CARiH

Failure Modes and Effects Analysis

Failure Modes and Effects Analysis (FMEA) is a tool for conducting a systematic, proactive evaluation of a process to spot hazards to patients or staff. In an FMEA, a multidisciplinary team meets to predict and record where, how, and to what extent the system might fail. This team should include all persons involved in the process. Then, the team works together to devise improvements to avert those failures.

The FMEA tool prompts teams to review, evaluate, and record
• Steps in the process
• Failure modes (What could go wrong?)
• Failure causes (Why would the failure happen?)
• Failure effects (What would be the effects of each failure?)

This is a proactive, rather than a reactive approach to potential breakdowns.
This priority on prevention may reduce risk of harm to both patients and staff. FMEA is useful in appraising a new process before implementation and in assessing the impact of a proposed change to an existing process.

Steps:

1) Select a process. Remember to break up complex processes. Do not work on large processes all at once.
2) Recruit a multidisciplinary team. Include everyone who is part of the process. Everyone may not need to join in the full discourse, but do not discuss any step without at least one person being there who does the task.
3) Map the process
4) Fill out the table with your team. List of the process steps in the left most column. Then, fill out the remaining columns:
    a) Failure Mode [What could go wrong?]: List anything that could go wrong during that step.
    b) Failure Causes [Why would the failure happen?]: List all causes for each of the failure modes.
    c) Failure Effects [What would be the effects of the breakdown?]: List all possible adverse effects for each of the failure modes.
    d) Likelihood of Occurrence (1–10): On a scale of 1-10, with 10 being the most likely. What is the likelihood the failure mode will occur?
    e) Likelihood of Detection (1-10): On a scale of 1-10, with 10 being the most likely NOT escape detection, what is the likelihood the failure will escape detection?
    f) Severity (1-10): On a scale of 1-10, with 10 being the most likely, what is the likelihood that the failure mode, if it occurs, will cause severe harm? Note this

does not refer to severity of harm but the likelihood that severe harm will occur.

g) Risk Profile Number (RPN): For each failure mode, multiply the three preceding scores. The lowest score will be 1 and the highest 1,000.
h) Actions to Reduce Occurrence of Failure: List steps to improve safety. Focus on for failure modes with the highest RPNs.

5) Use RPNs to plan improvement efforts. Failure modes with high RPNs should get priority. Failure modes with low RPNs are not likely to affect the overall process much and should be a low priority. Identify the failure modes with the top 10 highest RPNs. The team should look at these ones first as improvement opportunities. Use FMEA to plan steps to reduce harm from failure modes.
    a) Consider the following if failure is likely to occur:
        i) Forcing function-, a physical constraint that makes committing an error impossible, such as medical gas outlets designed to take only matching gages.
        ii) Verification step, such as independent double-checks, bar coding on drugs, or alert screens.
        iii) Change other processes that add to causes.
    b) Consider the following If the failure is likely to escape detection:
        i) Find other events that may occur before the failure and can serve as warnings for the failure event
        ii) Add a step to the process that takes place earlier in the process to avoid the failure mode.
        iii) Consider using devices with alarms to alert users when values are approaching unsafe limits.
    c) Consider the following if the failure is likely to cause serious harm:
        i) Identify early warning signs that failure has occurred, and train staff to see them for prompt intervention. Drills are useful in these scenarios.
        ii) Provide information and resources, such as reversal agents or antidotes, at points of care for events that may call for urgent action.
    d) Run FMEA to gauge the potential impact of changes under consideration. The RPN can be a good balancing metric.
    e) Use the RPN to monitor and track improvement.

Template:

Steps in the Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Profile Number (RPN)	Actions to Reduce Occurrence of Failure
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
							Total RPN (sum of all RPNs):	

Failure Mode: What could go wrong?
Failure Causes: Why would the failure happen?
Failure Effects: What would be the consequences of failure?
Likelihood of Occurrence: 1–10 [10 = very likely to occur]
Likelihood of Detection: 1–10 [10 = very unlikely to detect]
Severity: 1–10 [10 = most severe effect]
Risk Priority Number (RPN): Likelihood of Occurrence × Likelihood of Detection × Severity