Failure Modes and Effects Analysis (FMEA)

Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. FMEA includes review of the following:

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences of each failure?)

Teams use FMEA to evaluate processes for possible failures and to prevent them by correcting the processes proactively rather than reacting to adverse events after failures have occurred. This emphasis on prevention may reduce risk of harm to both patients and staff. FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.

NOTE: Use the interactive Failure Modes and Effects Analysis Tool on IHI.org (http://www.IHI.org/ihi/workspace/tools/fmea/) to create your FMEA, automatically calculate the risk priority number (RPN) of your process, evaluate the impact of process changes you are considering, and track your improvement over time.

This tool contains:

Background

Failure Modes and Effects Analysis (FMEA) was developed outside of health care and is now being used in health care to assess risk of failure and harm in processes and to identify the most important areas for process improvements. FMEA has been used by hundreds of hospitals in a variety of Institute for Healthcare Improvement programs, including Idealized Design of Medication Systems (IDMS), Patient Safety Collaboratives, and Patient Safety Summits.

General Instructions

Step One: Select a process to evaluate with FMEA

Evaluation using FMEA works best on processes that do not have too many subprocesses Instead of doing an FMEA on a large and complex process, such as medication management in a hospital, try doing an FMEA on subprocesses or variants. Conducting an FMEA of the entire medication management process would be an overwhelming task. Instead, consider individual FMEA analyses of the medication ordering, dispensing, and administration processes.

Step Two: Recruit a multidisciplinary team

Be sure to include *everyone* who is involved at any point in the process. Some people may not need to be part of the team throughout the entire analysis, but they should certainly be included in discussions of those steps in the process in which they are involved. For example, a hospital may utilize couriers to transport medications from the pharmacy to nursing units. It would be important to include the couriers in the FMEA analysis of the steps that occur during the transport itself, which may not be known to personnel in the pharmacy or on the nursing unit.

NOTE: You can use the interactive FMEA Tool on QualityHeatlhCare.org to complete all of the following steps. [http://www.IHI.org/ihi/workspace/tools/fmea/]

Step Three: Have the team meet together to list all of the steps in the process

Number every step of the process, and be as specific as possible. It may take several meetings for the team to complete this part of the FMEA, depending on the number of steps and the complexity of the process. Flowcharting can be a helpful tool for outlining the steps. When you are finished, be sure to obtain consensus from the group. The team should agree that the steps enumerated in the FMEA accurately describe the process.

Step Four: Have the team list failure modes and causes

For each step in the process, list all possible "failure modes"—that is, anything that could go wrong, including minor and rare problems. Then, for each failure mode listed, identify all possible causes.

Step Five: For each failure mode, have the team assign a numeric value (known as the Risk Priority Number, or RPN) for likelihood of occurrence, likelihood of detection, and severity

Assigning RPNs helps the team prioritize areas to focus on and can also help in assessing opportunities for improvement. For every failure mode identified, the team should answer the following questions and assign the appropriate score (the team should do this as a group and have consensus on all values assigned):

- *Likelihood of occurrence: How likely is it that this failure mode will occur?*

  Assign a score between 1 and 10, with 1 meaning "very unlikely to occur" and 10 meaning "very likely to occur."

- *Likelihood of detection: If this failure mode occurs, how likely is it that the failure will be detected?*

  Assign a score between 1 and 10, with 1 meaning "very likely to be detected" and 10 meaning "very unlikely to be detected."

- *Severity: If this failure mode occurs, how likely is it that harm will occur?*

  Assign a score between 1 and 10, with 1 meaning "very unlikely that harm will occur" and 10 meaning "very likely that severe harm will occur." In patient care examples, a score of 10 for harm often denotes death.

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								

Step Six: Evaluate the results

To calculate the Risk Priority Number (RPN) for each failure mode, multiply the three scores obtained (the 1to 10 score for each of likelihood of occurrence, detection, and severity). For example, the failure mode "Wrong medication selected" has a 3 for likelihood of occurrence, a 5 for likelihood of detection, and a 5 for severity, for an overall RPN of 75. The lowest possible

score will be 1 and the highest 1,000. Identify the failure modes with the top 10 highest RPNs. These are the ones the team should consider first as improvement opportunities.

To calculate the RPN for the entire process, simply add up all of the individual RPNs for each failure mode.

Step Seven: Use RPNs to plan improvement efforts

Failure modes with high RPNs are probably the most important parts of the process on which to focus improvement efforts. Failure modes with very low RPNs are not likely to affect the overall process very much, even if eliminated completely, and they should therefore be at the bottom of the list of priorities.

- **Use FMEA to plan actions to reduce harm from failure modes:**
  - If the failure mode is likely to occur:
    - Evaluate the causes and see if any or all of them can be eliminated.
    - Consider adding a forcing function (that is, a physical constraint that makes committing an error impossible, such as medical gas outlets that are designed to accept only those gauges that match)
    - Add a verification step, such as independent double-checks, bar coding on medications, or alert screens.
    - Modify other processes that contribute to causes.
  - If the failure is unlikely to be detected:
    - Identify other events that may occur prior to the failure mode and can serve as "flags" that the failure mode might happen.
    - Add a step to the process that intervenes at the earlier event to prevent the failure mode. For example, add pharmacy rounds to remove discontinued medications from patient care units within 1 hour of discontinuation, to decrease the risk that the medications will still be available for use (the failure mode).
    - Consider technological alerts such as devices with alarms to alert users when values are approaching unsafe limits.
  - If the failure is likely to cause severe harm:
    - Identify early warning signs that a failure mode has occurred, and train staff to recognize them for early intervention. For example, use drills to train staff by simulating events that lead up to failure, to improve staff ability to recognize these early warnings.
    - Provide information and resources, such as a reversal agents or antidotes, at points of care for events that may require immediate action.

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- **Use FMEA to evaluate the potential impact of changes under consideration.**

  Teams can use FMEA to discuss and analyze each change under consideration and calculate the change in RPN if the change were implemented. This allows the team to "verbally simulate" the change and evaluate its impact in a safe environment, prior to testing it in a patient care area. Some ideas that seem like great improvements can turn out to be changes that would actually increase the estimated RPN.

- **Use FMEA to monitor and track improvement over time.**

  Teams should consider calculating a total RPN for the process as described above and then set a goal for improvement. For example, a team may set a goal of decreasing the total RPN for the medication ordering process by 50% from the baseline.

Failure Modes and Effects Analysis

Steps in the Process	Failure Mode	Failure Causes	Failure Effects	Likelihood of Occurrence (1–10)	Likelihood of Detection (1–10)	Severity (1–10)	Risk Priority 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