

# Medical Device Security and Safety: A Public Health Approach

Dale Nordenberg, MD  
HIMSS Town Hall Webinar  
December 15, 2011

# MDISS

Medical Device Innovation,  
Safety, & Security Consortium

MDISS receives membership dues from industry members

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# Objectives

1. Defining and scoping a public health problem
2. Overview of medical device safety
3. Introduction to MDISS
4. Highlight key MDISS initiatives

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# Public Health Perspective

- Three parameters define the importance of a public health problem
  - Breadth of exposure, e.g. incidence/prevalence
  - Depth of impact, e.g. morbidity and mortality
  - Preventability

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# Medical Device Exposure

- Centers for Disease Control and Prevention (CDC) estimates annual patient encounters
  - 35 million hospital discharges
  - 100 million hospital outpatient visits
  - 900 million physician office visits
- Most of these encounters likely include a networked medical device

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# Medical Device Adverse Events

- Many devices can cause serious harm if they malfunction
  - Linear accelerators
  - Infusion pumps
  - Defibrillators
  - Insulin pumps
- Difficult to identify security related malfunction as a root cause

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# Medical Device Security Practice

- There are many important security related best practices and security technologies that are available but that are not being deployed to secure medical devices
- Opportunity to integrate improved security functions in medical devices
- These opportunities are preventable risk

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# Innovation Imbalance

- HIT innovation and adoption is rapid, accelerating
- HIT interoperability is accelerating and includes networked medical devices
- The rate of innovation and adoption of ICT security is lagging significantly behind HIT innovation
- The gap represents a major public health risk

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# Exponential Enablers

## Halving (or Doubling) Times

Microprocessor Cost Per Transistor halves	1.1 years
Magnetic Data Storage cost halves	1.3 years
Dynamic Random Access Memory (RAM) – bits stored per Dollar doubles	1.5 years
Average Transistor Price halves	1.6 years
Processor Performance in MIPS per dollar doubles	1.8 years
Bandwidth per dollar doubles	1.9 years
Transistors in Processors doubles	2 years
Power Consumption Per Node Doubles	1.5 years

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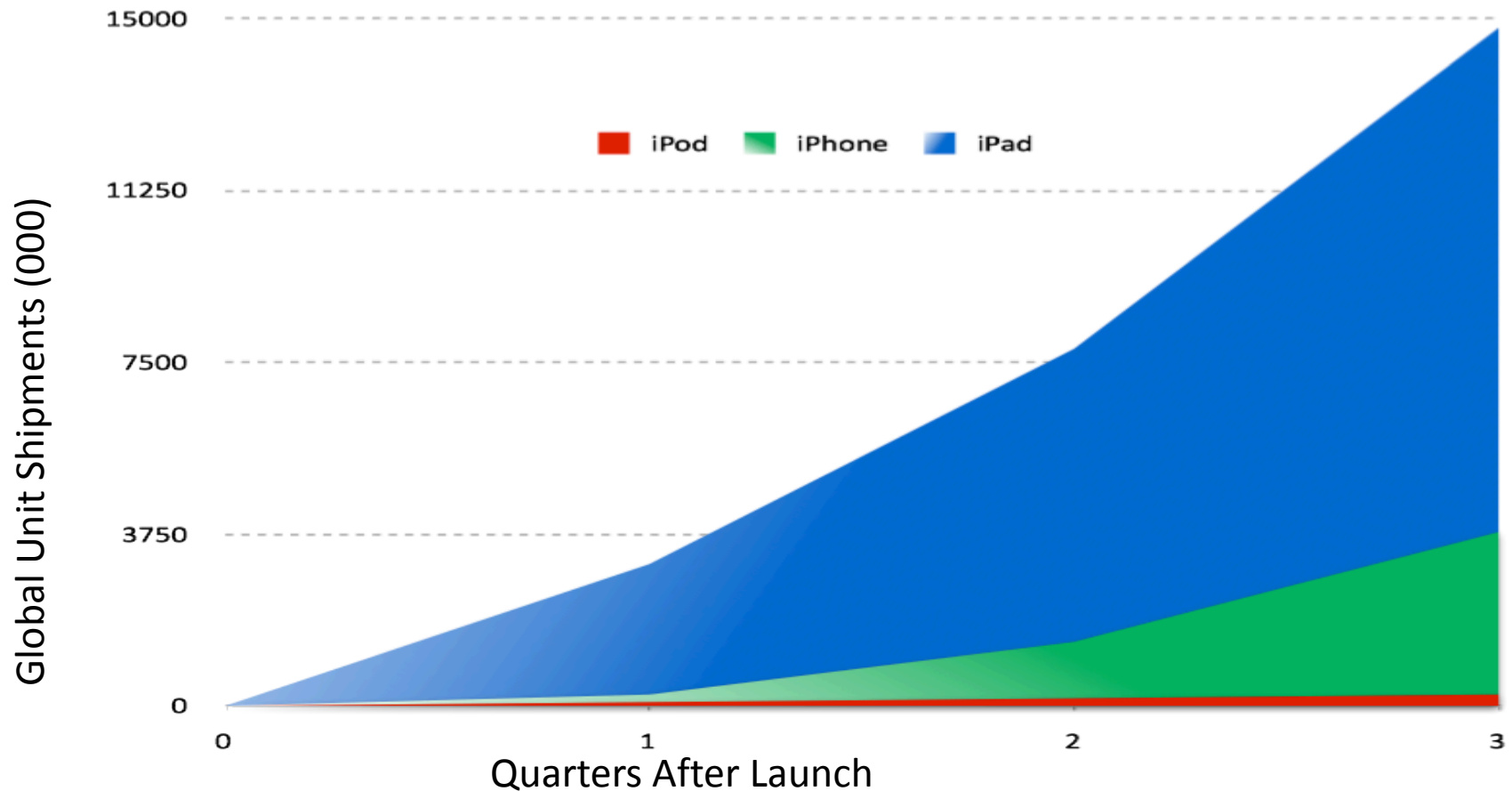
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# Accelerating Innovation

First 3 Quarters Cumulative Unit Shipments, iPod vs. iPhone vs. iPad



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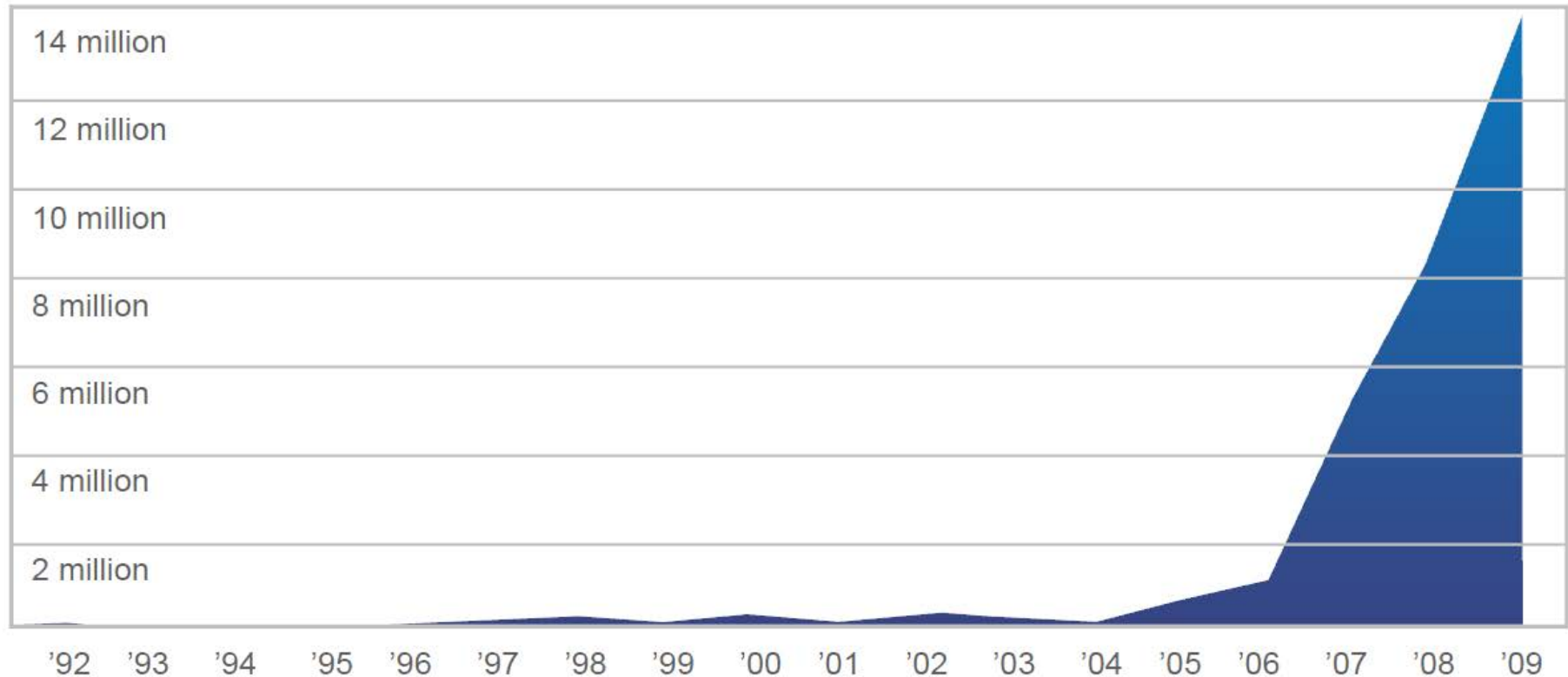
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# Accelerating Security Risks

Malware detected by year



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# Public Health Systems Level Risk Mitigation Strategy

- Create a medical device security conceptual and technical framework
- Medical device stakeholder ecosystem addresses the weak links in the medical device security framework
- Conduct surveillance of security related adverse events and improve

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# Medical Device Safety Background

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# Cardiac Implantable Devices

- FDA recalled 23 types of implantable products in the first half of 2010
- **Nation-wide demand for all IMDs is projected to increase 8.3 percent annually to \$48 billion by 2014** while cardiac implants in the U.S. will increase 7.3 percent annually representing approximately \$16.7 billion in 2014
  - Freedonia Group, Cardiac Implants, Rep. Buyer, Sept. 2008, [http://www.reportbuyer.com/pharma/healthcare/medical devices/cardiac implants.html](http://www.reportbuyer.com/pharma/healthcare/medical%20devices/cardiac%20implants.html)
- From 1997 to 2003, approximately 400,000 to 450,000 ICDs were implanted globally, the majority of these implants were done in the USA, and there were at least 212 deaths attributed to failure of these ICDs
  - Robert G. Hauser & Linda Kallinen, Deaths Associated With Implantable Cardioverter Debrillator Failure and Deactivation Reported in the United States Food and Drug Administration Manufacturer and User Facility Device Experience Database, 1 Heart Rhythm 399, t <http://www.heartrhythmjournal.com/article/S1547-5271%2804%2900286-3/>
- In 2008, approximately 350,000 pacemakers and 140,000 implantable cardioverter defibrillators (ICD) were implanted in the United States, according to a forecast on the implantable medical device market published earlier this year
  - Sanket S. Dhruva et al., Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices, 302 J. Am. Med. Ass'n 2679 (2009)

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# Medical Device Software Failures

- Between 1983 to 1997, 2,792 quality problems that resulted in recalls of medical devices and of problems, 383 were related to device software
- Of the recalled devices, 21 percent were cardiac
- 98 percent of the software failures analyzed were detectable by best practice quality assurance methods
  - Dolores R. Wallace & D. Richard Kuhn, Failure Modes in Medical Device Software: An Analysis of 15 Years of Recall Data, 8 Int'l J. Reliability Quality Safety Eng'g 351 (2001), available at <http://csrc.nist.gov/groups/SNS/acts/documents/nal-rqse.pdf>.

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# Infusion Pumps Software Failure

- Between 2005 and 2009, the FDA received approximately 56,000 infusion pump-related adverse event reports
  - ↳ Many of these were associated with significant morbidity and mortality
- Software malfunction was a frequent cause for infusion pump malfunction
- Hundreds of thousands of infusion pumps were recalled and scores of models were implicated
- FDA is providing support to manufacturers
  - Review of code submitted by manufacturers
  - Collaborative development of open source safety models and reference standards
  - White Paper: Infusion Pump Improvement Initiative April 2010, Center for Devices and Radiological Health U.S. Food and Drug Administration,  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm>

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# Linear Accelerators

## Software Related Deaths

- Therac-25 machines
  - Software problems lead to 6 well known cases of death or severe adverse events between 1985-1987 resulting in machine recall
  - Catalyzed safety concerns and resulted in initiatives to improve safety profile of linear accelerators
    - An Investigation of the Therac-25 Accidents, Nancy Leveson, *IEEE Computer*, Vol. 26, No. 7, July 1993, pp. 18-41.
- Radiation related adverse events are likely underestimated
  - Many adverse events are difficult to detect because many are initially subclinical, e.g. increased exposures leading to malignancy
  - “My suspicion is that maybe half of the accidents we don’t know about,” said Dr. Fred A. Mettler Jr.
    - Radiation Offers New Cures, and Ways to Do Harm, NY Times, January 23, 2010

# Risk Reality Check - Hacking Machines vs. People

- In 2007 and 2008, health related websites were hacked with the intent to cause harm
  - Coping with Epilepsy website
  - Epilepsy Foundation website
- In both instances, computer animations were posted that triggered migraines and seizures among visitors with epilepsy variants associated with photosensitivity

Hacking of 'medical devices' to intentionally cause harm will occur

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# Silicon-Based Defects

## Etiology of Carbon-Based Diseases

Implanted medical devices have enriched and extended the lives of countless people, but ***device malfunctions and software glitches have become modern 'diseases' that will continue to occur.*** The failure of manufacturers and the FDA to provide the public with timely, critical information about device performance, malfunctions, and 'fixes' enables potentially defective devices to reach unwary consumers.”

Capitol Hill Hearing Testimony of William H. Maisel,  
Director of Beth Israel Deaconess Medical Center,  
May 12, 2009

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# Medical Device Vulnerability

## Patient Safety

“These [medical device] infections have the potential to greatly affect the world-class patient care that is expected by our customers. In addition to compromising data and the system, these incidents are also extremely costly to the VA in terms of time and money spent cleansing infected medical *devices.*”

Roger Baker

*Assistant Secretary for Information and Technology*

Department of Veterans Affairs

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# Medical Device Security Challenges

- The **national biomedical device network** remains a largely **unrecognized** entity
- **Multidisciplinary expertise is required** to understand medical device risks and consequently design, implement, and manage medical devices and their associated biomedical device networks to optimize patient safety
- Stakeholders have **not yet built the multidisciplinary expertise** required to optimize medical device safety profiles along the medical device life cycle
- Security breaches in the health care industry escalate each year and represent an increasing patient risk as the prevalence of networked medical devices increases

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# Medical Device Security Challenges (cont.)

- Medical device network dysfunction is a potential **national security risk**
- The **security of medical devices**, given that they operate as part of a networked system, **receive inadequate attention**
- **Limited information** is reported regarding the extent of the potential exposure, risks, and risk mitigation strategies
- **Regulatory focus is often about a ‘point in time’** assessment while networked medical devices are continuously exposed to rapidly evolving technology risks
- **Collaboration is lacking among all stakeholders** in developing practical solutions
- **The engineering, informatics, and public health science to leverage real-time data streams from networked devices is immature**

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# Our Mission

The Medical Device Innovation, Safety and Security Consortium (MDISS) protects the public's health and well-being by advancing innovation and computing risk management practices to ensure wide availability of innovative and safe medical devices

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# Our Organization

- We are a collaborative and inclusive nonprofit professional organization committed to advancing quality healthcare with a focus on the safety and security of medical devices
- As a public-private partnership, we serve providers, payers, manufacturers, universities, government agencies, technology companies, individuals, patients and patient advocates

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# G1: A public private partnership effectively catalyzes the development of a safe and secure national bio-device network

- Build and facilitate a public and private collaborative.
- Establish a governance structure to ensure the community serves stakeholder needs
- Establish appropriate committees to identify and address specific issues
- Ensure representation across government, manufacturers, providers, payers and broader technology companies including infrastructure, security, device components and services companies

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# G2: Security risks associated with medical devices are well understood and appreciated across the industry

- Establish a public/private reporting infrastructure to accurately assess the national exposure and identify, track and trend incidents
- Ensure the public/private surveillance and adverse incident response model protects the interests of patients, providers, manufacturers and regulators
- Develop case definitions for security risks and medical device associated adverse events
- Develop a data collection network that support premarket clinical trials and postmarket adverse event surveillance
- Leverage the data collection network to support innovation in medical devices

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# G3: Medical devices and associated networks are safe and secure

- Establish best practices for securing legacy medical devices
- Develop “Delivery of Care Criticality Framework” for managing medical device and bio-device network security
- Establish business requirements and use cases for the development of new medical devices
- Develop training materials
- Produce scholarly papers that progress the knowledge base for digitally enabled medical device security and safety
- Improve accessibility of medical device security testing data
- Establish collaborative dialogue between a significant number of healthcare delivery organizations and manufacturers and other industry partners to influence product design, implementation, and performance

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# Consortium Initiatives

## Examples

- Medical device expert network
- Collaborative medical device requirements development
- Pre-procurement support
- Determination of scope of the security challenges based on robust epidemiologic methods
- Collaborative medical device security testing
- Standards, policy, guidelines, and regulatory briefings, updates, explanation, and implications
- Education and training
- Simulated medical device network

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# Administrative Overview

## Organization

- The consortium organization will have the following attributes
  - 501c3 non-profit\*
  - Consortium will be governed by an executive advisory group and a general advisory group
  - Working groups will be established per advisory group recommendations
- The consortium is funded through industry stakeholder membership fees

\*pending

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# Membership Ecosystem

- Providers
- Payers
- Pharmaceutical/OTC manufacturers
- Research organizations, universities, institutes
- Device manufacturers
- Component manufacturers
- Information technology providers
- Information security professionals
- Public sector
- Clinical/contract research organizations (CROs)
- Patients
- Patient advocacy organizations

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# Become Involved

- Contribute to the community
  - Share your needs
  - Share your experience
- Receive educational materials and news updates
- Participate in working groups and initiatives

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# Acknowledgements

Significant contributions to the development and operations of MDISS continue to be made by representatives from numerous organizations including Kaiser Permanente, VA/VHA, John Muir Health, DOD, and others.

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# Thank You

For information, please contact:

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# An IT Security Discussion for Medical Devices

## Putting a Saddle on a Zebra

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Chair, HIMSS Privacy and Security Committee

Virtual Town Hall Meeting to Explore Mobile Device

Security/Risk Management

December 15<sup>th</sup>, 2011

# Learning Objectives

- ▶ Identify importance of this issue to this audience
- ▶ Provide 10 lessons-learned on IT security management and CE-IT convergence
- ▶ Explore [HIMSS Privacy & Security Toolkit](#)
- ▶ Address a framework of organizational responsibility for medical device and IT security

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# Identify the Importance of this Issue to this Audience

- ▶ HIPAA is almost 20 years old; enter HITECH
- ▶ Put “teeth” where HIPAA lacked it
- ▶ Can be \$50,000 per year for willful neglect
- ▶ Violation (e.g., disclosure of PHI in ANY breach)
- ▶ Up to \$1.5M; NO max penalty (multiple violations)
- ▶ HITECH: Coming Soon...Fed & State Rules...  
”How to Sue for Damages from PHI breaches!”



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# Evolution of Healthcare - Past



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# Evolution of Healthcare - Present



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# Where is the medical device and where is the IT system?



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# Identify the Importance of this Issue to this Audience

IT = Mission Critical while CE = Life Critical

One size IT security best practices, indiscriminately applied in healthcare = patient safety risk

External & International Regs (FDA)/(ISO)

OEMs/Vendors slow or unwilling to respond

Patient Safety, Information Security, Public Trust

We are at a Strategic Inflection Point (Andrew Grove, Intel)



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# Identify the Importance of this Issue to this Audience

Inflection Point Imperative (Convergence)

Healthcare Info Security CE-IT inflection point?

From Snapshot to Continuous Monitoring

GAO 2012 Agenda (Implantable Med Devices)

Phase 2/3 Meaningful Use; HIPAA 2.0

Cloud Computing and Virtual Infrastructure

BYOD for end users

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# Lessons-learned on IT security management and CE-IT convergence

1. Know what is on your network

Again...Know what is on your network

2. Do Risk Management planning and Quality

Assurance system BEFORE an event happens

Numerous tools for Step-by-Step Risk Mgt

3. Segmented architecture to isolate and group medical devices into integrated VLANs

4. Strive for Continuous State of Assuredness

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# Lessons-learned on IT security management and CE-IT convergence

5. Patch management is key but too reactive

6. Team approach b/t biomed engineering and IT

Only patch what's been properly validated

Even if cleared, make sure the patch works in your environment

7. Establish clear, concise requirements for information security in organization

Include in request for proposals & contracts

HIPAA compliant & DIACAP'd claims misused

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# Lessons-learned on IT security management and CE-IT convergence

8. Maintain a formal business relationship between IT, CE, and clinical system administrators

Must be on Enterprise IT Steering Committees

9. Make sure medical devices are part of the enterprise COOP, Disaster Recovery, & backup plan

10. Stay up to date on current guidance

Myths and assumptions in medical device & IT security management has been legendary

Bonus! Invest in cross training & cross-pollinating team

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# Explore HIMSS Privacy & Security Toolkit

*The HIMSS Privacy & Security Toolkit*  
*Privacy & Security Toolkit for Small Provider*  
*Organizations*

*Patient Identity Integrity Toolkit*

What You'll Find:

Manufacturer Disclosure Statement for  
Medical Device Security (MDS2) (v2 coming)  
Risk Assessment Tools (Step by Step)  
Best Practices, Case Studies, Whitepapers  
Relevant Guidance and Law

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# Explore HIMSS Privacy & Security Toolkit

Recently Posted and In Development

Health Information Risk Assessment and Mgt

Patient ID Integrity Toolkit—Security Safeguards

Security of Mobile Computing Devices in the  
Healthcare Environment

Risk Assessment Working Group Toolkit

*\*\*\*Working w/ NIST on Risk Assessment Tool*

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# Address a framework of organizational responsibility for medical device and IT security



[bobstanke.com](http://bobstanke.com)

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# Monash GrangeNet Network

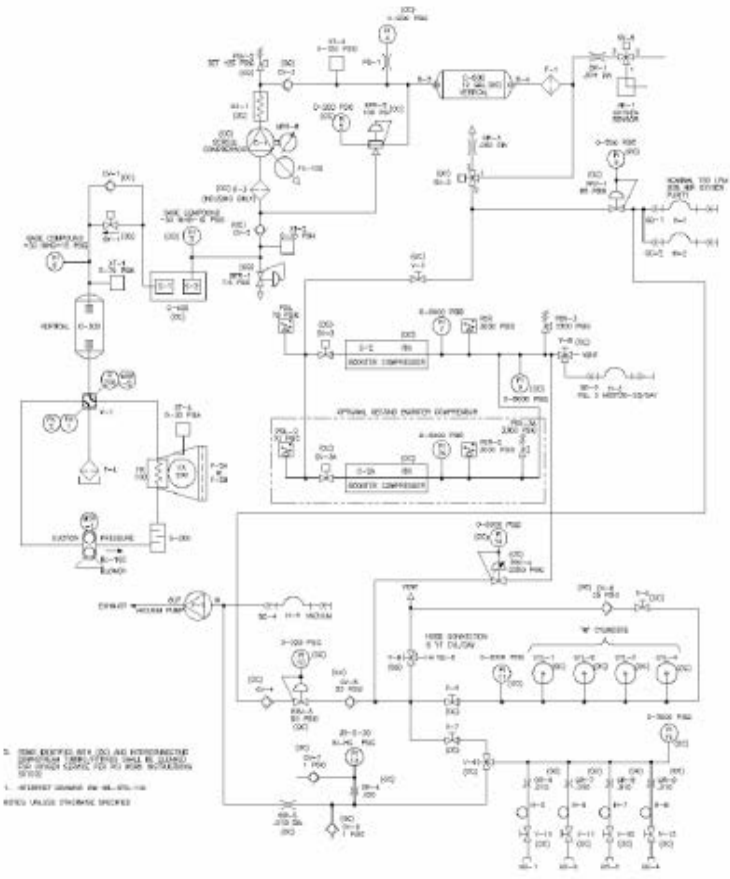
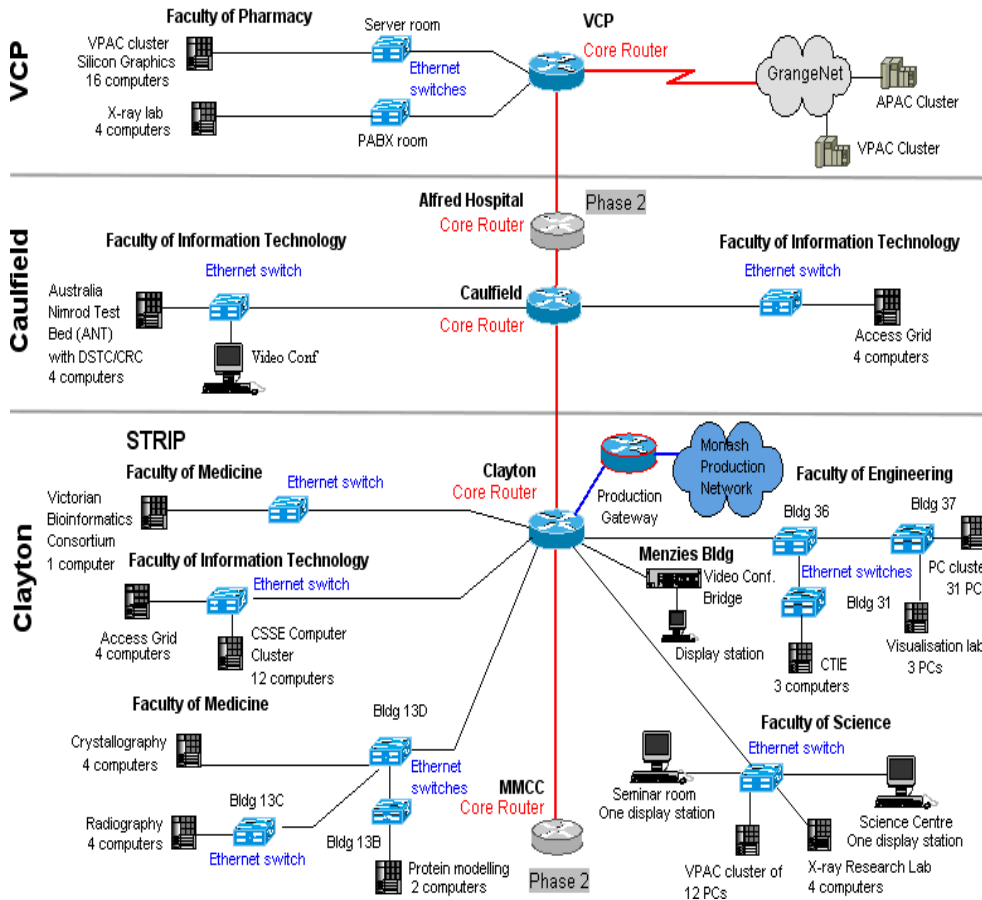
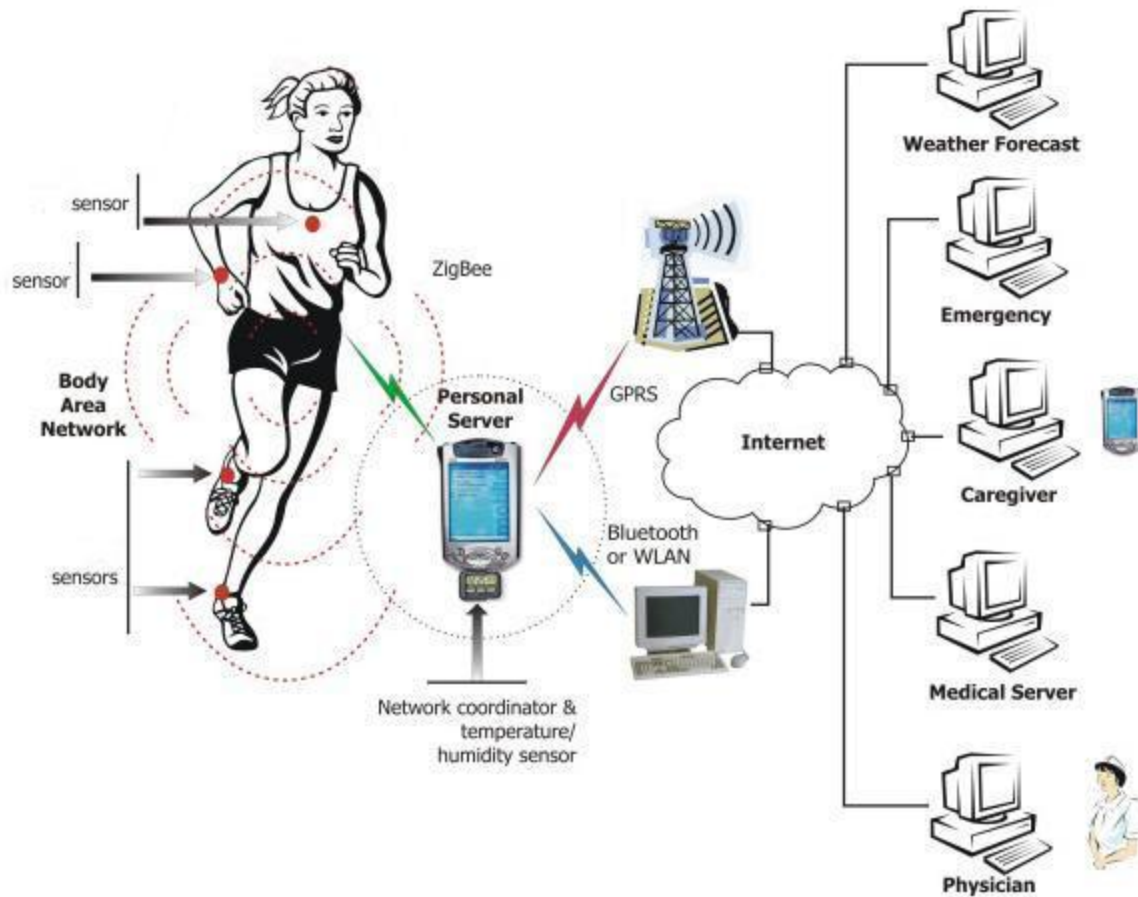


Figure 5. Flow Schematic.

Mr Steve Walker, "It's All Greek to Me, 2008"

# Body Area Networks



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# Personal Area Networks



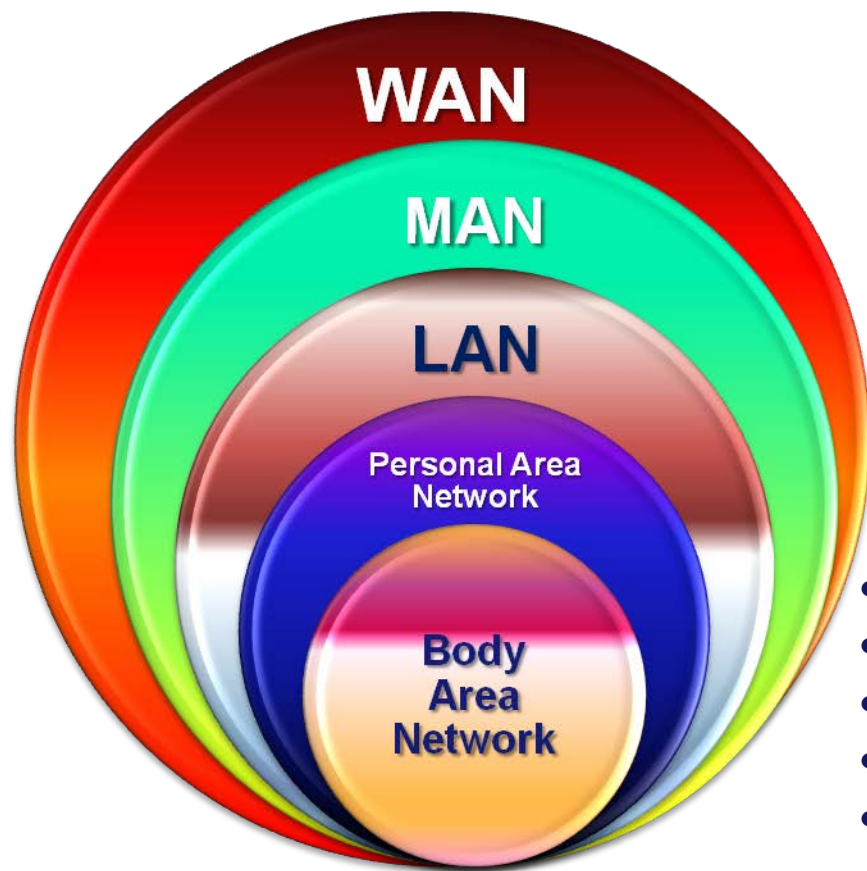
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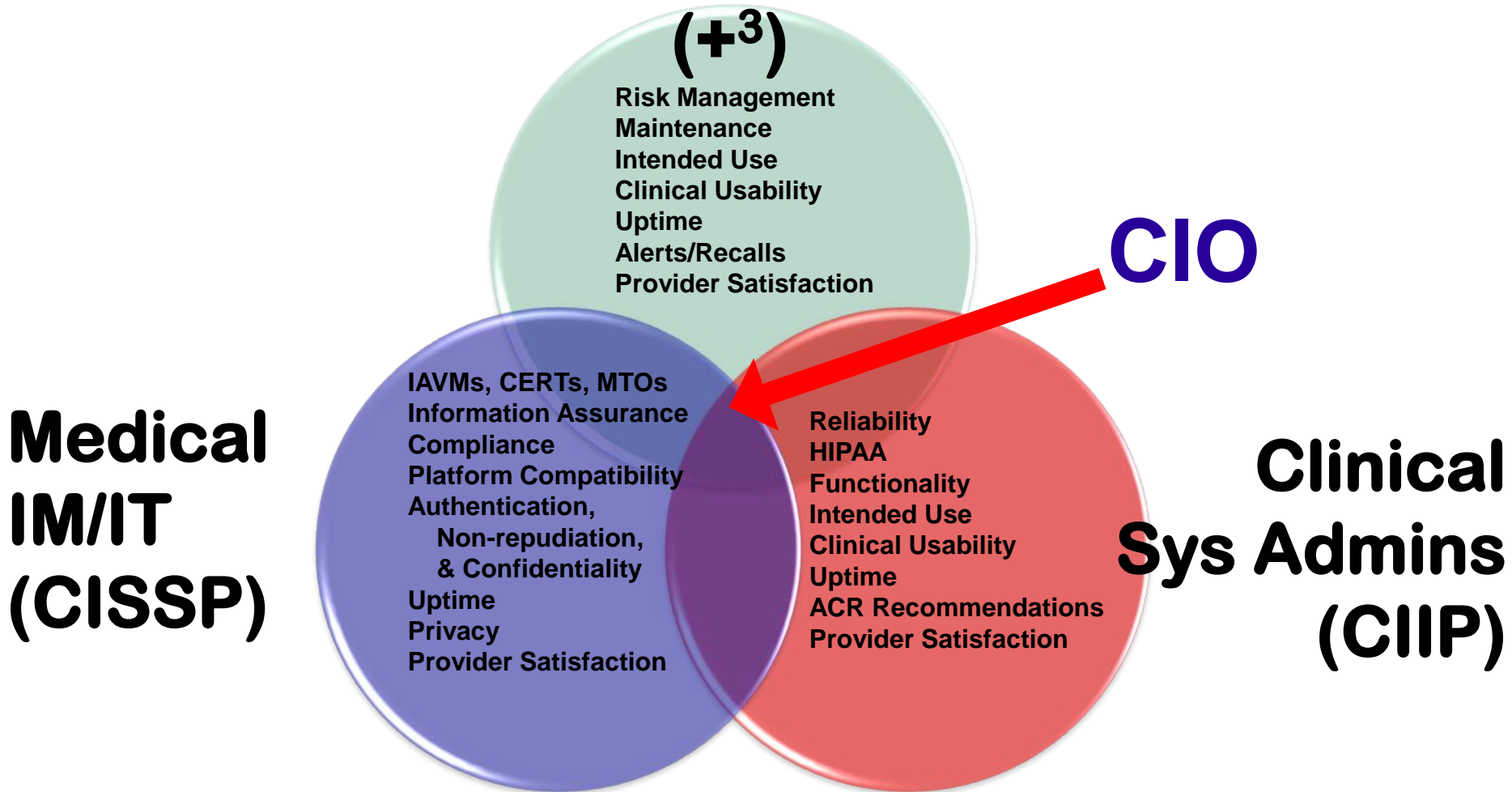
# All Together Now



**BAN and PAN add to integrated networking platforms**  
**Medical Devices reside/use all these**  
**A team approach is imperative**

- RFID
- DICOM
- IEEE 802.11x / WiFi
- Bluetooth, ZigBee (2.4 GHz)
- IEEE 11073
  - medical instrumentation bus

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# Potential Framework Best Practice

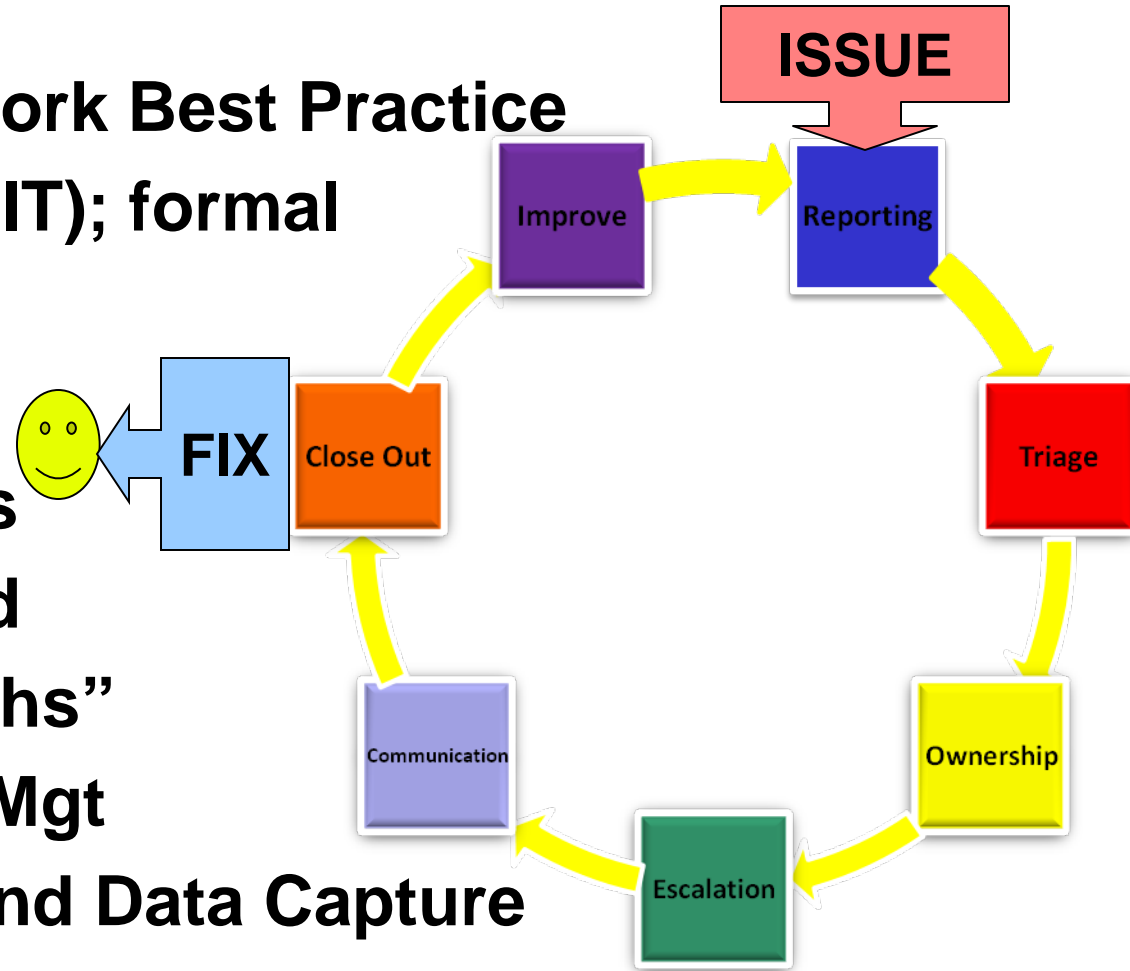
Build a team (CE-IT); formal or informal

Determine Roles & Responsibilities

Less on ‘turf’ and more on “strengths”

Focus on ISSUE Mgt

Documentation and Data Capture



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Medical Device implementations are typically heavily Information Tech-dependent projects (PMO)  
Clinical Engineering/IT (CE-IT) shared concerns  
Safety/environment of care, capital planning, budgeting, acquisition, product eval, facility design/innovation and risk management

Enterprise expertise/common vendor knowledge  
Next stages of “meaningful use,” EHR, security issues, and medical device intercommunications

CE-IT convergence core Defense in Depth risk mgt



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# CE-IT Convergence may be hard



But it must be done

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