Failure Modes and Effects Analysis

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Unlike Root Cause Analysis, which is performed after an adverse outcome, Failure Modes and Effects Analysis (FMEA) is a proactive risk analysis tool. FMEA employs a stepwise approach to prioritize potential interventions to reduce the risk of failure and mitigate resultant harm. First, the team identifies ways a process could fail. Next, the team scores how frequently these failures could occur, how easily a failure could be detected before causing harm, and the level of patient harm likely to result from a failure (Table 1). A Risk Priority Number (RPN) is then calculated for each failure mode and used to set priorities. FMEA can be performed while designing a new process or improving an existing process.

To perform an FMEA:

1. Gather a team including stakeholders in many different roles to fully understand all the steps in the current or proposed process.
2. Map the process with the team.
3. Begin completing a FEMA table like that in Table 2.
    a. List the process steps.
    b. Brainstorm ways each process step could fail, asking, "What could go wrong (Failure Mode), why would it go wrong (Cause of Failure), and how would it affect the patient (Effect of Failure)?" Steps may have more than one Failure Mode or Cause of Failure.
    c. Generate active discussion as the team scores, on a scale from 1-10 (higher is less desirable), how likely each failure is to occur (Occurrence), how likely the failure can be detected before it affects the patient (Detectability), and the degree of harm if the failure reaches the patient (Severity). These values will be somewhat subjective.
4. Calculate the RPN for each potential cause of failure by multiplying the Occurrence, Detection, and Severity scores.
5. Prioritize improvement work to focus on the higher RPNs. Review the individual scores that led to the higher RPN to focus your efforts further. The most impactful improvements are commonly stronger interventions that reduce the Occurrence or Detectability scores. Often, Severity cannot be adjusted. Consider recalculating how the RPN changes if a given intervention is implemented.

Example: A multidisciplinary obstetrical care improvement team learns that, at a nearby hospital, a baby developed HIV after being born to a mother with undetected HIV. They want to reduce the risk of this happening at their hospital. They complete an FMEA form (Table 2). After considering the RPNs, they agree to standardize lab review, risk assessment, and ordering. At the 34-week prenatal visit, the Medical Assistant (MA) now reviews available HIV results, complete a risk assessment tool, and pends an HIV order if needed. A similar process now occurs on Labor and Delivery with the admitting nurse. To measure the effectiveness of these interventions, the team plans to measure the percentage of high risk patients whose medical record includes both a 3rd trimester risk screen and a 3rd trimester HIV result.

Table 1: Suggested Scales for Scoring

Occurrence How likely is the failure to occur?	**Detectability** How likely will the failure be detected?	**Severity** What is the degree of harm if the failure reaches the patient?		**Score**
Very frequently	Never	Death or permanent life-changing outcome	Ex: Loss of limb or organ function	9-10
Frequently	Rarely	Permanent impact on activities of daily living or ability to work/Reversable life-threatening harm	Ex: Permanent nerve damage, delayed lab follow-up requiring ICU admission	7-8
Occasionally	Sometimes	Permanent condition with little effect on overall functioning/Reversable harm that requires a higher level of care or additional monitoring	Ex: permanent numbness from surgical positioning with normal function, delayed infection diagnosis that now requires admission.	5-6
Rarely	Often	Minimal temporary harm	Ex: Insertion of expired IUD that is quickly replaced.	3-4
Very rarely	Always	No harm	Ex: Infant receives adult vitamin K dose: no sequelae.	1-2

Table 2: Completed FMEA Form

Process Step	**Failure Mode**	**Cause of Failure**	**Effect of failure**	**Occur-rence**	**Detect-ability**	**Severity**	**Risk Priority Number**	**Potential Actions to Reduce RPN**
Screen high-risk patients in 3rd trimester.	High-risk status not identified	Risk assessment not performed	Potential perinatal HIV transmission. Patient also untreated.	5	5	7	175	At 34-week visit, Medical assistant (MA) completes screening, pends the order if needed, and forwards to provider.
		No 3rd trimester visits attended	Same	4	3	7	84	Admitting labor nurse checks labs, performs risk screen, and pends HIV tests as needed.
	Lab not drawn	Lab not ordered	Same	2	3	7	42	MA pends HIV order for positive screen.
		Patient skipped lab	Same	3	3	7	63	MA draws lab in clinic room.

Additional Resources

1. Institute for Healthcare Improvement. Failure Modes and Effects Analysis (FEMA) Tool. https://www.ihi.org/library/tools/failure-modes-and-effects-analysis-fmea-tool. Accessed 2.22.2026.
2. ASQ. Learn about quality. FMEA. https://asq.org/quality-resources/fmea. Accessed 3.22.2026