

Module 3: Part 2

Applications

Failure Mode Effects and Criticality Analysis (FMECA)

► Objectives

Define failure mode effects and criticality analysis (FMECA)

Discuss its importance in mitigating potential risk exposures throughout the organization

Examine the FMECA process from beginning to end

Disseminate FMECA results so that others can learn and conduct similar projects

Review a sample FMECA



https://www.jointcommission.org/assets/1/18/PSC_for_Web.pdf

<https://psnet.ahrq.gov/primers/primer/31/high-reliability>

► Risk mitigation



Enterprise risk
management (ERM)
approach

- Existing processes
- New service lines
- Removal of service lines
- Staffing changes
- Equipment upgrades
- IT modifications

► FMECA process

Select process to be analyzed

- New or removal of service line
- Problematic processes
- Equipment changes



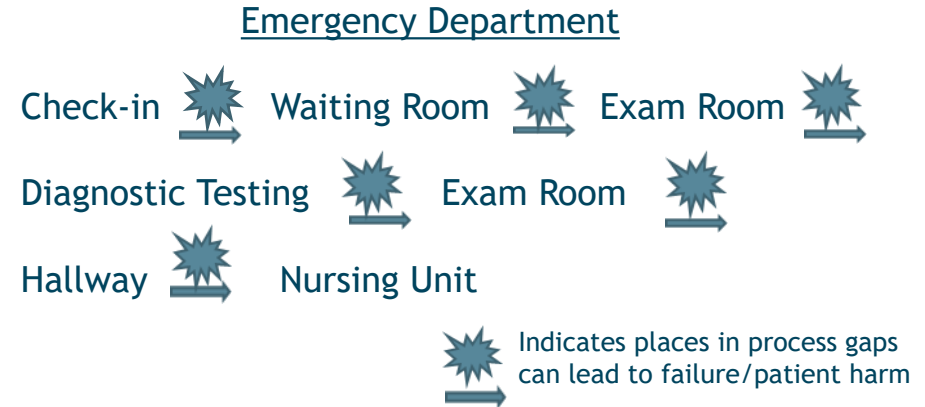
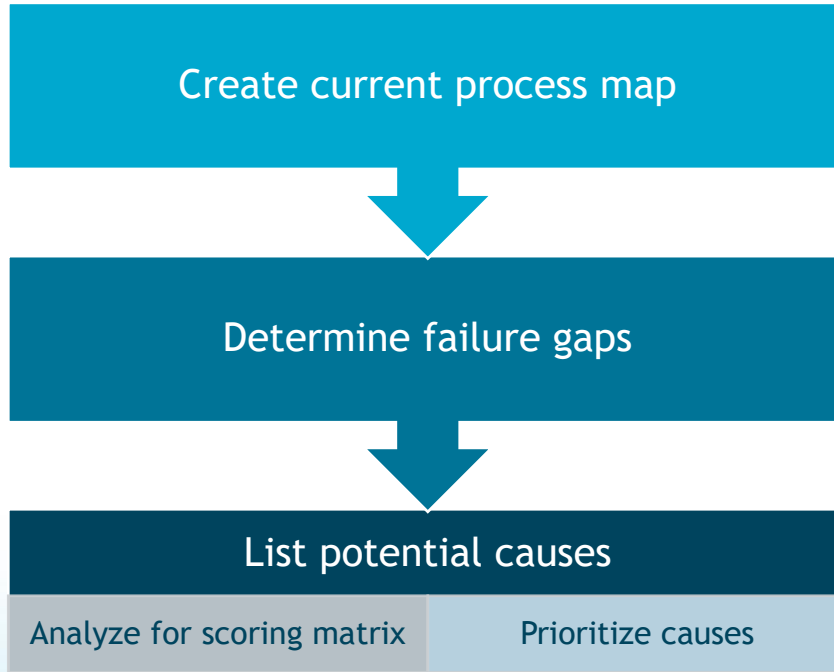
Designate team members and roles

- Management
- Risk management, quality, and patient safety professionals
- Front line staff
- Ancillary staff (as needed)
- Community members/patients

<https://www.jcrinc.com/assets/1/7/PS17.pdf>

<http://www.ihl.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx>

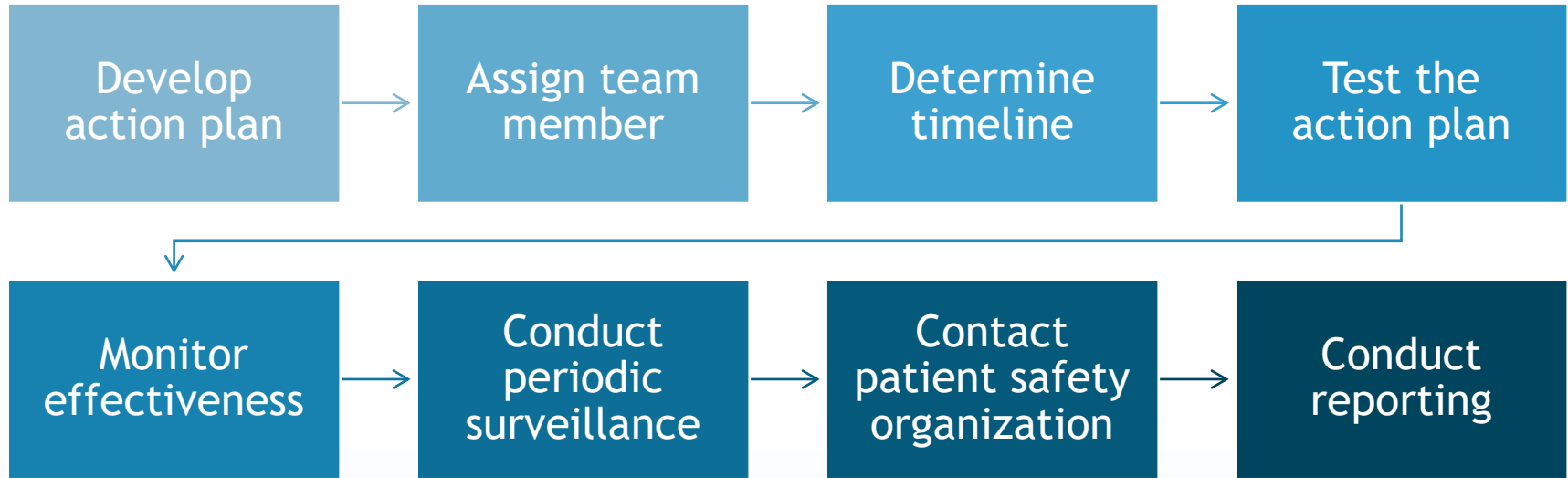
► FMECA procedure



<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/GuidanceForFMEA.pdf>

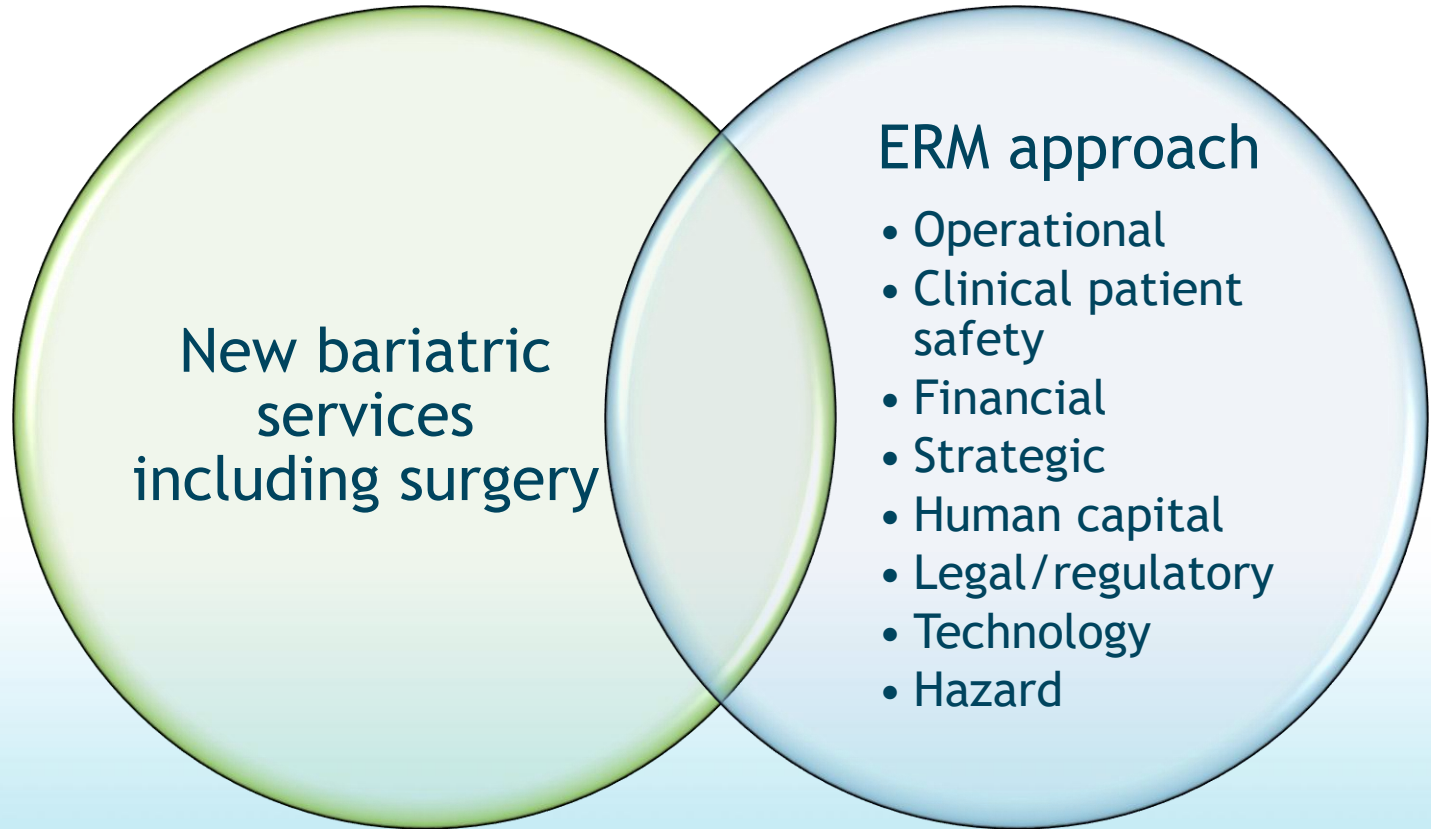
<https://www.jointcommission.org/assets/1/18/Fmeca.pdf>

► FMECA procedure



<http://www.ihl.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx>

► Sample FMECA



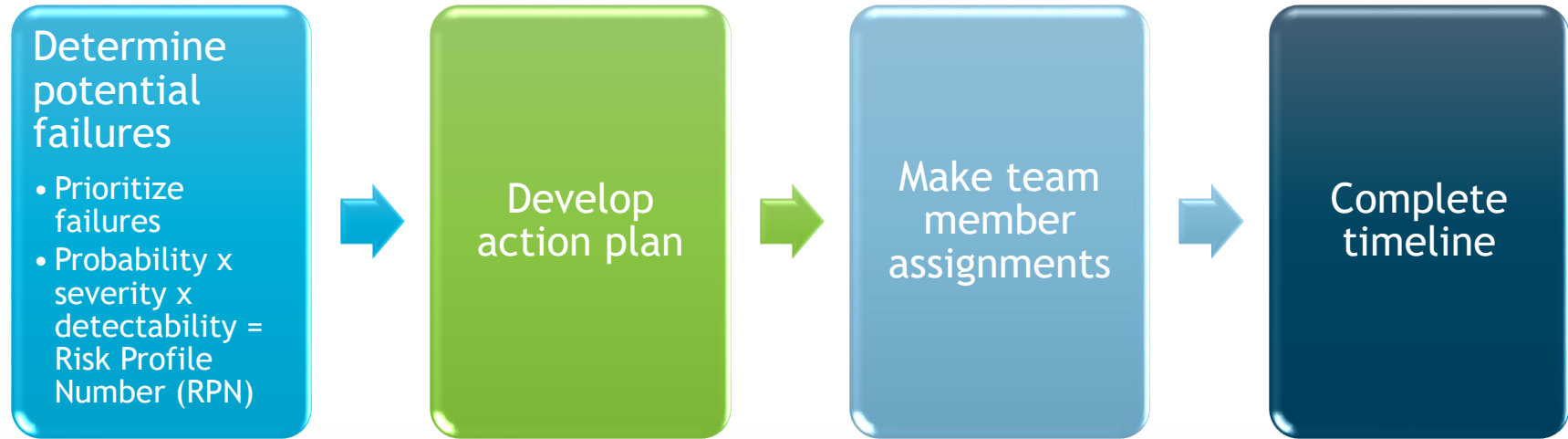
► Sample FMECA

Process mapping

- Data from other organizations
- Based on industry standards
- Existing structure, staff, and support
- Additional organizational needs

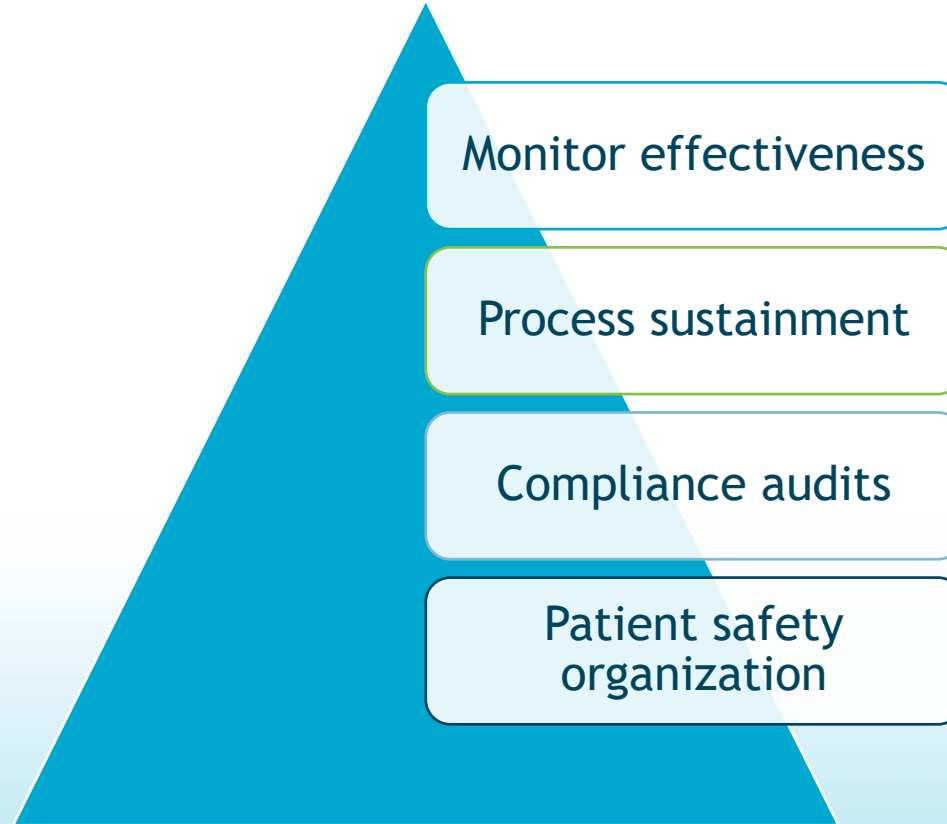
<https://asmbs.org/integrated-health/mbsaqip>

► Sample FMECA



<https://psnet.ahrq.gov/primers/primer/20/human-factors-engineering>

▶ Sample FMECA



► Quiz question

Failure mode effects and criticality analysis is a tool used often within high reliability organizations because of its:

- A. Cost containment obsession
- B. Drive to be competitive
- C. Preoccupation with failure
- D. Preoccupation with success



► Response

Failure mode effects and criticality analysis is a tool used often within high reliability organizations because of its:

C. Preoccupation with failure

Rationale: In order to continually improve system operations an organization must routinely and objectively analyze its processes to determine where potential gaps exist. This aids in understanding the diverse range of errors that can lead to failure.

Environment of Care & Emergency Response

► Objectives

Understand the risk management role in the organization's environment of care (EOC)

Identify potential environmental risks to the organization

Recognize steps in preparation for, and response to, these risks

Identify recovery efforts following an environmental event

► Environment of care

Responsibility

- Safety officer
- Facilities manager
- Security manager
- Environmental services manager

Safety/EOC committee

Environmental rounds

Resources

- Fire marshal
- Emergency management officials
- Local AHJs (authorities having jurisdiction)
- Insurance companies

► Emergency management



► Identification

Environmental risks

- Earthquake
- Flood
- Tornado
- Hurricane
- Fire

Terrorism

- Active shooter
- Biological
- Chemical
- Violence
- Cyber

▶ Preparation

- ▶ Self-assessment
- ▶ Coordinate with local fire, emergency management, EMS, and police
- ▶ Coordinate with essential service providers
- ▶ Review insurance coverage
 - ▶ Property and business interruption
 - ▶ Directors & Officers (D & O)
 - ▶ General, professional, and auto liability
 - ▶ Workers' compensation
 - ▶ Aviation
- ▶ Develop/update a written emergency preparedness plan
- ▶ Conduct drills

► Operational preparation

Employees

- Plan for those on site, and those to be called in
- Plan for support systems
 - Facilities to house employees and possibly their families
 - Employee pay/hours
 - Counseling/support

Mutual Aid

- Agreements

Security

Service Reduction

Training

- Education
- Drills

Multifacility systems

► Implementation and response

► Incident commander

- Senior management
- Transfer to next commander

► Communications

- Responsibility of one individual
- Establish continual flow of information

Internal:

- Medical staff
- Managers and employees
- Trustees, governing board, and volunteers
- Coordination with government agencies and organizations

External:

- Media

▶ Recovery

- ▶ Plan should include recovery
 - ▶ Possible facility inspections
 - ▶ Command center closure
 - ▶ Documentation
 - Financial
 - Repairs
 - ▶ Employees and patients
 - Counseling
 - ▶ Communications
 - Employees
 - Media
- ▶ Final goal to resume normal operations

► Resources

- Carroll, R. (2011). Emergency management. In P. Nakamura, R. Carroll (Eds.), *Risk Management Handbook for Healthcare Organizations*, 6th ed. (pp. 513-537). San Francisco, CA: Jossey-Bass.
- Centers for Disease Control and Prevention. (n.d.). Hospital all-hazards self-assessment. Retrieved from https://www.cdc.gov/phpr/readiness/healthcare/documents/hah_508_compliance_final.pdf
- Emergency Medical Services Authority California (EMSA). Hospital Incident Command System (HICS). Retrieved from https://emsa.ca.gov/wp-content/uploads/sites/47/2017/09/HICS_Guidebook_2014_11.pdf
- FirstHealth of the Carolinas. Environment of care - Safety management plan. Retrieved from http://moore.fastcommand.com/docs/Environment_of_Care_Safety_Management_Plan.pdf

► Resources

- MedPro Group. (2018). Preparing your healthcare practice for environmental emergencies. Retrieved from <https://www.medpro.com/documents/10502/2820774/Preparing+Your+Healthcare+Practice+for+Environmental+Emergencies.pdf>
- Missouri Hospital Association. (2012). Preparedness and partnerships: Lessons learned from the Missouri disasters of 2011. Retrieved from https://www.jointcommission.org/assets/1/6/Joplin_2012_Lessons_Learned.pdf
- The Joint Commission. Joint Commission Perspectives. Retrieved from <https://www.jointcommission.org/assets/1/6/EOCManagementPlans.pdf>
- The Joint Commission. Survey activity guide for health care organizations. Retrieved from https://www.jointcommission.org/assets/1/18/Lab_2018_SAG_Issue_Date_Dec_2017.pdf

► Quiz question

Environment of care and emergency preparedness are the responsibilities of (select all that apply):

- A. All employed personnel and board members
- B. Housekeeping
- C. Maintenance and security
- D. Senior leadership



▶ Response

Environment of care and emergency preparedness are the responsibilities of (select all that apply):

A. All employed personnel and board members

Cybersecurity

Protecting Your Information Technology Systems

► Objectives

Describe cybersecurity and its importance to a healthcare organization

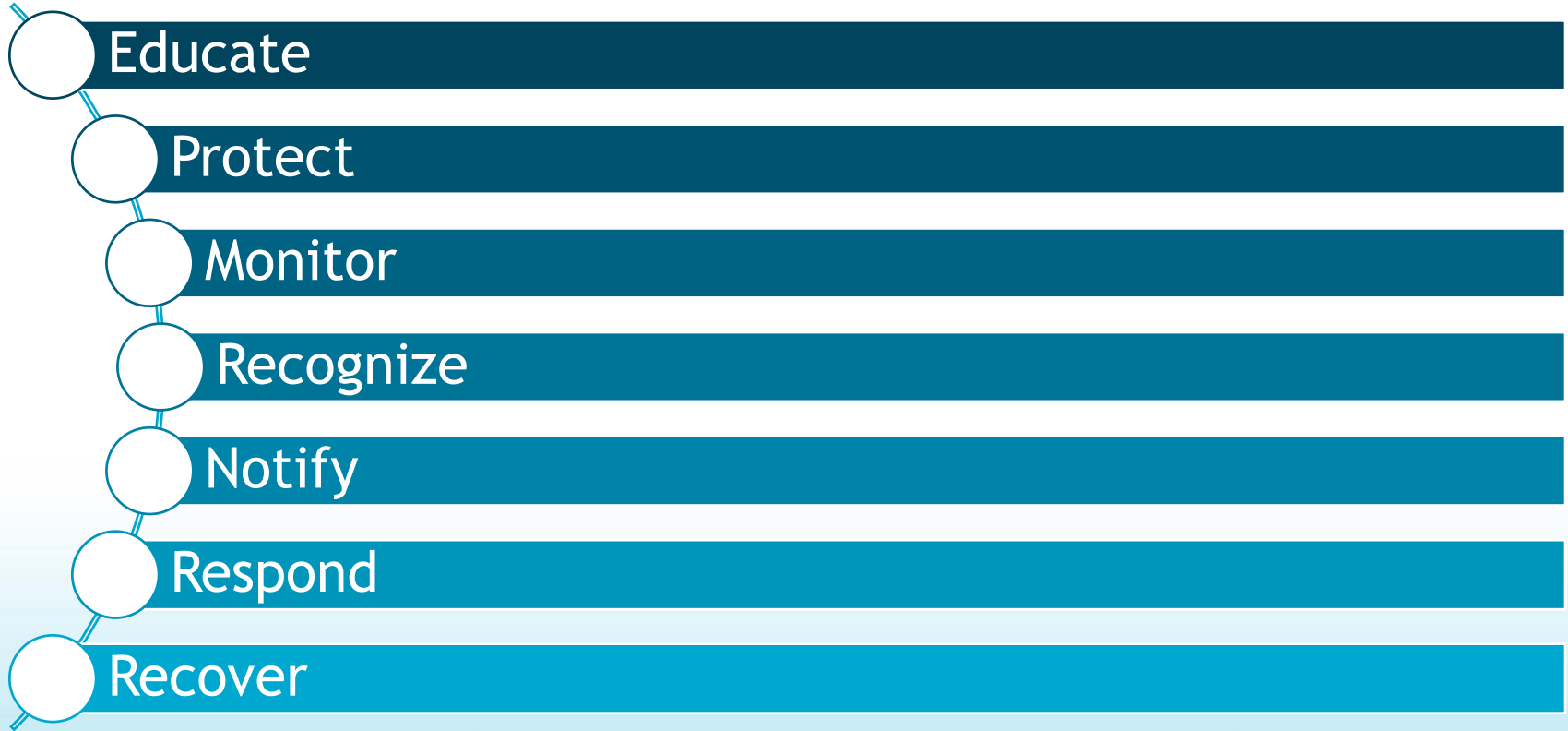
Recognize vulnerable medical device systems

Examine cyber breaches using an enterprise risk management approach

Identify reporting requirements for cyber breaches

Discuss key points of a cybersecurity preparedness plan

► Cybersecurity



► Medical device systems

Diagnostic imaging



Patient monitoring



Alarm notification



Therapeutic infusion



Life critical

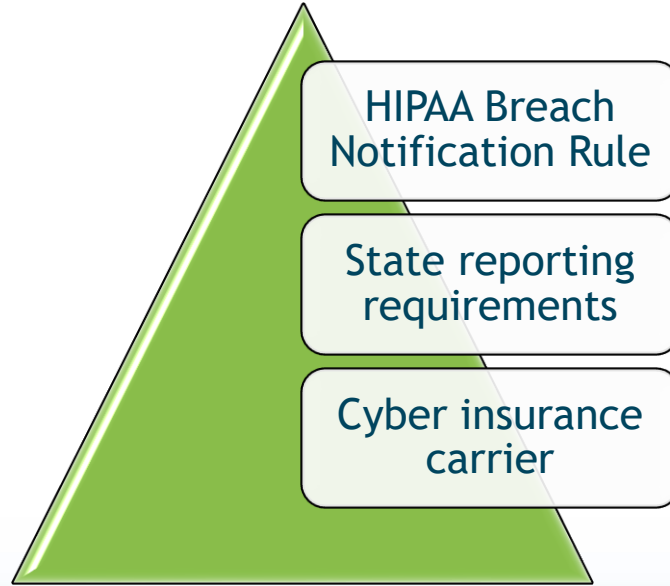


► Breach impact

Enterprise risk management (ERM)

- Operational
- Clinical patient safety
- Financial
- Strategic
- Human capital
- Legal regulatory
- Technology
- Hazard

▶ Reporting



<https://www.hhs.gov/hipaa/for-professionals/breach-notification/breach-reporting/index.html>
<https://healthitsecurity.com/features/state-data-breach-notification-laws-critical-to-healthcare-orgs>

► Organization preparedness



Network
failures

- Policies and procedures
- Notifications
- Downtime processes
- Resources
- Recovery
- Insurance

► Resources

- ▶ Department of Health and Human Services. (2017). Better protecting the healthcare system - and, ultimately, patient care - against cyberattacks. Retrieved from <https://www.hhs.gov/blog/2017/06/02/better-protecting-healthcare-system-against-cyberattacks.html>
- ▶ Health Care Industry Cybersecurity Task Force. (2017, June). Report on improving cybersecurity in the healthcare industry. Retrieved from <https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf>
- ▶ Healthcare IT News. (2017). HHS CISO: 3 things hospitals should do right now to strengthen cybersecurity. <https://www.healthcareitnews.com/news/hhs-ciso-3-things-hospitals-should-do-right-now-strengthen-cybersecurity#gs.5QpWW8A>
- ▶ HIPAA Journal. (2018). HIMSS warns of exploitation of API vulnerabilities and USB-based cyberattacks. Retrieved from <https://www.hipaajournal.com/category/healthcare-cybersecurity/>
- ▶ MedPro Group. Patient safety and liability concerns in the era of electronic records. Retrieved from https://www.medpro.com/documents/10502/2820774/Article_Patient+Safety+and+Liability+Concerns.pdf
- ▶ MedPro Group. (2017). Risk resources: Cybersecurity. Retrieved from https://www.medpro.com/documents/10502/2824311/Risk+Resources_Cybersecurity.pdf

► Quiz question

In purchasing a new electronic health record system for the organization or office practice, what additional services should you be most interested in procuring? (Select all that apply)

- A. Stand-up work stations for all staff
- B. Continuous IT monitoring services
- C. Encryption capabilities
- D. Ongoing HIPAA compliance auditing



▶ Response

In purchasing a new electronic health record system for the organization or office practice, what additional services should you be most interested in procuring?

- B. Continuous IT monitoring services
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► Disclaimer

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