FMEA: A 5-STEP GUIDE TO PROACTIVE RISK ASSESSMENT

What is FMEA?

A proactive, team-based method for identifying and preventing potential failures in a process *before* they result in harm. FMEA helps you prioritize risks so you can focus your improvement efforts where they will have the greatest impact.

The 5 Steps of FMEA

1. **Map Your Process:** Visually map out every step of the clinical workflow you are analyzing.
2. **Brainstorm & Analyze Failures:** For each step, brainstorm potential Failure Modes (what could go wrong?), the Effects (consequences of the failure), and the Causes.
3. **Score Each Failure Mode:** On a scale of 1-10, assign a score for:
   - **Severity (S):** How severe is the effect on the patient?
   - **Occurrence (O):** How frequently is the failure likely to occur?
   - **Detection (D):** How easily can the failure be detected before it causes harm?
4. **Calculate the Risk Priority Number (RPN):** Multiply the three scores to quantify the risk. RPN = Severity x Occurrence x Detection
5. **Prioritize and Act:** Rank the failure modes by their RPN. Address the highest-scoring items first by developing action plans to reduce their severity, lower their occurrence, or improve their detection.

Clinical Examples

Using the RPN formula: **Severity** × **Occurrence** × **Detection** = **RPN**

Failure Mode 1 — Medication Labels Look Similar		
Factor	**Rationale**	**Score**
Severity	Two drugs with near-identical labels could cause a patient to receive the wrong medication — potential for serious harm or death	**10**
Occurrence	Similar-looking labels are encountered several times a week on a busy ward	**8**
Detection	No reliable automated check; relies on nurse double-verification, which is inconsistently applied	**7**
RPN	10 × 8 × 7	**= 560**

Failure Mode 2 — Infusion Pump Battery Dies Mid-Infusion		
Factor	**Rationale**	**Score**
Severity	Interrupts drug delivery; clinician is alerted and can intervene quickly — significant but rarely life-threatening	**7**
Occurrence	Preventive maintenance is in place; occurs roughly once a month	**4**
Detection	Pump emits an audible alarm before full shutdown, and a low-battery warning appears on screen	**2**
RPN	7 × 4 × 2	**= 56**

What the RPN Scores Tell the Team

The label-confusion failure scores **ten times higher** (560 vs. 56), so it rises to the top of the action list first. The high severity and occurrence mean even modest detection improvements won't be enough on their own — the team should pursue a design-level fix, such as requiring pharmacy to use color-coded, clearly differentiated labels or implementing a barcode scan at the bedside before administration.

The battery failure, while worth monitoring, is largely self-announcing thanks to the pump's alarm, keeping its Detection score low (which is *good* — a low detection score means the problem is *easier* to catch). Standard preventive maintenance is likely sufficient for now.

Key Takeaway

RPN lets the team compare apples to oranges — a labeling hazard vs. an equipment failure — on a single numerical scale, making prioritization explicit and defensible rather than a matter of gut feeling.

Helpful Tips

- FMEA is a team sport! Involve people from all roles who touch the process.
- Don't get stuck perfecting the scores. Their main purpose is to help you prioritize.
- After implementing changes, re-score the RPN to measure your improvement.

Scoring Cheat Sheet

Score	Severity (S)	Occurrence (O)	Detection (D)
1-2	Minor / No effect	Extremely unlikely / Rare	Almost certain to be detected
3-4	Low severity	Low likelihood	High chance of detection
5-6	Moderate severity	Moderate likelihood	Moderate chance of detection
7-8	High severity	High likelihood	Low chance of detection
9-10	Catastrophic effect	Extremely likely / Inevitable	Almost impossible to detect