation may cause adverse vital sign changes</td>
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</table>

We need assisted vigilance because it is impossible to for humans to be eternally vigilant.
“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.
BP is low -> Stop Infusion

Interoperability: Remote Control

Run down the hallway
Isolation Precautions!
- Hat
- Mask
- Gloves
- Gown
Blood pressure is still dropping!
Why is interoperability so difficult to implement?

• The OR is a clinical, non-engineered, environment
• ORF PnP problem space is at the nexus of hardware, software, and networking technologies
• Prior efforts failed to achieve interoperability
• Poorly-defined safety and business models
A “Holy Grail”: Smart Alarms & Decision Support

- Require data fusion
- Seamless data acquisition and display
- Derivation of contextual information from rich data sources -> Context
Context Example

• Your head is wet!
• What should you do?
Example of the challenge of “Smart Alarms”

Pulse Oximetry (SpO₂) monitor
Question: Appropriate alarm, or nuisance alarm?

Utility of alarm depends on what will happen next ...
(Home monitoring or pre-operative setting)

If the patient is an adult with Obstructive Sleep Apnea (OSA)
If the patient is an adult with Obstructive Sleep Apnea (OSA)

The two *nuisance* alarms reveal desaturations that occur every night, and probably do not require immediate intervention.

J. Goldman, MD 2005
This patient has just received an **opioid** for pain relief.

Alarm heralds a potentially catastrophic desaturation! An intelligent system would have to know all the relevant contextual information.

J. Goldman, MD 2005
What contextual data was required to produce clinically meaningful alert?

- Oxygen saturation value ($\text{SpO}_2$)
- Patient demographics
- Co-morbidities (e.g. sleep apnea)
- Treatment environment (OR, hosp room, PACU, home, etc)
- Medications administered (dose, time)

CONTEXT!
Deriving Context by Association

• Radianse IPS
• Allow CONTEXT-base analysis or association
• Identify start of anesthesia care. Associate:
  – Patient tag
  – Anesthesiologist’s tag
  – Present in induction room
Radianse Indoor Positioning System (active RFID + IR)
**Association**: Using Indoor Positioning System used to automatically determine the time of “start of anesthesia care”
Data Fusion

- Common display of disparate signals and data
- Integrate data to facilitate decision support
- Apply clinical algorithms (protocols) to produce intelligent alarms
  - Current clinical alarms reliably announce violation of parameter threshold – but may be clinically irrelevant
  - Improve sensitivity of clinically useful alarms
  - Improve specificity – reduce false and nuisance alarms (by interpreting data in context of other information)
Future State

*Future State with ORF PnP in place: Comprehensive Data Communication*

- Data collection and population of the EMR would be seamless
- Data fusion from disparate devices would simplify extraction of information from data
- Remote (wired and wireless) control would be routine
  - Extend clinician’s reach
  - Permit safety interlocks
- Decision support would be enabled
  - Intelligent information display
  - Smart (adaptive) Alarms
- Closed-Loop Control would be routine
ORF PnP at Work: Device Control

- Device-device control, safety interlocks
- Remote user actuation of devices
  - Bedside control of devices beyond reach, using innovative Human-Device Interfaces
- “Distributed” medical devices
  - distribute CPU, HCI, sensor networks, etc.
  - Physiologic Closed-Loop control Systems
    - (ISO/IEC JWG5 and ASTM F29.21)
“Utopian State” ORF PnP at Work

EMR + Clinical “Rules” Interface
Rules/Alarm settings, Process Exceptions

Remote alarms and data presentation

Vital Signs

Patient data (demographics, labs)

Medical device state

Clinical Context (e.g. stage of procedure) Image recognition, motes, etc.

J. Goldman, MD 2005
(If systems are standardized) Validated Clinical “Rules” Could be Shared Globally

This technology will change the world

J. Goldman, MD 2005
## ORF PnP System Attributes

<table>
<thead>
<tr>
<th>Capability</th>
<th>Safety</th>
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<tbody>
<tr>
<td>Ubiquitous data acquisition and presentation</td>
<td>√</td>
</tr>
<tr>
<td>Decrease technology deployment barriers</td>
<td></td>
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<tr>
<td>Enable safety interlocks</td>
<td>√</td>
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<tr>
<td>Extend connectivity of healthcare environment</td>
<td>√</td>
</tr>
<tr>
<td>Enable decision support</td>
<td>√</td>
</tr>
<tr>
<td>Enable adaptive alarms, closed loop control, sensor networks</td>
<td>√</td>
</tr>
<tr>
<td>Hot-swappable networked medical devices</td>
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Mission of Medical Device Plug-and-Play Program

The mission of the medical device plug-and-play interoperability program (MD PnP) is to lead the development and adoption of non-proprietary networking standards and ancillary systems to enable widespread clinical use of medical device data, and to enable network-based medical device control, to enable innovation in patient safety and healthcare efficiency.
Goals of MD PnP Program I/II

• Guide the development and adoption of bus-independent open networking standards to support medical device interoperability

• Define a safe “least-burdensome” regulatory pathway for any proposed system in partnership with the US FDA. Identify pathway that will support PnP concept, i.e., that will not require re-validation or re-clearance of entire system as each new independently validated device is added to PnP network.

• Elicit high-level user requirements for MDPnP; refine and deploy first for the ORF – as the ORF PnP domain.

• Develop a PnP lab “sandbox” populated with medical devices and test equipment to:
  – evaluate the performance of proposed interoperability standards
  – model clinical use cases (in simulation environment)
  – develop and test related network safety and security systems
  – perform interoperability and conformance testing
Goals of PnP Program II/II

- Develop and test archetypal use cases to demonstrate potential safety benefits of improved medical device interoperability and verify alignment of proposed interoperability standards with clinical requirements
- Convene diverse stakeholders and maintain their engagement.
- Identify sustainable funding pathway
- Establish a National Center for Medical Device Interoperability and Patient Safety
ORF PnP Program

• WG1 Clinical Requirements
• WG2 Regulatory and Legal
• WG3 System Architecture
• WG4 User Interface
www.ORFPnP.org

Operating Room of the Future
Developing a Plug-and-Play Open Networking Standard

Plug-and-Play Interoperability for the Operating Room of the Future
A multidisciplinary project to standardize communication and control of medical devices in the OR of the Future.

The purpose of this website is to disseminate project information and to provide Working Group web forums. The Working Group forums provide an online community and are open to all project contributors. Please register and participate at www.orfpnp.org/workgroups/index.php.

The latest plenary meeting for this initiative took place on November 15-16, 2004, hosted by the FDA, and focused on assessing the regulatory framework and developing functional requirements for medical device plug-and-play standards.

A clinical requirements focus group session was held at the annual meeting of the Society for Technology in Anesthesia (STA) on January 13th. Check this website again soon for the results of that session and more upcoming events!

You can view the presentations from the May 2004 CIMIT/TATRC-sponsored kick-off symposium on the CIMIT/ORF website http://cimit.org/orfpnp.html.

Julian M. Goldman, MD
Massachusetts General Hospital
contact information

For information about the OR of the Future project: www.CIMIT.org
## Plug-and-Play Connectivity for the Operating Room of the Future

Multidisciplinary project to develop standards for communication and control of medical devices in the O.R. of the Future

You last visited on 29 Sep 2004 05:36 am
The time now is 29 Sep 2004 12:12 pm

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<td>25 Aug 2004 07:10 am Julian Goldman</td>
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<td>15 Sep 2004 05:27 pm Todd Cooper</td>
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<td><strong>Nov 2004 Meeting Planning</strong>&lt;br&gt;Planning for November 2004 meeting at FDA in Rockville, Maryland</td>
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<td>14 Sep 2004 11:23 am Sue Whitehead</td>
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<td><strong>Clinical Requirements (WG1)</strong>&lt;br&gt;Essential requirements and wish lists for ORF PnP connectivity. Working Group 1 Leader: John Howse, MD (Kaiser Permanente) Moderator: John</td>
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<td>No Posts</td>
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<td>2</td>
<td>23 Sep 2004 02:47 pm Jennifer Henderson</td>
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## Meetings to Date

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<tr>
<th>Meeting</th>
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<th>Attendees</th>
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<th>Govt</th>
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<td>Cambridge</td>
<td>84</td>
<td>43</td>
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<td>At ASA Oct 04</td>
<td>Las Vegas</td>
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<td>2&lt;sup&gt;nd&lt;/sup&gt; PnP Nov 04</td>
<td>FDA</td>
<td>75</td>
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<td>At STA Jan 05</td>
<td>Miami</td>
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FDA Nov 15-16

- Two-day meeting hosted by FDA in Rockville
- 75 attendees
- Federal agencies (NIST, NSF, TATRC)
HCMDSS

• High-Confidence Medical Device Software and Systems
• Multi-agency involvement (NSF, NIST, FDA, NITRD, DoD, NSA)
STA: January 13, 2005

- Society for Technology in Anesthesia
- Miami
- Session attracted 50 clinicians and engineers, users and producers
“Requirements”

• High-level functional clinical requirements
• Prep sheet for STA:
  – Abe Abramovitz (Datascope)
  – Rob Clark (Draeger)
  – John Robinson (Philips)
  – Robert Tham (GE)
Instructions for Requirements Session

• The proposed standards could permit seamless connectivity of medical devices to allow data communication and control of medical devices.
• The unique challenge of this project is that we are striving to develop an infrastructure for innovation. Therefore, it is important to define the high-level general system requirements without getting bogged down in the details of technical specifications.
• Manufacturers need to know what you want the system to do, so that they can determine how to best provide the desired functionality.
• Think of examples of connectivity that could a) solve current clinical problems, b) improve safety or efficiency, or c) enable innovative clinical systems of the future.

• Assume that there are no technical, economic, legal, or regulatory obstacles to deploying a comprehensive ORF PnP system.

• What clinical challenges exist today that could be solved by the proposed system?

• Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?

• How would this approach affect the practice environment, both clinically and from a business perspective?

• What risks may be introduced by a PnP system, and how could they be mitigated?
working on requirements = messy
Example of Clinical Rule

- Clin example: central line w/low platelets
- Risk profile changes; decision to go/no go may change; operator experience requirement may change
- One solution: Comprehensive integrated data display; easily identify potential risk factors, and relative or absolute contraindications to procedure.
- Sounds great. Won’t work
- Need automated system based on comprehensive automated contextual analysis and process exceptions with medical smart dust monitoring of the environment
- (Figure w/animations to illustrate process)
PnP Interoperability Lab “Sandbox”

- Open this summer at CMIT/MGH
- Work with U Penn, Live Data, Drager Medical, IXAAT, GE, to develop demonstration safety interlock systems and integrated data displays
  - Ventilation synchronization
  - Insufflation Interlock
  - Insufflation smart alarm
- Develop open-source standards “reference models”
Inside the OR of the Future

Judy LaRusu Reddy

As technology like laparoscopy and minimally invasive surgery continue to gain acceptance in the OR, we need to ask ourselves, how does it all work together? Will it work in our OR? Will we need to change our OR design to accommodate these changes? Will the technology work in our facility?

A MILAN study was done to determine if the technology works. The results were published in the Journal of the American College of Surgeons. The study found that laparoscopic surgery was associated with a shorter length of stay and a lower rate of complications than open surgery. This study was done at a single institution, but it is hoped that future studies will be done to confirm these findings.

The results of this study are encouraging, but we mustn’t forget that technology is only as good as the people who use it. As technology continues to advance, we must continue to train our staff to use it effectively. We must also continue to evaluate the technology to ensure that it is meeting the needs of our patients.

In conclusion, the technology is here. We just need to make sure that we are ready to use it. We must be sure to evaluate the technology to ensure that it is meeting the needs of our patients. We must also continue to train our staff to use it effectively. Only then can we truly say that we are ready for the OR of the future.
Plug-and-Play in the Operating Room of the Future

Julian M. Goldman, Richard A. Schrenker, Jennifer L. Jackson, Susan F. Whitehead

Although intraoperative patient safety has improved significantly, the OR is still a complex and potentially hazardous environment where clinicians depend on teamwork and a patchwork of systems to mitigate hazards instead of using automated safety systems. Surprisingly, smart alarms and automated decision support tools are still absent from the clinical environment. Clinical engineers and clinicians have proposed innovative technical solutions to mitigate clinical hazards, but they cannot affordably implement novel solutions when real-time medical device data acquisition or control is required. Partly as a result of the lack of medical device interoperability, many self-evident improvements have been predicated, and safety
Challenge: Difficult to update legacy systems and standards
Is this where we are today?
Which would you rather have?

“running on empty”

Legacy medical systems

“time to empty”

Future medical systems
Thank you

www.orfpnp.org

julian@acmeanesthesia.com