



A HEALTHY PREOCCUPATION WITH FAILURE: LEVERAGING FMEA TO DRIVE SAFETY

This program is approved by NAHQ®
for 1.0 CPHQ CE credit.

Anticipate failures, reduce risk, and protect service continuity by operationalizing Failure Mode and Effects Analysis (FMEA).



PRESENTER

- Michelle is a registered nurse with 29 years of experience in the acute care hospital setting.
- Spent two decades leading transformative Quality initiatives in Director, Vice President, and System Director roles.
- Work has spanned Quality & performance improvement, regulatory compliance, patient safety, risk management, and infection prevention.
- Currently serves as the AVP of Quality, Compliance and Standards at Vastian

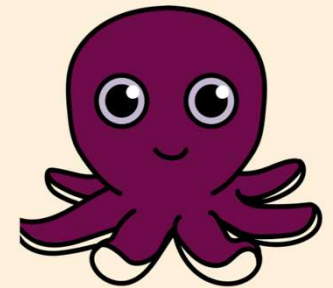
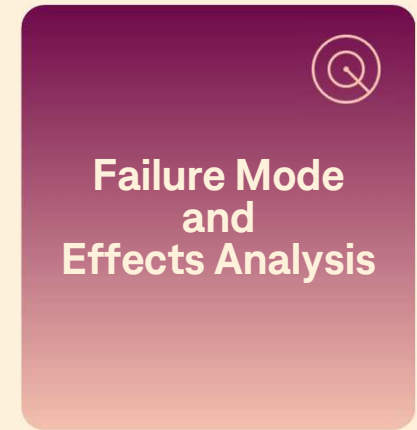


Michelle Hilburn,
MSN, RN, CPHQ, CPPS
AVP, Quality, Compliance & Standards
Vastian



LEARNING OBJECTIVES

- Establish core FMEA principles to enable consistent, effective, risk-based decision-making.
- Position FMEA as an enterprise capability that anticipates failure and strengthens organizational resilience.
- Demonstrate how proactive risk analysis advances patient safety, regulatory readiness, and operational reliability.
- Identify why traditional FMEA often underperforms, including systemic barriers that limit sustained value.
- Translate insight into action through a practical, structured FMEA example.





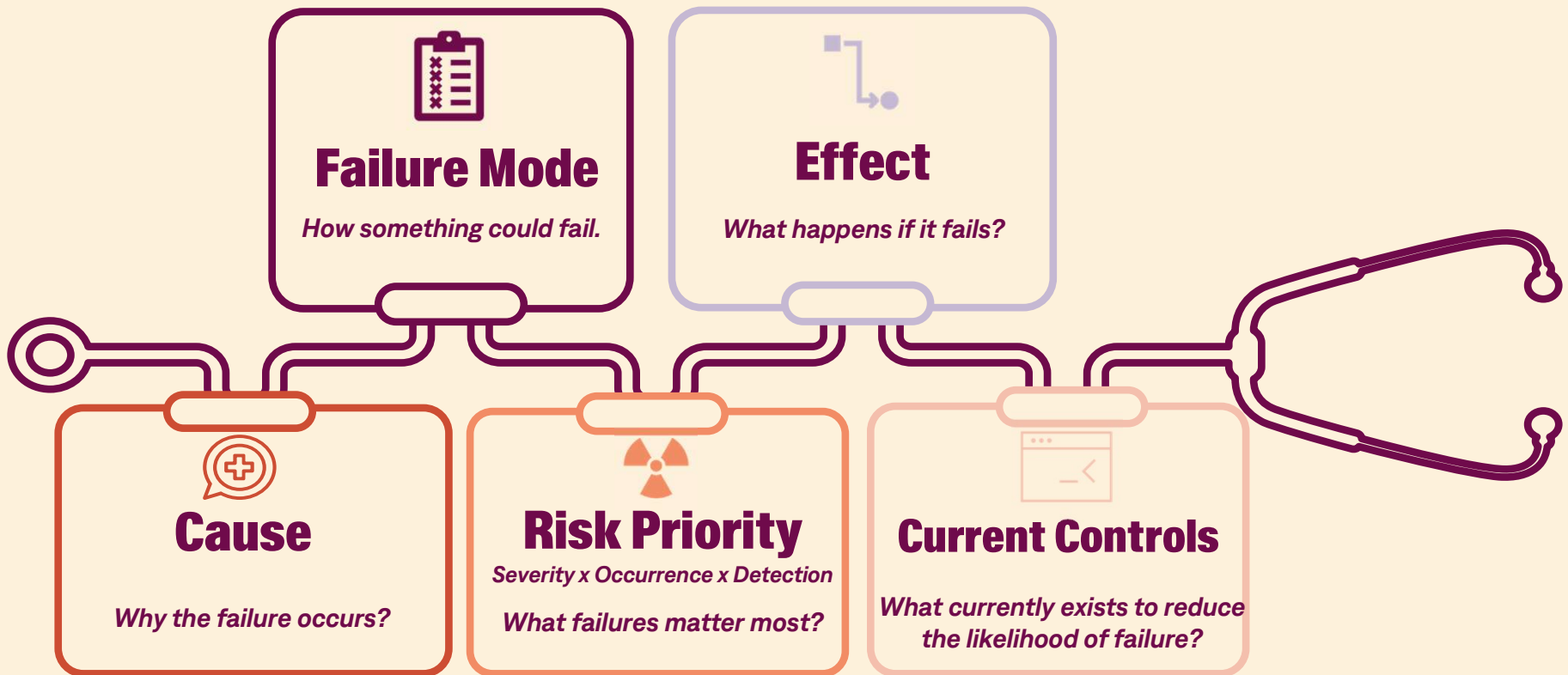
WHAT IS FMEA?

Failure Mode and Effects Analysis

A structured, systematic, proactive method used to identify potential failures in a process, product, or system and assess their impact so that they can be prioritized and addressed before they occur and have potential to cause an adverse event.

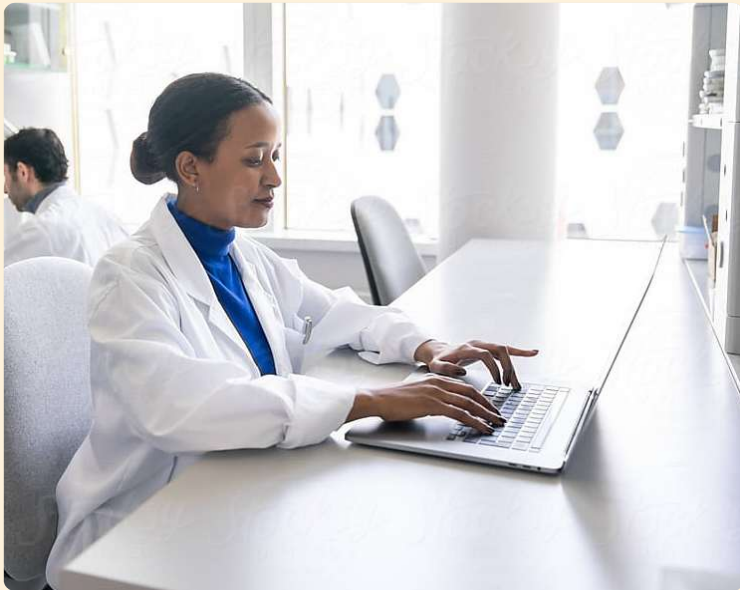


KEY COMPONENTS OF FMEA





WHY FMEA MATTERS IN HEALTHCARE?



1) HELPS PREVENT HARM

2) MAINTAIN OPERATIONS

3) ENHANCES PATIENT SAFETY

4) PROMOTES COLLABORATION



POLLING QUESTION #1

Approximately how long has it been since your organization conducted a Failure Mode Effects Analysis?

- 1. Less than 6 months**
- 2. 6 months to 1 year**
- 3. 1 year to 18 months**
- 4. More than 18 months**



BENEFITS AND BARRIERS OF TRADITIONAL FMEA IN HEALTHCARE

- Identifies high-risk areas proactively
- Multidisciplinary participation
- Strengthens improvement efforts when explicit link to actions, owners, due date, verification of completion
- Aligns with Quality & Safety goals
- Governance path for decisions



- Treated as a deliverable, not a decision tool
- Too resource-intensive, time-consuming
- Scoring variability undermines credibility
- Limited visibility across departments
- Action aren't owned, funded, or tracked to completion



POLLING QUESTION #2

**What are the primary challenges with conducting Failure Mode Effects Analysis (FMEA) at your hospital/healthcare organization?
(Select up to 3)**

- 1. Insufficient time to execute FMEA at a sufficient frequency**
- 2. Difficulty conducting FMEA year-over-year**
- 3. Lack of staff to complete tasks associated with the FMEA**
- 4. Highly manual process**
- 5. Competing priorities**
- 6. Challenge in determining what high-risk process to evaluate**



HERE'S HOW IT WORKS...



FMEA INITIATION & TEAM SELECTION

FMEA Initiation


1. Date FMEA Initiated

2. Designating FMEA Team

- Facilitator(s)
- Executive Sponsor(s)
- Other Team Members
 - Quality/Safety
 - Operational Leader(s)
 - Frontline Staff
 - Informatics
 - Supply Chain


FMEA Team ▾

FMEA Facilitator(s) * Select one or more users

 Shelley Hilburn ✕

+ Select additional users


FMEA Executive Sponsor(s) * Select one or more users


 Dr. Gregory Davis (889018) ✕


+ Select additional users


Additional FMEA Team Members * Recommend selecting 8-10 multidisciplinary team members


Select one or more users

 Allison Walters ✕

 Judi Bennett ✕

 Michael Cummins ✕

 Tim Westover ✕

 Chelsey Coker ✕



PRACTICAL EXAMPLE: FAILURE MODE

Failure Mode ▼

Name and describe the potential process failure being analyzed. *

Example: Prolonged outage of the hospital's pneumatic tube delivery system

Prolonged outage of the hospital's pneumatic tube delivery system.

Failure Scenario *

Describe the potential failure of a high-risk clinical process or failure of a process that could lead to catastrophic delay or patient harm. What could go wrong? Why would it happen?
Example: The hospital's pneumatic tube system suffers a mechanical failure halting the hospital's ability to transport medications and lab specimens between the patient care units and the Pharmacy or Lab. The mechanical issues require replacement parts that will take two weeks to be delivered plus installation time.

The hospital's pneumatic tube system suffers a mechanical failure halting the hospital's ability to transport non-narcotic medications from the Pharmacy to the patient care units and specimens between the patient care units and the Lab. The mechanical issues require replacement parts that will take a minimum of two weeks to be delivered plus additional installation time by the Facilities Department.



RISK PRIORITIZATION

Potential Severity *

- 1 = No Harm or Delay in Care/Process
- 2 = Potential for Harm or Delay
- 3 = Mild Harm or Short Delay
- 4 = Moderate Harm or Long Delay
- 5 = Severe Harm or Death

Likelihood of Occurrence *

- 1 = Almost Never
- 2 = Low Probability
- 3 = Occasional occurrence likely
- 4 = Repeated occurrences likely
- 5 = Occurs frequently

Likelihood of Detection *

- 1 = Very Low - Very unlikely to be detected
- 2 = Low - Unlikely to be detected
- 3 = Moderate - Failure may be detected
- 4 = High - Failure is likely to be detected
- 5 = Very High - Failure is almost certain to be detected

Total Risk Score/RPN = Potential Severity x Likelihood of Occurrence x Likelihood of Detection
A total risk score/RPN ≥ 75 warrants a FMEA.

80

Ranges: LOW: Value ≤ 74

HIGH: Value ≥ 75



EFFECTS ANALYSIS

Effects Analysis ▾

Current Controls (Select all that apply) *

What is currently in place to prevent or reduce the likelihood of failure?

Example: Weight limits on what can be transported in the pneumatic tube system, a cleaning procedure, preventive maintenance and inventory of spare parts maintained at facility.

- Policy and/or Standard Operating Procedure
- Employee Education
- Preventive Maintenance
- Redundant System or Operation (i.e. duplicate equipment, ability to revert to manual process easily))
- Other

Facilities maintains an inventory of spare parts

Effects of Failure *

Describe how the failure will affect normal operations or processes. What would be jeopardized due to the failure?

Example: Failure of the hospital's pneumatic tube system will cause an inability for the Pharmacy to deliver STAT medications rapidly to the patient care units. Additional human resources will be necessary to deliver the medications physically and regulatory standards on who can handle and transport medications will need consideration. The patient care units will lose the ability to quickly send collected specimens to the Lab. Specimen collection containers, a chain of custody and human transport system will be necessary. Delays in these two processes could cause delay of patient care.

Failure of the hospital's pneumatic tube system will cause the inability for the Pharmacy to deliver STAT non-narcotic medications rapidly to the patient care units without having to leave the main Pharmacy. As a result, additional human resources (within scope) will be necessary to deliver the medications physically, and regulatory standards on who can handle and transport medications will be to be taken into consideration. Likewise, the patient care units will lose the ability to quickly send collected specimens to the Lab for processing. Specimen collection receptacles, a chain of custody record and human transport system will be necessary to get the specimens from the patient care units to the Lab. Delays in the medication and specimen delivery processes have a high likelihood of causing delays in patient care and potential delays in timely diagnosis.



PREVENTATIVE ACTIONS

Improvement Owner	Corrective Action	Due Date
Director of Operations	Develop extended downtime procedure	5/30/2026
Education Manager	Assign learning course to Pharmacy, Lab, and Nursing staff related to the new extended downtime procedure and review tube system weight limits.	6/1/2026
Director of Facilities Management	Purchase additional parts for the pneumatic tube system when available from the manufacturer and retain in Facilities inventory.	6/30/2026



TASK ASSIGNMENTS & EXECUTED ACTIONS

Corrective tasks are completed by those assigned:

- **External tasks managed outside the QMS are marked complete inside the system once completed by the Owner/Responsible Person.**
- **Internal tasks stemming from corrective actions are assigned, completed, and tracked automatically inside the QMS.**



QUESTIONS

CONTACT US

Michelle Hilburn
AVP, Quality, Compliance & Standards
michelle@vastian.com

Anthony Sweet
Account Executive, East
Anthony@vastian.com

LaDonn Wakefield
Account Executive, West
LaDonn@vastian.com

www.vastian.com

877-776-8460