



CIMIT

FDA Workshop
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Clinical Perspective on Interoperable Medical Device Systems

Julian M. Goldman, MD

Medical Director, Biomedical Engineering, Partners HealthCare
Director, CIMIT Medical Device Interoperability Program (MD PnP)
Attending Anesthesiologist, Massachusetts General Hospital / HMS

Outline

1. Innovation outside of healthcare has changed our expectations for healthcare
2. Medical device are key data sources for EMRS
3. Safe stand-alone devices are not adequate to maintain patient safety. System solutions are required to create “error resistance”
4. There are clinical requirements, and strong clinical demand for medical device interoperability to enable system integration

Real-time status

ENTER PROMO CODE

1. DELIVERY OR CARRYOUT 2. GET STARTED 3. CHOOSE SIDES/DESSERTS 4. CHECKOUT

BUILD YOUR OWN PIZZA

ONLINE COUPONS

YOUR DOMINO'S ORDER: 888 Walnut Street Newton, MA

ORDER SUMMARY

Waiting for you to create an order!

1. CHOOSE SIZE & CRUST

CLASSIC HAND TOSSED

ORIGINAL CHEESE

THICK CRUST

BRICKEN CRUST

Specifically engineered to be big, fun, and perfectly portable. Pick a size:

Large (14")

XLarge (16")

NEXT >

From: order@dominos.com
 Reply-To: online.ordering@dominos.com
 Date: Saturday, July 11, 2009 6:34 PM
 To: jregister@gmail.com
 Subject: Your Domino's Pizza Order

Track your order in real time with Pizza Tracker:
<http://www.dominos.com/home/tracker/pizzaaetracker.jsp?uph=617957001&uid=57+EVERETT+5TR7CNEWTON+CENTER57CWS7CIG459>

Order #: 48
 Date: 7/12/2009 6:34PM

Thank you for placing your order at [Dominos.com](http://www.dominos.com)! If you have any questions about your order, please call the store directly at 617-332-7222.

In case the store needs to reach you, we'll call the phone number below. If you do not answer we will be unable to deliver your order.

Your Domino's Store (#3743)
 888 Walnut Street, Newton, MA 02159
 617-332-7222

Order Summary
 1 Large(14") Brooklyn Pizza, Whole: Cheese, Original Marinara, Black Olives, Onions, Banana Peppers \$26.49

Domino's Pizza

PIZZA TRACKER

SHARE ON FACEBOOK

ORDER PLACED PREP BAKE BOX DELIVERY

YOU GOT IT MADE - Erin began creating your order at 6:36 PM

888 Walnut Street Newton, MA

Domino's Pizza

You've got 30 minutes and you've got Domino's coming your way. The delivery experts at Domino's have specifically engineered the Pizza Tracker to keep you up to date on the status of your order from the moment it's prepared to the second it leaves our store for delivery. Now, you got tracking where no tracking has ever gone before.

Domino's Pizza

PIZZA TRACKER

SHARE ON FACEBOOK

ORDER PLACED PREP BAKE BOX DELIVERY

YOU GOT IT HEATWAVED - We packaged your order and placed it in a hot HeatWave bag at

888 Walnut Street Newton, MA

Domino's Pizza

You've got 30 minutes and you've got Domino's coming your way. The delivery experts at Domino's have specifically engineered the Pizza Tracker to keep you up to date on the status of your order from the moment it's prepared to the second it leaves our store for delivery. Now, you got tracking where no tracking has ever gone before.

Domino's Pizza

PIZZA TRACKER

SHARE ON FACEBOOK

ORDER PLACED PREP BAKE BOX DELIVERY

YOU GOT IT ON THE WAY - Our delivery expert, Luciano, left the store with your order at 6:49 PM

888 Walnut Street Newton, MA

Domino's Pizza

You've got 30 minutes and you've got Domino's coming your way. The delivery experts at Domino's have specifically engineered the Pizza Tracker to keep you up to date on the status of your order from the moment it's prepared to the second it leaves our store for delivery. Now, you got tracking where no tracking has ever gone before.

Domino's Pizza

PIZZA TRACKER

SHARE ON FACEBOOK

ORDER PLACED PREP BAKE BOX DELIVERY

YOU GOT IT - We hope you're enjoying your meal!

888 Walnut Street Newton, MA


Domino's Pizza

You've got 30 minutes and you've got Domino's coming your way. The delivery experts at Domino's have specifically engineered the Pizza Tracker to keep you up to date on the status of your order from the moment it's prepared to the second it leaves our store for delivery. Now, you got tracking where no tracking has ever gone before.

A platform for innovation ...

An iPhone gets Zipcar drivers on their way

Updated 9/29/2009 9:53 PM | Comments  3 | Recommend  26

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 Enlarge

By By Jefferson Graham, USA TODAY

Zipcar chief technology officer Luke Schneider says the iPhone application promises to be popular with lots of the car-sharing company's members.

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.


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

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 iGoogle

 More

Landing gear not down? -> Smart alarm
Example of error resistant integrated system



Contextual awareness requires data from several sensors and systems: altitude, airspeed, etc. to augment vigilance
“Hudson River Over-ride” – Pilot remains in control

Conclusion #1

Other industries have elegant and effective system solutions.
Wouldn't these capabilities be useful for patient care?

Challenge: Capturing complete and accurate EMR data

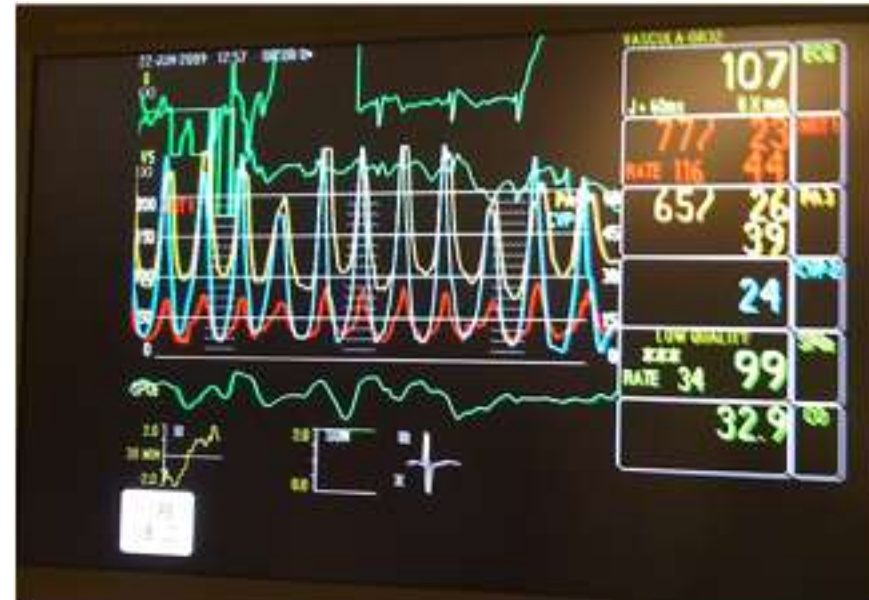
This EMR is dependent on manual entry of all non-physiologic data. That's a lot of manual data.



How can this data be interpreted once in the EMR?



Bedside physiological monitor



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. EMR data incorrect.



Result: False alarms, incorrect permanent record.
Since no waveforms recorded, no possibility of subsequent analysis.

“Protocol Watch: severe sepsis screening”

Action required!!



Sleep-deprived patient



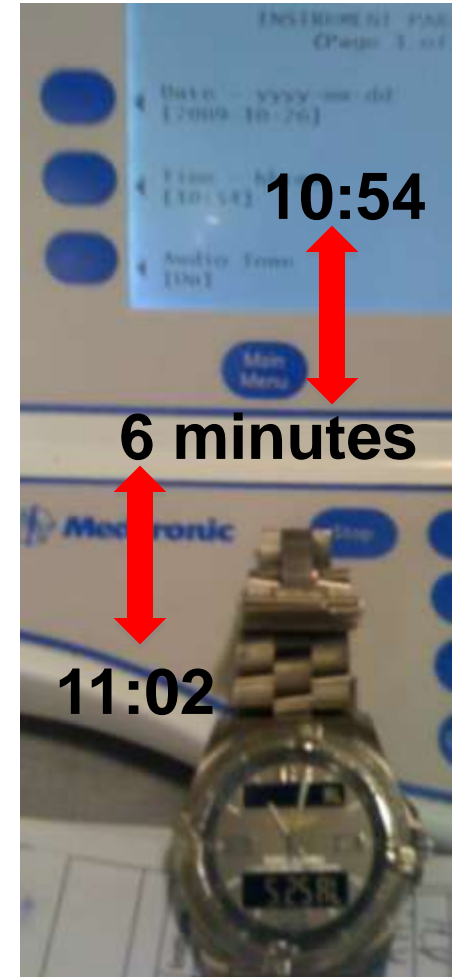
Nuisance alarm ... all night long!
Algorithm was missing: temp, wbc, glucose, ... context

New Problems are Emerging

- With broad use of EMRS, we are starting to see latent problems emerging
- Different data on different system screens
- Questionable time stamps for point of care data

New Lab Results			
Action	Abbreviation	Time	Value
<input checked="" type="checkbox"/> Acknowl...	ACT	11:06 AM	192

ACT – appeared to be checked too soon after heparin administration
Cause – Device does not use NTP



ACT Machine



Conclusion #2

- Medical devices are critical data sources and data consumers.
- Effective connectivity is essential to create complete, accurate, useful, contextually rich records.

4 Examples of needs, and clinical procedures and associated safety issues

(Source: MD PnP program
“Clinical Scenario” Repository)

Scenario: Surgical Fires

600 surgical fires each year



Laser worked as intended,
but the patient died ...



The most severe burns are “blast injuries” of the lungs
caused by burning endotracheal tubes

Airway Laser Surgery + O₂ -> Fire

- O₂ in respiratory gas supports combustion.
- If laser hits tracheal tube, could produce devastating burn.
- Surgical team must “remember” to minimize O₂

Tracheal
Tube with
Enriched O₂



A Solution: Laser-O₂ Interlock

- Measure breathing circuit O₂ concentration. (This is already measured.)
- Safety interlock or alarm to prevent laser activation if O₂ > 25%
- Option: “dynamic check list” prior to activating laser

Proposed and published in 1999!

NOT Commercially available



Scenario: Failure to ventilate

Cardio-Pulmonary Bypass



← or →



Normal routine: Switch from anesthesia machine ventilator to cardiopulmonary bypass machine, and back to ventilator (after bypass)

Failure to Ventilate

- Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.
- Anesthesiology. 87(4):741-748, October 1997 13 Years
- “... In the second case, the anesthesiologist forgot to resume ventilation after separation from cardiopulmonary bypass... Both patients sustained permanent brain damage.”
- All the medical equipment functioned as intended, but the patients were injured anyway!

Cardio-Pulmonary Bypass smart alarm (not available!)



Should
alarm if
both off



Smart system would provide warning if both ventilator and bypass pump are off.

Almost every surgical team has experienced this error!

Scenario: Imaging and ventilation

Example: Cholecystectomy (gall bladder removal) with intraoperative 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



X-ray



Ventilator

“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.

The medical devices worked
as intended

But the patient died

Alternative: Synchronize x-ray with ventilator - examples

@ exhalation: cholangiogram, angiograms

@inspiration: routine chest radi



NOT COMMERCIALY AVAILABLE

Integration of devices into a networked 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
Am. J. Respir. Crit. Care Med., Volume 160, Number 6, December 1999, 2067-2071

11 years

Solution has been demonstrated in MD PnP Lab



CIMIT Medical Device
Interoperability Lab
Cambridge, Mass

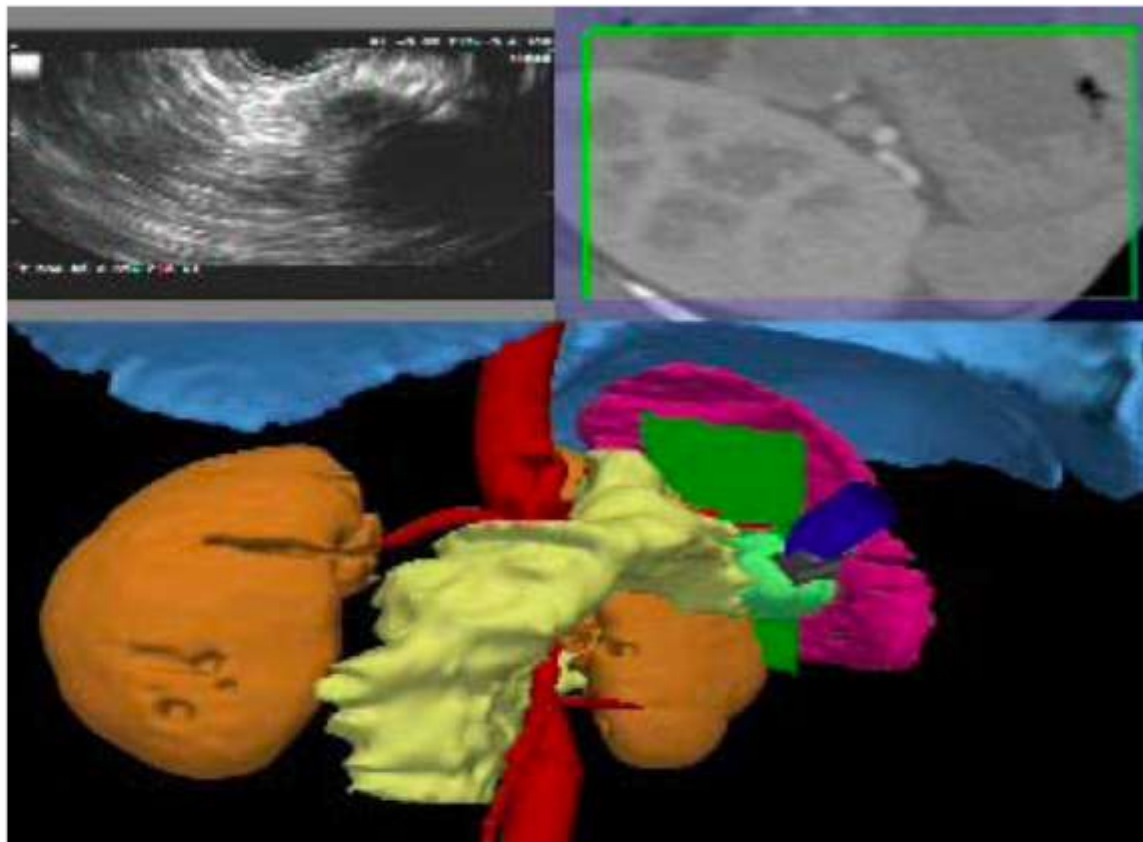


What is required for safe synchronization of ventilator and x-ray exposure?

- Not safe to externally “control” life-critical ventilator in mixed-vendor (heterogeneous) network
- Ventilator could provide real-time signal to trigger x-ray, or
- Ventilator could have pause feature + autonomous restart. Pause would be activated by x-ray over network connection.
- These requirements have been incorporated into new draft ventilator standards
- BUT, functions needed at medical device interfaces have not been fully elucidated, and regulatory paradigm is unclear

Image Registered Gastroscopic Ultrasound (IRGUS) of the Human Pancreas: Display

B-Scan
Ultrasound
Image



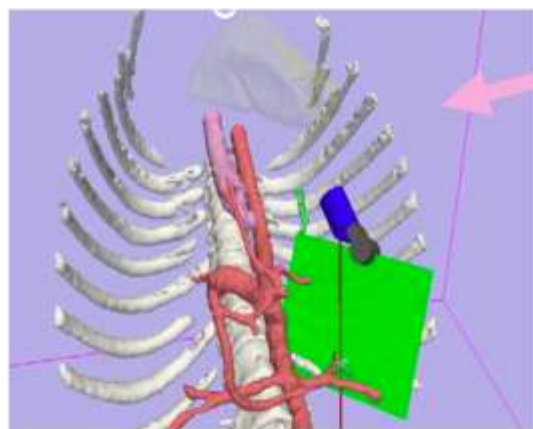
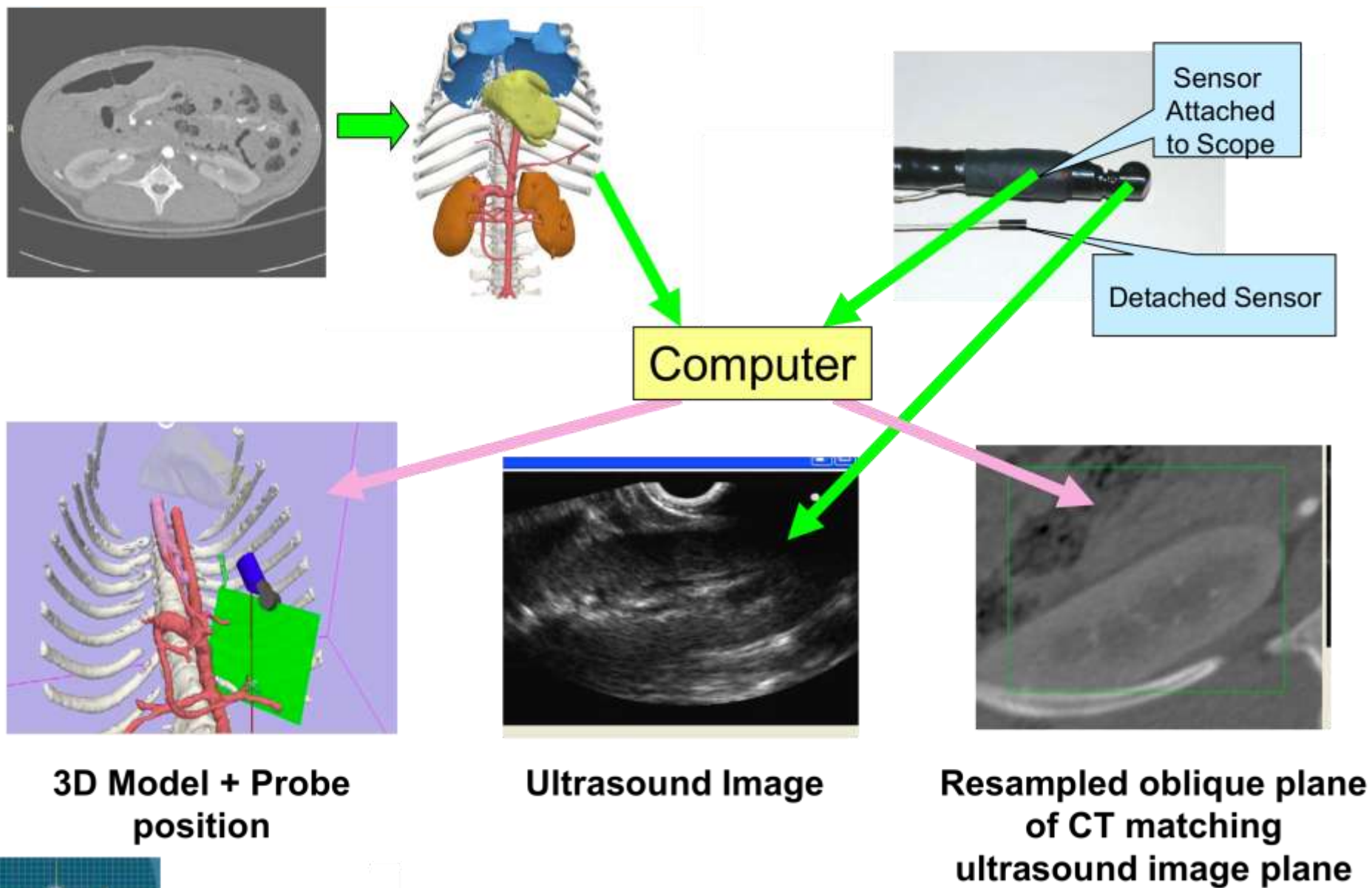
Reformatted
CT Data in US-
Defined Plane



3D CT-Based
Model of
Patient for
Navigation and
Biopsy Probe
Positioning



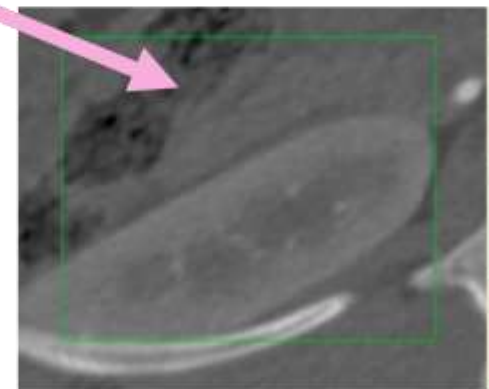
Data Processing & Display



3D Model + Probe position



Ultrasound Image



Resampled oblique plane of CT matching ultrasound image plane

Conclusion #3

- Many longstanding problems cannot be fixed, and patients are being injured.
- Improvements in patient safety, clinical care, and healthcare efficiency require heterogeneous (mixed-vendor) systems solutions.
- Scalable, versatile integration requires medical device interoperability. Interfaces must be updated to support required functionality.

Clinical Requirements

- Clinical scenarios are necessary to assure that interoperability standards and manufacturer-provided solutions will support clinical improvements in safety and efficiency.
- Carefully documented scenarios are needed
- MD PnP program has been eliciting requirements since 2005. Developed requirements methodology.

Req #	Clinical Scenario	Current Hazards	Proposed State	Future Hazards
CLN-050	ESU causes interference on ECG	Risks to patient safety due to poor diagnostics	Notify devices of ESU activity to eliminate/reduce ESU interference, or flag bad data	none
CLN-011	Difficult to reposition patient, cables, devices due to cluttered physical environment ("malignant spaghetti")	Devices could get disconnected, causing patient harm; it is difficult to maintain a clean environment with cables; visual paths of clinicians can be obstructed	Uncluttered environment, allowing appropriate communication between devices, information system, and patient; ease of movement of desired resources without barriers (NOT WIREFESS)	Possible interference of communication paths

EXAMPLE Clinical Scenario worksheet

CLN-052	Operating room lights and anesthesia task lights are not coordinated	Can end up in total darkness	Interconnect lighting, such that when room lights go off, anesthesia machine task light does on	May want to work in the dark. Must permit override
CLN-048	Electronic medical record is missing medical device-generated data	Lack of adequate data for clinical decision-making	Comprehensive medical record, with capture of all medical device-related data in EMR: patient ID, personnel, equipment IDs, "ESU on" vs. "ESU off" (especially for later analysis)	EMR may become "bloated", overly complex
CLN-017	Laser, x-ray use in the OR	Unprotected personnel may enter OR unknowingly	Laser/xray outputs network message for automatic notification outside clinical environment during laser use	Failure of notification system; wrong room, wrong device activated

ASTM F2761-2009 “Integrated Clinical Environment”

Clinical context and clinical scenarios

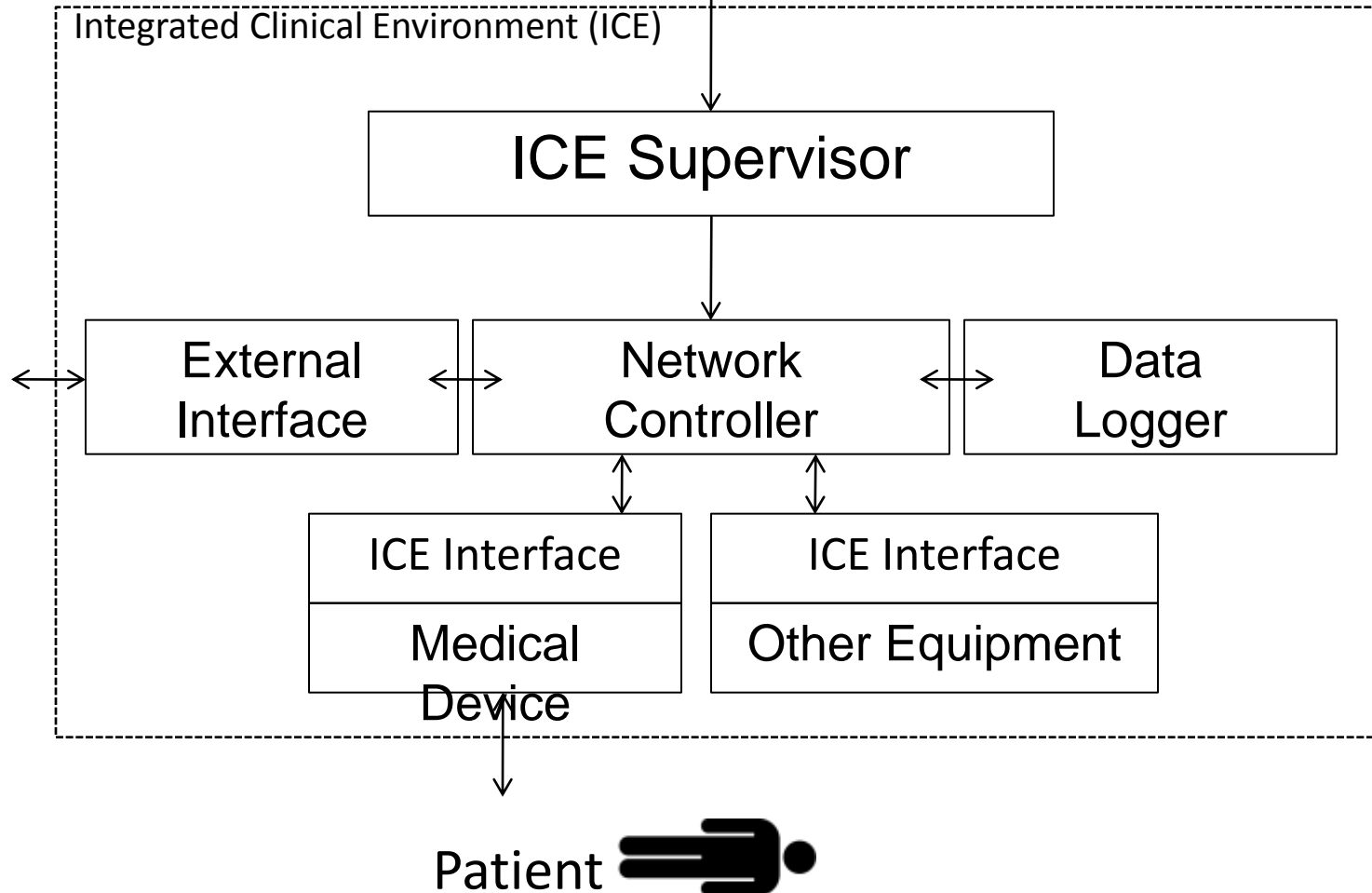
1. Safety Interlock (PCA infusion)
2. Synchronization of equipment (X-ray - ventilator synchronization)
3. Process control/workflow (Heparin monitoring via PTT testing)
4. Smart alarm system (annunciate alarm when ventilator not re-started after cardiopulmonary bypass)
5. Decision support (integrate bedside data and observations to activate Rapid Response Team)
6. Physiological Closed Loop Control (artificial pancreas via intravenous infusions)
7. Plug-and-play connectivity

Functional Elements of the Integrated Clinical Environment

ASTM standard F2761-2009



Clinician





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*

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 Permanente
- Released Oct 17, 2008

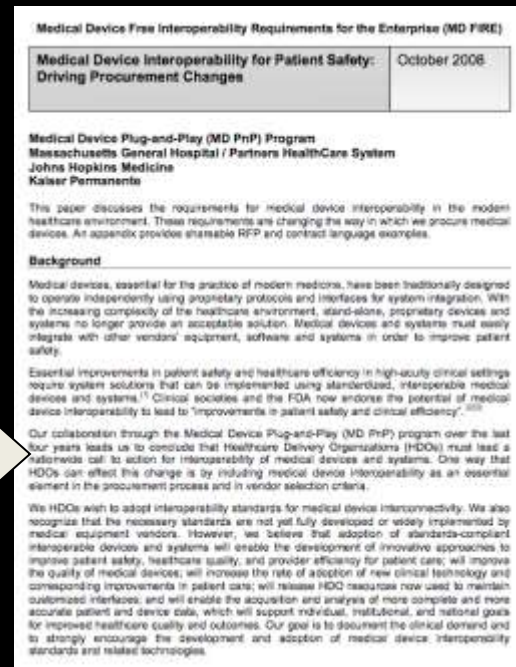
[5 Stakeholder groups from each organization:](#)

[Purchasing/materials management, BME, IS, Clinical, Legal](#)

MD FIRE

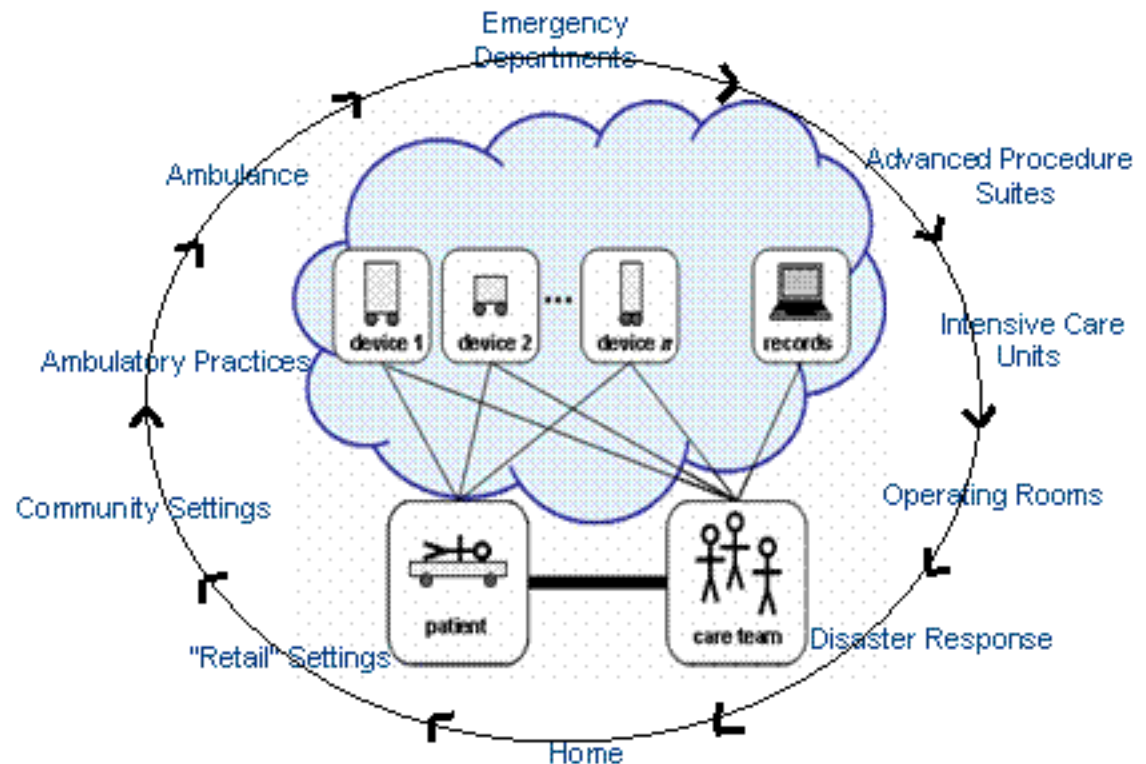
“Healthcare Delivery Organizations (HDOs) must lead a nationwide call to action for interoperability of medical devices and systems. One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria.”

Download: http://mdpnp.org/MD_FIRE.php



Conclusion #4

- Clinicians, biomedical engineers, health delivery organizations, and medical societies want market access to interoperable devices to enable innovation and reduce the cost and complexity of device-EMR integration



It all began with a new way of thinking.





CIMIT

MD PnP[™]
Getting connected for patient safety[™]

PARTNERS
BioMedical
ENGINEERING

Contact info:

www.jgoldman.info

MD PnP Program
www.mdppnp.org

Adoption of medical device interoperability 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. Facilitation of disaster preparedness: real-time inventory of hospital equipment in-use and national stockpiles
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)
8. Increased quality and completeness of international research databases
9. Reduce cost of devices and their integration, and reduce accelerating EMR-adoption costs
10. Closed-loop control of therapeutic devices and safety interlocks (e.g. ventilation, medication and fluid delivery)