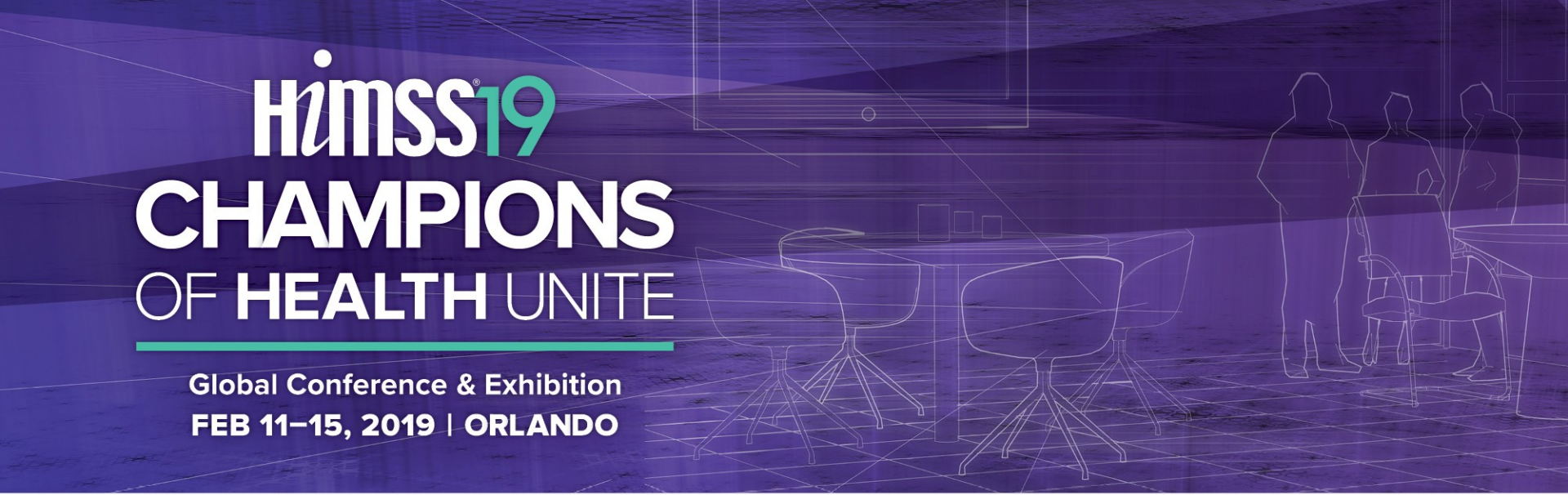

Medical Device Cybersecurity Incident Preparedness/Response

U.S. FOOD & DRUG ADMINISTRATION

Session 257, February 14, 2019

MITRE

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Conflict of Interest

Suzanne Schwartz, M.D., MBA

Margie Zuk, M.S.

Has no real or apparent conflicts of interest to report.

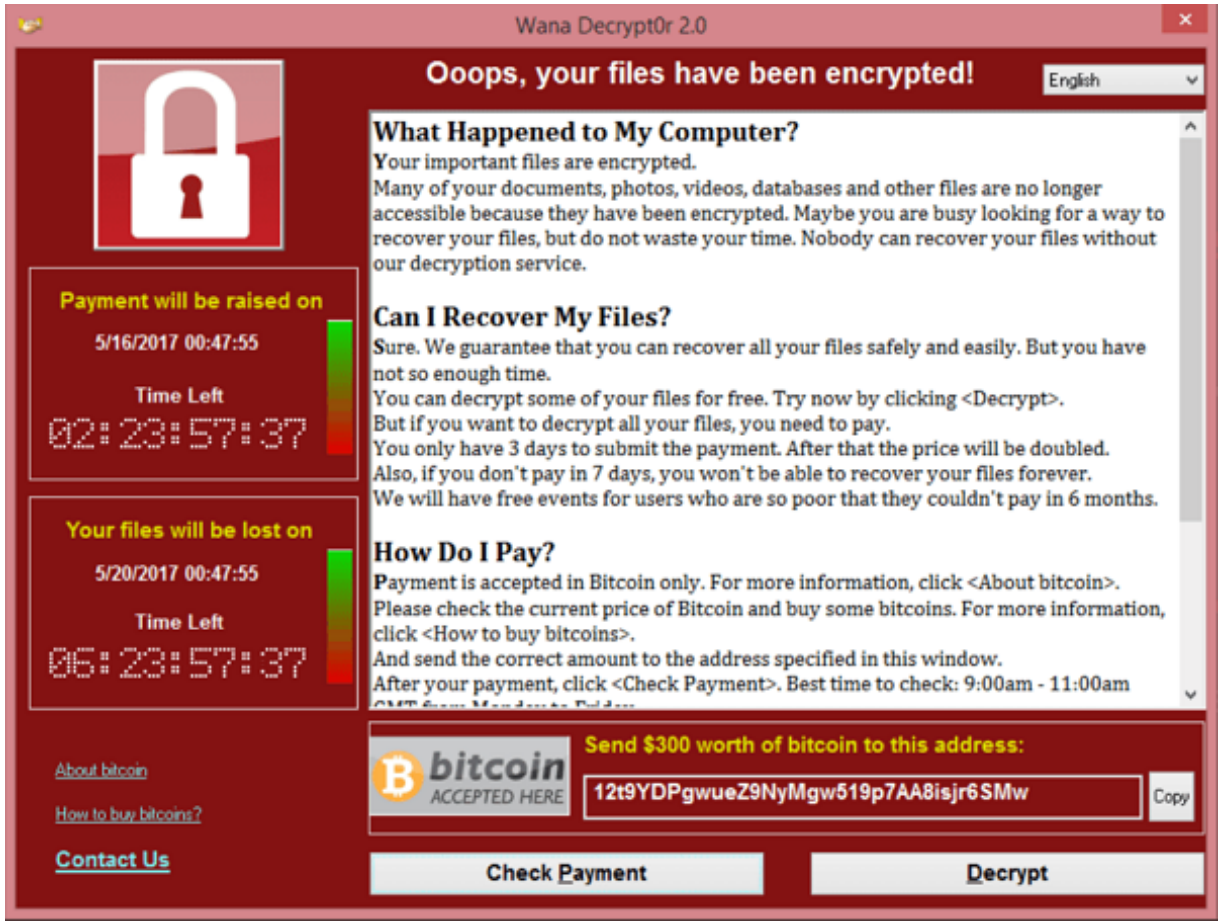
Agenda

- Medical Device Cybersecurity Incident Response Challenges
- FDA Initiatives
  - Medical Device Safety Action Plan
  - Premarket Guidance
  - Medical Device Cybersecurity Sandbox
  - Regional Response Playbook
- Future Directions

Learning Objectives

- Describe some of the challenges a Health Delivery Organization (HDO) may face in responding to a cybersecurity incident potentially affecting one or more of its medical devices
- Identify regional entities an HDO may collaborate with in preparing for and responding to a medical device cybersecurity incident
- Discuss some of the ways that HDOs and device manufacturers can improve medical device cybersecurity incident preparedness and response

Challenges



Challenges: Evolving Our Thinking

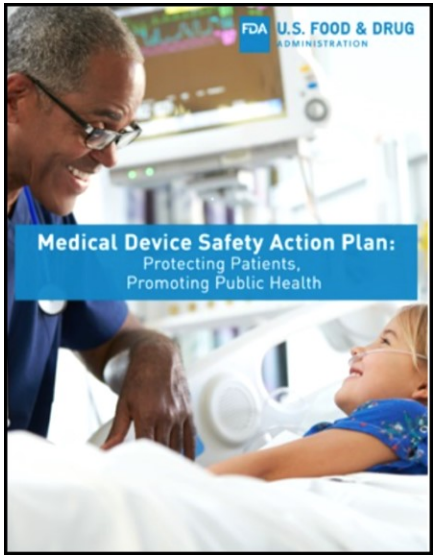
- **Coordinated** vs. **non-coordinated** disclosure of device vulnerabilities
  - Ability to get to ground truth as fast as possible so that mitigations can be proactively communicated and executed in a timely manner
    - JnJ Animas Insulin Pump
  - Non-coordinated disclosure results in delayed assessments, communications, and mitigations
    - St Jude/Abbott pacemakers and ICDs

Challenges: Evolving Our Thinking (Continued)

- Impact on HPH critical infrastructure and potential disruption of clinical care
  - Patching OS is not routine with safety-critical systems
    - WannaCry Global Cyber Attack (May 2017)
    - Petya/notPetya (July 2017)
  - Delays in diagnosis/treatment intervention can result in patient harm too
- Potential for remote, multi-patient (i.e., scaled) attack of highest concern for harm

Medical Device Safety Action Plan: Advancing Medical Device Cybersecurity

- Update 2014 premarket guidance
- Consider seeking additional premarket and postmarket authorities to:
  - Require firms to build capabilities to **update & patch device security into a product's design** and to include appropriate data supporting this capability in premarket submissions to FDA for review
  - Require firms to develop a "**Software Bill of Materials" (SBOM)** and to share with customers
  - Require that firms adopt policies and procedures for **coordinated disclosure of vulnerabilities** as they are identified



Medical Device Safety Action Plan (Continued)

- Request appropriations for seeding establishment of a **CyberMed Safety (Expert) Analysis Board (CYMSAB)** functioning as a public-private model, and serving the ecosystem as a neutral entity

2018 Highlights

- *Medical Device Safety Action Plan* (April 2018)
- Perspective piece in American Heart Association Journal *Circulation* (September 2018)
- FDA Commissioner's Statement (October 2018):
  - Strong commitment to efforts that bolster medical device cybersecurity
  - Regional Incident Preparedness & Response Playbook – MITRE publication (October 2018)
  - Execution of 3-way MOUs with H-ISAC for 2 newly stood up ISAOs for medical device vulnerability reporting (October 2018):
    - MedISAO
    - Sensato

2018 Highlights (Continued)

- Report on Advancing Coordinated Vulnerability Disclosure – MDIC publication (October 2018)
- Execution of Memorandum of Agreement with Department of Homeland Security (October 2018)
- New FDA Draft Premarket Cybersecurity Guidance & Announcement of FDA-convened Public Workshop, January 29-30, 2019

2018 Premarket Draft Guidance: Revision Background

- New guidance is needed as medical device cybersecurity continues to evolve
- Changes proposed to the guidance based on lessons learned from routine vulnerability management, response activities, engaging stakeholders including working with manufacturers pre- and post-market.
- Examples of recent threats:
  - Malware/ransomware attacks, e.g., WannaCry, notPetya, Meltdown and Spectre

Revision Approach

- Leveraged the 2014 premarket guidance document
  - Kept alignment with NIST 5 core functions
  - Similar structure
  - Maintained focus on documentation related to requirements of the QSR (21 CFR Part 820)
- Provided additional granularity to help manufacturers implement cybersecurity in the premarket setting
  - Expanded on maintaining properties of authenticity, availability, integrity, and confidentiality through design, risk management, and labeling
  - Labeling grounded in statutory and regulatory requirements; for example:
    - Adequate directions for use, 21 CFR 801.5
    - For prescription devices, 21 CFR 801.109(c)

What's New

- Designing trustworthy devices
- Preventing multi-patient attacks
- Tiering system – information to be provided in premarket submission is geared to level of risk:
  - Tier 1 – higher risk
  - Tier 2 – lower risk
- Cybersecurity Bill of Materials
  - Leverages purchasing controls in QSR (21 CFR 820.50)
- System level threat models

Tier Criteria

Tier 1 "Higher Risk"

A device is a Tier 1 device if the following criteria are met:

- The device is capable of connecting (e.g., wired, wirelessly) to another medical or non-medical product, or to a network, or to the Internet; AND
- A cybersecurity incident affecting the device could directly result in patient harm to multiple patients.

Examples of Tier 1 devices:

implantable cardioverter defibrillators (ICDs), pacemakers, left ventricular assist devices (LVADs), brain stimulators and neurostimulators, dialysis devices, infusion and insulin pumps; and the supporting connected systems that interact with these devices such as home monitors and those with command and control functionality such as programmers.

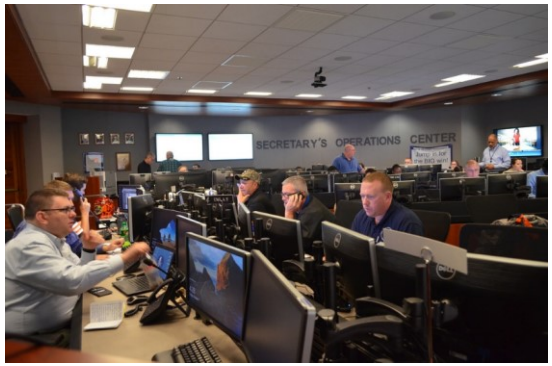
Tier Criteria (Continued)

Tier 2 “Standard Risk”

- A medical device for which the criteria for a Tier 1 device are not met.

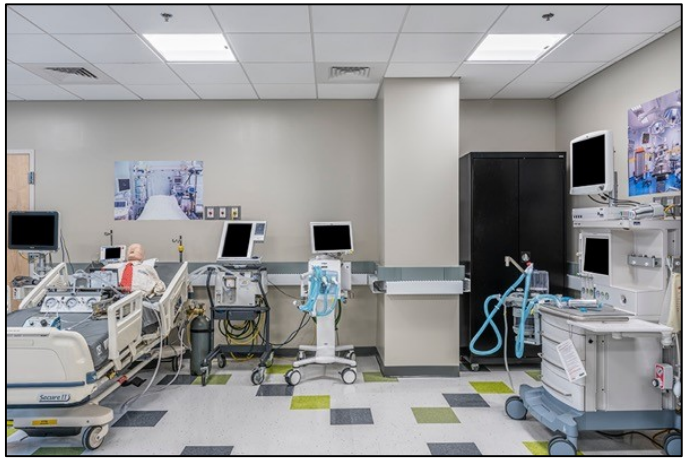
Improving Preparedness and Response for Medical Device Cybersecurity Events

- Preparedness
  - Pre-position research about medical device vulnerabilities and proposed mitigations
    - ➢ Develop **medical device cybersecurity sandbox**
- Response
  - Enhance readiness and coordinated response to exploits or attacks affecting medical devices across all levels of government as well as the user community
    - ➢ Develop **regional medical device preparedness and response playbook**



Medical Device Cybersecurity Sandbox

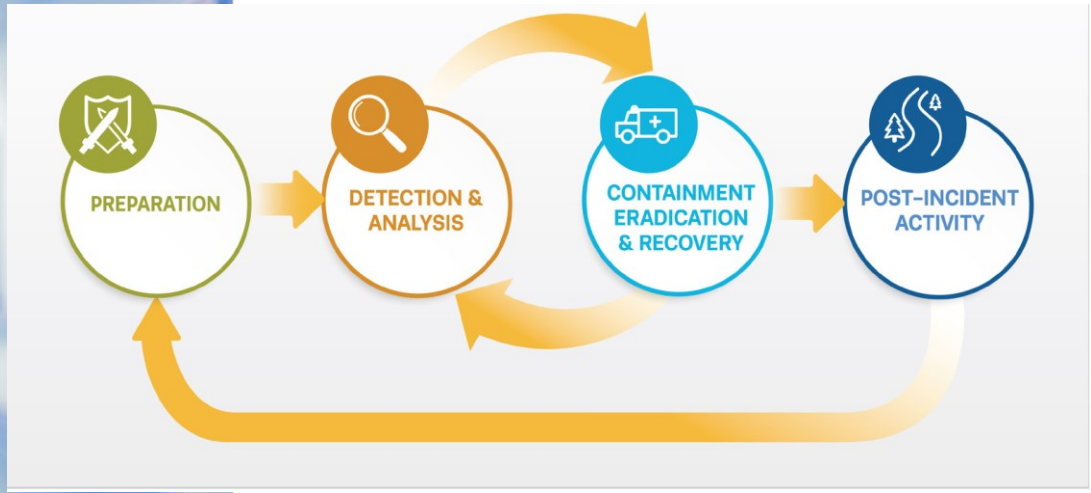
- **Collaboration between Partners Healthcare/MGH's Medical Device Plug and Plan (MD PnP) Lab, MITRE, and FDA**
  - Working with medical device manufacturers to validate the concept of a cyber sandbox using physical devices in a realistic biomedical environment
  - Developing clinical scenarios and use cases based on devices and known vulnerabilities
  - Develop and validate mitigations
  - Red teaming / penetration testing the devices



Playbook for Responding to Significant Cybersecurity Events

- *Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook*
  - Published playbook based on:
    - input from HDO focus groups
    - observing cybersecurity exercises in NY and DE
    - organizing a Boston-area workshop on WannaCry experiences
  - Playbook goal: better integrate cyber, clinical and preparedness/ response activities

Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook



Draft Published October 2018:
https://www.mitre.org/securemed

Comments accepted at securemed@mitre.org

Looking Ahead 2019

- Complete CVSS clinical rubric & submit for Medical Device Development Tool (MDDT) qualification
- Further enhance public-private partnership collaborations to collectively address CISA
  - Healthcare Industry Cybersecurity Task Force
  - 405D
  - HSCC Task Group 1B *Joint Security Plan*
  - Dedicated effort on defining and operationalizing Software Bill of Materials
- CYMSAB Pilot currently under development (with MITRE support)
- Additional ISAOs in formation for device vulnerability info-sharing

Looking Ahead 2019 continued

- International Medical Device Regulators Forum (IMDRF) new medical device cybersecurity work item:
  - FDA and Health Canada co-leads
- Expand x-stakeholder participation in DefCon Biohacking Village Device Hacking Lab, with the following goals:
  - Increase medical device manufacturer (MDM) presence
  - Introduce to clinical community
  - Engage HDOs
- Leverage cross-agency / multi-stakeholder collaborative efforts:
  - NTIA (Dept of Commerce) Multi-stakeholder engagement on software component transparency includes representation on WGs from: HDOs, MDMs, device trade organizations and FDA
  - NCCoE (NIST/Dept of Commerce) working with industry to develop use cases for medical device security

Questions?

- Please complete online session evaluation

#HIMSS19

Medical device cybersecurity is a shared responsibility

Your input is important to us!

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https://www.fda.gov/medicaldevices/digitalhealth/ucm373213.htm