

## FMEA

### Failure Modes and Effects Analysis (FMEA)

FMEA is a pro-active improvement tool that provides a systematic method of evaluating a process by:

- Identifying where and how it might fail.
- Assessing the relative impact of different failures.
- Identifying the parts of the process most in need of improvement.

Initially developed by the military and industry, FMEA is now used in a variety of industries, including healthcare, to assess risk of failure and harm in processes and to identify the most important areas to focus on improvements.

### Getting Started

Create your own FMEA by convening a multidisciplinary team to consider the following for each step of your chosen process:

- Failure modes - What could go wrong?
- Failure causes - Why would the failure happen?
- Failure effects - What would be the consequences of failure?

It is important to have representation of the multidisciplinary team when undertaking your FMEA. Each discipline will have important views and experience on part of the process. Mapping the process is useful as a starting point.

For each failure mode, assign a numeric value for:

- 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.

### Prioritising your Improvement Effort

Calculate a Risk Profile Number (RPN) for each failure mode:

- Likelihood of Occurrence × Likelihood of Detection × Severity
- Prioritise your improvement effort on failure modes with the highest RPNs, remember your aim is to reduce your RPN
- Consider individual RPN components:
  - Reduce severity first:

- pay special attention to 9 and 10s regardless of total RPN
- then occurrence – has greatest overall benefit
- then detection – be sure to test effectiveness

### Severity

If the failure is likely to cause severe harm:

- Identify early warning signs that a failure mode has occurred, and train staff to recognise them for early intervention.
- Provide information and resources (e.g. reversal agents) at points of care for events that may require immediate action.

### Occurrence

A key component of improving safety is to minimise the opportunity for error. If the failure mode is likely to occur:

- Can any causes be eliminated?
- Is the process standardised?
- Can a forcing function be added?
- Add a verification step (e.g., bar coding on medications).
- Modify other processes that contribute to causes.

### Detection

If the failure is unlikely to be detected:

- Can previous events serve as “flags” to indicate likely occurrence?
- Add an intervention step earlier in the process (e.g., add pharmacy rounds to remove discontinued medications within 1 hour).
- Consider device alerts when values are approaching unsafe limits.

### Review your process

Periodically (a few times a year) revisit your process:

- Update your FMEA based on changes you have made.
- Track your RPN over time to see improvement.
- Develop balancing measures to ensure that a change in one part of the system does not negatively impact another part of the system.

For further guidance on using FMEA, and for examples, please visit the SPSP extranet.