2023 ACCE CE-IT Symposium

Securing IoMT Proactively

Collaboration Between Information Technology and Clinical Engineering Profession
Medical Device Security
Why it is so hard, and what can you do about it?

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Phil is the VP Medical Device Security for Health-ISAC, working with Medical Device Manufacturers (MDMs) to help improve privacy and security while coordinating with Health Delivery Organizations (HDOs) to ensure implementations are practical and achievable. Phil is a subject matter expert and contributor to Health-ISAC’s Medical Device Security Information Sharing Council (MDSISC). He has over 30 years of technical and operational leadership experience in healthcare and life sciences. Previous positions include Chief Product Officer at Medsec, Global Leader for Medical Device Technology at Deloitte, Vice President of Operations at MDISSL, and National Director of Technology Operations at Catholic Health Initiatives.
The spectrum of technologies supporting health care is staggering, and medical devices are a large part of the complex ecosystem delivering patient care. The things medical devices enable caregivers to do is genuinely awe-inspiring.

This diversity of technology is also more connected than ever before. Healthcare is an information business, and medical device technology generates much of the data supporting patient care. The burden of ensuring this technology remains safe to use, protects patient data, and is available when needed, falls squarely on the shoulders of HTM staff. As bad actors crank up attacks on healthcare, HTM staff increasingly take on cybersecurity responsibility. This extra duty may seem daunting, but HTM staff are more prepared than they realize.

This session will discuss the challenges of securing medical devices and what HTM staff can do to reduce the threat surface, limit the blast radius, and improve the efficiency and effectiveness of response and recovery activities for their organization.
Healthcare is under attack

- Hollywood Presbyterian Medical Center
- 434 bed Level II trauma center serving a multicultural urban LA community
- Feb. 5, 2016 – staff reported inability to access records
- Internal emergency declared
- Record access/sharing not possible
- Patients diverted
- FBI & local Law enforcement called in
- 40 bitcoin ($17,000) already paid
- Recovery declared on February 15th
- Locky ransomware spread via MS Word
Breach count by entity type

<table>
<thead>
<tr>
<th>Year</th>
<th>Avg $/breach</th>
<th>Breaches</th>
<th>Healthcare Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>$9,300,000</td>
<td>554</td>
<td>$5,152,200,000</td>
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<tr>
<td>2020</td>
<td>$7,130,000</td>
<td>537</td>
<td>$3,828,810,000</td>
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<tr>
<td>2019</td>
<td>$8,000,000</td>
<td>397</td>
<td>$3,176,000,000</td>
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</table>
Individual records by entity type

Individuals Affected

- Business Associate
- Health Plan
- Healthcare Clearing House
- Healthcare Provider

Survey Says!

• Healthcare organizations with a higher percentage of connected medical devices suffer more cyberattacks.

• Nearly half (48%) of healthcare cyberattacks impact patient care, and two in three (67%) affect patient data.

• More than half (53%) of healthcare IT staff view the current cybersecurity threat landscape as high or extreme.

• Less than half (43%) of practices say they always change default passwords on connected medical devices, and less than a third (32%) always update them when a patch is available.

A woman dies during a cyber-attack on a hospital

- September 10, 2020
- Düsseldorf University Hospital
- Russian based hackers - "Doppelpaymer"
- 78-year-old woman suffering from an aortic aneurysm
- 30 Servers - hospital on divert - connection to ambulance severed
- Diverted 32Km (~20m) delaying treatment by more than 1 hour
- 1st ever reported death attributed to cyberattack
- Negligent-homicide investigation
Medical Devices and IoT

1. Purpose built devices for hundreds of purposes
2. Designed for precision and reliability
3. Technology debt – life cycle disparity
4. Lack of manufacturer transparency
5. Software as a Medical Device

Medical Modalities
1. Imaging
2. Monitoring
3. Therapeutic
4. Diagnostic
5. General

IoT Modalities
1. Environmental Monitoring
2. Utilities
3. Life Safety
4. Access Control
5. Transport
FDA observed medical device vulnerabilities

• Network-connected medical devices infected or disabled by malware
• Malware on hospital computers, smartphones/tablets, and other wireless mobile devices used to access patient data, monitoring systems, and implanted patient devices
• Uncontrolled distribution of passwords
• Failure to provide timely security software updates and patches
• Security vulnerabilities in off-the-shelf software designed to prevent unauthorized device or network access
Why is this so hard?
Security incidents will grow as IoMT technology advancement accelerates

- **2019: Implanted defibrillators telemetry protocol flaw**
  Some implanted defibrillators were found to contain vulnerabilities that would allow them exploited by attackers who had the right knowledge of the devices and close proximity to an individual possessing one.

- **2016: Insulin pumps remotely exploitable**
  Rapid7 and Johnson & Johnson disclosed three vulnerabilities in an insulin pump system that could be remotely exploited.

- **2018: Poor security on PACS systems**
  PACS (picture archiving and communication system) are used for picture archiving and communication system. Security researchers found several vulnerabilities both in commercial and open-source PACS.

- **2014: Anaesthesia delivery system bugs.**
  The anaesthesia delivery system is used in hospitals to deliver oxygen, anaesthetic vapor, and nitrous oxide to during surgical procedures. Software bugs were found so serious that they could cause severe injury or death, even just plugging a phone into the USB port.

Securing medical devices in a increasingly connected world, Andy Bridgen, 1/21/20
Internet of Things

• Global IoT spending is expected to reach $1t in 2023
• 7b IoT devices
  • 3x to 24b by 2030
• US medical device manufacturing revenue $50b in 2023
• 3.4% growth rate
• US healthcare expenditure
  • $4.3t in 2021 ($12,914/person)
• 16.8% of gross domestic product (GDP) in 2019

https://www.insiderintelligence.com/insights/healthcare-industry/
Basic infusion pump management system

Figure 5-1 Basic System

NIST.S.P.1800-8 Securing Wireless Infusion Pumps in Healthcare Delivery Organizations
Sample diagnostic imaging system

Figure 3-2 Scenario One: Sample Radiology Practice Workflows

NIST.SP.1800-24 Securing PACS
Telehealth Remote Patient Monitoring system
Healthcare matrix

• 6,400 acute care hospitals
• Urban, teaching or trauma
• Suburban & community
• Rural & critical access

• ↑400 ancillary care locations each
• Diagnostic & surgery centers
• Clinics, wellness, & pharmacy
• Physician practices

• FDA
  • 6,750+ Product Codes
  • ~530 connectable
  • ~100 clinical functions

• 380,000+ medical devices
• Approximately 100k connectable
• 1,200 makes and models
• 350+ manufacturers

• ~20 manufacturers account for 80% of device count in an acute care setting
Hospital ransomware attack allegedly led to infant's death

- Springhill Medical Center
- July 2019 - > 3 weeks
- Mother not informed during admission (8 days into the attack) for a scheduled labor induction
- Fetal distress not detected, Emergency C-section
- 1st confirmed death pending court decision
Complex Lifecycle Management

- Breadth of technologies
- Legacy devices
- Variety of care delivery environments
- Multiple responsible parties
- Dilution of priorities
- Regulatory uncertainty

Figure 1: Main Areas and Phases of Lifecycle Management
What can you do about it?
You know what to do

- HTM JOB #1 IS MAINTENANCE OPERATIONS
- CYBER IS A FAILURE MODE
- PREPARE AND RESPOND
• Governance & Operating Model
• Secure Procure
• Maintain
• Monitor
• Respond
• Dispose

Program Elements
Governance and Operating Model

• Governance
  • Who makes what decisions
    • Environment of Care
      • Regulatory requirements
      • Risk Management
      • Patient Safety
    • Performance Improvement Plans
    • Spending authority
    • Data Protection
    • Staff Management
    • Education & Training

• Operating Model
  Medical Equipment Management Plan (MEMP)
    • Equipment inventory
    • Program performance monitoring and reporting
    • Equipment maintenance program
    • Incident monitoring and reporting
    • Equipment failure response
    • Response to product notices and recalls
Risk Management

• HTM keeps it running
• IT keeps it talking
• Safety changes may impact security
• Security changes may impact safety
• Not just failure, there is intent

• Business owner decision
Asset Management

**IT**
- Standards compliance
- Risk assessment
- IP address, MAC address
- OS & patch level, components
- Vulnerability scanning

**HTM**
- Install base alignment
- Incoming Inspection
- Asset ID, RTLS tag
- Make, model, version
- Passive scanning
Secure Procurement

Evaluation of fit through multiple stakeholder lenses

- Clinical benefits
- More procedures or procedure types
- Staff efficiencies and satisfaction
  - Finance
  - Increased revenues
  - Decreased costs
- Serviceability
  - Reliability
  - Service strategy
- Risk Management
  - Safe to use
  - Secure to operate
  - Future proof
Legacy Equipment

- AHA Useful life - 7-12 years
- OS is out of support
- Manufacturer no longer supports
- Bailing wire and bubblegum
- Clinically useful
- A backup
- End of Life/Support
  - Risk assessment
  - Support costs
  - Capital planning
  - No Longer Use Threshold
Maintenance

- Asset management
  - Access and authorization
  - Physical Access
- Scheduled maintenance
- On demand maintenance
- Parts sourcing and inventory
- Operating and service manuals, instructions for use, technical bulletins
- User training

- Specialized management tools
  - CMMS = Work Orders = Uptime requirements
  - CMDB = Tickets = SLA response times
- Correlation is essential
### RACI

<table>
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<tr>
<th>Tasks</th>
<th>HDO Technology</th>
<th>HDO Clinical</th>
<th>MDM Product</th>
<th>MDM Support</th>
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<tr>
<td>Secure Configuration</td>
<td>RA</td>
<td>I</td>
<td>C</td>
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<td>OS Patching</td>
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<td>I</td>
<td>A</td>
<td>R</td>
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<td>A</td>
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</tr>
<tr>
<td>Remote Access Control</td>
<td>RA</td>
<td>C</td>
<td></td>
<td>C</td>
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- **Responsibility Assignment Matrix**
  - Responsible – the doer
  - Accountable - the decider
  - Consulted – the provider
  - Informed – kept abreast

- **Integral with**
  - Service strategy
  - Response plan
Monitoring

• Scheduled maintenance compliance
• Changes in failure rates
• Changes in failure types
• Service logs
• Changes in cost of service
• Quality issue investigation
• Lost/missing assets
• Location

• Vulnerability monitoring
• Comms traffic patterns
• Comms traffic anomalies
• Event logs
• Last activity
Response

• On demand repairs
• Clinician assistance
• Equipment check
• Planned maintenance
• Help desk
• RTO
  • Recovery Time Objective
  • Return to Operations
• RPO
  • Recovery Point Objective

• Risk Assessment is key but which one?
  • Organizational Impact
    • Elements
      • Patient, staff safety
      • PHI, Big PHI
      • Operational Interruption
      • Revenue slash
      • Reputation
  • Prioritizes everything
Disposal

• Drivers
  • Final Failure
  • Planned replacement
  • End of Support
  • Repurpose

• Requirements
  • Remove organizational risks
    • PHI, credentials, configuration, etc.
  • Plan disposal during onboarding
    • Push PHI to the data center
    • Ghosted hard drive
- Understand the risk
- Consistent prioritization
- Business owns risk
- Team sport

You Got This

- Dispose
- Govern & Operate
- Secure Procure
- Maintain
- Monitor
- Respond
Questions?