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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).

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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

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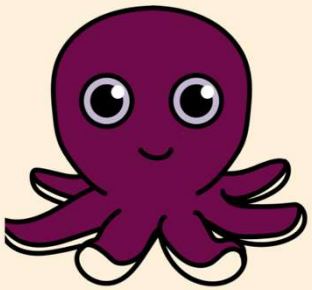
LEARNING OBJECTIVES

- 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.

Failure Mode and Effects Analysis

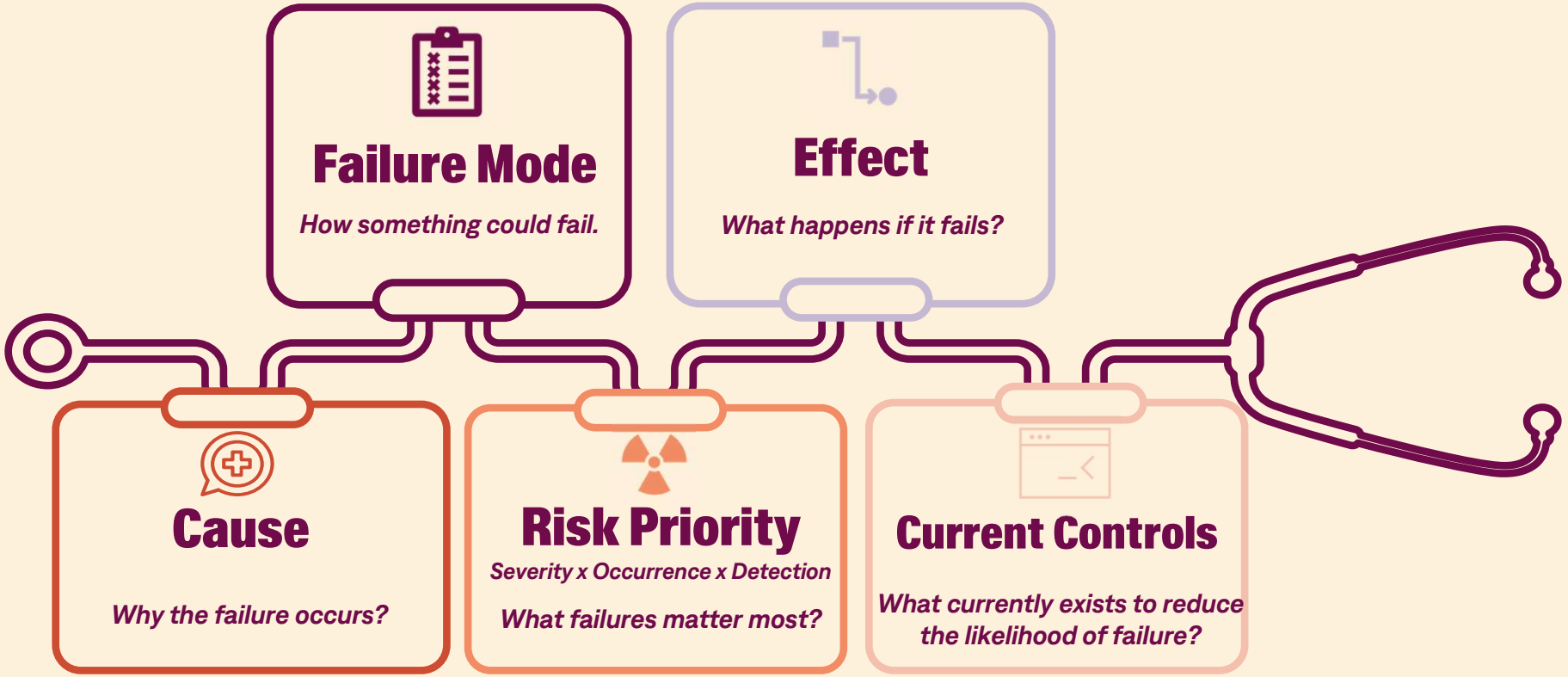


WHAT IS FMEA?

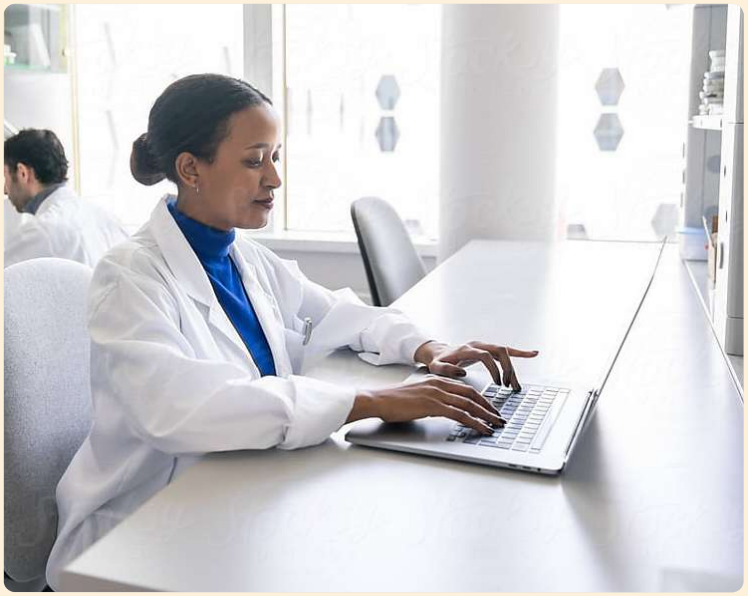
Failure Mode and Effects Analysis

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)

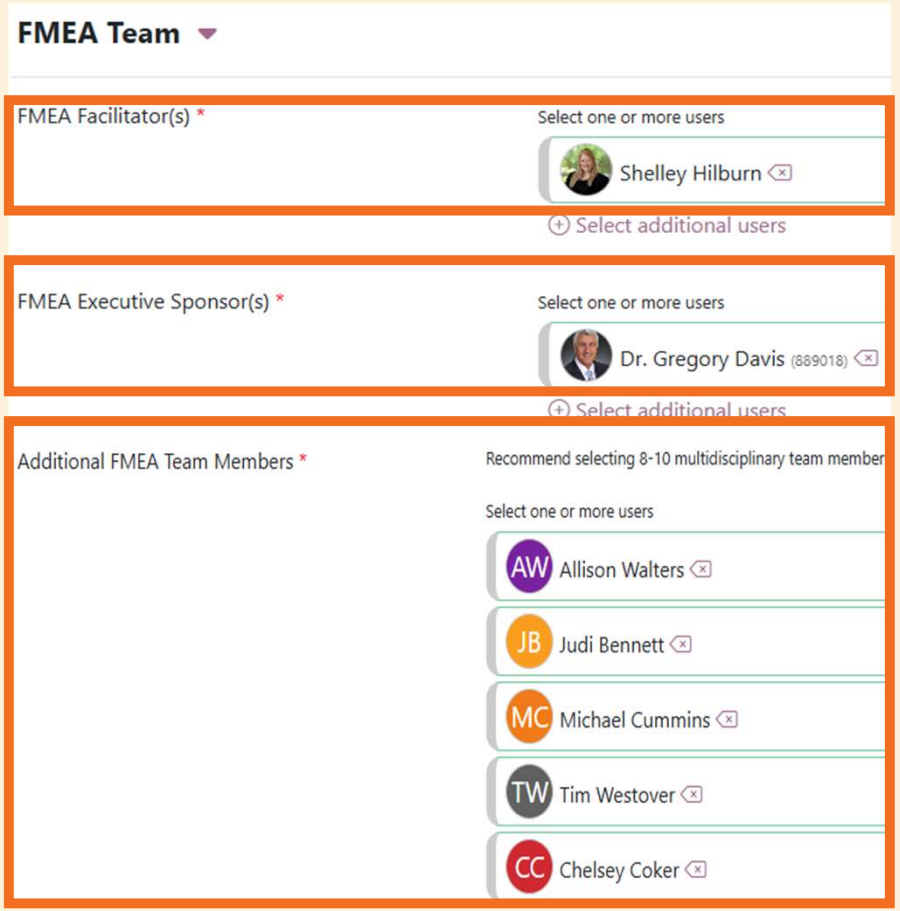
1. Insufficient time to execute FMEA at a sufficient frequency
2. Difficulty conducting FMEA year-over-year
3. Lack of staff to complete tasks associated with the FMEA
4. Highly manual process
5. Competing priorities
6. Challenge in determining what high-risk process to evaluate

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



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

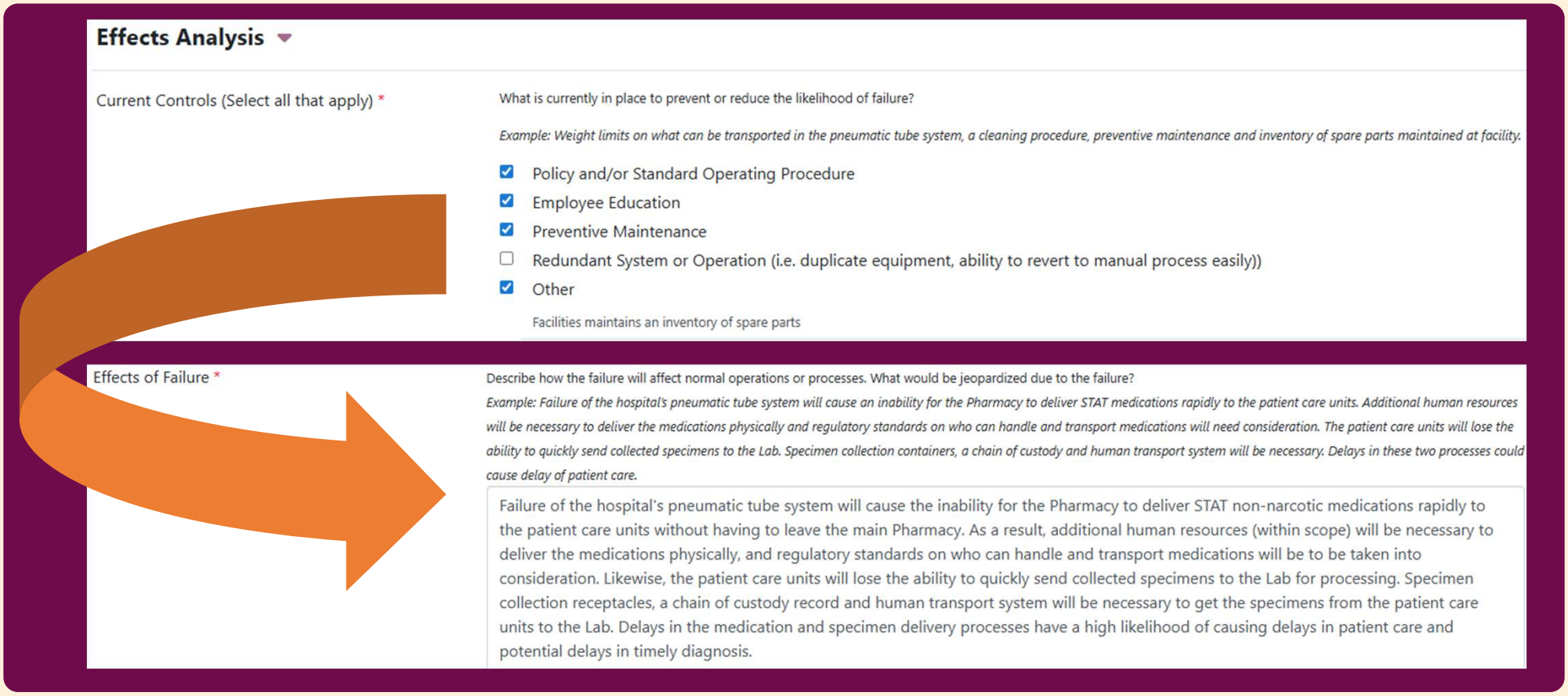
A total risk score/RPN ≥ 75 warrants a FMEA.

80

Ranges: LOW: Value <= 74

HIGH: Value >= 75

EFFECTS ANALYSIS



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

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