Institute for Healthcare Improvement

QI Essentials Toolkit:

Failure Modes and Effects Analysis (FMEA)

Failure Modes and Effects Analysis (FMEA) is a tool for conducting a systematic, proactive analysis of a process in which harm may occur. In an FMEA, a team representing all areas of the process under review convenes to predict and record where, how, and to what extent the system might fail. Then, team members with appropriate expertise work together to devise improvements to prevent those failures — especially failures that are likely to occur or would cause severe harm to patients or staff.

The FMEA tool prompts teams to review, evaluate, and record 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.

IHI's QI Essentials Toolkit includes the tools and templates you need to launch and manage a successful improvement project. Each of the nine tools in the toolkit includes a short description, instructions, an example, and a blank template. NOTE: Before filling out the template, first save the file on your computer. Then open and use that version of the tool. Otherwise, your changes will not be saved.

- Cause and Effect Diagram
- Driver Diagram
- **Failure Modes and Effects Analysis (FMEA)**
- Flowchart
- Histogram
- Pareto Chart
- PDSA Worksheet
- Project Planning Form
- Run Chart & Control Chart
- Scatter Diagram

Instructions

1) Select a process to evaluate with FMEA.

Evaluation using FMEA works best on processes that do not have too many sub-processes.

If you're hoping to evaluate a large and complex process, such as medication management in a hospital, divide it up. For example, do separate FMEAs on medication ordering, dispensing, and administration processes.

2) 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 of the steps that occur during the transport itself, which may not be known to personnel in the pharmacy or on the nursing unit.

3) Have the team list all of the steps in the process.

Working with a team that represents every point in the process you're evaluating, establish a mutually agreed upon, ordered list of all the steps in the process.

- Tip: Flowcharting can be a helpful tool for visualizing a process. Learn more at http://www.ihi.org/resources/Pages/Tools/Flowchart.aspx.

Draw a nine-column table as shown below.

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) Fill out the table with your team.

In the left-most column, input the numbered list of the steps in the process. Then, working with the members of the team who are involved in specific steps, fill out the remaining columns as follows:

- **Failure Mode** [*What could go wrong?*]: List anything that could go wrong during that step in the process.
- **Failure Causes** [*Why would the failure happen?*]: List all possible causes for each of the failure modes you've identified.
- **Failure Effects** [*What would be the consequences of the failure?*]: List all possible adverse consequences for each of the failure modes identified.
- **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?*
- **Likelihood of Detection** (1-10): *On a scale of 1-10, with 10 being the most likely NOT to be detected, what is the likelihood the failure will NOT be detected if it does occur?*
- **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 does occur, will cause severe harm?*
- **Risk Profile Number** (RPN): For each failure mode, multiply together the three scores the team identified (i.e., *likelihood of occurrence x likelihood of detection x severity*). The lowest possible score will be 1 and the highest 1,000. To calculate the RPN for the entire process, simply add up all of the individual RPNs for each failure mode.
- **Actions to Reduce Occurrence of Failure**: List possible actions to improve safety systems, especially for failure modes with the highest RPNs.
    a) Tip: Teams can use FMEA to analyze each action under consideration. Calculate how the RPN would change if you introduced different changes to the system.

5) 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 low RPNs are not likely to affect the overall process much, even if eliminated completely, and they should therefore be at the bottom of the list of priorities.

Identify the failure modes with the top 10 highest RPNs. These are the ones the team should consider first as improvement opportunities.

- **Use FMEA to plan actions to reduce harm from failure modes.**
    a) 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.

b) 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.

c) 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 reversal agents or antidotes, at points of care for events that may require immediate action.

- **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.

Example: Failure Modes and Effects Analysis (FMEA) – Medication Dispensing Process

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
Orders are written for new medications.	The first dose may be given prior to pharmacist review of the orders.	Medication ordered may be available and easily accessed in the dispensing machine.	Patient may receive incorrect medication, incorrect dose, or a dose via incorrect route.	6	5	1	30	Assign clinical pharmacists to patient care units so that all medication orders can be reviewed as they occur.
Orders are written to discontinue a medication or change the existing order.	Orders are written to discontinue a medication or change the existing order.	All doses needed for a 24-hour period are delivered to the drawer. Drawer is not changed until next routine delivery. 24-hour supply of refrigerated medications is delivered. Multi-dose vials may be kept in the patient-specific drawer. Medications are available in dispensing machine.	Patients may receive medications that have been discontinued or the incorrect dose of a medication that has been changed.	10	5	5	250	Schedule pick-ups of discontinued medications, including refrigerated medications, twice per day. Use dispensing machine screen to verify all information regarding current and discontinued medications prior to each administration.
Orders are written for a non-standard dose of a medication.	Nursing staff may prepare an incorrect dose when manipulating the medication.	Staff prepare the dose using medications from the dispensing machine and manipulate them to get the dose ordered.	Patient may receive an incorrect dose.	3	5	4	60	Prepare all non-standard doses in the pharmacy and dispense each as a patient-specific unit dose.

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
Pharmacy staff fill dispensing and storing devices with medications.	Errors may occur during filling and medications may be placed in incorrect bins.	Many medications are placed in the dispensing machine at one time. Multiple medications and doses are placed in patient-specific drawers.	Patient may receive a medication that has not been prescribed.	3	5	5	75	Use bar code scanning for all medications to verify information prior to administration. Involve patients and families in verification before each administration.
Medications requiring refrigeration and intravenous solutions are stored separately.	The wrong medication may be selected.	Medications are stored together and may not be in patient-specific bins, so it is easy to select the wrong one.	Patient may receive an incorrect medication, incorrect dose, or via incorrect route.	3	5	5	75	Use bar code scanning for all medications to verify information prior to administration. Involve patients and families in verification before each administration.
Medications packaged in multi-dose vials are available.	The incorrect dose may be drawn from the vial.	Staff must draw each dose prior to administration without a double-check.	Patient may receive an incorrect medication, incorrect dose, or via incorrect route.	4	5	7	140	Prepare each dose in pharmacy and dispense each as a single-unit dose. Remove multi-dose vials from dispensing machines.

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
Nursing staff access medications for administration from storage device.	Nursing staff may bypass proper procedure to access medications.	Nursing bypass of procedure may depend on proximity of machines to patient rooms, as nurses may want to decrease time traveling back and forth.	Patient may receive an incorrect medication, incorrect dose, or via incorrect route.	7	5	8	280	Use bar code scanning for all medications to verify information prior to administration. Involve patients and families in verification before each administration.
Staff access narcotics for administration.	Staff with substance abuse problems may be diverting narcotics.	System for access may allow incorrect information to be entered (e.g., staff may be able to enter names of other staff).	Clinical staff may be working in an impaired state.	5	5	10	250	Use individually assigned identification cards that must be swiped through a card reader or use thumbprint readers to access narcotics.

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Template: Failure Modes and Effects Analysis (FMEA)

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