Envisioning Active Surveillance:

Public Health Perspective

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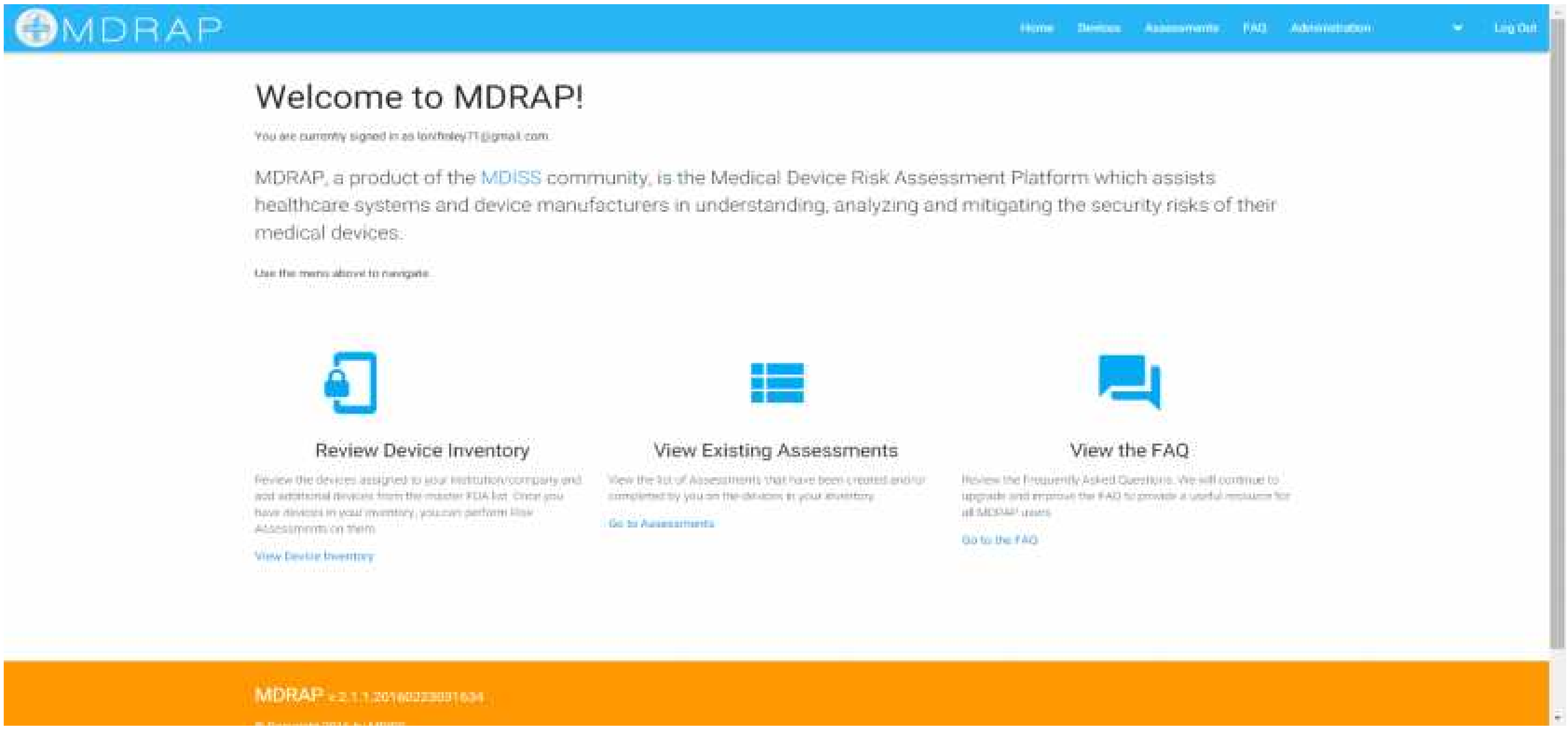
MDRAP


MDRAP
Home
Devices
Assessments
FAQ
Administration
Log Out
Welcome to MDRAP!
MDRAP, a product of the MDISS community, is the Medical Device Risk Assessment Platform which assists healthcare systems and device manufacturers in understanding, analyzing and mitigating the security risks of their medical devices.
Use the menu above to navigate.
Review Device Inventory
Review the devices assigned to your institution/company and add additional devices from the master FDA list. Once you have devices in your inventory, you can perform Risk Assessments on them.
View Device Inventory
View Existing Assessments
View the list of Assessments that have been created and/or completed by you on the devices in your inventory.
Go to Assessments
View the FAQ
Review the Frequently Asked Questions. We will continue to upgrade and improve the FAQ to provide a useful resource for all MDRAP users.
Go to the FAQ
MDRAP

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Best Practices Legacy-Drag

New Digital Health Infrastructure Demands New Best Practices

<u>Devices are infrastructure components</u>

- Human infrastructure
- Health system infrastructure
- Community infrastructure

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

Cyber-safety risk can be mitigated through engineering practices
Benefits patients, health systems and manufacturers

Institute of Medicine
Health Care Quality AIMS

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

The medical devices are a core component of healthcare quality

Connected Health: Benefit Versus Risk
Defining a Public Health Problem

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

Safety Perspectives
The Numbers are Impressive

Estimating patient exposures to digitally enabled and networked medical devices

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

Exploring Probability of Adverse Events

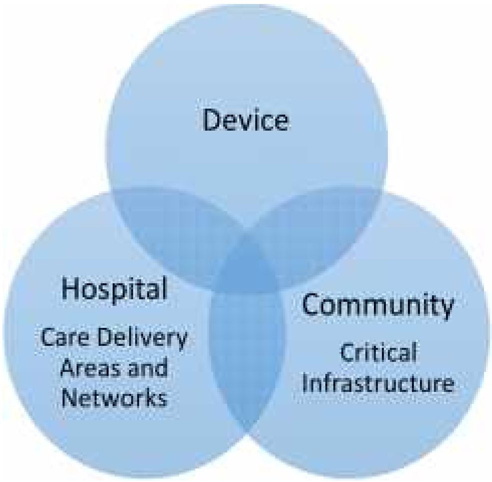
Adverse Event Rate	Adverse Events
1% (.01)	10,000,000
0.10% (.001)	1,000,000
0.01% (.0001)	100,000
0.001% (.00001)	10,000
0.0001% (.000001)	1,000

What would Dr. Semmelweis say ?

Jurisdictional Chasms
Patient Safety Challenges Across 'Infrastructures'

Stakeholders, priorities, policy, etc. varies by jurisdiction

Focus Area	Oversight Organization
Device Characteristics	FDA
Hospital & Device Networks	Joint Commission HFAP* DNV*
Community / Critical Infrastructure	DHS State/Local Health Departments

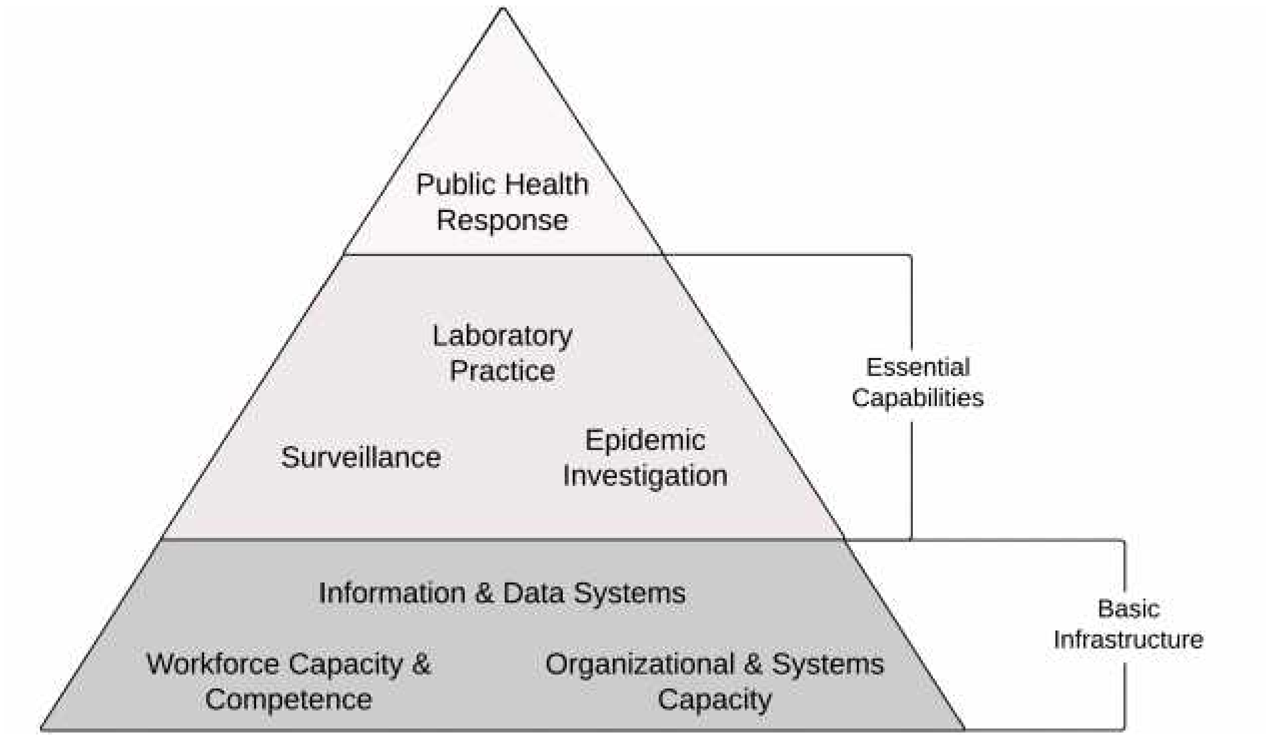


- Healthcare Facilities Accreditation Program (HFAP)
- Det Norske Veritas Healthcare, Inc. (DNV)

Public Health Systems Approach

EBS – Evidence based science

Impact Driven Surveillance



Source: Public Health Foundation

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Vaccine Safety Monitoring Portfolio of Systems

Portfolio of Systems

- Vaccine Safety Monitoring –
- VAERS
- CISA
- Vaccine Safety Datalink (VSD)
- **Emergency Preparedness**

- VAERS
  - Passive surveillance system
  - Provides source for potential safety signals
- VSD
  - Automated data collection from 9 health care organizations
  - Rapid Cycle Analysis (RCA) allows VSD to detect adverse events following vaccination in near real-time so the public can be informed quickly of possible risks
  - Also supports research with near-complete capture of all vaccinated children

Source: http://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/emergencypreparedness/index.html

VSD Active Surveillance Experience

Abstract

OBJECTIVE:

To describe the Vaccine Safety Datalink (VSD) project's experience with **population-based, active surveillance** for vaccine safety and draw lessons that may be useful for similar efforts.

PATIENTS AND METHODS:

The VSD comprises a **population of 9.2 million people annually in 8 geographically diverse US health care organizations**. Data on **vaccinations and diagnoses are updated and extracted weekly**. The safety of 5 vaccines was monitored, each with **5 to 7 prespecified outcomes**. With sequential analytic methods, the **number of cases of each outcome was compared with the number of cases observed in a comparison group** or the number expected on the basis of background rates. If the test statistic exceeded a threshold, it was a signal of a possible vaccine-safety problem. Signals were investigated by using temporal scan statistics and analyses such as logistic regression.

RESULTS:

Ten signals appeared over 3 years of surveillance: **1 signal** was reported to external stakeholders and ultimately **led to a change in national vaccination policy**, and **9 signals were found to be spurious** after rigorous internal investigation. **Causes of spurious signals included imprecision in estimated background rates, changes in true incidence or coding over time, other confounding, inappropriate comparison groups, miscoding of outcomes in electronic medical records, and chance**. In the absence of signals, estimates of adverse-event rates, relative risks, and attributable risks from up-to-date VSD data have provided rapid assessment of vaccine safety to policy-makers when concerns about a specific vaccine have arisen elsewhere.

CONCLUSIONS:

Care with data quality, outcome definitions, comparison groups, and length of surveillance are required to enable detection of true safety problems while minimizing false signals. Some causes of false signals in the VSD system were preventable and have been corrected, whereas others will be unavoidable in any active surveillance system. Temporal scan statistics, analyses to control for confounding, and chart review are indispensable tools in signal investigation. The VSD's experience may inform new systems for active safety surveillance.

Source: Pediatrics. 2011 May;127 Suppl 1:S54-64. doi: 10.1542/peds.2010-1722I. Epub 2011 Apr 18.

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Measuring Surveillance System Performance

Does it work?

Key System attributes

- Simplicity
- Flexibility
- Data quality
- Acceptability
- Sensitivity
- Positive predictive value
- Representativeness
- Timeliness
- Stability

Is it useful?

Use of information

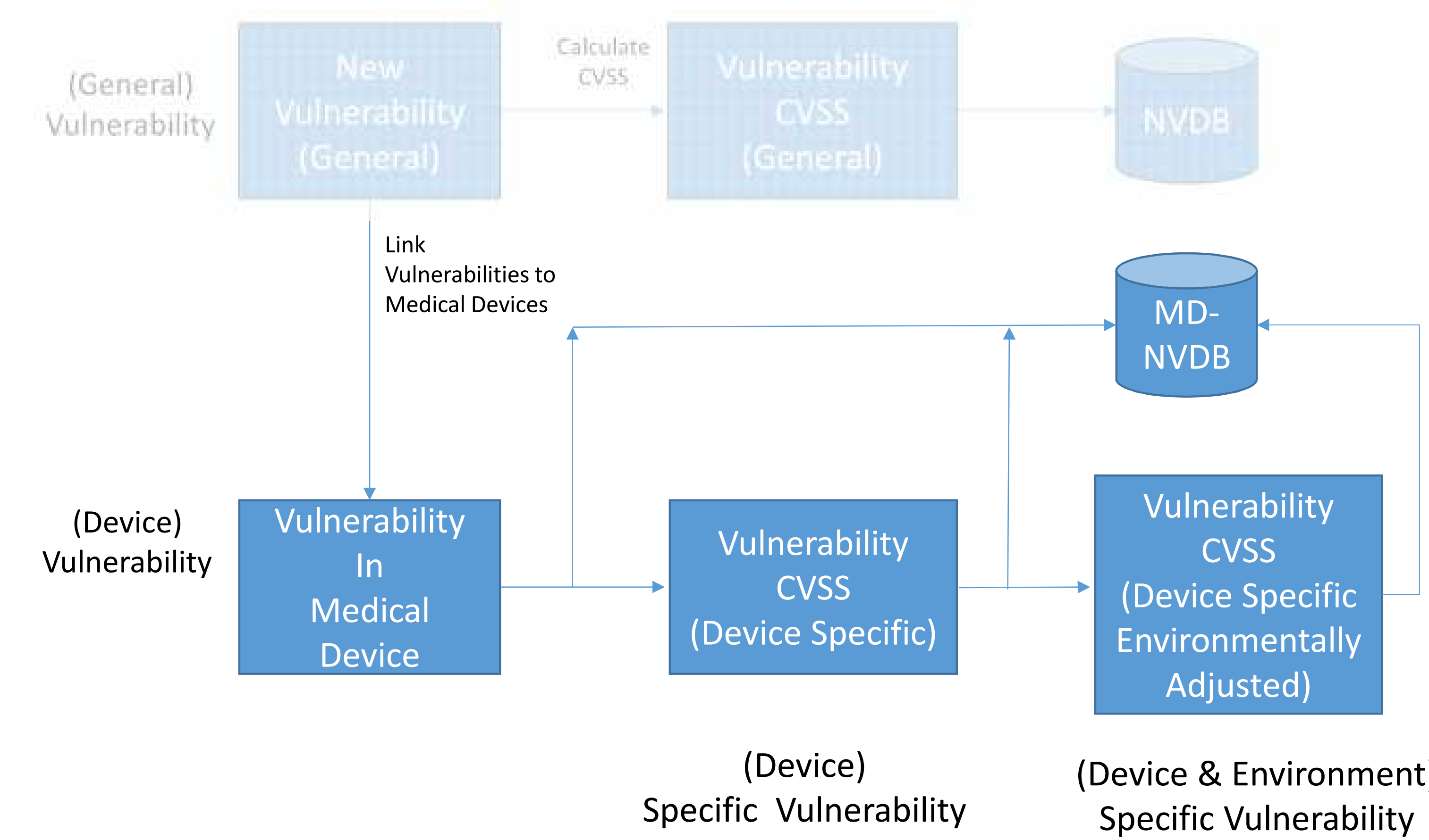
- Users
- Actions taken
- Impact

Methods Driven

Digital Infrastructure Fully Tapped
Use the Data – Secure the Infrastructure

- Consortium driven collaboration
  - Supports **innovation, scalability, impact and sustainability**
- Translation of a technology problem (cyber risk) into a healthcare delivery solution
  - **Patient centric**, care delivery centric and population centric approaches)
- Development of novel
  - **Data assets** for device cyber risk exposure
  - Analytics to **assess impact of cyber risk exposure on device** in the care delivery areas under study
  - Analytics to **detect patient safety signals** related to medical device cyber risk exposure

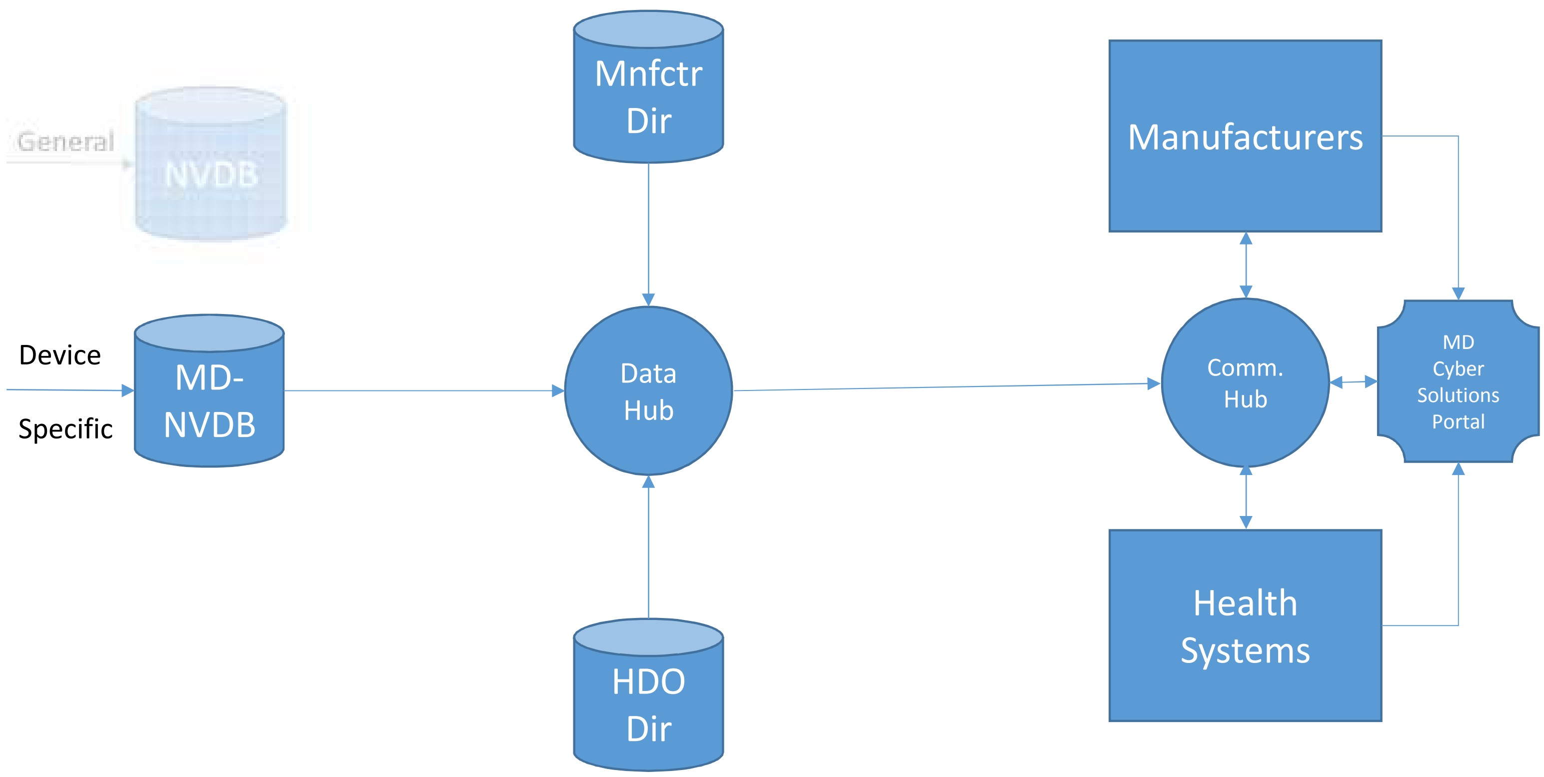
Medical Device CVSS
Contextualizing Vulnerability



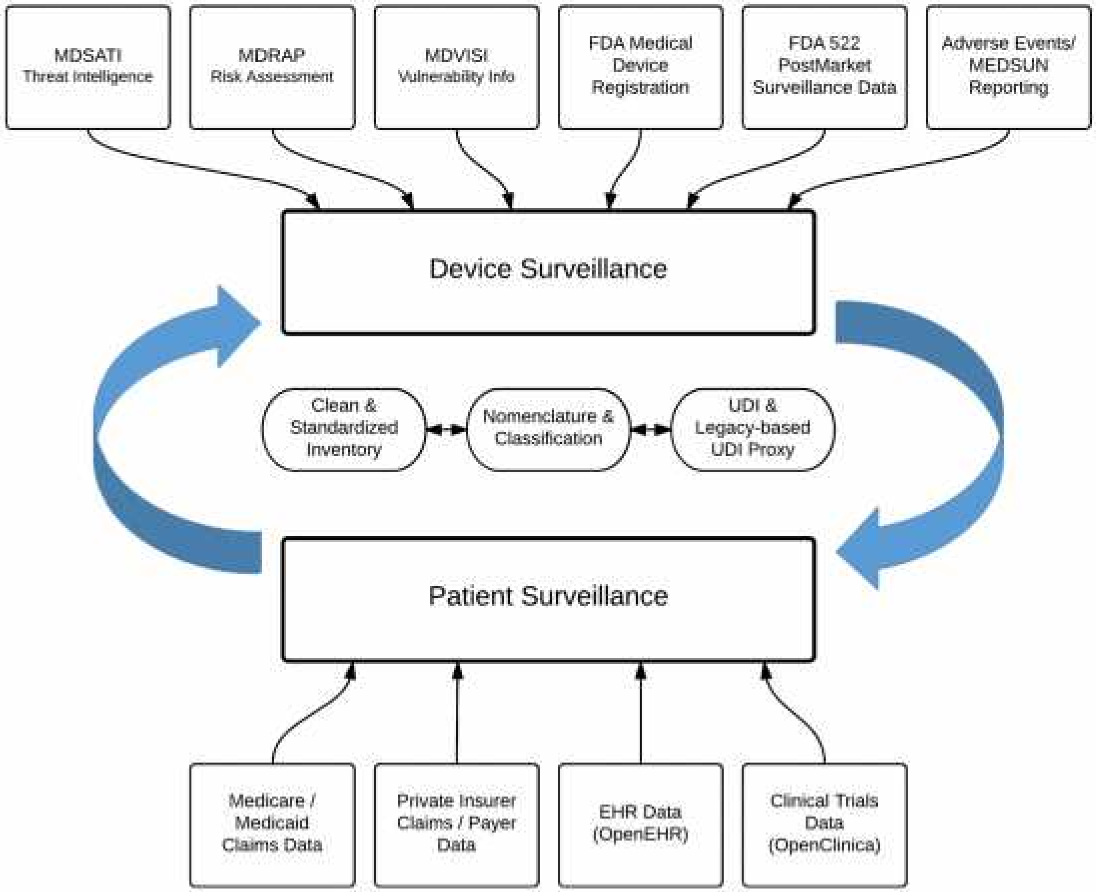
CVSS – Common Vulnerability Severity Score

Medical Device CVSS
Public Health Initiative

Vulnerability Databases **MDVISI**

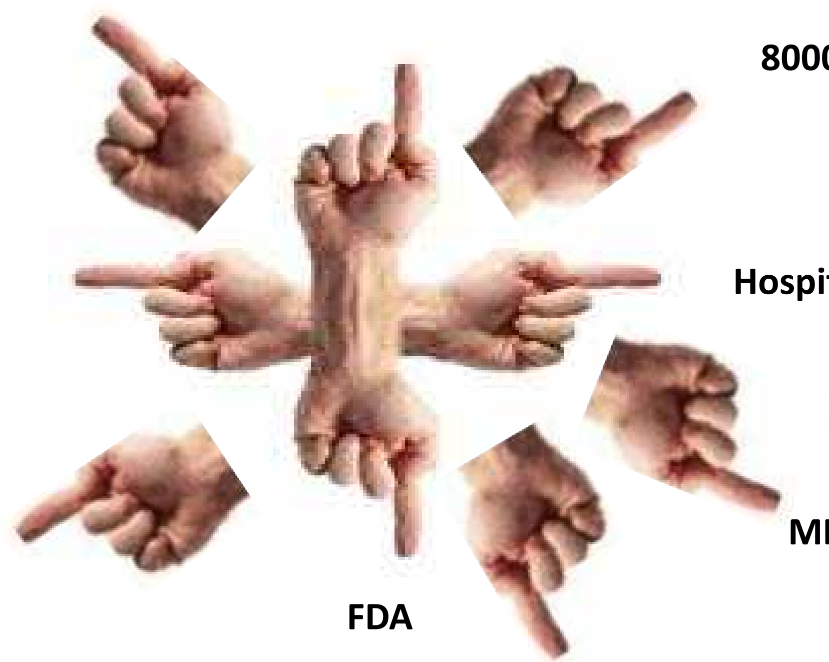


Digital Infrastructure: Risk and Reward



Point of Care Risk in the Enterprise Hiding Behind Every Handoff

Who’s Responsible
Origins, Destinations, Directions



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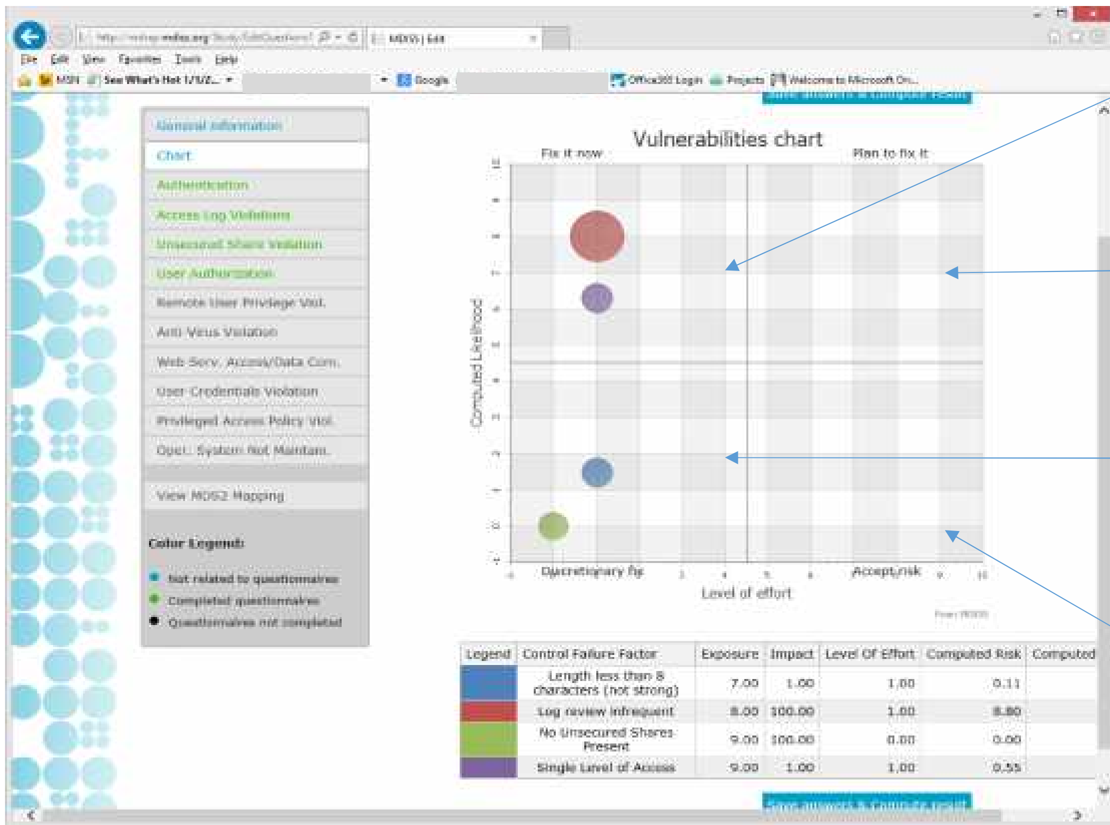
MDRAP Screenshot
Risk Graphic with Magic Quadrant Visualization

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



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

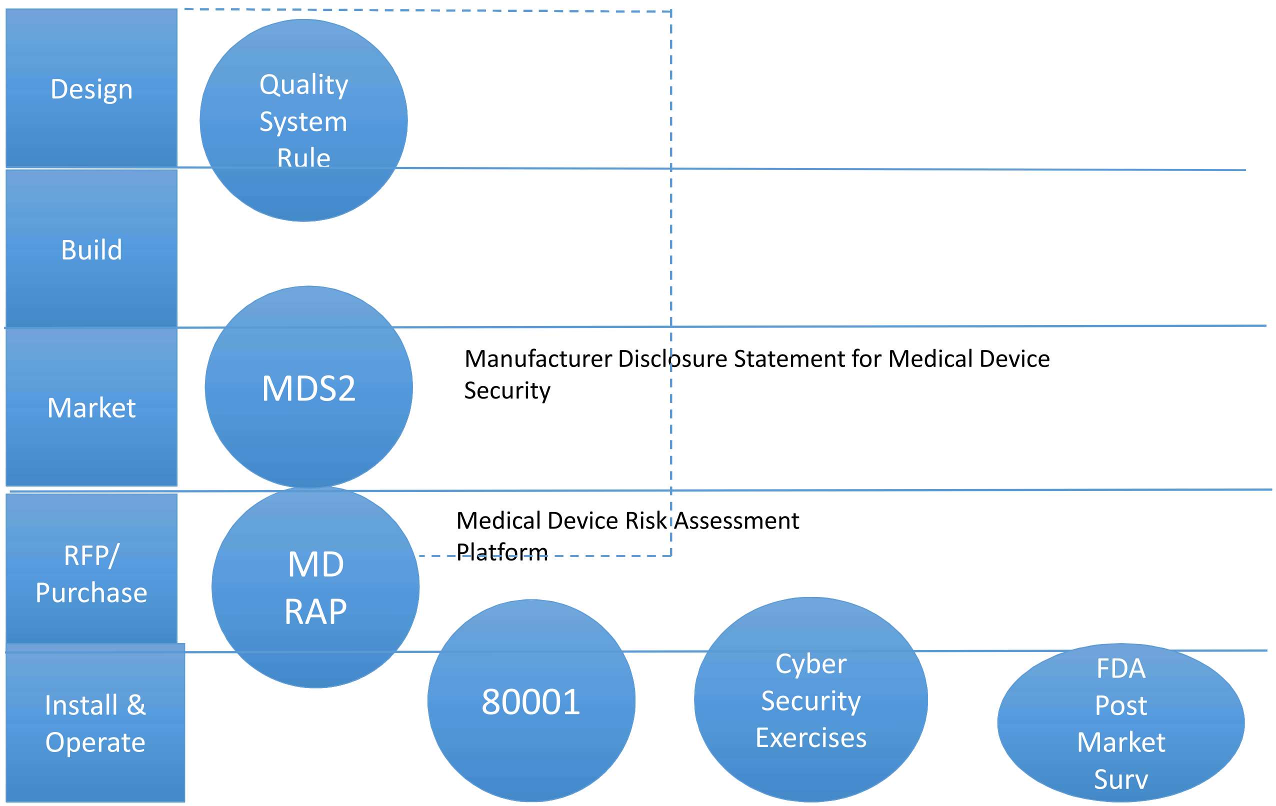
Risks are high priority but costly to fix
- Higher likelihood
- Higher cost

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

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

*Level of effort is similar to cost

Market-based public health: collaborative acceleration



A Cyber Security Public Health Initiative

- MDRAP, MDVISI and MDSATI: Key Attributes of Cyber Surveillance Programs
  - A non-profit initiative
  - A community-driven collaborative based on broad stakeholder input including manufacturers, health systems, technology companies and government agencies
  - Supported by the Department of Homeland Security, Cyber Security Division; working with ICS-CERT
  - Closely integrated with the programs of the National Health Information Sharing and Analysis Center (NHISAC)
  - Participating in the NIST National Cybersecurity Center of Excellence (NCCOE) medical device cybersecurity program
  - Collaborating with FDA on development of new surveillance and safety assessment methods
  - Coordinating with HHS Assistant Secretary for Preparedness and Response
  - Representatives on the NMDES Planning Board and the ONC HIT Standards FACA

Opportunity for 'dual use'
- Cyber and non-cyber
- Person
- Health system
- Critical infrastructure

The Surveillance Loop: Impact Assessed