2019 CE-IT Symposium
“Safe and Effective Application of Networked Medical Systems”
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President’s message

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Chief Biomedical Engineer, VA Greater Los Angeles Healthcare System
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Member Editorial Boards, JCE, BI&T and 24x7 magazine
ACCE Mission

- To establish a standard of competence and to promote excellence in clinical engineering practice
- To promote safe and effective application of science and technology in patient care
- To define the body of knowledge on which the profession is based
- To represent the professional interests of clinical engineers.
Today’s Program

▸ Safe Networking of Medical Equipment and Systems
▸ Medical Device Security including Patching of Medical Equipment
▸ Disaster Recovery Planning
▸ Emerging Technologies and their Impact on the Hospital Operations
▸ Long-Term Capital Planning
Medical Device Security
including
Patching of
Medical Equipment

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Medical Device Security

Considerations for achieving a safe and secure medical device ecosystem

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Medical Director, Partners HealthCare Biomedical Engineering
Director, MGH Program on Medical Device Interoperability & Cybersecurity (MD PnP)

Disclosures: None
Outline

- Why is cybersecurity a unique challenge?
  - Conceptually
  - Technically
  - Clinically
- The relationship between security and interoperability
- The greatest healthcare risk of cybersecurity (hint - it’s not technical)
- What can we do today?
Cybersecurity Challenges of Medical Device Systems in contrast to corporate IT systems

- Highly specialized, often unique, systems
  - Network configurations may differ with each vendor and each hospital

- Clinical requirements (such as alarm transmission) may preclude monitoring with Intrusion Detection System technology

- Device s/w version levels, patch levels, configurations are not standardized across the industry and version info typically cannot be read over network

- Networks span a diversity of vendors - regulated and non-regulated
  - Medical device vendors, Integration vendors, IT infrastructure vendors

- Devices as "Black Boxes"
  - Don't have visibility into internal device functions
Understanding the cybersecurity mindset: “best” vs “worst” intentions

- We are patient safety experts - we use best practices to support positive patient outcomes

- Medical device risk-management historically presupposes that use environment contains well-intentioned caregivers

- Cybersecurity is based on attackers with nefarious intent. They exploit weaknesses in systems that were designed to be safely used by those with good intentions.

- Hardening the legacy ecosystem is non-trivial for device manufactures, the FDA, and HDOs

  - Statement from FDA Commissioner: [https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622074.htm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622074.htm)
Malware infection of medical device - can it be detected?

- Malware designed for desktop operating systems may exhibit strange behavior on medical devices. Devices may reboot, distort the screen display, or - ??

- If multiple devices in fleet are affected, a high level of suspicion of malware infection is appropriate.

- Device failure “cybersecurity-awareness”: Swapping devices may not solve the problem! New devices on network may be affected.
  - Manual documentation is basis for “downtime” procedures for EMRs. What is “downtime” procedure for malware-induced “fleet failure”?
    - Ventilator approach - use a self-inflating ventilation bag
    - Will we need to create more equipment-failure backup plans?
Stuxnet "cyberweapon"

- Designed to infect Siemens PLC - programmable logic controllers used for automation.
- Destroyed ~ 1000 gas Uranium enrichment centrifuges (Natanz, Iran)
- Man-in-the-middle attack

“One of the first things this Stuxnet variant does is take steps to hide its tracks, using a trick straight out of Hollywood. Stuxnet records the cascade protection system’s sensor values for a period of 21 seconds. Then it replays those 21 seconds in a constant loop during the execution of the attack. In the control room, all appears to be normal, both to human operators and any software-implemented alarm routines.”

HL7 non-secured communications are susceptible to man-in-the-middle attack (next slide)

https://www.linuxincluded.com/hl7-medical-attacking-defending/
Modifying ECG Heart Rate value between bedside monitor and nursing central station display

Experimental setup:

- Nursing Central Station running Windows XP embedded
- Tools - network data sniffer (Wireshark), disassembler
- Medical devices interact with unencrypted UDP communication
- Emulation and real-time injection with ARP (address resolution protocol)

But, what is “normal” device/system behavior?

► Would we know that data is being modified?
Foreseeable Causes of Missing and Spurious data in EHR/EMR

**Missed bradycardia in EHR**

- Monitor reveals low SpO₂ “84%” at 2:07
- Minimum rate in EHR ~ 45

**Missing low SpO₂ in EHR**

- No evidence of SpO₂ = 84% in EHR
- (Blue ticks representing SpO₂ values)

**Falsely low SpO₂ data in EHR**

- SpO₂ Low
- Spuriously low SpO₂ in EHR caused by NIBP cuff inflation (Circled in red)
- Return of Pulse Ox plethysmogram

The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems

(NIHMSID 775190 &nbsp; Publ.ID: AAJ-D-16-01257)

2019 ACCE CE-IT Symposium
Cybersecurity for Hospitals and Healthcare Facilities

- Speculates on the possible....
- Helps avoid a “failure of imagination”
Anesthesia Machine

<table>
<thead>
<tr>
<th>Malicious Hacker Activity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spoof oxygen failure alarm</td>
<td>Ritchie whistle sounds when oxygen pressure is 38 psi (pounds per square inch) descending. Newer machines have an electronic sensor.</td>
</tr>
<tr>
<td>Disable Nitrous cut-off or oxygen failure protection device</td>
<td>The nitrous-oxide regulator is a “slave” of the oxygen regulator (i.e., if oxygen pressure is lost then the other gases cannot flow past their regulators).</td>
</tr>
<tr>
<td>Disable hypoxic-mixture alarms</td>
<td>Hypoxy guards (ratio controllers) prevent gas mixtures that contain less than 21% to 25% oxygen being delivered to the patient.</td>
</tr>
<tr>
<td>Mute all alarms</td>
<td>Anesthetist is unaware of hazardous condition.</td>
</tr>
<tr>
<td>Disable interlocks between the vaporizers</td>
<td>Designed to prevent inadvertent administration of more than one volatile agent concurrently.</td>
</tr>
<tr>
<td>Change display information</td>
<td>Makes it impossible to monitor the gases and cause confusion as to the flow for oxygen, air and nitrous oxide.</td>
</tr>
<tr>
<td>Cause machine to sound random alarms</td>
<td>Interferes with patient procedure.</td>
</tr>
<tr>
<td>Interfere with system monitoring the patient’s heart rate, ECG, blood pressure, and oxygen saturation</td>
<td>Makes it impossible to monitor the inhaled and exhaled concentration or partial pressure of CO² (carbon dioxide), and an indirect monitor of the CO² partial pressure in the arterial blood.</td>
</tr>
<tr>
<td>Change the dosage doled out to patients</td>
<td>Possible catastrophic consequences (patient not fully anesthetized, overdose medication, drug-drug interactions).</td>
</tr>
<tr>
<td>Cause the machine to reboot</td>
<td>Wipes out the configuration settings.</td>
</tr>
</tbody>
</table>
Robotic Surgical Device

<table>
<thead>
<tr>
<th>Malicious Hacker Activity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change display information</td>
<td>Confuses medical laser technician.</td>
</tr>
<tr>
<td>Spontaneous reboot</td>
<td>Wipes out the configuration settings. Delay extends the procedure increasing time patient under anesthetic.</td>
</tr>
<tr>
<td>Cause machine to sound random alarms</td>
<td>Interferes with patient procedure.</td>
</tr>
<tr>
<td>Mute all alarms</td>
<td>Surgeon is unaware of hazardous condition.</td>
</tr>
<tr>
<td>Turn off video feed</td>
<td>Surgeon stops the procedure and converts to non-robotic procedure.</td>
</tr>
<tr>
<td>Cause uncontrolled movement or arms</td>
<td>Surgeon stops the procedure and converts to non-robotic procedure.</td>
</tr>
<tr>
<td>Turn off robot</td>
<td>Surgeon stops the procedure and converts to non-robotic procedure.</td>
</tr>
<tr>
<td>Cause network to drop packets</td>
<td>Interferes with patient procedure.</td>
</tr>
</tbody>
</table>
# Infusion Pump

<table>
<thead>
<tr>
<th>Malicious Hacker Activity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spoof pump with low battery message</td>
<td>Pump ceases to communicate with hospital network.</td>
</tr>
<tr>
<td>Override patient pendant button</td>
<td>Pump does not administer pain medication when requested, or provides too much when patient pendant button is pushed.</td>
</tr>
<tr>
<td>Spoof pump that door is open</td>
<td>Pump pauses administering medication. Observation should be used to ensure quantity matches—visual verification is needed.</td>
</tr>
<tr>
<td>Spoof pump that total dosage was delivered when only partial was done</td>
<td>Patient does not receive full dosage prescribed.</td>
</tr>
<tr>
<td>Cause pump to misidentify barcode and download wrong parameters from the drug library for drug being administered</td>
<td>Incorrect autoprogram is administered with incorrect bolus; loading dose, constant fixed-rate, and lockout limit, causes over- or under-infusion, and possibly exceed dose upper limit.</td>
</tr>
<tr>
<td>Defeat purge process, alter purge rate</td>
<td>Air may not be removed from the syringe line.</td>
</tr>
<tr>
<td>Spoof occlusion pressure</td>
<td>Pump pauses administering medication.</td>
</tr>
<tr>
<td>Mute all alarms</td>
<td>Nurse is unaware when pump fails.</td>
</tr>
<tr>
<td>Turn off pump, encrypt internal files</td>
<td>Patient does not receive medication. A ransom is demanded to unlock pump files.</td>
</tr>
<tr>
<td>Change stored protocols in pump memory</td>
<td>Patient receives incorrect therapy, possibly exceeding dose limit.</td>
</tr>
<tr>
<td>Cause pump to prime continuously</td>
<td>Patient does not receive medication.</td>
</tr>
<tr>
<td>Change display information</td>
<td>Causes confusion as to what drug was given, what loading dose, and so forth.</td>
</tr>
<tr>
<td>Cause pump to sound random alarms</td>
<td>Interferes with patient therapy.</td>
</tr>
<tr>
<td>Cause the pump to reboot</td>
<td>Wipes out the configuration settings.</td>
</tr>
</tbody>
</table>
Will cybersecurity issues send us back to the “good old days” (dark ages)?

Hopefully not! Innovation increasingly requires integration of sensors, actuators, and apps. It is incumbent on us to improve security while increasing data availability and device integration.
Future medical devices and controllers will be increasingly networked to enable autonomous closed-loop care delivery

- Maintaining the security of autonomous medical systems is vital to assure safety
- Remote/virtual and autonomous systems may increase risk exposure by removing a trained operator from the loop

Regional Healthcare Delivery Organization Medical Device Cybersecurity Workshop - December 2017

- Under FDA support, MITRE and the MD PnP program organized a workshop to
  - Share lessons learned from managing medical devices during the WannaCry attack
  - Identify opportunities to better prepare health systems for future cyber attacks
  - Identify opportunities to improve regional and national sharing

- Brought together IT staff, biomedical engineers, and clinicians from Boston-area hospitals

- Results incorporated in new report: “The Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook “ (10/1/18)

MD PnP Medical Device Cybersecurity Sandbox - Collaboration between FDA, MITRE, MGH

Goals:

- The ability to test and validate vulnerabilities, mitigation strategies, and cyber resilient, clinical configurations that enable continued clinical operation in the face of cyber-physical hazards, in support of local, regional, and national preparedness goals.

- A realistic, biomedical environment that supports both preparedness exercises and live cyber-physical incident response activities, with the capability to test solutions in real time.

- The identification and sharing of medical device vulnerabilities, vetted mitigation strategies, and cyber resilient configurations, in direct support of the FDA’s postmarket guidance policy calling for greater transparency and adoption of coordinated vulnerability disclosures.
Medical Device Interoperability & Cybersecurity Program
“MD PnP” Lab
65 Landsdowne St., Cambridge, MA

3200 Sq. Ft. Suite contains 4 labs:
• Interop Lab
• Epic BME Integration Lab
• Cyber Lab
• Electronics Lab
• Extensive configurable network environment

Program established 2004. Lab rebuilt 2017
MD PnP Lab Network Architecture

Lab Network Architecture Description

- **External VRF** – MD PnP router is logically outside of the hospital firewall to minimize risk to operational systems.
- **Server Closet Switch Pair** – VLANs = LAN, Domain Servers (e.g. LDAP), Medical Device Servers, Cybersecurity Servers.
- **Interoperability Lab Switch Pair** – VLANs = Interoperability, Event Hosting, Custom Network 1 and 2.
- **Cybersecurity Lab Switch Pair** – VLANs = Cyber w/ EXT, Cyber w/o EXT, Custom Network 3 and 4.
Current MD PnP Lab Capabilities

- Dedicated DMZs for Research
- External VRF for hosting External Servers
- Dedicated Access Point for Operational Networks
- Dedicated Access Point for Research Networks
- Dedicated Wireless Controller
- Aggregated SPAN port data collection for wired networks
- Ability to integrate and/or access Partners HealthCare network and data center technologies
- Network Packet Inspection Software
- Network Traffic Shaping Software
- Full visibility into all network and server systems
- HardenedBSD Based Router and Firewalls
- Dedicated Managed Switching, Access Points, Wireless Controller
- Custom and dynamically changeable VLANS
- Virtual Machine Hosting Cluster
- Network Authentication
- Multi-Factor VPN Access into Each Network Segment (fine grained control)
- Dedicated Penetration Testing Servers
- Dedicated SPAN data collection ports per network
- Dedicated Data Collection Servers
- Dedicated High Performance Workstations for Penetration Testing and Network Analysis

Lab buildout to support PHS operational projects (pre-procurement assessment) and FDA/MITRE, DHS, and DOD research initiatives
Must we Trade Interoperability for Cybersecurity?

Some say:
“Networked systems increase attack surface and vulnerabilities”
“Close ALL interface ports” (epoxy has been proposed)

Is that possible today?
How would devices be patched? Upgraded?
How would data be integrated? Send data to EHR? Data Dashboard Analytics?
Relationship between Interoperability and Cybersecurity

- Like corporate IT networks, next-gen interoperable systems can enable monitoring of device status and behaviors and clinical effects of nefarious activity.

- Cybersecurity requires baselining, data acquisition, and monitoring.

- Comprehensive, contextually rich data from networked devices enables improved cybersecurity.

- Can’t monitor devices hidden behind “dongles”.
Comments on the draft guidance are due by March 18th.
Summary

- Most medical device systems are not networked (nor capable of being networked) in a manner that permits the application of modern cybersecurity tools and principles.
- We must be vigilant to both protect patients and equipment, and prevent security concerns and solutions from interfering with patient care and inhibiting needed innovation.
- Non-networked devices are not necessarily secure.
- Start preparing now.
What can we do now?

- “Defense in depth” - layers of security, starting with well-designed hospital network that is firewalled from the Internet and segmented (not “flat”)
- Maintain good “Cyber Hygiene”
- Build org relationships and processes
  - Consider creating a Medical Device Cybersecurity Response plan (MD-CRP)*
- Vigilance - device misbehavior may be cybersecurity related. Train staff to report.
- Complete device inventory with OS, s/w, patch info
- Safety - prepare for loss of access to device connectivity (e.g. to EHR) or basic functions (blank screen, no output)
- Include cybersecurity requirements in procurement
  - Disclosures, independent testing, standards

* [https://www.stahq.org/userfiles/files/044_STA_18AM_Abstract_Goldman%28414%29.pdf](https://www.stahq.org/userfiles/files/044_STA_18AM_Abstract_Goldman%28414%29.pdf)
Guidance on Network Segmentation
from the Health Sector Coordinating Council


Compiled by Julian Goldman, MD
February 11, 2019
HHS and HSCC Release Voluntary Cybersecurity Practices for the Health Industry

The Health Sector Coordinating Council (HSCC), in partnership with the U.S. Department of Health and Human Services, is pleased to announce the release of the "Health Industry Cybersecurity Practices (HICP): Managing Threats and Protecting Patients" publication. The four-volume publication seeks to raise awareness for executives, health care practitioners, providers, and health delivery organizations, such as hospitals. It is applicable to health organizations of all types and sizes across the industry.

This industry-led effort was in response to a mandate of the Cybersecurity Act of 2015 Section 405(d), to develop practical cybersecurity guidelines to cost-effectively reduce cybersecurity risks for the healthcare industry. The publication marks the culmination of a two-year effort that brought together more than 150 cybersecurity and healthcare experts from industry and the government. The consensus-based document was developed and released under the auspices of the HSCC Joint Cybersecurity Working Group, a public-private partnership to enhance healthcare and public health cyber and critical infrastructure security and resilience.

The publication consists of four volumes:

1. The **Main document** of the publication explores the five most relevant and current threats to the industry and recommends 10 Cybersecurity Practices to help mitigate these threats.

2. **Technical Volume 1** discusses these 10 cybersecurity practices for small healthcare organizations. It is intended for IT and IT security professionals.

3. **Technical Volume 2** discusses these 10 cybersecurity practices for medium and large healthcare organizations. It is intended for IT and IT security professionals.

4. **Resources and Templates** provide additional resources and materials that organizations can leverage to develop policies and procedures as well as assess their own cybersecurity posture, through a Cybersecurity Practices Assessment Toolkit.

For more information on this effort and to download a copy of the publication, please visit the 405(d) website at [www.phe.gov/405d](http://www.phe.gov/405d) and [https://www.phe.gov/Preparedness/planning/405d/Pages/hlc-practices.aspx.](https://www.phe.gov/Preparedness/planning/405d/Pages/hlc-practices.aspx)
Health Industry Cybersecurity Practices:
Managing Threats and Protecting Patients
<table>
<thead>
<tr>
<th>6.M.B</th>
<th>Network Segmentation</th>
<th>NIST FRAMEWORK REF:</th>
</tr>
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<tbody>
<tr>
<td></td>
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<td>PR.AC-5</td>
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Partitioning networks into security zones is a fundamental method of limiting cyberattacks. These zones can be based on sensitivity of assets within the network (e.g., clinical workstations, general user access, guest networks, medical device networks, building management systems, IoT networks) or standard perimeter segmentations (e.g., DMZ, middleware, application servers, database servers, vendor systems). Examples of standard network zones follow:

- **Perimeter defenses**: Most organizations host services that are accessed through the internet. A robust defense strategy should be deployed to monitor these “front doors.”

Best practices for perimeter defenses include the following:

- Implement highly restrictive rules on inbound and outbound ports and protocols. Use default-deny rules in firewalls and enable access only when clearly understood.
- Restrict DMZ from middleware, application, and database servers. DMZ controls are critical, because these servers are exposed to the internet and have a large threat footprint.
- Restrict the ability for DMZ servers to log in directly to servers on the inside network, specifically using remote desktop protocol, server message block, secure shell (SSH), or other remote access ports (tcp/3389, tcp/445, tcp/139, tcp/22).
- Ensure that local administrator passwords are unique to each DMZ server and do not use these passwords for any other server in the organization.
- Ensure that DMZ servers cannot connect directly to the internet. Instead, these servers should access the internet through outbound proxy services. Outbound proxy rules should limit the sites, URLs, IPs, and ports that a DMZ server can access to only whitelisted sites required for updates or application functionality. Be cautious of whitelisting hosting organizations like Amazon Web Services: malicious actors may use them to download malware to a compromised server.
- Consider this type of restriction configuration for partner WAN links or site-to-site VPN connections. Do not permit access to systems/applications that are not required by the user.
• **Data center networks**: Servers in the data center should be segmented into appropriate zones. Several different layers of segmentation may occur within data center networks, including
  o database servers;
  o application servers; and
  o middleware.

• **Critical IoT assets**: It is important to restrict access to assets that have a potentially high impact on the business or patients if compromised. Management and patching of security vulnerabilities in IoT devices is often limited. Examples include medical devices, security cameras, badge readers, temperature sensors, and building management systems. These assets generally exist outside of the data centers. Without proper segmentation, they may infiltrate general access networks. To achieve segmentation in the physical buildings, leverage multiprotocol label switching to build out virtual networks and place these network access restrictions behind core firewalls.

• **Vendor access**: Vendor access should be limited based on need. It should be temporary, and only access to required information should be granted. Some assets are managed exclusively or accessed by third-party vendors. These vendors may need continual access to the organization’s network. It is important to segment this vendor access from other networks and limit the vendor’s ability to access other parts of your corporate network. Whether these networks exist inside or outside of the data center, the principles are the same. In 2015, Target was the victim of a cyberattack leveraging these exact channels.\textsuperscript{25} Common examples include building management systems, security systems, physical access controls, and persistent tunnels required to enable cloud functionality.

• **General access networks**: The majority of your workforce will operate on general access networks. These are “edge” networks that provide connectivity back to the services offered in data centers, the internet, or other assets. General access networks require a sense of openness when communicating with services that are hosted by the organization. However, restrictions should be implemented that prohibit the assets in one general access network from communicating with the assets in another general access network. This critical control that can help stop the outbreak and spread of malware and ransomware attacks.
- Guest networks: It is common for organizations to provide guest access to the internet, especially in provider organizations visited by patients and their friends and families. Access to the internet is a core value of provider organizations. However, it must be restricted and controlled appropriately. These restrictions should exist on wireless networks, where it is most common, as well as wired networks often located in public spaces or conference rooms. Explicitly prohibit access to the internal network; guest users should access the organization using the same front door through which they access the rest of the internet. Lastly, as much as possible, limit the ability of your workforce to access guest networks.

About the speaker

Juuso Leinonen is a Senior Project Engineer at ECRI Institute.

- Manages medical device research/testing projects with published articles on medical device cybersecurity, infusion pumps, and telehealth.
- Investigates medical device problems, hazards, and accidents.
- Developed a standardized process for ECRI Institute medical device security testing and evaluation.
- Principal investigator for top 10 Health technology Hazard 2018 Ransomware and Other Cybersecurity Threats to Healthcare Delivery Can Endanger Patients

Volunteer Work:
- UL 2900-2-1 STP, IHE PCD Planning Committee, ACCE Membership Committee, ACCE Education Committee
Agenda

- ECRI Institute - Cybersecurity as a Top 10 Health Technology Hazard
- Medical device IT and security alerts
- Challenges of patching medical devices
- Recommendations
Independent, not-for-profit research institute

Mission:

- Improve patient safety, cost effectiveness, and quality of healthcare
“The country’s most respected laboratory for testing medical products” – New York Times

Multidisciplinary staff composed of: PhD’s, MDs, RNs, scientists, engineers, health care professionals

Independent, objective, conflict free expertise

Internationally known as the “Consumer Reports” of healthcare

Over 70% of US hospitals rely on ECRI services
ECRI’s Top Ten Health Technology Hazards
What it is, and why we do it

- Annual report identifying high-impact health technology hazards

Health technology hazards are device or system faults, design features, or methods of use that might, under certain circumstances, place patients or users at risk

- Produced by ECRI Institute's Health Devices Group to:
  - Shine a light on health technology safety issues that have the clear potential to:
    - Cause death or serious injury
    - Adversely affect patient care
  - Provide healthcare professionals with a tool they can use to:
    - Set patient safety priorities — We identify topics that we believe warrant attention for the coming year
    - Implement effective changes to help prevent future occurrences

2018 - #1. Ransomware and Other Cybersecurity Threats

2017 - #6. Software Management Gaps Put Patients, and Patient Data, at Risk

2016 - #10. Misuse of USB Ports Can Cause Medical Devices to Malfunction

2015 - #9. Cybersecurity: Insufficient Protections for Medical Devices and Systems
#1 - Ransomware and Other Cybersecurity Threats to Healthcare Delivery Can Endanger Patients
#1 - Ransomware and Other Cybersecurity Threats to Healthcare Delivery Can Endanger Patients

- Ransomware attacks can disrupt healthcare delivery by:
  - Rendering health IT systems unusable
  - Preventing access to patient data and records
  - Affecting the functionality of networked medical devices or disabling third-party services
  - Disrupting the supply chain for drugs and supplies
  - Affecting building and infrastructure systems

- Such disruptions can compromise or delay care
Top 10 Health Technology Hazards 2019

#1 Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations

- Malicious actors are increasingly targeting remote access systems to infiltrate networks
  - Many devices incorporate remote access functionality e.g., PACS
  - Unmaintained systems can be exploited to:
    - Install ransomware or other malware
    - Steal data or render it unusable

- Attacks can severely hinder healthcare operations by:
  - Rendering devices or systems inoperative
  - Degrading their performance
  - Compromising the data they hold
ECRI AlertsTracker - Recall Management System

SamSam Ransomware Infections May Affect Care Delivery

Ethicon—Gen11 Systems: Software Update May Result in Inability to Use Non-OEM Reprocessed HARMONIC ACE +7 Ultrasonic Devices [ECRI Exclusive User Experience Network]

Philips—iSite and IntelliSpace Picture Archiving and Communications Systems: May Exhibit Potential Cybersecurity Vulnerabilities
Medical Device IT Alerts

ECRI Institute - AlertsTracker Database
Medical Device Cybersecurity Alerts

ECRI Institute - AlertsTracker Database
Responding to Security Alerts - Challenges with Patching Medical Devices

- Patching or update often required to respond to a security alert
- Many facilities lack a formal patch management plan and urgent patching strategy
Challenges with Patching Medical Devices

- Impractical to keep systems updated
  - Thousands of medical devices from hundreds of vendors
  - Can directly impact clinical workflow i.e., system downtime
  - Manual updates commonplace
  - May require vendor assistance i.e., Field Service Engineer

- Prioritizing updates
  - How to effectively target limited resources?

- Patch availability
  - Vendor security alert does not mean a fix is available
  - Vendors claim that the device software cannot be updated due to FDA requirements
Medical Device Vendor - Challenges with Patching Medical Devices

- Difficulty in getting to the right person within an healthcare facility
  - No great centralized method to communicate about available updates / patches
- Manufacturer information portals require user/customer to actively seek the information
- Software update/patch validation requires significant resources
Recommendations

- Designate a project owner/champion for medical device security alerts
  - May be in Clinical Engineering and/or IT
  - Emerging role of Medical Device Security Specialist
Recommendations

- Establish a process to review and respond to medical device security alerts
  - Where to get the alerts?
    - ICS-CERT, Vendor, ISAOs, ECRI
  - Who to contact with the manufacturer?
    - Establish a list of medical device security contacts
  - How to respond when fix is not available?
    - Identify scalable compensating controls practical for your facility
Questions and Discussions
Disaster Recovery Planning (network recovery)

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Universal Health Services, Inc.  
Christopher.Nowak@uhsinc.com
Session Description

- This session will discuss disaster planning for the medical enterprise. The abrupt disruption of all or part of the operations of any business could negatively impact patient care and revenue. Therefore, every business, in order to minimize the negative effects of an abrupt disruption to the business enterprise, a disaster plan is a necessity.
About the speaker:

- Currently the Technical Lead for the Healthcare Sector Team within the National Cybersecurity Federally Funded Research and Development Center (NCF), operated by the MITRE Corporation.

- Co-author of multiple cybersecurity guidance publications that offer the healthcare industry detailed instructions for securing electronic health records on mobile devices and wireless infusion pumps in healthcare delivery organizations.

- Supported DHS, IARPA and MITRE research projects in software assurance, secure programming, static analysis, and software weaknesses and vulnerability research.

- Guest researcher for the Software Assurance Metrics And Tool Evaluation (SAMATE) project at the National Institute of Standards and Technology (NIST).

- Received a bachelor’s degree in computer science and a master’s degree in software engineering from the University of Maryland.
Mission:
Accelerate adoption of secure technologies: collaborate with innovators to provide real-world, standards-based cybersecurity capabilities that address business needs

https://www.nccoe.nist.gov/
Collaborative Hub

- The NCCoE works on critical national problems in cybersecurity.
- The NCCoE has access to a wealth of expertise, resources, relationships, and experience.
Risk Based Approach to Enhance Disaster Recovery and Minimize the Impact of Disruption
NIST Cybersecurity Framework

https://www.nist.gov/cyberframework
Improving Recovery & Security Capabilities

Source: NIST SP 800-184 - Guide for Cybersecurity Event Recovery
NCCoE Portfolio

- Attribute Based Access Control (SP 1800-3)
- Consumer/Retail: Multifactor Authentication for e-Commerce
- Data Integrity: Identifying and Protecting
- Data Integrity: Detecting and Responding
- Data Integrity: Recovering (SP 1800-11)
- Derived PIV Credentials (SP 1800-12)
- DNS-Based Email Security (SP 1800-6)
- Energy: Identity and Access Management (SP 1800-2)
- Energy: Situational Awareness (SP 1800-7)
- Financial Services: Access Rights Management (SP 1800-9)
- Financial Services: IT Asset Management (SP 1800-5)
- Healthcare: Securing Electronic Health Records on Mobile Devices (SP 1800-1)
- Healthcare: Securing Wireless Infusion Pumps (SP 1800-8)
- Healthcare: Securing Picture Archiving and Communication Systems (PACS)
- Healthcare: Securing Telehealth Remote Patient Monitoring Ecosystem
- Hospitality: Securing Property Management Systems
- Mitigating IoT-Based DDoS
- Manufacturing: Capabilities Assessment for Securing Manufacturing Industrial Control Systems
- Mobile Device Security: Cloud and Hybrid Builds (SP 1800-4)
- Mobile Device Security: Enterprise Builds
- Mobile Threat Catalogue
- Privacy-Enhanced Identity Federation
- Public Safety/First Responder: Mobile Application SSO
- Secure Inter-Domain Routing
- TLS Server Certificate Mgmt
- Transportation: Maritime: Oil & Natural Gas
- Trusted Geolocation in the Cloud (NISTIR 7904)


https://www.nccoe.nist.gov/healthcare
Relevant Resources for DR

- Framework for Improving Critical Infrastructure Cybersecurity Draft Version 1.1
- NIST SP 800-184 Guide for Cybersecurity Event Recovery
- NIST SP 800-61 Computer Security Incident Handling Guide
- NIST SP 800-150 Guide to Cyber Threat Information Sharing
- NIST SP 1800-11 DRAFT Data Integrity: Recovering from Ransomware and Other Destructive Events
About the speaker:

• Currently the Healthcare Technology Management Leader responsible for an enterprise-wide program which includes 28 acute care hospitals, free standing emergency departments, imaging centers and clinics across the United States.

• Certified Security Compliance Specialist and Certified HIPAA Professional through

• Biomedical Device Integration architect and implementation director

• Responsible for Medical Device Cybersecurity Solutions

• Board Chairman, Association for the Advancement of Medical Instrumentation Credentials Institute (ACI)
About my employer:

- Universal Health Services (UHS), one of the nation’s largest hospital management companies, has more than 350 acute care hospitals, behavioral health facilities and ambulatory centers across the U.S., Puerto Rico and the U.K. As we continue to grow, we stay focused on making health a positive and local experience.

- 6,127 Acute Care Hospital Beds

- Independence Physician Management (IPM), a subsidiary of UHS, operates within six states and the District of Columbia through 500+ providers, IPM is dedicated to the support and service of acute care facilities, with limited services for behavioral health. Its focus is on the acquisition, employment and recruitment of independent physicians.

- Publicly traded for-profit healthcare management corporation

- Crossings Healthcare - a software solutions company (https://crossingshealthcaresolutions.com/)
Disaster Recovery - Strategy and Planning

- Storms, Fire, Floods, Oh my!
- CYBER ATTACK!
- What constitutes a disaster?
- Small operations vs. large operations
  - Disaster Planning for all
- Predicting the unpredictable
- High Availability vs. Disaster Planning
  - HA - no disruption or continuity of business ops
  - DP - involves downtime, sometimes day, weeks, months, i.e. Nuance $98MM
Disaster Recovery - Strategy and Planning

► What is needed for preparing the DP
  ► A complete and solid inventory of hardware and software applications (CMMS)
  ► Vendor relationship management
  ► Risk rank inventory items
    ► Multi-disciplinary team - to define business tolerances for hardware and software applications
    ► Risk ranking prioritizes and balances the needs of the caregivers and the business while creating the expectations for the appropriate leadership teams
    ► Mission critical apps/hardware
    ► Non-mission critical apps/hardware
<table>
<thead>
<tr>
<th>Information</th>
<th>History Log</th>
<th>PM Schedule</th>
<th>Information Services</th>
<th>Contracted Service</th>
<th>Expansion</th>
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</thead>
</table>

### Name Plate
- **Tag/Asset**: 158-002169
- **Description**: X-RAY, CT
- **Type**: RADIOGRAPHIC UNIT, COMPUTED TOMOGRAPHY
- **Serial No.**: 30027859
- **Manufacturer**: TOSHIBA AMERICA MEDICAL SYSTEMS
- **Model**: AQUILION PRIME
- **Model Name**: AQUILION PRIME
- **Orig. Manufacturer**: TOSHIBA AMERICA MEDICAL SYSTEMS

### Administration
- **Building**: 
- **Cost Center**: CT SCANNER
- **Responsible Center**: CT SCANNER
- **Risk/Inclusion Factor**: 13
- **Location**: 
- **as of**: 03/08/2017
- **In Service**: 03/08/2017
- **Status**: Active
- **as of**: 03/08/2017

### Purchase Information
- **Supplier**: TOSHIBA AMERICA MEDICAL SYSTEMS
- **Ownership**: Purchased
- **Purchase Order**: 
- **Purchase Cost**: 485803.27
- **Estimated Acquisition Cost**: 

### Service Information
- **Condition**: Excellent
- **as of**: 01/31/2019
- **Site ID**: 30027859
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<th>Tag</th>
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**Device**

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<thead>
<tr>
<th>Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>EIN</td>
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<td>Description</td>
<td>X-RAY, CT</td>
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<td>Available Modules</td>
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**FDA Details**

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<tbody>
<tr>
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<td>12/31/2049</td>
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<tr>
<td>Disapproved Date</td>
<td>12/31/2049</td>
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<tr>
<td>Reason</td>
<td></td>
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<table>
<thead>
<tr>
<th>Device Type</th>
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<tbody>
<tr>
<td>Critical Device</td>
<td></td>
</tr>
<tr>
<td>SOX Regulated</td>
<td></td>
</tr>
<tr>
<td>PCI Regulated</td>
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<tr>
<td>Computer Based</td>
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## Operating System

<table>
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<th>Value</th>
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<tbody>
<tr>
<td>OS Developer</td>
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<tr>
<td>OS Version</td>
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<td>License Key</td>
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<td>Last Update</td>
<td>12/31/2049</td>
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<tr>
<td>Updated By</td>
<td></td>
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<tr>
<td>Firmware Version</td>
<td></td>
</tr>
<tr>
<td>BIOS Version</td>
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</table>

- **Firewall Enabled**: False
- **OEM Restricted**: False
- **Under OEM Warranty**: False

<table>
<thead>
<tr>
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<tr>
<td>AE Title</td>
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<td>DICOM</td>
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## Installed Software

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<tr>
<th>Version</th>
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</tr>
</tbody>
</table>

- **Software**: (dropdown menu)
- **SW Version**: (dropdown menu)
- **Revision Level**: (dropdown menu)
- **Install Date**: 12/31/2049
- **Method Used**: (dropdown menu)
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<tr>
<td>Store/Transmit ePHI</td>
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<tr>
<td>Logon Compliance</td>
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<tr>
<td>Password Compliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto Logoff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Encryption</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[Image of the HIPAA -- Webpage Dialog window]
Disaster Recovery - Strategy and Planning

▶ Responsibilities - key roles and the parties that need to be involved.
  ▶ Who declares the disaster?
  ▶ Roles for the C-Suite all the way down through the organization are defined and understand the processes of the DR plan.
  ▶ Who’s who listing and their roles and contact information
  ▶ Depth to the plan - Roles defined to the extent of “back-up” staff in the event of vacation or the inability of the primary role to fulfill obligations.
Disaster Recovery - Strategy and Planning

► DR Communications
  ► Plan for the worst! Do not assume that telecommunications or network operations (ip phones/e-mail/text) would be available
  ► Written plans in place for not only internal staff/employees but also external vendors, suppliers and emergency personnel.
Disaster Recovery - Strategy and Planning

- SLA’s - strong definition of services in the event of a disaster
  - Performance defined with penalties
  - Hidden fees?

- Continuous Maintenance
  - Be cognizant of changes within the business - new applications, retired applications, hardware needs, communication plans and human capital changes.

- Plan Ownership
Disaster Recovery - Strategy and Planning

► TEST, TEST, and TEST!!!!

► If you are not testing your plan, then you don’t really have a plan.

► How often?

► How comprehensive?

► Consider testing the plan in subsets to meet desired frequency and completeness as the business can tolerate

► Checklists

► Impact of staff turn-over - test your employees

► Include your vendors in any testing strategies
Questions and Discussions
Safe Networking of Medical Equipment and Systems

L Michael Fraai, MS, CCE
Executive Director: Biomedical Engineering & Device Integration
Brigham and Women’s Hospital

Bridget Moorman, CCE
President
Bmoorman Consulting, LLC
HIMSS 2019: CE-IT Symposium
“Safe Networking of Medical Systems”

L Michael Fraai, MS, CCE
Executive Director: Biomedical Engineering & Device Integration
About the speaker

Michael, a native of Curaçao, has an Undergraduate Degree in Biomedical Engineering from Tulane University, New Orleans, LA and a Graduate Degree from the Hartford Graduate Center/RPI, Hartford, CT.

Michael joined the Brigham and Women’s Hospital in 1994 as a Clinical Engineer. In 1997 he was promoted to Assistant Director of Biomedical Engineering then in 2002 he was offered the role of Director. Most recently in 2014 Michael was promoted to the position of Executive Director of Biomedical Engineering & Device Integration.

Michael focuses on strategic & innovative use of technology to match the current clinical practice model in the hospital.

Michael is responsible for implementing a hospital-wide telemetry system, a patient care network of 1000+ devices and maintaining an inventory of 24,000+ medical devices covering the BWH's distributed campus.
Brigham Health

- National leadership in patient care, quality improvement and patient safety initiatives, and its dedication to research, innovation, community engagement, educating and training
- Brigham and Women’s Hospital (BWH) employs ~16,000 people; 3,000 physicians, fellows and residents; more than 1,000 researchers and 3,113 nurses
- In 2011, performed the first full face transplantation in the US
- Inpatient admissions totaled approximately 46,000
- Biomedical Engineering supports ~26,000 patient care devices
- BWH went live on 05/30/15 with one of the largest EHR installations in the US that included Biomedical device integration (BMDI)
- 793 licensed beds
  - 146 ICU beds
- Patient care network ~ 1600 devices
  - 489 Telemetry beds
  - 43 Operating rooms
- BMDI integrated into EHR system
  - ~1900 devices
Agenda

- Medical systems & Safe Networking
- Methodology
- Devices connected on the IS network
- Dedicated Patient Care/ Vendor Networks
- The process
- Lessons learned
Partners eCare Goals

- One Patient, One record, One Team and One Partners Statement
- Consistent, standardized processes
- One system integrated across the enterprise
  - 2 Academic Medical Centers
  - 17 Community hospitals
- Safe networking of medical systems becomes critical
  - The importance of architecture and configuration for security
    - Across entity
    - Across system
Safe Networking of Medical Systems

- Devices connected directly on the IS network
  - Hardwire
  - Wireless
- Dedicated Patient care networks interfaced to an IS network
  - Devices that are connected on a dedicated network which interfaces to the IS network
- Physical security of networks
  - Access to network infrastructure i.e. closets
- Network Security configuration
Methodology used

- Develop clinical and technical requirements for security, redundancy and uptime
- Collaborate with your IS department
- SMDZ (Safe Medical Device Zone) configured on the IS network
- Configure routers
- Vendor configuration on the networked devices to ↑ security and limit access
- Involve vendors and hold them accountable to meet the current security standards especially for your institution/enterprise
- Network monitoring/management tools
Directly connected devices on your IS network

- Examples include:
  - RFid systems
  - ECG archival systems
  - Patient access ultrasound devices

- Collaborate with your IS department to understand the requirements before purchase and connection

- Often vendor submission documents are used
  - (Partners Vendor Information Security Plan (VISP))
a. **Access Control**
*Describe the technical, operational, and management controls used to provision access to systems and data. Include how user accounts, privileged access, and access to data (i.e. least privileges, access roles, permission) are managed for an employee over time. Include access authorization, management approval, access reviews. This should include both the vendor’s internal security practices and application design (where applicable).*

b. **Identification and Authentication**
*Describe the organization’s identity and authentication policy, standards and procedures, including how users access Partner Services, Systems, data and how those users are identified and authenticated. Examples include unique user accounts, password configuration and policy enforcement, federated identity management, 2-factor authentication.*

c. **Awareness and Training**
*Describe organizational requirements related to workforce information security awareness and training, including how employees are trained on securing devices, accounts, applications, services and data.*

d. **Audit and Accountability**
*Describe organisational requirements related to audit information, including what events are audited, the retention of audit information (i.e. how long are they retained, are they protected), and monitoring and auditing for unauthorized information disclosure. Describe what information is captured in audits and logs such as name, user ID, date and timestamp, access activity details.*

e. **Certification, Accreditation, Security and Risk Assessments**
*Describe how the organization certifies the information systems used for the solution are secure. Also, describe how the organization certifies the computing environments of subcontractors. Examples include SOC 2 Type 2 audits, other audit and certification activities, vulnerability scanning, penetration testing, internal review procedures. Also, describe the organization’s approach for assessing risk, including whether formal risk analysis are performed, and whether vulnerability assessments and penetration testing are performed for the information technology resources used for the solution.*

f. **System and Communications Protection**
*Describe the organization’s communication security policies, standards and procedures, including the organization’s secure transmission capabilities, and how the organization secures the information technology resources from external threats. This section should also describe the controls implemented to secure data and documentation as it is transmitted over untrusted networks (e.g., the internet). Examples include network perimeter security, intrusion detection, encryption of data-in-transit.*

g. **Configuration Management**
*Describe the organization’s configuration management practices for all systems, including whether baseline configuration information is recorded, and the access restrictions implemented to enforce change management. Describe the organization’s change management process.*
Directly connected devices on your IS network

- Discuss use of an SMDZ
- Contain devices in a dedicated zone
  - Limit traffic as much as possible within that zone
- Device configuration
  - Open ports configurations are not desired
  - ↓ Risk posture by working with your IS department
- Collaborative & participate in the IS vendor security reviews
- Realize that one device with a weak security profile can expose your entire IS network
Patient Care Networks or Vendor Networks connected to IS

Monitoring Device Integration Strategy – Operating Room

- Dedicated real-time patient care networks
- Vendor serial networks connected to IS
- Use of Routers are usually preferred
- Limit traffic in and out
- If using HSRP (Hot standby router protocol) Routers ensure that they are configured well
Patient Care Networks or Vendor Network connected to IS

- Examples include:
  - Dedicated real-time patient care networks
  - Vendor serial networks connected to IS
- Use of Routers are usually preferred
  - Limit traffic in and out
  - If using HSRP (Hot standby router protocol) Routers ensure that they are configured as well
- Often in an SMDZ with similar devices that may need to interact with each other
- Information security plan reviews for network security of both networks
The Process: Connecting Devices

- Collaborate **EARLY** with your IS department to start the review process
- Have Security Surveys completed **beforehand**
- Understand/identify clinical workflow so that the configurations **do not** compromise clinical care
- Test and validate the system/interface through **several scenarios**
- Stay current for security level changes in your institution
- Be conscious of software upgrades!
  - Impact on security profile
Lessons learned

- You will have to interface devices to meet the clinical workflows
  - EMRs
  - Communication systems
- It is **not** a static process
- Hold the vendors accountable to meet current security standards
- Minimize customization for ease of support
- Develop training plans
- Verify and test your configurations
- Develop and practice downtime procedures
Contact information

L. Michael Fraai: lfraai@bwh.harvard.edu

LinkedIn:
https://www.linkedin.com/in/michael-fraai-1b777b3
Bridget A. Moorman has 28 years’ experience in the clinical engineering field and currently consults internationally across the healthcare technology industry specializing in medical device interoperability and integration. She has worked for Kaiser Permanente doing strategic technology management for cardiovascular services, patient monitoring, OB/GYN data management and biomedical device interfacing to the EPIC EMR system. She has also worked for University Medical Center in Tucson, AZ, as a clinical engineer and supporting the artificial heart program. She served as Chair of the CCE Board of Examiners from 2011-2013.
““To protect the network, DoD officials enforce strict cyber standards on all information technology. Medical devices, however, are not "information technology," explained McGraw. Rather, they are "medical technology." It is a subtle yet significant difference.

Information technology includes computers and supporting equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services and related resources.

Medical technologies are single purpose systems intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.”

Overview

- Definitions
- Purpose of networking
- Questions to ask
- Flow diagrams for determination
- Exercise
- Keep in mind
Definitions

- **Definition of safe**
  - secure from liability to harm, injury, danger, or risk

- **Definition of networking**
  - use of a system of computers and peripherals that are able to communicate with each other

- **Definition of medical device**
  - any article or healthcare product intended for use in the diagnosis of disease or other conditions, or the use in the care, treatment of prevention of disease which does achieve any of its primary intended purposes by chemical action or by being metabolized (FDA)
Purpose of Networking

- Data flow
  - transmission to another system

- Data aggregation/association/affiliation
  - example: patient demographics associated with physiological measurement
  - centralization of patient information

- Communication with minimal manual or human intervention
Questions to ask

- How is device used/data used in clinical workflow?
- How fast is workflow?
  - Episodic or long-term
  - Real-near-real time
  - Validation
  - Store-forward
- What type of networking?
  - Wired
  - Wireless
  - None
- How is networking capability accomplished on the device?
  - Dongle
  - Embedded
Questions to ask

- What is range of device (use)? Fixed? Mobile?
  - Examples: scale, monitor for ICU/ER

- Is the device part of another system?
  - Monitor to central to gateway

- How sophisticated is the networking protocol on the device?
  - Static or dynamic IP?

- How much bandwidth is required?
  - Example: Telehealth-dermatology needing high fidelity video
Questions to ask

- Outside Healthcare Enterprise
  - Location determining availability of quality telecommunication capability
    - Ex: Home situation
      - Store and forward?
      - Plain old telephone service (POTS)?
Flow diagrams for determination: Workflow

Workflow

Static

Bed Based

Device Based

Dynamic

Patient throughput frequency

Access to patient demographic information
Flow diagrams for determination: Data

- Episodic data
  - Numerical
  - Graphical
  - Images

- Continuous data
  - Numerical
  - Graphical
  - Images

- Aggregation

- Context-Meta
Flow diagrams for determination: Network capability
Flow diagrams for determination: Device type

Device Type

- Fixed
- Mobile
- Part of System

Device Based
- IT based
Flow diagrams for determination: Location and bandwidth

- **Device Location**
  - Hospital
  - Clinic
  - Patient Home

- **Bandwidth Requirement**
  - Real-time high throughput
  - Episodic
  - Store and Forward

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Exercise

- Should scales in clinic be connected to network?
- Should monitors in ER be connected to network?
- Should specialty devices in ICU (ECMO monitor) be connected to network?
- Should monitors in ICU be connected to network?
CHIME: Healthcare’s most wired results 2018

Information Sent Directly from Patient-Monitoring Equipment to the EHR
(n=618)

- Blood glucose: 83%
- Bedside blood pressure: 80%
- Bedside pulse oximetry: 79%
- EKG: 77%
- Bedside lab tests: 72%
- Fetal monitor data: 71%
- Bedside temperature: 65%
- Cardiovascular catheter output: 51%
- Ventilator data: 47%
- Intracranial monitor data: 39%
- IV pump data: 25%
- In-bed scale data: 10%

Keep in mind

- Just because you can connect a medical device to a network does not necessarily mean you should

- Need to understand workflow, the environment and the definition of safe in those situations!
Questions and Discussions
Emerging Technologies and their Impact on the Hospital Operations

Thomas Skorup, MBA, FACHE
Vice President, Applied Solutions
ECRI Institute
tskorup@ecri.org
In this session, participants will learn about emerging technologies that may impact hospital operations and patient outcomes. Mr. Skorup explores the challenges related to successfully forecasting healthcare and technology innovation. Further, he reviews specific leading edge technologies that ECRI Institute and other leading organizations predict will disrupt healthcare delivery in the coming years. Strategies are discussed for addressing challenges related to technology adoption.
About the speaker

- Leads ECRI Institute’s Applied Solutions Group onsite consulting service, and manages major projects with healthcare organizations.
- More than 30 years experience forecasting, planning, procuring, and managing the unique challenges that healthcare technology poses to healthcare service delivery.
- Adjunct Faculty, School of Nursing, Villanova University
- Board certified in healthcare management and a Fellow of the American College of Healthcare Executives.
- MBA, Health Administration, Fox School of Business, Temple University
- BS, Biomedical Engineering Technology, Milwaukee School of Engineering
How ECRI Started

- A fiercely independent, nonprofit, mission focused organization committed to improving the **safety, quality, and cost effectiveness** of healthcare through evidence-based research and testing, benchmarking, and collaboration with the healthcare community.

"Anger is a great source of energy. I focused it on improving technology and patient safety."

- Joel J. Nobel, MD, Founder of ECRI
Outline

- Building a Bridge To The Future
  - The Forecasting Chasm—Seeing around corners
  - The Technology Chasm—Where is technology headed?

- Action Steps
  - Strategies for success
  - Three technology truths
What seems obvious ...
... may not be!
Ignore trends at your peril...

Kodak once had 85% of photographic film business!

In the U.S. patients want robotic prostatectomies...

Kodak engineer Steve Sasson talks about how he created the first digital camera in December 1975.
Foolish Tech Prediction 1
Thomas Watson, President of IBM, 1943

"I think there is a world market for maybe five computers."

Foolish Tech Prediction 2

*Darryl Zanuck, Executive at 20th Century Fox, 1946*

> Television won't be able to hold on to any market it captures after the first six months. People will soon get tired of staring at a plywood box every night."

Foolish Tech Prediction 3

Alex Lewyt, President of Lewyt Vacuum Company, 1955

- "Nuclear-powered vacuum cleaners will probably be a reality within ten years."

Foolish Tech Prediction 4

Ken Olsen, Founder of Digital Equipment Corporation, 1977

- There is no reason anyone would want a computer in their home."

Foolish Tech Prediction 5
Robert Metcalfe, Founder of 3Com, 1995

"Almost all of the many predictions now being made about 1996 hinge on the Internet's continuing exponential growth. But I predict the Internet will soon go spectacularly supernova and in 1996 catastrophically collapse."

A few common technology themes...

- Look for the “breakthroughs”, but also the “bridges”
- Get Real---Become a “Technology Realist” (Neither a Luddite nor a technophile be)
- Understand the evidence.
The Forecasting Chasm

- Trends are easier to predict than breakthroughs and are often evolutionary in nature.
  - Evolutionary or Revolutionary?
    - Laparoscopic Cholecystectomy
    - 3D Laparoscopic Imaging?
    - Drug-eluting stent?
    - Robotically-assisted laparoscopic surgery?
    - Transcatheter aortic valve replacement?
To thy own self be true...

where are you?

---

**Figure 2.** Adopter Categorization on the Basis of Innovativeness

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Reprinted with permission from Rogers.²¹

D. Berwick, JAMA, April 16, 2003-Vol. 289, No. 15 (Reprinted)

Copyright 2003 American Medical Association. All rights reserved.
Does this new technology provide a clinical or strategic advantage?
The Forecasting Chasm

- Watch for the tipping point  - Malcolm Gladwell.
  - Law of the Few - Connectors
  - The Stickiness Factor
  - The Power of Context

- BRCA1/2 mutation testing
- Others?
Which new technology will stick?

And actually make a difference?
And what are outcomes we expect from technology in healthcare?

- Longer life?
- Better life?
- Higher productivity?
- Healthier populations?
- Happier people?
Where is technology headed?
ECRI Institute Top 10 C-suite Watch List

- ECRI experts polled for topics regarding....
  - Something newsworthy
  - The potential to positively impact patient outcomes in major illnesses, diseases, or injuries
  - Ready or near ready for implementation
  - Turf wars or, conversely, improved collaboration
  - Improving patient and staff safety
  - A marketplace differentiator
ECRI Institute
Top 10 Hospital C-suite Watch List (2018)

1. Apps for Addiction
2. Direct to Consumer Genetic Testing
3. Acuity-adaptable Rooms
4. Insertable Cardiac Monitor
5. Virtual Reality for Pediatrics
6. Non-medication Treatments for Alzheimer’s Disease
7. (Nearly) Pain-free Blood Draw
8. Neonatal MRI System
9. GammaTile™ Cesium 131 vs. Brain Tumors
10. Microhospitals
1. Apps for Addiction

- First prescription digital therapeutic (reSET-O™, PearTherapeutics) to receive FDA clearance app as a prescription-only adjunct treatment

- Nearly doubled the rate of abstinence and increased retention in treatment

- Benefits include:
  - Fewer patient relapses
  - Decreases in patient admissions or readmissions
  - Reduction in overdose incidents and ED visits
2. Direct-to-Consumer (DTC) Genetic Testing

Emerging Uses (beyond ancestry):

- Epigenetic analysis to determine biological age (as compared to chronological age)
- Diet & exercise strategies based on individual genotype
- Customized advice on skin care (topical creams, professional treatments)

Growing implications for hospitals and health systems.

Increased healthcare service demands from patient anxiety from unexpected test results.

Source: Credence Research
3. Acuity-adaptable Rooms

- Keeps a patient in the same room from admission to discharge, regardless of acuity level. Patient transfers/handoffs are a known safety issue.

- **Benefits:** improve workflows and patient safety, decrease LOS, reduce costs.

- **Challenges:**
  - Maintaining staff competencies across all acuity levels
  - Choosing right patient groups: cardiac, transplant, oncology
  - Accommodating care standards for each acuity level (e.g., sightlines for critical care vs. privacy for improved patient)
4. Insertable Cardiac Monitor

- 6 million people in the U.S. have atrial fibrillation (AF).

- **Abbott Confirm Rx™ ICM**
  - Insertable cardiac monitor transmits to patient’s smartphone which sends data to the treating physician
  - Replaces bulky and retrospective Holter recording
  - Provide event marking capability

- Worldwide ICM estimated market at $800M
5. Virtual Reality for Pediatrics

- VR distraction for kids with chronic conditions requiring frequent procedures like infusion therapy or needlesticks.

- Studies have shown a decline in pain for the children and a decline in anxiety scores of their parents.

- appliedVR offers headsets with about 20 different VR experiences
  - At about $2,500-$3,800, plus annual licensing

- Lucille Packard Children’s is using VR in all of its patient rooms.
6. Non-medication Treatment for Alzheimer’s Disease

- 5.5M Americans have Alzheimer’s dementia, which is the 6th leading cause of death in the U.S.

- Transcranial magnetic stimulation (TMS) with computer-based cognitive training (NeuroAD Therapy System) AND the patient’s pharmacologic therapy.
  - Full 6-week course costs up to $10,000.

- Received CE mark; denovo FDA clearance pending.
7. Nearly Pain-free Blood Draw

- Reducing blood draw amounts and simplifying blood draws.

- Seventh Sense Biosystems TAP® (touch activated phlebotomy) uses 30 microneedles to collect 100 microliters of blood over 2-3 minutes.

- Targeted audience:
  - Pediatrics who require frequent blood draws
  - Monitoring of outpatient adherence
  - Currently only cleared for A1c testing

- Gates Foundation grant, and LabCorp and Novartis partnerships may accelerate development.
8. Neonatal MRI System

- Reduces risk of neonate transport for MRI for edema or hemorrhage.

- Embrace® Neonatal MR System (Aspect Imaging) is a point-of-care NICU-based MR for <9.9 lbs. neonates.

- Benefits:
  - Integrated incubator to control body temperature and measure vital signs during procedure
  - No safety zone/shielded room
  - Low noise scans
9. GammaTile™ Cesium-131 vs. Brain Tumors

- Reduces time between surgery and radiation treatment.

- Gamma Tile Radiation Therapy System (GT Medical Technologies)
  - Intraoperatively delivered brachytherapy that standardizes seed placement and improves dose targeting

- Cesium-131 seeds incorporated into a bioabsorbable collagen mesh that neurosurgeon and radiation oncologist suture into place.

- Improved survival (4 mos.) and lower cost ($25k) compared to stereotactic radiosurgery

- FDA 510(k) pending
10. Microhospitals

- New less acute care paradigm
- Between an urgent care center and a full service hospital
  - ED and inpatient beds
  - No critical care beds
  - Surgery, pharmacy, radiology
  - Dietary, EVS, Materials
- Branding opportunities in fast growing or underserved areas.
- Beware of cannibalizing existing services that may already be underutilized.

https://pbs.twimg.com/media/Cmnk0IDWEAEcOwI.jpg
Cleveland Clinic
Top 10 Medical Innovations for 2019

#1 Alternative Therapy for Pain: Fighting the Opioid Crisis
#2 The Advent of AI in Healthcare
#3 Expanded Window for Acute Stroke Intervention
#4 Advances in Immunotherapy for Cancer Treatment
#5 Patient-Specific Products Achieved with 3D Printing
#6 Virtual and Mixed Reality for Medical Education
#7 Visor for Prehospital Stroke Diagnosis
#8 Innovation in Robotic Surgery
#9 Mitral and Tricuspid Valve Percutaneous Replacement
#10 RNA-Based Therapies

https://innovations.clevelandclinic.org/Summit/Top-10-Medical-Innovations.aspx
Outline

► Building a Bridge To The Future
  ► The Forecasting Chasm—Seeing around corners
  ► The Technology Chasm—Where is technology headed?

► Action Steps
  ► Strategies for success
  ► Three technology truths
Strategies for Success

- Implement evidence-based technology decision-making process

- Add organized technology horizon-scanning into your five-year strategic capital plan

- Ensure your healthcare strategy includes a clinical technology strategy
Strategies for Reducing Costs

- Look for collaboration partners

- Look for “standardization” opportunities and “risk mitigation” strategies

- Approach multi-year vendor partnerships carefully
Three Technology Truths

1. Fortune favors the bold (Latin proverb)

2. Facts are stubborn things (John Adams)

3. Data is not the plural of anecdote (various authors)
Fortune favors the bold
Facts are stubborn things

Who remembers the Monty Hall problem?
Data is not the plural of anecdote
FROM THE FILMMAKERS OF THE ACADEMY AWARD-NOMINATED DOCUMENTARY

THE INVISIBLE WAR AND THE HUNTING GROUND

A NETFLIX ORIGINAL DOCUMENTARY

THE BLEEDING EDGE

A GROUNDBREAKING INVESTIGATION INTO THE CRIMES OF BIG MEDICAL

What you don’t know can hurt you.
Foolish Tech Prediction 6

Nathan Myhrvold, former Microsoft CTO, 1997

"Apple is already dead."

Questions and Discussions
Long Term Capital Planning

Carol Davis-Smith, CCE
President
Carol-Davis Smith & Associates
Carol@CDSAssoc.com

Jennifer Ott, CCE, FACCE
Medical Equipment Specialist - Project Manager
NorthStar Management, LLC
Jennifer.Ott2@mercy.net
Session Description

- A *panel discussion* that will explore diverse perspectives and challenges impacting our ability to define long-term capital plans for medical devices and systems.

- Particular attention will be paid to the impact of networked medical device systems and the inherent challenges of cybersecurity.

- The **objective** is to inform clinical engineering and information technology professionals such that they can engage in the capital planning process more confidently and effectively.
Panelists

Carol is a certified clinical engineer with 30 years of experience in academic and not-for-profit medical centers, group purchasing, consulting, and executive leadership. Through collaborative leadership and technical engagement, she has built successful teams across all aspects of the medical device lifecycle.

Carol Davis-Smith, CCE
President / Owner
Carol Davis-Smith & Associates, LLC

Jennifer is a certified clinical engineer with 28 years of experience in academic, for-profit, and not-for-profit healthcare systems. Her current role manages hospital construction projects with a focus on medical equipment planning and implementation. She provides leadership skills to the variety of disciplines necessary for a successful team and project.

Jennifer Ott, CCE, FACCE
Medical Equipment Specialist ~ Project Manager
Northstar Management, LLC
Panelists

Mary is a Registered Nurse with 37 years’ experience in the acute and ambulatory settings working mainly with Pediatric patients. She has been a Clinical Manager of the Acute Infusion team with Smiths Medical for 10 years. Her primary focus is collaborating with the acute care customer’s multi-disciplinary team from the pre-sale/pre-planning phase through successful implementation of infusion pumps.

Mary Johnson, BSN, RN
Clinical Manager, Acute Infusion - Professional Services
Smiths Medical

Mike is a certified materials & resource professional with 30 years of healthcare experience in children’s hospitals and the Association for Health Care Resource & Materials Management (AHRMM). As a supply chain and UDI subject matter expert, he collaborates with health systems, manufacturers, and other industry and regulatory leaders from across healthcare on the advocacy, adoption, and implementation of the UDI.

Mike Schiller, CMRP
Vice President of Healthcare Engagement
Matrix IT
Topics of Discussion

- “Long-term” versus “Short-term” capital planning
- Decision-makers
- Relevant information
- “Approval” versus “Funding”
- Policy - Process - Procedures ("How to")
- Resources - tools, expertise, timing
- Large projects - construction/renovation
- Networked medical devices
- Cyber threats and security
- “Train wrecks” and memorable successes
- CE/IT professionals involvement
The following 3 pages are examples/tools provided by our colleagues at AHRMM
## Example Criteria to Rate Equipment

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<th>Criteria</th>
<th>High (9)</th>
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<th>Weight</th>
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<tr>
<td>Lifecycle Stage</td>
<td>Exceeding useful life (10 yrs. or greater)</td>
<td>Within normal useful life (between 3 and 9 years)</td>
<td>New technology (0-2yrs old)</td>
<td>25%</td>
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<td>Service History</td>
<td>CES overall rating Poor based on # of service events and CAR (service Cost to Asset Ratio)</td>
<td>CES overall rating Fair based on # of service events and CAR (Cost to Asset Ratio)</td>
<td>CES overall rating Good or Excellent based on # of service events and CAR (Cost to Asset Ratio)</td>
<td>30%</td>
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<td>Utilization</td>
<td>Top 25% of usage within Allina</td>
<td>Usage between 25% and 75% of usage within Allina.</td>
<td>Lowest 25% of usage within Allina</td>
<td>15%</td>
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<td>End of Service Life, Parts Availability</td>
<td>EOL and/or CES can not support</td>
<td>OEM has not declared EOL but useful life has been exceeded</td>
<td>OEM has not declared EOL, parts are readily available</td>
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PANEL DISCUSSION
Note: Presentation slides will be posted on ACCE website
www.accenet.org
Thank you for attending!

HIMSS and ACCE have compiled the following sessions, as a recommendation, which may be of interest to you. All times listed are ET.

**Health Technology Alliance & ACCE Award’s Reception**
Tuesday, February 12 | 6:00 pm – 8:00 pm | Convention Center | Level 2 W240C
Network with ACCE members, experts from Clinical Engineering, Health Technology Management, and Medical Device Domain—all are welcome to attend! Join Arif Subhan, President/ACCE and Steven Wensing, CTO/HIMSS in congratulating the 2019 ACCE/HIMSS Excellence in Clinical Engineering and Information Technology Synergies Award recipient. Scan QR code to RSVP

**CIO Perspective – Strong I/T & HTM Bond**
Wednesday, February 13 | 9:00am – 9:45am
Convention Center | HIMSSSpot | Lobby C
Investments in clinical technologies are increasingly becoming integrated into healthcare organizations’ I/T infrastructure. The bond between I/T and HTM must be strong and cohesive to ensure a strong infrastructure that fully supports care delivery. This session describes success factors in this relationship and highlights one organization’s journey. Presenters Pam Arora, CIO/VP at Children’s Health, and Sue Schade, Principal at Starbridge Advisors. Both AAMI board members and previous recipients of the HIMSS-AAMI John E. Goold Jr. CIO of the Year Award.

**Presenting the Case of Cybersecurity Education of Clinicians – ACCE collaborator sponsored session**
Wednesday, February 13, 2019 | 1:00 – 2pm | Convention Center | Level 3 W311A
Today’s security risks are too complex and the risk to care delivery and patient safety is too high for cybersecurity to be relegated to the pure technical realm. Cybersecurity programs can only succeed if based on a holistic approach that involves a constructive partnership between stakeholders. This session will explore how organizations can improve cybersecurity when decisions are made as a partnership between security-educated clinicians and security professionals that balances patient and societal needs for health, safety and security. Presenters: Axel Wirth, Distinguished Technical Architect, Symantec Corporation and Dr. Joseph Schneider, Clinical Assistant Professor, UT Southwestern Medical Center.

**A Practical Approach to Medical Technology Capital Planning**
Thursday, February 14, 2019 | 11:30am-12:30pm | Convention Center | Level 3 | W311A
Most healthcare organizations usually have a set capital budget for medical technology acquisitions. In this day and age, technology has become increasingly complex, devices are interfacing with each other as well as Electronic Medical Records; and Cybersecurity has taken a front and center seat on medical equipment and systems decisions. In this session, we will explore how three different leading healthcare organizations have coped with these issues, different strategies used to address them, and lessons learned from this process. Speakers: Irr Kalloli, Director, Clinical Technology and Biomedical Engineering, Stanford Children’s Health and Kevin Kreitzman, Assistant Director, Clinical Engineering, Brigham and Women’s Hospital.

Join the Health Technology Alliance [http://www.healthtechnologyalliance.org/](http://www.healthtechnologyalliance.org/) or scan QR.

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