Impact of MDI on Device Assessment & Acquisition

Presented by: American College of Clinical Engineering

June 4, 2016 | Tampa, FL

PART 1
Welcome!

• Be sure to visit the ACCE Booth 1033

• Share your AAMI experiences with us using #acceaami16
Welcome!

• Thank you for joining us at the ACCE Symposium at AAMI16!

• Before we begin, let’s cover some house-keeping:
  • Symposium Duration: 7:00AM – 11:00AM (4 hours)
  • Enjoy light breakfast courtesy of: aramark
  • 15 Minute break at ½ way mark
    • Thank you for coming back on-time!
  • Please hold your questions until the Q&A session
    • Don’t want to come to the microphone? Submit your questions by email at any time:

  acce.aami16@gmail.com
Welcome!

Moderators:
Christopher Falkner
Technology Innovations Mgr.,
Garfield Innovation & Design Center
Kaiser Permanente

Jennifer Defrancesco
Chief Biomedical Engineer,
Department of Veterans Affairs

Presenters:
Thank you for keeping your presentation to 10 minutes 😊

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<td><strong>Keynote Speaker</strong></td>
<td>Elliot Sloane</td>
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<td><strong>Assessment</strong></td>
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<td>(1) Changing technology standards</td>
<td>Kenneth Fuchs</td>
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<td>- Interoperability Standards</td>
<td>Jennifer Ott</td>
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<td>- Device/System specs &amp; considerations</td>
<td>Jeff Peacock</td>
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<td>David Jamison</td>
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<td>(1) Changing Process Considerations</td>
<td>Robert Maliff</td>
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<td>- Cost models (Sas, VMs, Cloud, etc.)</td>
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<td>Angie Mulinix</td>
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<td>- Internal Support (collaborative model)</td>
<td>Roberto Torres, Jr.</td>
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<td>- Software Support Contracts</td>
<td>Samantha Jacques</td>
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<td>- Petching &amp; Security (CE-IT)</td>
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<td>10:50 – 11</td>
<td><strong>Closing Remarks</strong></td>
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Keynote Presentation:

Elliot Sloane

President & Founder at Center for Healthcare Information Research and Policy (CHIRP)
Medical Device Integration (MDI)

Nobel’s First Law & Sloane’s First Law

Presented by Elliot Sloane, PhD, CCE, FACCE, FHIMSS

Center for Healthcare Information Research and Policy (CHIRP)
Osprey, FL USA
My bio? A HIMSS and ACCE Fellow, on a “road less traveled,”
Four Decades in Health Technology and Information Systems

15 years in non-profit research, development, & independent testing, standards, and forensic investigation of medical technologies

At ECRI Institute, from “bench” to CIO and COO
- Worked with FDA on medical device standards
- Computerized arrhythmia detection disclosure and apnea monitors
- Forensic investigations of patient injuries and deaths
- Breakthrough ICT computer systems for medical device management, databases, & nomenclatures,
“Hazard Reports,” feature comparisons, product directories, medical device maintenance, and safety assurance

10 years in a publicly-traded corporation, medical device manufacturing, repairs, 24x7 rental/delivery, and medical device and drug manufacturing and distribution

At MEDIQ Life Support Services, from COO through CTO and CRO
Registered with FDA as device and drug manufacturer
Owned and managed a fleet of 500,000 medical devices nationwide

15+ years as a professor, consultant, businessman, and AAMI, IEEE, & HIMSS volunteer
- focused on Medical Informatics, Health Systems Engineering, Medical Device Data Systems Research, Wireless Medical Devices, and Patient Safety
- Serve on many HIMSS privacy, security, standards, and education committees

Ongoing Research Professor and graduate instructor at Villanova University
Nobel’s First Law: 
*The Conservation of Trouble*

First presented by my friend and mentor, 
**Joel J. Nobel, MD**, during his AAMI 2003 
Dwight Harkin Award Speech

“Think of it as the engineers’ variant of the Legislators’ Law of Unintended Results. It simply states that trouble is incompressible. You *squeeze it here, and it oozes out there*. I first expressed it at Senate Health Subcommittee hearings on medical device amendments in 1973. It proved prescient in the early years of device regulation.” (emphasis mine, EBS)
MDI issues emerging from Nobel’s First Law

• Expansion of integrated devices to automate data capture and improve safety *simultaneously* expands complexity of wired/wireless network, storage, and security problems

• Last week’s news bite: over half of US hospitals experienced ransomware attack last year! (The other half may not know...
Or, perhaps, “No good deed goes unpunished?”

- Let’s be honest and take ownership: we are the victims of our own success!
  - Ted Cohen, Alan Lipschultz, and I collaborated on a CE-IT Convergence Article for AAMI in 2001
  - ACCE, AAMI, and HIMSS formalized the IHE Patient Care Device Domain in 2005
    - MDI is a fact of live worldwide; IHE PCD devices are being tested at IHE Connecathons around the globe.
Other MDI “Conservation of Trouble” ahead?

• Mobility has created “Where in the World is Mario?”
  • I can use my new Vonage phone service, but “Al Gore’s Internet” 411 services think I am in Florida

• Internet of Things (IoT)
  • EXPLOSION of smart light bulbs, outlets, thermostats in the extended environment of care, all chattering via wireless and wired networks

• Opportunities?
  • Light bulbs (and virtually any powered object) can serve as wireless access point for adaptive mesh networks, replace wi-fi clutter…
  • “Sentient Hospital™,” where some safety monitoring is built into the environmental systems
New Li-Fi, light based (From Discovery News)

You may soon be able to connect to the internet nothing more than a simple lamp. Li-Fi, or “light fidelity”, is a **new wireless technology** that just premiered at the Mobile World Congress, the world’s largest mobile tech fair – in Barcelona. French start-up Oledcomm says the new technology is 100 times faster than conventional Wi-Fi.

“Laboratory tests have found that Li-Fi can transmit information at almost unbelievable speeds, over **200 gigabytes per second**. That’s fast enough to **download 23 DVDs’ worth of information in the literal blink of an eye**.”

“Unlike **Wi-Fi**, which can potentially broadcast your information far and wide, Li-Fi signals **can be directed at a single user**, which in turn helps keep their activity more **private**. And because it’s **easy to restrict**, it could be used in locations like **hospitals** or schools.”
As prices crash, how long before they show up in lobbies, clinics, and hospital

As the price point topples for IoT devices, how will you even know where they are?
Conservation of Trouble?

• “Trouble is incompressible... When you squeeze it one place, it oozes out another...”

As I opined to a ripple of nervous laughter among the 1200 attendees at this year’s HIMSS Interoperability Symposium: “How hard could it be? We’re only moving 1’s and 0’s from one place to another, folks!”

And, as my good friend and colleague Todd Cooper opines: “And what could POSSBILY go wrong, anyway?”

So, for the young digital natives in our tribe, start thinking about how we (you) are going to manage BLINK data at the speed of light when BLINK every electronic object in a patient’s room may be running many parallel 200 GB/s streams of bidirectional life critical information...
Sloane’s First Law:  
*The Computer is an Idiot!*

Observed and presented in my graduate courses and research since 2000.

“A digital computer is nothing more than an abacus that can add and subtract 1s and 1s incredibly fast. **No more, and no less!**”

“We make a huge mistake when we attribute intelligence to computers. ALL apparent computer capabilities are clever simulations, written by humans, to simulate life with a FAST abacus.”

“A computer does NOT give a damn about the outcome.”
If any of the planes gave a damn, they might have taken back control to save themselves, the passengers, or the victims on the ground....

- At least 3 points are needed to define a line, 4 a trend...
Grand challenges: Creating SAFE self-driving cars, planes, and medical devices…

Innovative solutions need *out-of-the box* thinking. e.g., Google recently patented a sticky hood, to keep pedestrians from bouncing off a self-driving car and being run over!

e.g., bad things happen when two objects try to occupy the same space and time.
Automation run amuck; **NO regard for medical device safety if Microsoft Windows in a device!**
And, some brainstorming ideas may be bad…

- Like this prototype “Super Bus” to overcome rush hour in Beijing and Shanghai!

*The rule of Agile Engineering: FAIL EARLY, before the mistake is expensive!*
The AAMI/UL 2800 Standards Project is working to formalize the design requirements and parameters for tightly coupled, life-critical medical devices.

i.e., Self-Driving MDI

One use case: A *multi-vendor morphine IV pump/system that can be controlled, or even shut off, by one or more physiologic monitors.*
"Regulation, regardless of its necessity and many virtues, would have prevented not only the development of (the) MAX (Cart), but the impetus it created, including a three-page spread in Life magazine, that made ECRI possible."

**New ideas are fragile and all too easily destroyed.** It is not simply that rules, regulations, budgets, approval processes, and attendant bureaucracy inhibit the implementation and testing of new concepts, but they shift one’s focus and energies from aggressive invention to defense.

At worst, however, they can discourage one from exploring an idea in the first place."
The FDA’s proposal to regulate medical device repair was inappropriate in 1999; it is even WORSE today, as this field goes through an incredible revolution, transformation, and re-invention.

Fixing tomorrow’s problems with yesterday’s ineffective solutions is a fool’s mission, and “Insanity is the act of repeating the same action expecting a different outcome each time.”
Our industry must invent **NEW System of Systems Engineering Life Cycle Management Tools** that address CE-IT interdependence!

We’ve been jawboning about this since at least 2006!
We need to adopt/adapt the V-Model Systems Engineering (INCOSE) model of reliable system engineering to CE and HTM.

INCOSE's latest System of Systems Engineering (SoSE) Guide embeds iterative V-Model simulation/modeling/verification/validation for design, development, procurement, AND lifelong management of complex systems...

AAMI and INCOSE are in deep dialog, including ACCE on these issues!
Ken Maddox made this webinar point, 5/20/16:

HTM/IT Bridge Role Summary

• This train is coming; get on board or get run over!

Or, as General George Patton said: “Lead me, follow me, or get the hell out of my way!”
I say: “Set aside your concerns, objections, and history. Both sides have CRITICAL contributions to make, and CE-IT will be forever co-mingled, co-dependent, and interdependent.”

CE, BMET, HTM, IT, PhD, MD or RN: We are all about saving lives and making a difference.

Get over it, and get on with it!”
And never forget these First Laws:

**The Conservation of Trouble**
Plan and be ready for unintended consequences because trouble is incompressible and will ooze out elsewhere.

**The Computer is an Idiot**
It does not care about outcome and can only add 1s and subtract 1s. NEVER believe the computer KNOWS, so be aware and responsible about automated systems!
Thank You!
Jump in, learn, and volunteer to help lead MDI and CE-IT in the 21st Century.
The water’s great; the opportunities HUGE!

Elliot B. Sloane, PhD, CCE, FACCE, FHIMSS
ebsloane@gmail.com
Moderator, CE-IT Collaboration Town Hall Webinars
Download ALL our past CE-IT presentations for free at www.CEITCollaboration.org for free!
Topic 1: Impact of MDI on Device Assessment
Sub-Topic 1: Changing Technology Standards

Ken Fuchs, Distinguished Fellow, Center for Medical Interoperability
Jennifer Ott, Medical Equipment Specialist, Northstar Management, LLC
Jeff Peacock, Solution Consultant, Kaiser Permanente
Dale Nordenberg, Exec Director and Founder, Medical Device Safety, Security Consortium
Assessment and Acquisition – Changing Technology Standards

Ken Fuchs, M. Eng., MBA
C4MI Distinguished Fellow, Medical Interoperability Chair, IEEE 11073 Standards Committee

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**Vision**
Accelerating the seamless exchange of information to improve healthcare for all

**Mission**
To achieve plug-and-play interoperability by unifying healthcare organizations to compel change, building a lab to solve shared technical challenges, and pioneering innovative research and development
Founding Members Possess Market Presence
Current Status – Medical Device Integration

- Electronic Health Records
- Other Applications (CDS, 3rd Party, Analytics, etc.)

Closed Middleware Solution
<Enterprise Component>

Closed Middleware
<BS Component>

Vendor Gateways and IT Systems

Non-Networked Medical Devices

Networked Medical Devices

Manual Data Entry

Proprietary
Standards-Based
Changing Landscape of MDI Standards & Profiles

Foundational

11073 Foundational
- Nomenclature
- Domain Info Model

Current

11073 Classic
Critical Care BS MDs
- Manager / Agent
- nonNW Pt-to-Point

11073 PHD
Personal Health Dev.
- Manager / Agent
- nonNW Pt-to-Point

11073 SDC
BS thru Enterprise MDs
- Peer to Peer
- NW Web-Services

OpenICE
Critical Care BS MDs
- Manager / Agent
- NW DDS

Emerging

HL7
- Observations

IHE PCD
Medical Device GWs
to IT Systems
- NW HL7

HL7 FHIR
- Resources

IHE PCD / FHIR
Medical Device GWs
to IT Systems
- NW REST
C4MI Interoperability Maturity Model (IMM)

- **Key Criteria:**
  1) Plug-and-Play; 2) 2-Way; 3) 1-Many Certified; 4) Trusted; and 5) Open Standards based
Desired State

Clinical Applications
(EHR, CDS, Analytics, Data Portals, mobile, etc.)

Application Interface(s)

Plug-and-Play Interoperability Platforms

Device Interface(s)

Medical Devices

Complete, 2-Way Interoperable Data

Complete, 2-Way Interoperable Data

Standards-Based Interface
Thank You

www.center4mi.org
Developing a Flexible Healthcare Infrastructure

Presented by Jennifer C. Ott  CCE FACCE
Academy for Healthcare Infrastructure

- National Institute of Building Sciences

- Collaborative Research Program
  - 25 private health care systems
  - 2 federal agencies
  - 10 critical issues
  - 5 selected for best current thinking process

- Five Teams
Teams

- Team One – Owner Organization for Successful Project Outcomes
- **Team Two – Developing a Flexible Healthcare Infrastructure**
- Team Three – Project Acceleration: Speed-to-Market Strategies
- Team Four – Defining the Net Generation’s Focus
- Team Five – Reducing Capital Costs

*Cost of initial capital investment in infrastructure is exponentially smaller than the life-cycle cost of the delivery of care, operating, maintaining and renovating a building after occupancy over its entire functional life.*
Need for Flexible Healthcare Infrastructure

- Lifespan of 50-100 years

- Design and position the most stable elements so as not to impede the more frequent change of volatile or dynamic elements
  - Stable – MEP and primary circulation
  - Dynamic – space plan of functional areas and FFE

- Includes both building systems and spatial conditions being able to accommodate changes in facility usage, clinical modalities, medical equipment, system loads, etc.

- Biggest impediment to change are utility systems

- Renovations and alterations within a building exceed the initial cost of a building by three times for a general building, healthcare is higher (Brand, 1994)
Six Layer of Change

- Site
- Structure
- Skin
- Systems
- Space Plan
- Stuff
Best Practices

• VA Hospital Building Systems – Integrated Building System

• Open Building Systems and the INO Hospital

Figure 6: Banner Estrella Expansion Planning
Best Practices

Figure 7: Banner Estrella Primary Infrastructure and Circulation
[diagrams courtesy of NBB]
Top Healthcare Design Mistakes

• Not designing with technology in mind
• Inadequate real estate to meet technology demands
• Thinking that wireless is the nirvana of connectivity
• Under-designing building/cabling infrastructure
• Poor design/coordination of power/cooling requirements
Best Practices

- Structured Cabling Guidelines
  - ANSI/TIA – 1179

- Equipment Rooms

- Entrance Facilities

- Cabling Guidelines
  - Backbone
  - Horizontal
  - Centralized Optical Fiber Cabling

- Pathway Considerations

- Bandwidth

- Work Area Density Guidelines
Thank You
The CERC: Connected Environments Requirements Catalog
Presented by Jeff Peacock
Medical Device Integration
Kaiser Permanente
The Problem

- Vendor A: Wireless connectivity for devices (but network credentials are available in clear text under “Network Credentials” on the main menu)
- Vendor B: Web-based administration utility (but only one account: Administrator)
- Vendor C: Data distributed to all facilities via a central hub in the datacenter (by broadcasting it across the entire network)
CERC Philosophy

- This is bad
CERC Organization

- Peripheral
- Integrated Clinical Environment
- System Life Cycle Management
- Reliability and Risk
- End to End Architecture
- Configuration
- Network Transaction
- Availability
### Examples

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<tr>
<th>ID</th>
<th>Requirement</th>
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<tr>
<td>NT.0001</td>
<td>Portable devices must be DHCP capable</td>
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<tr>
<td>PM.0001</td>
<td>Device should provide plug and play functionality with peripherals that are needed for operation of the equipment.</td>
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<tr>
<td>AM.0001</td>
<td>Device should be able to continue its primary clinical function if non-essential component and/or system accessories cease functioning.</td>
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<tr>
<td>RR.0001</td>
<td>The biomed device manufacturer should submit a vulnerability scan report using an industry accepted tool.</td>
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<tr>
<td>CM.0001</td>
<td>The vendor must support systems in all the states where we do business.</td>
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<tr>
<td>SL.0001</td>
<td>Vendor must communicate end of sales life dates and end of service life dates to KP in a defined timeline.</td>
</tr>
<tr>
<td>IE.0001</td>
<td>Remote access tools used by vendors must include an audit trail that we can review.</td>
</tr>
<tr>
<td>EA.0001</td>
<td>RTLS is required for all mobile assets that have a battery and wireless card.</td>
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Bottom Line
MDRAP

MD-Cyber-Risk and Safety Initiative

Medical Device Risk Assessment Program

Dale Nordenberg, MD
MDISS
AAMI Conference
ACCE Session
June 2016
Welcome to MDRAP!

You are currently signed in as kristen.taylor71@gmail.com.

MDRAP, a product of the MDISS community, is the Medical Device Risk Assessment Platform which assists healthcare systems and device manufacturers in understanding, analyzing and mitigating the security risks of their medical devices.

Use the menu above to navigate.

- **Review Device Inventory**
  - Review the devices assigned to your institution/company and add additional devices from the master FOA list. Once you have devices in your inventory, you can perform Risk Assessments on them.
  - View Device Inventory

- **View Existing Assessments**
  - View the list of Assessments that have been created and/or completed by you on the devices in your inventory.
  - Go to Assessments

- **View the FAQ**
  - Review the Frequently Asked Questions. We will continue to upgrade and improve the FAQ to provide a useful resource for all MDRAP users.
  - Go to the FAQ
Institute of Medicine
Health Care Quality AIMS

- Safe - Avoiding preventable injuries, reducing medical errors
- Effective - Providing services based on scientific knowledge (clinical guidelines)
- Patient centered - Care that is respectful and responsive to individuals
- Efficient - Avoiding wasting time and other resources
- Timely - Reducing wait times, improving the practice flow
- Equitable - Consistent care regardless of patient characteristics and demographics

The medical devices are a core component of healthcare quality
MDRAP

Connected Health: Benefit Versus Risk
Defining a Public Health Problem

- Three parameters define the importance of a public health problem
  - Breadth of exposure, e.g. incidence/prevalence
  - Depth if impact, e.g. morbidity and mortality
  - Preventability
Safety Perspectives
The Numbers are Impressive

Estimating patient exposures to digitally enabled and networked medical devices

1. One billion encounters per year
2. Each encounter, on average, has 10 exposures to a medical device
3. Assume 10 years of legacy risk as the national healthcare landscape will continue to have inadequately secured devices
4. Over ten years, 100 billion patient exposures with medical devices

Exploring Probability of Adverse Events

<table>
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<th>Adverse Event Rate</th>
<th>Adverse Events</th>
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<tr>
<td>1% (.01)</td>
<td>10,000,000</td>
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<tr>
<td>0.10% (.001)</td>
<td>1,000,000</td>
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<tr>
<td>0.01% (.0001)</td>
<td>100,000</td>
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<tr>
<td>0.001% (.00001)</td>
<td>10,000</td>
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<tr>
<td>0.0001% (.000001)</td>
<td>1,000</td>
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Best Practices Legacy-Drag

New Digital Health Infrastructure Demands New Best Practices

- The nation’s healthcare system operates on a national biomedical device network
- The connected care environment has evolved more rapidly than associated best practices
- The ‘health system’ has not adequately budgeted or committed to important practices needed to secure today’s health system infrastructure
  - Assessment of devices
  - Cyber-security exercises
  - Monitoring
  - Updating and patching
A Cyber Security Public Health Initiative

- The MDRAP Program is
  - Supported by the Department of Homeland Security, Cyber Security Division
  - A non-profit initiative
  - A community-driven collaborative based on broad stakeholder input including manufacturers, health systems, technology companies and government agencies
  - Closely integrated with the programs of the National Health Information Sharing and Analysis Center (NHISAC)
  - Participating in the NIST National Cybersecurity Center of Excellence (NCCOE) medical device cybersecurity program
New Assessment

Complete the form below to create a new Assessment. After you click on the "Create" button, you will be routed to your new assessment to complete the selected Question Set.

- Tracheal Seal Monitor
- MDISS

Assessment Title/Name
Assessment_Test_123

Description
Assessment of Tracheal Seal Monitor using MDISS created on 2/23/2016

CREATE

Back to List
MDRAP

Location

Device Operation Status
- Select a Status
- Pre-procurement
- Implementation in progress
- Deployed/Operational

Facility/Building
- Select a Facility/Building
- Cape Center
- Fair Oaks Health Center
- Cape Center Urgent Center

Facility/Building
- Cape Center

Device Operation Status
- Select a Status

Location
- Select a Location
- Floor 2

ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING
### Assessment Test 123

- **Tracheal Seal Monitor**

**ASSESSMENT QUESTIONS**

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<tr>
<td>Other Questions Affecting Exposure*</td>
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<tr>
<td>Automatic Logoff</td>
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<tr>
<td>Audit Controls</td>
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<tr>
<td>Authorization</td>
<td></td>
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<tr>
<td>Cyber Security Product Upgrades</td>
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<tr>
<td>Malware Detection / Protection</td>
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<tr>
<td>Person Authentication</td>
<td></td>
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<tr>
<td>System and Application Hardening</td>
<td></td>
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<tr>
<td>Transmission Confidentiality</td>
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<tr>
<td>Transmission Integrity</td>
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#### Transmission Integrity

**More Information...**

1.1 **Transmission Confidentiality**

- [ ] Can Private Data be transmitted only via a point-to-point dedicated cable?
  - [ ] Yes
  - [ ] No

**ADD NOTE**

1.3 **Is Private Data encrypted prior to transmission via a network or removable media?** (If yes, include in the notes which encryption standard is implemented)
Assessment Inventory

Assessments

This is a list of your Assessments. You may view/edit any of these by clicking on the title. To add a new Assessment click the add new button to the right.

- Cape Center Assessment
  Blood Glucose Monitoring System
  last modified 10/29/2015
  This is a real life description of an assessment on a real actual medical device.

- New Assessment for Glucose Monitoring
  Blood Glucose Monitoring System
  last modified 10/29/2015
  This is a great test of the assessment capability of the System.

- Review of Wireless Vital Signs Monitor
  Wireless Vital Signs Monitor (WVSM)
  last modified 10/29/2015
  Review of Wireless Vital Signs monitor for New Location
MDRAP Screenshot
Risk Graphic with Magic Quadrant Visualization

Uses the “Magic Quadrant” graphic display to improve management’s understanding of the risks

- Risks are high priority to fix and not costly
  - Higher likelihood
  - Lower cost

- Risks are high priority but costly to fix
  - Higher likelihood
  - Higher cost

- Risks that may wait for remediation
  - Lower likelihood
  - Lower cost

- Risks that may wait for remediation
  - Lower likelihood
  - Higher cost

*Level of effort is similar to cost
Device Portfolio Risk Management with MDRAP

- Standardized analysis of device risk allows for a unified view for a population of devices
- Understanding of exposure and vulnerabilities within and across departments and care contexts
- Identify common vulnerabilities that could be remediated as a group
Scored Components:

**Exposure** – evaluation of the type and extent of data maintained on the device/application databases, and the exposure (attack surface – e.g. internet connectivity and how data is communicated), and external environmental protections available within the enterprise to protect devices and applications.

**Effectiveness** of control implementation – questions about how specific security controls are implemented are responded to in building the evaluation of control effectiveness.

**Impact** – measure of the impact to the institution of various forms of breach of the institution’s security (compromise of a particular control).

**Level of Effort to Remediate** – this is an evaluation of the difficulty/cost to remediate any particular deficient control – it is based on 2 factors: the willingness of a vendor to perform the remediation, and the cost of a remediation. Note that some remediation can be done without vendor cooperation – often in adding external controls reducing the attack surface.
Analytics

Externally Set Components:

**Threat / Experience Modifier** – a variable set for the duration of any given analytic session which reflects the motivation of attackers to exploit any specific control. This variable is set by the security team for each control and updated annually as industry experience finds the incidence of attacks in the wild to be increasing or decreasing.

**Severity** – this is another variable set by the security team and reflects the impact to Information Technology Systems (ITS) department if a control failure is experienced, and as a result IT resources and time (and cost) are involved in having to restore normal operations and retrain information workers. This is really the only variable which is dependent on the ITS group providing input to the remediation LOE in the event of control failure.
Analytics Elements

Computed Score Dimensions:

Likelihood – this is the “Y” axis on the graphic in the previous slide, and represents the computed likelihood that a control failure will occur for this control:

\[
\text{Computed Likelihood} = (\text{Exposure & Effectiveness}) \times \text{Threat Modifier}
\]

Risk – this is the size of the bubble in the graphic. It represents in one number the risk to the enterprise of a compromise of a particular control based on how the control is implemented (or not implemented), the impact to both the institution and the information services department in remediation, and of course, the likelihood of compromise.

\[
\text{Computed Risk} = (\text{Computed Likelihood} \& \text{Impact} \& \text{Severity})
\]
Welcome to MDRAP!

You are currently signed in as lonfinley73@gmail.com.

MDRAP, a product of the MDISS community, is the Medical Device Risk Assessment Platform which assists healthcare systems and device manufacturers in understanding, analyzing and mitigating the security risks of their medical devices.

Use the menu above to navigate.

Review Device Inventory

View the list of Assessments that have been created and/or completed by you on the devices in your inventory.

Go to Assessments

View Existing Assessments

View the FAQ

Review the Frequently Asked Questions. We will continue to upgrade and improve the FAQ to provide a useful resource for all MDRAP users.

Go to the FAQ
Sub-Topic 2: Pre-Procurement Testing & Simulation

David Jamison, Executive Director, ECRI Institute
John Garguilo, Computer Scientist, Nation Institute of Standards & Technology
Ted Cohen, CE Manager, UC Davis Medical Center
Jeff Peacock, Solution Consultant, Kaiser Permanente
Assessment- Testing and Simulation
Presented by David Jamison

ECRI Institute
More complex devices
More systems of devices
More opportunity for “Systems Issues”
What has ECRI Seen?

• An 8-minute time discrepancy between a cardiac monitoring system and the EHR that was receiving streamed physiologic data resulted in misleading information about patient blood pressure and could have resulted in inappropriate therapy
  • [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec;9(4)/Pages/143.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec;9(4)/Pages/143.aspx)

• Performing network vulnerability scanning on medical device systems that were supposed to be omitted resulted in persistent telemetry reboot and monitoring outage

• Microsoft OS computers received alerts that free upgrades to Windows 10 are available. Updating the OS of medical device computers can render devices or their accessories inoperable, and end-users with admin privileges may be tempted to accept the free upgrade.
What can you do?
Test, Build, Simulate, and Test Again!

Introducing our Panelists:

• John Garguilo, NIST
• Ted Cohen, UC Davis
• Jeff Peacock, Kaiser Permanente
Thank You!

Sometimes, things look different once you build them… 
Semantic Interoperability of Medical Devices
John J. Garguilo, Computer Scientist

National Institute of Standards and Technology
U.S. Department of Commerce
Key Discussion Outline and Topics

• Background - Work & Research Areas, Scope
• Committee Work: Standards, Domain Groups
• Conformance Software Test Tooling
  ▪ HL7 Tooling and Domain Conformance Tools
    ➢ Semantic messaging
  ▪ On-line IEEE MDC Nomenclature dBase
    ➢ Common Standards-based Terminology
  ▪ Domain Information Model Editor work and tool
    ➢ Model *is* the Standard
Patient Care Health Device Connectivity

Departmental Devices and Mgmt Systems

Hospital Device Gateway(s)

Hospital Health Records

Remote EHRs

Acute care
Cardiology
Surgery
ER, ICU, others …

Internal Hospital Network

IHE DEC Profiles: PCD+RTM, PIB, SPD, ACM, PIV, WCM, IDCO …

IHE Content Profiles, XDS, XDR

Health Information Exchange

Note: IHE Profiles shown above were recently (March 2016) demonstrated at HIMSS16 and AAMI16; IHE DEC PCD-01 Technical Framework “Final Text” version first became available in Q3 2011.

Slide developed and provided by Paul Schluter, GE Healthcare
Personal Health Device Connectivity

Devices aka Agents
- Continua PAN
- Continua LAN
- ZigBee
- Bluetooth
- USB
- ISO
- IEEE

Aggregation Manager
- Continua WAN
- W3C
- IHE

Telehealth Service Center
- HRN
- IHE

Health Records
- Continua HRN

Note: Continua 2014 Version (and subsequent updates) Guidelines available today; The Continua WAN interface uses the IHE DEC PCD-01 transaction over Web Services.

Slide developed and provided by Paul Schluter, GE Healthcare
Medical Device Interoperability Using ‘Profiles’ To Advance Rigorous Testing

Testable Assertions: IHE-PCD Validation Requirements Used by NIST Test Tools

Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD)
Medical Device Interoperability
NIST Test Environments and Services

Test Artifacts
- Conformance Profile
- HL7 Tables
- ‘Device’ Test Agents
- ISO/IEEE 11073/Rosetta Terminology

Test Harness (Java Code)

Test Execution

HL7 V2 Message Validation Report

Results
HL7 V2 Message

User / Device

Vendor

System Under Test

Instance Test Environment
E.g., IHE-PCD Conformance Testing of an HL7 V2 IHE-PCD Message using a NIST Web Application Client

Isolated System Test Environment
E.g., IHE-PCD Functional Behavior Conformance Testing using a NIST Web Application Client and Test Agents

Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD)
Named after the Rosetta Stone, the PCD Rosetta Project maps existing and proprietary vendor parameters and units-of-measure for virtually all physiological measurements to the ISO/IEEE 11073-10101 vital signs nomenclature and related standards such as UCUM.

This will facilitate real-time interoperability between devices and systems, including EHR systems using the IHE PCD-01 Technical Framework.

This level of collaboration for the common good is open to all vendors in the IHE PCD.
IHE-PCD Rosetta Terminology Mapping

Vendor Semantics

- Vendor A
- Vendor B
- Vendor C

ISO/IEEE 11073 Semantic Standards

- Vendor Terms RTM
  - 1731 rows
- Harmonized Terms hRTM
  - 879 terms

IHE PCD Technical Framework Content

- HL7 V2 Messages
- HL7 V3 CDA/CCD
- 11073 PnP Comm

- Open consensus process
- Observation identifiers and co-constraints
- New terms incorporated into standards
- hRTM used for conformance testing

Slide developed and provided by Paul Schluter, GE Healthcare
• Thank You! 😊
Challenges in Testing Integrated Systems

Ted Cohen, MS, CCE, FACCE

UC Davis Health System
UC Davis’ Virtual Network Overlay

Gold=GP (General Purpose)
Blue=Clinical GP
Green=CLC (Clinical Life Critical)
Pre-procurement Considerations

• Know clinical needs and workflow
• Is project a current system expansion or new?
• Vendor question list: MDS\textsuperscript{2} or custom list
• Can the device/system really do what the vendor says it can do in our environment?

• Pre-purchase Testing:
  • Proof of concept (lab, simulation suite, clinical environment (no pt)), clinical pilot
• Scalability?
Test Plans for a Complex Environment

Medical Devices  Serial to TCP/IP  Middleware  Interface Engine  EPIC EMR

- Confirm end-to-end connectivity
- Confirm full data set from each device-type flows into flow sheet(s) for all parameters in all modes
- Fail over test: Test backup systems
Test Failure Examples

We do testing to find and resolve problems before “go-live”. However ...

• Could better testing have caught these problems?:
  • HL-7 testing (anesthesia machine units of measure)
  • DHCP/BootP server backup problem
  • Infusion pumps: scaling problem
Another Test and Support Method

Interface Support system

Future CMMS interface (IHE PCD MEM-DMC)
In Conclusion …

- Hospitals continue to “reinvent the wheel”, and vendors continue to “push” proprietary, vendor-based solutions.
- CE/HTM community needs to advocate manufacturers’ implementation of standards/profiles (Visit the IHE PCD demo at the AAMI Interoperability Showcase!)
- Education of everyone, including CE, IT and vendor staff.
Testing at SGC
Presented by Jeff Peacock
Medical Device Integration
Kaiser Permanente
FAQs

• Opened on June 26, 2006
• Jointly funded by Kaiser Permanente’s National Facilities Services, Information Technology, and National Patient Care Services groups
• The center contains 37,000 square feet used for
  • live simulations
  • technology testing
  • product prototyping and evaluation
  • clinical training
• an exact re-creation of an entire hospital
  • med-surg
  • labor and delivery
  • operating rooms
  • emergency rooms
  • recovery rooms
  • mock work stations
  • hallways
  • waiting rooms
  • and more
Goals

• Developing device integration roadmaps that are driven by clinical workflow and business needs.

• Creating common integration methodologies, architecture, network, and security standards for all biomedical devices.

• Driving common standards across vendors, thus reducing the variability, integration and operational cost.

• Developing common and consistent device and solution nomenclature

• Minimizing the learning curve for of new products and new process in the care environment

• Eliminating “1.0 testing” on patients
Workflow Studies
Specialty Studies
Devices in the Home
Last Thoughts

• Recreate real-life clinical environments as much as possible
  • Helps identify the unexpected and unknown

• Use an isolated hospital-grade network
  • Control the chaos
  • Keep it valid

• Don’t under-estimate the impact of minor noise when scaled
Q&A

Come to the microphone OR
Submit questions to:

acce.aami16@gmail.com