The OR of the Future: 
Current activities and 
Health IT implications

Julian M. Goldman, MD
Director, CIMIT Program on Interoperability, and
Medical Device “Plug-and-Play” Interoperability Program
Depts. Of Anesthesia and Biomedical Engineering
Massachusetts General Hospital and Harvard Medical School
Boston, Massachusetts
Lecture Goal:
You will be able to answer 2 Questions

- What is an “OR of the Future”?
- How can the Health IT community improve patient safety in acute care environments?
Massachusetts General Hospital

- Established 1811 (Ether demonstrated in 1846)
- 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
A trip down memory lane...
The early days

Farnam Operating Amphitheatre
Yale New Haven
http://www.ynhh.org/general/history/oldsur.html
Fast forward
Clinical environments are crowded with technology

Anesthesia EMR or AIMS
(Anesthesia Information Management System)

Lifesaving surgery using modern equipment in typical older OR
Typical OR: Advanced surgery, modern equipment, "legacy" supporting systems
The Paradox: “minimally invasive surgery” yields “maximally invasive” technology!
The ORF is a “living laboratory” to study the impact of process change, technology, and team work, on safety and productivity.
CIMIT: Center for Integration of Medicine and Innovative Technology

CIMIT Mission: To improve patient care by facilitating collaboration of engineers and clinicians to catalyze development of innovative technologies emphasizing minimally invasive diagnosis and therapy.
Re-engineering the perioperative process: Goals of the ORF

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

1999-2000 Discovery

- Assemble Team
- Technology scavenging

2001 Model-Design

- Computer Animated Model
- Outcome Measurement: Built discrete event simulation model that validated concept of 3 rooms and parallel processing
- Full Size Mock up
- Est. new model for multi-industry collaboration

2002 Construction

- Industry: 9 Partners > $2m
- Training: Multiple dry runs
- Room opened Aug 2002
- 150 Cases 9/1-12/31
- 50% reduction in turnover
- Education-Outreach: Live post grad course

2003 Implementation

- >780 cases performed (9-5PM)
- Team training: Designed 1st interdisciplinary OR team simulation
- Education-Outreach, publications
- Part of DOD ORF Nat’l Initiative
- Won Healthcare Design Team Award

2004-2007

- Measure - Iterate

Outcome Measurements
- Applications of RFID
- Convened consensus conference on interoperability (MD PnP program)
Simulation courtesy of Dr. James Stahl
ORF Suite at MGH

Self contained OR suite

Control  Emergence  Induction

OR
Induction Room
Induction of anesthesia
Entering OR

Photo: Dr. W. Sandberg
Click and go
Emergence/early recovery room
<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>Attending</th>
<th>Service</th>
<th>Anesthesia</th>
<th>Category</th>
<th>Procedure</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>49</td>
<td>02/02/07</td>
<td>09:30</td>
<td>1:15</td>
<td>Unit</td>
<td></td>
<td></td>
<td>BERGER, DAVID L.</td>
<td>GENERAL</td>
<td>GENERAL SURGERY</td>
<td>TRANSPARENT</td>
<td>LAPAROSCOPIC CHOLECYSTECTOMY</td>
<td>SCHEDULED</td>
</tr>
<tr>
<td>49</td>
<td>02/02/07</td>
<td>14:00</td>
<td>1:00</td>
<td>Unit</td>
<td></td>
<td></td>
<td>BERGER, DAVID L.</td>
<td>GENERAL</td>
<td>GENERAL SURGERY</td>
<td>TRANSPARENT</td>
<td>PIQUROSAL HERNIA REPAIR</td>
<td>SCHEDULED</td>
</tr>
<tr>
<td>49</td>
<td>02/02/07</td>
<td>12:20</td>
<td>1:30</td>
<td>Unit</td>
<td></td>
<td></td>
<td>BERGER, DAVID L.</td>
<td>SAME DAY</td>
<td>SAME DAY ADMT</td>
<td>GENERAL</td>
<td>LOW ANTERIOR RESECTION: AVAIL 49 EM</td>
<td>SCHEDULED</td>
</tr>
<tr>
<td>49</td>
<td>02/02/07</td>
<td>16:00</td>
<td>2:15</td>
<td>Unit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6 1818 -> PRA8

2 - Thin Horse Attack
5 - Red
6 - Staff Damage
6 - Pich
1 - Bulk 35% Bone
1 - Bulk 35% Bone
2 - Dile Vam
2 - Cloud 1 - Start
21 - Rabid LRM - Scared
22 - whiskey 2x - Bored
26 - LRM star - depressed
24 - C
27 - Power Grid
28 - PM Beam
29 - eco - Better/Hidden
33 - fret 1 - Larp
LiveData OR-Dashboard

Patient: Claus, Santa
Gender: M
Age: 23 M
Weight: 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, Mccraday
  - Scrub: Herrold, Guinevere
  - Circ: Hobbs, Rainie
  - Scrub: Hiles, Gareth

- **Anesthesiology**
  - Atten: Larson, Bonnie
  - CRNA: Richardson, Shawn

- **Pediatric Surgery**
  - Prim: Herndon, Piety
  - Fellow: Hoffhants, Alex
  - Assist: Townsend, Wymond

- **Other Surgery**
  - Prim: Candles, Essie
  - Assist: Harper, Payton

- **Induction room**
  - Downing, Hubert
  - Next Patient

Case Setup: 150 HR, 50 SpO2, 100 BIS, 75 PA, 200 Insufflation
Time Out: 65 HR, 65 SpO2, 100 BIS, 60 PA, 150 Insufflation
Intraop: 65 HR, 65 SpO2, 50 BIS, 60 PA, 30 Insufflation

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

Case Log:
- Case 4545 (x - 07:55): 06:00
- Case 124575 (08:00 - 12:15): 08:00
- Case 4585 (12:14:15): 12:00
- Case 8181 (16:00 - 18:00): 16:00
Optimized monitor placement
Re-direct traffic
“Perioperative Nurse”

- Trained to perform pre-op and *PACU functions
- Admits patient in induction room, checks records and consent forms, applies anesthesia monitors
- Visits OR to obtain update on patient status
- Recovers patient for 10-20 minutes
- Transports patient to PACU (and performs handoff to PACU nurse)

* PACU = “post anesthesia recovery unit”
Perioperative Nurse
Perioperative Nurse
Perioperative Nurse
Perioperative Nurse
Perioperative Nurse
Benefits of Emergence Room or “early recovery room”

- Early transport out of ORF (even if asleep/intubated or airway not completely stable)
- Proximity permits easy management by surgical team
- Buffer PACU waiting list
- Eliminate PACU transport delay (18-> 3 min!!)
- All of these factors reduce non-operative time
### Results of Process Changes

<table>
<thead>
<tr>
<th>Process Variable (minutes)</th>
<th>ORF Mean ± SE</th>
<th>Traditional OR Mean ± SE</th>
<th>p values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total wait time</td>
<td>55 ± 3.2</td>
<td>80 ± 3.2</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Pre-anesthesia wait time</td>
<td>6.6 ± 1.4</td>
<td>14.9 ± 1.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total pre-op anesthesia time</td>
<td>49 ± 3</td>
<td>64 ± 3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>OR pre-op anesthesia time</td>
<td>13.5 ± 1.5</td>
<td>31.8 ± 1.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>OR emergence time</td>
<td>8.3 ± 1.3</td>
<td>18.7 ± 1.1</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

N = 124 consented patients

All of the times controlled by anesthesia are markedly reduced. This has translated into a substantial and reproducible improvement in OR throughput as compared to traditional ORs. The ORF can accomplish as many as 10 general surgery cases (laparoscopic and open) during regular working hours. (Sandberg et al, 2004)
Clash of technology ...
The joy of legacy systems …

Provides an excellent opportunity to introduce errors into the EMR!
What is an “ORF”?

- 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.
- These *may* include:
  - Surgical robots
  - Minimally invasive surgery suites
  - Innovative Health Information Technologies
  - Redesign of entire perioperative environment
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
ORF perspective on data integration

• Comprehensive integration of data from clinical and environmental systems, using the latest computer-science methodologies, will prevent errors and inefficiencies
  – Smart Alarms
  – Decision Support
  – Workflow support
“I give up. Where’s the patient?”
Cables required for various monitors to connect to Anesthesia EMR
Lessons from the ORF

• Pushing the boundaries of “traditional” care and has revealed the limitations of current systems

• Advanced technology teases us with the promise of integrated and “error resistant” systems, but these latent opportunities have not been realized.

• Intractable problems:
  – “One off” solutions are not practical
  – Absence of medical device interoperability is a costly barrier to safety innovation
Iraq

Reality
Reality
Remember telephone plugs B.S.?

B.S. = Before Standardization
Point-of-Care Medical Devices (wired ⇒ wireless and mobile)

- Monitors
- Oximeter
- Infusion Pumps
- Bar Code Scanner
- BP

Data Integration, Analysis, and Display

- Cell / PDA
- Tablet PC
- Workstation
- Medication Station
- Electronic Medical Record

Medication Station

Electronic Medical Record
Interoperability is better now ...

Ethernet, Internet, USB memory
Interoperability has become pervasive

• The Consumer Electronics Experience is changing expectations:
  – USB memory, printers, and other hardware may be connected by consumers to computers with no expensive programming required.
  – Standard data formats allow digital pictures and documents to emailed and viewed anywhere.

Connectivity is used to support “safety interlocks” at the system level in many potentially hazardous products.
  – Example: The cruise control is disengaged when the brake pedal is pressed.
Apple, Cisco Reach Accord Over iPhone

By NICK WINGFIELD
February 22, 2007; Page B4

Apple Inc. and Cisco Systems Inc. agreed to resolve a trademark dispute over the term iPhone that had threatened to put a damper on the introduction of Apple's most eagerly anticipated electronics product in years.

Under their agreement, Cisco, of San Jose, Calif., and Apple, of Cupertino, Calif., are free to use the iPhone trademark on their respective products throughout the world. Cisco will drop a lawsuit it filed against Apple in federal court in San Francisco, accusing Apple of infringing on a Cisco trademark with a forthcoming cellphone called the iPhone, due out in June.

In a joint statement, Apple and Cisco said they will explore opportunities for making their products work better together "in the areas of security, and consumer and enterprise communications." The companies said other terms of the settlement are confidential, declining to comment further.
Everywhere* but Healthcare

- Healthcare has minimally benefited from standards based interoperability.
- Focus has been on the “xHR”. Successes have been at IT-level data transfer (HL7, DICOM), not at Biomedical Engineering level (patient connected devices)
- Advances in patient safety and healthcare efficiency cannot yet benefit from interoperability of medical technology.

*almost everywhere. DRM is a notable exception
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 has not received the same attention
- Diagnosis and therapy is usually performed with medical devices!
Problems with Discharge Summaries

“The current method of discharge summary production and distribution is unacceptable. The high number of errors (36.4%) and the low rate of receipt (27.1%), indicates that resources invested in the production of the discharge summary could be better utilized to improve information transfer.” [NSW Australia] General practitioner-hospital communications: a review of discharge summaries. J Qual Clin Pract. 2001 Dec;21(4):104-8.

• We must improve quality of records (like the discharge summary) before we introduce systems to distribute them widely.
Why interoperability?  
The Acute-Care End-Game

- Create context for decision support using data from devices and databases
- Free clinicians to explain clinical needs, and free marketplace to deliver solutions
  - Improve patient safety
  - Improve workflow efficiency
- Decrease cost of ownership of medical devices and hospital networks.
  - KP CIS integration cost is ~ 40% TCO
  - Interoperability standards will save KP ~$40M annually for 10 years.
Example of Safety Interlock

Brake / Automatic Transmission
Value of data integration:
Landing gear not down? -> **Smart ALARM**

**Contextual awareness and safety interlocks require data from several device and systems**
Planes, trains, automobile. Why not medical devices?

- Single-vendor device integration is easily achievable
- Devices from multiple vendors, assembled by end users or system integrators, run into interoperability barriers
5 examples of clinical procedures that could benefit from connected medical devices
Airway Laser-O$_2$ Interlock

- Measure inspired O$_2$ during anesthesia
- Prevent activation of airway laser if O$_2$ > x

NOT AVAILABLE

- (Doctorate thesis project of Sem Lampotang, PhD, Univ. of Florida, Gainesville)
Cardio-Pulmonary Bypass

Smart system would provide warning of ventilator off and CPB pump flow = 0. I found one anesthesiologist who has NOT forgotten to ventilate after CPB.
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

Example: Cholecystectomy
“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/need more coffee?
- At its root, this is a system problem
Solution: “synchronization”

Synchronize or “gate” x-ray to expose image at end of expiration. We are implementing this use-case in the MD PnP Lab.
MD PnP Lab at CIMIT
Cambridge, MA
Opened May 2006
Ventilator - Xray Simulation at ASA Scientific Exhibit
October 15, 2006
A 49-year-old woman underwent an uneventful total abdominal hysterectomy. Postoperatively, the patient complained of severe pain and received intravenous morphine sulfate in small increments. .. while in the post-anesthesia care unit (PACU), she began receiving a continuous infusion of morphine via a patient-controlled analgesia (PCA) pump. A few hours after leaving the PACU and arriving on the floor, she was found pale with shallow breathing, a faint pulse, and pinpoint pupils. The nursing staff called a “code” and the patient was resuscitated and transferred to the intensive care unit on a respirator... The patient ultimately died.

-AHRQ Morbidity and Mortality website

PCA = Patient-Controlled Analgesia
PCA Monitoring

• Treating pain can be hazardous
• Can we reduce the risk of pain management by using patient monitors already in our hospital inventory to monitor on patients PCA medications?
• Goal: Integrate monitors with an intelligent “controller” to:
  – Detect respiratory disturbance
  – Lock-out pain medication infusion NOT AVAILABLE
  – Activate nurse-call

PCA = Patient-Controlled Analgesia
Proposed PCA Safety Monitoring

PCA Pump
(With patient button)

User Interface

"Computer"

Nurse call

Interoperability System

Patient

Monitoring system

Krishnan & Cortes and
MD PnP Program
MGH dept. of BME, 2006
Challenges

• Algorithm development
  – Data to design PCA monitoring algorithms is limited, because hospitals cannot currently connect to devices!!

• Device integration
  – Today, cannot easily integrate monitors, infusion pump, and nurse call to implement safety interlock. Especially from multiple manufacturers.

• Liability
  – Is the system a new medical device? Who will be responsible for failures?
  – Solution: Record all alarms and data to support QA/forensic analysis and vendor cooperation
Are these good ideas?

• If so, then why don’t we have them available in our hospitals?
• Why not connect these devices and solve these problems?
• Because “one-off” solutions complicated and expensive, and there are concerns about regulations and liability.
MD MP3 ™
Medical Device Plug-and-Play Platform

• Key “ecosystem” functions for delivering point-of-care technologies:
  – Plug and play architecture
  – Data logging
  – Security (e.g. for HIPAA compliance)
  – Device authorization

• Support data acquisition, decision support, actuator control

• Share with other research groups for other applications
Overview of the Medical Device “Plug-and-Play” Interoperability Standardization Program (MD PnP)

MGH and CIMIT (Center for Integration of Medicine and Innovative Technology) initiated a program in 2004 to lead the adoption of open standards for medical device interoperability to improve patient safety.

Three 2-day plenary sessions, smaller meetings, and clinical focus groups have elicited input to shape the mission and strategy and identify clinical requirements.

Over 65 institutions and > 500 experts (clinicians and engineers) are involved. Many support provider-mandated conformance to interoperability standards.
What is the scope of effective medical device interoperability?
There are two distinct – but closely related – capabilities of medical device interoperability:

1. **Data communication** capability will enable complete and accurate data acquisition by the EMR/AIMS from medical devices. Comprehensive data acquisition will support the development of remote monitoring, advanced clinical decision support systems, and intelligent alarms.

2. **Medical device integration** capability will permit the control of medical devices into networks to produce “error-resistant” systems with safety interlocks to decrease use-errors, closed-loop systems to regulate the delivery of medication and fluids, and remote patient management (e.g. remote ICU).
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.

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
   - model clinical use cases (in simulation environment)
   - develop and test medical device network safety and security systems
   - serve as a resource for medical device interoperability
MD PnP Program collaborators

- Massachusetts General Hospital
- Brigham and Women’s Hospital
- Draper Laboratory
- Dräger Medical
- Partners Healthcare
- Kaiser Permanente
- LiveData
- Penn University of Pennsylvania
- CIMIT
- TATRC
- MITRE
- FDA
- CDRH
- Geisinger
- and, NIST
- NSF
- American Society of Anesthesiologists
- Society for Technology in Anesthesia
- And others …
Clinical Requirements

• Clinical scenarios are being collected from clinicians and clinical engineers worldwide, to assure that interoperability standards and manufacturer-provided solutions will support clinical improvement in safety and efficiency.

• PHS ISRC grant to clarify concepts and systems for: “clinical scenarios”, “use cases”, “specifications”

• Example of clinical scenarios and proposed solutions (format provided by FDA)
<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/xray outputs network message for automatic notification outside clinical environment during laser use</td>
<td>Failure of notification system; wrong room, wrong device activated</td>
</tr>
</tbody>
</table>
New standard in preparation: “ICEMan”

- Integrated Clinical Environment Manager
- Risk management standard for MD PnP “ecosystem”
- Does not specify technology
Kaiser Contract Language

- **Medical Device Plug and Play.** Supplier agrees to participate with Kaiser in the development of a medical device plug and play integration standard (the "Integration Standard"), and ... will make reasonable efforts to conform to the Integration Standard when approved and formulated by the parties in writing. Until the Integration Standard is approved, Supplier intends to continue ... to provide open interfacing protocols ...
How might the functional layers “fit together”?  
(MD PnP architecture working group)

Top layer: Loosely coupled Enterprise CISs and beyond

Local “patient centric” layer: ICEMan with monitors, actuators etc. (e.g. Ethernet, IEEE 11073)

Sub-layers: tightly integrated systems to support Physiologic Closed Loop Control Systems (e.g. CAN technology)
Imagine products so intelligent they help manage one's health at home. Imagine an alliance of the finest companies joining forces to improve the quality of people's lives. Imagine highly integrated systems that seamlessly work together. We are the Continua Health Alliance.

THE TIME FOR TECHNOLOGY-BASED HEALTH CARE SOLUTIONS IS NOW.

Health begins at home, but time pressure or a lack of motivation may keep generally healthy individuals from maintaining exercise and weight management programs. Individuals with a chronic disease, such as diabetes or heart disease, may experience trouble with treatment plans, and the elderly, who may be less able to physically or mentally maintain their own health, require greater access to in-home care and supervision.
Adoption of medical device interoperability will support:

1. Clinical decision support systems
2. Smart clinical alarms
3. Medical device safety interlocks
4. Closed-loop control of ventilation, medication and fluid delivery
5. Support of remote healthcare delivery (home, battlefield, e-ICU)
6. Automated system readiness assessment (prior to starting invasive clinical procedures)
7. Complete, accurate electronic medical records
8. Increased quality and completeness of national research databases
9. Facilitation of disaster preparedness: real-time inventory of hospital equipment in-use and national stockpiles, and rapid deployment of devices in makeshift emergency care settings
Achieving Success

- End-user demand (IHDNs, physicians, risk managers, patient safety advocates, CIOs)
- FDA and other government agencies can keep barriers low
- Phased implementation: connect -> interoperate
- Support meaningful use-cases
- Risk Mitigation for new MD PnP paradigm
  - ICEMan ecosystem standard
  - FDA MD PnP “experiments”
  - Vendor neutral lab evaluation
- Collaborate
MD PnP Challenges

• Proprietary medical device systems; long capital equipment cycles (12 years!)
• Limited comprehensive, vetted user requirements (clinically/safety based)
• Absence of proven standards matched to clinical requirements
• Tendency to silo standards that would limit interoperability across continuum of care
• Limited funding for development
• Limited recognition of complexity of challenges in IT-BME convergence and lack of system integrators to build the middleware
• Legal (liability) concerns
• Regulatory pathway questions
Meeting Notification:
Joint Workshop On High Confidence Medical Devices, Software, and Systems (HCMDSS) and Medical Device Plug-and-Play (MD PnP) Interoperability

June 25-27, 2007
Cambridge, Mass

See http://rtg.cis.upenn.edu/hcmdss07/index.php3
HIMSS07 University Row 7806-7808

www.MDPnP.org  www.jgoldman.info