Quality and Safety Series

Failure Mode and Effects Analysis (FMEA)

OBJECTIVES

- Define and describe the components of an FMEA.
- Identify the uses for an FMEA.
- Outline the steps to complete an FMEA.

What Is FMEA?

F Failure

M Mode

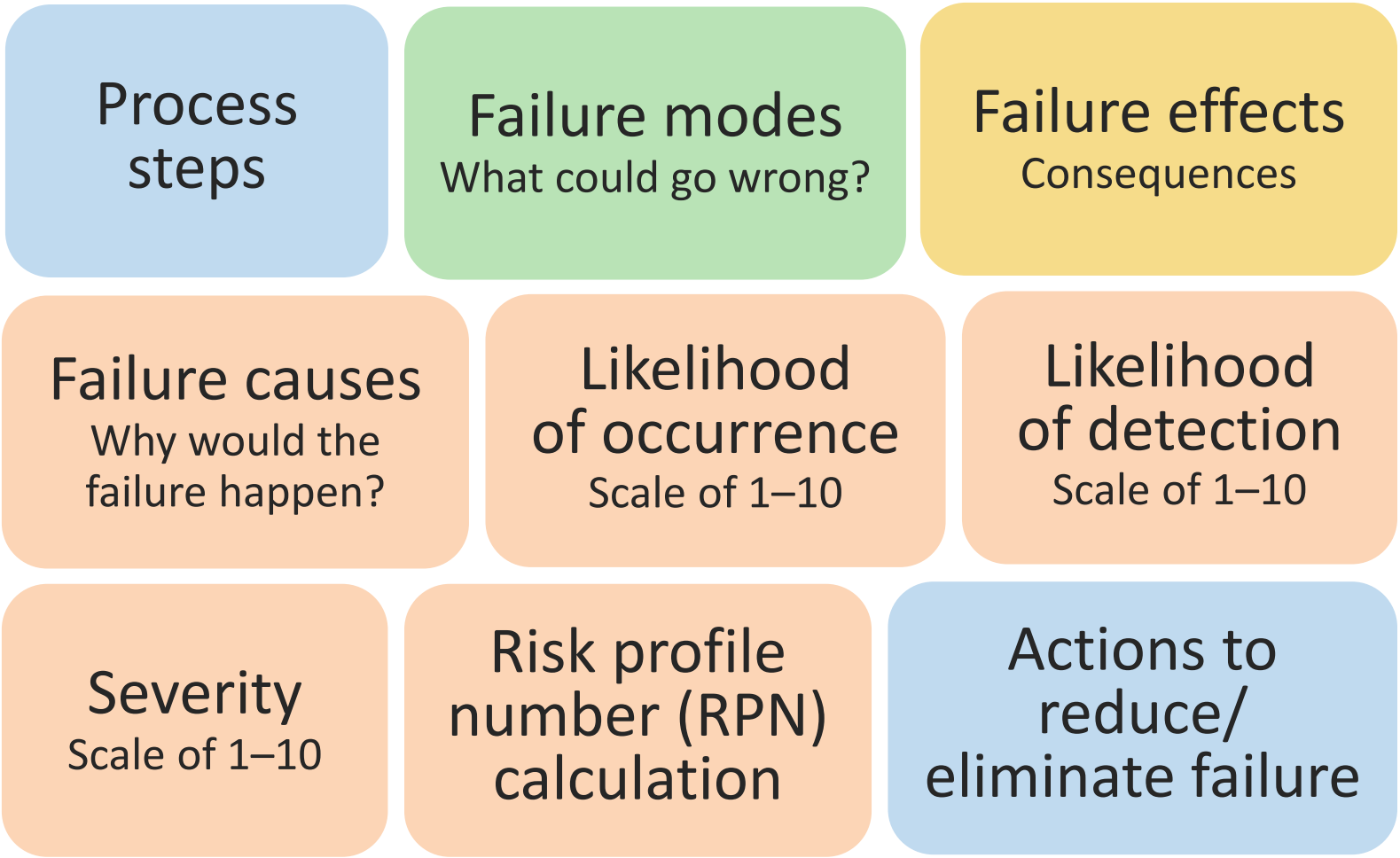
E Effect

A Analysis

- A systematic approach.
- Entails proactive analysis.
- Identifies potential failures in a process.
- Ranks and prioritizes.
- Has the goal of reducing or eliminating points of failure.

Institute for Healthcare Improvement. (2021). Failure modes and effects analysis (FMEA) tool. Retrieved from http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx#:~:text=Failure%20Modes%20and%20Effects%20Analysis%20(FMEA)%20is%20a%20systematic%2C,most%20in%20need%20of%20change.

FMEA Components



Institute for Healthcare Improvement. (2021). Failure modes and effects analysis (FMEA) tool. http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx#:~:

Occurrence and Detection Scoring

Occurrence

Level	Score	Incidence	Definition
Remote	1	< 10%	No known occurrences or rare
Low	3	10%–30%	Possible but no know data to support
Moderate	5	40%–60%	Documented but less frequent
High	7	70%–80%	Documented and frequent
Very High	10	90%–100%	Documented and almost certain to occur

Detection

Level	Score	Incidence	Definition
Very High	1	9 out of 10	Almost always detected
High	3	7 out of 10	Likely to be detected
Moderate	5	5 out of 10	Moderate likelihood of detection
Low	7	2 out of 10	Low likelihood of detection
Remote	10	0 out of 10	Detection not possible

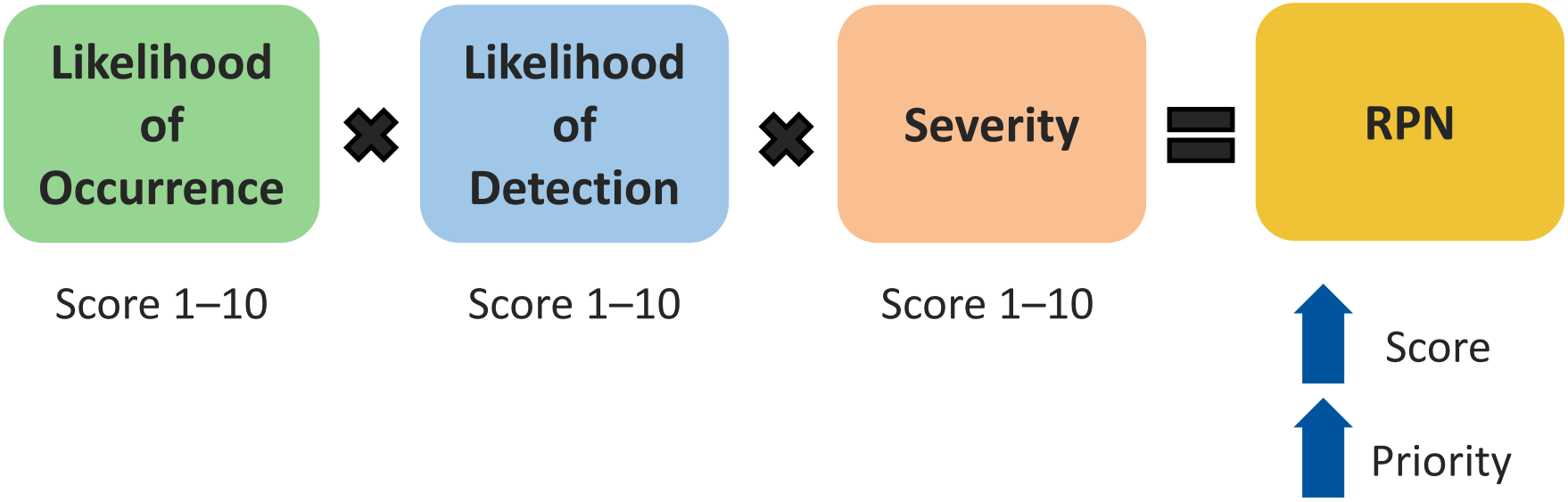
Institute for Healthcare Improvement (2021). Failure modes and effects analysis (FMEA) scoring system. Retrieved fromhttp://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisScoringSystem.aspx

Overall Severity Scale Scoring

Severity	Level	Score	Definition
	No impact	1	No impact
	Slight impact	2	May affect the system
	Moderate system problem	3	May affect the patient
	Major system problem	5	May affect the patient
	Minor injury	7	Temporary patient harm
	Major injury	9	Permanent harm or disfigurement
	Terminal injury or death	10	Result in mortality

Institute for Healthcare Improvement (2021). Failure modes and effects analysis (FMEA) scoring system. Retrieved fromhttp://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisScoringSystem.aspx

RPN

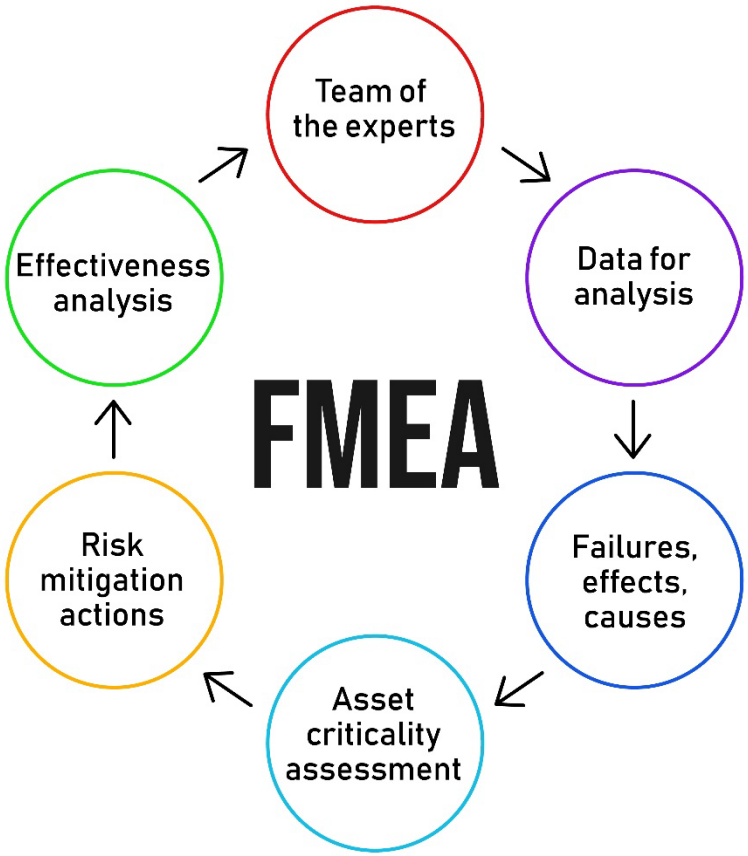


Lean Six Sigma. Risk Priority Number. https://www.leansixsigmadefinition.com/glossary/risk-priority-number-rpn/#

When to Use an FMEA

- At the initial design of a process.
- To identify “weak links” in a process.
- To redesign a process.
- After process failures.
- As a foundation for a control/sustainability plan.

Steps to Completing FMEA



- Assemble your team.
- Identify process and scope (process mapping).
- List all steps needed to complete a process.
- Identify real/potential failures, effects, and causes.
- Rank occurrence, detection, and severity.
- Calculate the RPN.
- Identify mitigation actions.

FMEA Example

Failure Modes Effect Analysis Worksheet															
Process Step	Potential Failure Mode	Potential Failure Effect	Severity (SEV)	Potential Causes	Occurance (OCC)	Current Process Controls	Detection (DET)	Risk Priority Number (RPN)	Action Recommended	Responsibility and Target Completion Date	Actions Taken	New Sev	New OCC	New Det	New RPN
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	How severe is the effect on the customer?	What causes the step to go wrong (i.e., how could the failure mode occur)?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?	Risk priority number calculated as SEV x OCC x DET	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.						
Updating Medication Reconciliation at Discharge (specific focus on cardiac medications following AMI)	Wrong dose listed	Permanent Harm	8	Lack of clear accountability on who completes medication reconciliation at discharge	10	Pharmacy staff have been assigned to review every record prior to discharge to validate accuracy. This is an interim measure implemented immediately after the concern was identified	1	80	Discharging physician is accountable for a correct med rec at discharge. Pharmacy staff will validate prior to discharge. Patterns of non-compliance will be brought to the attentiong of the CMO	Dr. Gray (CMO) 4/21/2021	All rec. actions	8	1	1	8
	Wrong frequency	Permanent Harm	9	Medical residents do not have access to this section in EMR	10	See above	1	90	Educate medical residents on medication reconcilation documentation and provide necessary access within the EMR	Bill (IT) 4/19/2021	All rec. actions	9	1	1	9
	Incorrect medication listed	Permanent Harm/Death	10	Nursing staff do not feel comfortable stopping a discharge if the medication reconciliation hasn't been completed	10	See above	1	100	Empower nursing staff to hold a discharge based upon medication reconcilation concerns. Immediate steps should be to notify pharmacy staff and attending physician for clarification.	Betty (CNO) and Dr. Gray (CMO) 4/9/2021	All rec. actions	10	1	1	10

FMEA Example (cont.)

Process Step	Potential Failure Mode	Potential Failure Effect	Severity (SEV)	Potential Causes	Occurance (OCC)	Current Process Controls	Detection (DET)
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	How severe is the effect on the customer?	What causes the step to go wrong (i.e., how could the failure mode occur)?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?
Updating Medication Reconciliation at Discharge (specific focus on cardiac medications following AMI)	Wrong dose listed	Permanent Harm	8	Lack of clear accountability on who completes medication reconciliation at discharge	10	Pharmacy staff have been assigned to review every record prior to discharge to validate accuracy. This is an interim measure implemented immediately after the concern was identified	1
	Wrong frequency	Permanent Harm	9	Medical residents do not have access to this section in EMR	10	See above	1
	Incorrect medication listed	Permanent Harm/Death	10	Nursing staff do not feel comfortable stopping a discharge if the medication reconciliation hasn't been completed	10	See above	1

FMEA Example (cont.)

Risk Priority Number (RPN)	Action Recommended	Responsibility and Target Completion Date	Actions Taken	New Sev	New OCC	New Det	New RPN
Risk priority number calculated as SEV x OCC x DET	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.						
80	Discharging physician is accountable for a correct med rec at discharge. Pharmacy staff will validate prior to discharge. Patterns of non-compliance will be brought to the attentiong of the CMO	Dr. Gray (CMO) 4/21/2021	All rec. actions	8	1	1	8
90	Educate medical residents on medication reconcilation documentation and provide necessary access within the EMR	Bill (IT) 4/19/2021	All rec. actions	9	1	1	9
100	Empower nursing staff to hold a discharge based upon medication reconcilation concerns. Immediate steps should be to notify pharmacy staff and attending physician for clarification.	Betty (CNO) and Dr. Gray (CMO) 4/9/2021	All rec. actions	10	1	1	10

FMEA Template

Failure Modes Effect Analysis Worksheet																
Process Step	**Potential Failure Mode**	**Potential Failure Effect**	**Severity (SEV)**	**Potential Causes**	**Occurance (OCC)**	**Current Process Controls**	**Detection (DET)**	**Risk Priority Number (RPN)**	**Action Recommended**	**Responsibility and Target Completion Date**	**Actions Taken**	**New Sev**	**New OCC**	**New Det**	**New RPN**
What is the step?	In what ways can the step go wrong?	What is the impact on the customer if the failure mode is not prevented or corrected?	How severe is the effect on the customer?	What causes the step to go wrong (i.e., how could the failure mode occur)?	How frequently is the cause likely to occur?	What are the existing controls that either prevent the failure mode from occurring or detect it should it occur?	How probable is detection of the failure mode or its cause?	Risk priority number calculated as SEV x OCC x DET	What are the actions for reducing the occurrence of the cause or for improving its detection? Provide actions on all high RPNs and on severity ratings of 9 or 10.						

1. Severity: Severity of impact of failure event. It is scored on a scale of 1 to 10. A high score is assigned to high-impact events while a low score is assigned to low-impact events.
2. Occurrence: Frequency of occurrence of failure event. It is scored on a scale of 1 to 10. A high score is assigned to frequently occurring events while events with low occurrence are assigned a low score.
3. Detection: Ability of process control to detect the occurrence of failure events. It is scored on a scale of 1 to 10. A failure event that can be easily detected by the process control is assigned a low score while a high score is assigned to an inconspicuous event.
4. Risk priority number: The overall risk score of an event. It is calculated by multiplying the scores for severity, occurrance, and detection. An event with a high RPN demands immediate attention while events with lower RPNs are less risky.

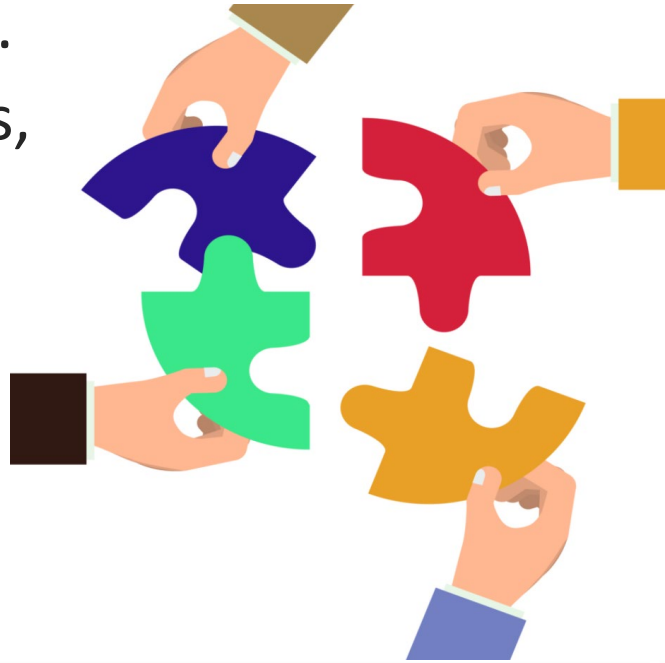
HSAG HQIC

Template available at: https://www.hsag.com/hqic/quality-series

HSAG HQIC

Key Take-Aways

- An FMEA is a systematic method for identifying real and potential failures in a process.
- An FMEA assists in prioritizing and ranking failures.
- Complete an FMEA as a team, with members who have a strong knowledge of the process.
- An FMEA can be used for new processes, after events, or as an ongoing monitoring tool.
- Use FMEA findings to mitigate failures and make processes changes.
- Complete an FMEA as a foundation for a control/sustainability plan.



Thank you!

Questions: hospitalquality@hsag.com

This material was prepared by Health Services Advisory Group (HSAG), a Hospital Quality Improvement Contractor (HQIC) under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services (HHS). Views expressed in this material do not necessarily reflect the official views or policy of CMS or HHS, and any reference to a specific product or entity herein does not constitute endorsement of that product or entity by CMS or HHS. Publication No. XS-HQIC-QI-10292021-01