Guidance for Performing Failure Mode and Effects Analysis with Performance Improvement Projects

Overview: **Failure Mode and Effects Analysis** (FMEA) is a structured way to identify and address potential problems, or failures and their resulting effects on the system or process before an adverse event occurs. In comparison, root cause analysis (RCA) is a structured way to address problems after they occur. FMEA involves identifying and eliminating process failures for the purpose of preventing an undesirable event.

When to use FMEA: FMEA is effective in evaluating both new and existing processes and systems. For new processes, it identifies potential bottlenecks or unintended consequences prior to implementation. It is also helpful for evaluating an existing system or process to understand how proposed changes will impact the system. Once you have identified what changes need to be made to the process or system, the steps you follow are those you would use in any type of PIP.

Directions: Use this guide to walk through FMEA. FMEA is a tool that will allow nursing homes to proactively identify and reduce potential failures within an existing or a proposed process. FMEA is very similar to what most people do every day. We try to anticipate what might go wrong and do what we can to prevent this from happening or minimize the effects. For instance, before leaving your home for work, you listen to the radio or television to find out where there may be traffic jams or delays in public transportation. By knowing if there are problems on the road, you can make changes to your driving route or mode of transportation to ensure you get to work on time. By knowing what might go wrong, you can make changes that reduce or prevent something from going wrong.

Facilities accredited by the Joint Commission or in states with regulations governing completion of FMEAs should refer to those requirements to be sure all necessary steps are followed.

Below is a quick overview of the steps of FMEA.

Steps	**Explanation**
1. Select a process to analyze	Choose a process that is known to be problematic in your facility or one that is known to be problematic in many facilities.
2. Charter and select team facilitator and team members	Leadership should provide a project charter to launch the team. The facilitator is appointed by leadership. Team members are people who are directly involved in the process to be analyzed.
3. Describe the process	Clearly define the process steps so that everyone on the team knows what is being analyzed.
4. Identify what could go wrong during each step of the process	Here is where the people directly involved in the process describe the problems that can or do occur.
5. Pick which problems to work on eliminating	The focus of improvements will be on those problems that happen quite often and/or or have a significant impact on resident safety when they do occasionally occur.
6. Design and implement changes to reduce or prevent problems	The team determines how best to change the process to reduce the risk of residents being harmed.
7. Measure the success of process changes	Like all improvement projects, the success of improvement actions is evaluated.

Step 1: Select a process to analyze

Nursing homes are complex organizations and involve processes in many areas, such as resident care, business operations, environmental services, and others. You can use FMEA to examine processes in any of these areas to proactively reduce risks to patient safety and improve quality of care and quality of life for residents.

When conducting FMEA on an existing process, consider selecting a process that is known to be problem-prone or potentially risky. For instance, do staff members consistently perform skin assessments promptly after admission? FMEA can be used to identify gaps and develop actions to make the process more efficient and safe. FMEA also helps to prepare for implementation of new processes. Are you concerned about how you will implement electronic health records? FMEA promotes systematic thinking in terms of "What challenges will we encounter? What can we do to meet these challenges?

Ask your employees what activities or processes have not yet provided the desired result. They may tell you there is a safety concern related to monitoring cognitively impaired individuals who like to wander. You can do FMEA on your process for regularly assessing these residents and protecting those found to be vulnerable for injury or elopement.

- ✓ **Helpful Tips:**
  - Be sure an identifiable process is chosen for FMEA. Instead of, "We will do FMEA on the problem of unexplained weight loss among some residents," consider doing FMEA on the process used in your facility to prevent residents from having an unexplained weight loss. Unexplained weight loss is an outcome, not a process. A process is a series of actions or steps taken to achieve an end.
  - Narrow the scope of FMEA as much as possible. For instance, when facilities try to do a project on a complex process such as medication administration the team often finds there are too many variables to take into account. The administration process can vary by unit, by type of medication, by time of day, and so on. It is best to narrow the focus. For instance, do FMEA on administration of a particular type of high-risk medication or a project on medication administration for a category of residents vulnerable to safety problems.
  - To get employees to support FMEA and make necessary process changes, senior management should consult staff members about processes they believe are challenging.
  - Consider using FMEA to evaluate new processes. It is a good technique for anticipating what could happen so processes can be made safer before full implementation.

Step 2: Select people for the team

Once it is decided that a Performance Improvement Project (PIP) will be conducted on a process using FMEA, leadership should begin by designating a facilitator for this team. Together they should create a charter that will help guide the team in managing the scope of the project and ensure the implemented changes reflect the FMEA findings. They should also work together in selecting staff to participate on the PIP team.

The facilitator is often someone already involved in QAPI in the facility. As managers, supervisors, and staff members gain experience in doing FMEA, more people in the facility can be trained to serve as FMEA facilitators.

The direct care staff selected to serve as team members should have day-to-day responsibilities for completing one or more steps in the process under analysis. A personal knowledge of what actually happens, not what should happen, is vital to the project success.

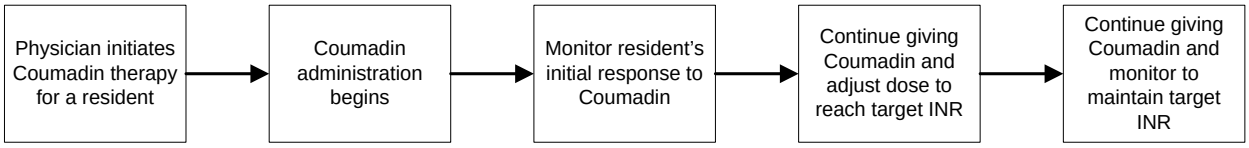
The number of people on a team depends on the scope of the process review. There should be at least one representative from each employee group involved in the process. For instance, if the project is aimed at the process of assessing residents for fall risk and protecting those found to be high risk, the team should include representatives from nursing (RN or LPN), direct care staff (nurse assistant or CNA), housekeeping, and physical therapy. Consider physician involvement when the process includes steps that involve physicians.

- ✓ **Helpful Tips:**
  - Minimize the number of management or supervisory level individuals on the team. Staff members may be inhibited from speaking up during critical discussions about process problems if their direct supervisor is in the room.
  - Involve direct care staff and those who have direct experience with the process being analyzed. It is important to understand the process as it is actually performed, including why staff make mistakes and develop work-a-rounds.
  - Include people from all shifts on the team, when possible. The experiences of staff working during the day may be much different than what happens during the evening and night shift. A successful FMEA is highly dependent on the ability of the team members to understand how a process now functions and what occasionally goes wrong.
  - It can sometimes be tempting to complete FMEA by interviewing those involved in the process, without any formal meetings of the team. While this might move the analyses along quicker, the frank discussions that occur during team meetings are more likely to lead to a successful FMEA – one that actually improves the safety of a high-risk resident care process.

Step 3: Describe the process

At the first meeting, the team clearly defines the process to be analyzed. The best way to do this is to construct a flowchart of the steps. (See the QAPI Flowchart Guide for more information on creating flowcharts) Using sticky notes, write down the first step in the process and each subsequent step. The process description does not need to be detailed. A high-level flowchart, with just the major steps identified, is usually sufficient.

The example below shows the steps in the process of starting Coumadin for residents not currently on this anticoagulant. The process starts with the physician ordering Coumadin for a resident and ends with ongoing monitoring of the patient's INR (a measure of blood coagulation) and clinical status.



Starting with a clear description of the process ensures that everyone on the team understands what is being analyzed. Once the team members agree that the process is clearly and accurately described, move to step 4.

If there is confusion about the actual process steps or if people cannot agree on what the process entails, do not continue on to step 4 of the FMEA. It may be necessary to refine the scope of the FMEA. For instance, one nursing home started FMEA on the process of admitting new residents. While describing the process, team members found that admission steps varied somewhat on the weekends. They chose to concentrate their analysis on the weekend admission process because it seemed to be the most problem-prone. They agreed to later do FMEA on weekday admissions.

- ✓ **Helpful Tips:**
  - If team members cannot agree on how the process currently works in their area and the process scope cannot be narrowed to obtain agreement, it usually is a signal of a very unreliable process. An unreliable process is one that is not performed consistently – people pretty much do whatever works best for them. FMEA should not be done on this process; instead, do a performance improvement project that is aimed at creating a redesigned standard streamlined process. Once that new process is designed, consider doing FMEA to reduce or eliminate mistakes that may occasionally occur.
  - For a complex process with many steps, it may be better to do several FMEAs by breaking-up the process into manageable bites. By focusing on just one part of the process, the team can complete the FMEA in much shorter time. For instance, there are several major steps to the process of identifying residents at high risk for falls and preventing falls in this group of residents. The team could do FMEA just on the assessment phase of the process and another on the prevention phase.

Step 4: Identify what could go wrong during each step of the process

Here is where the knowledge and experience of team members are vital. For each process step identified in step 3, the team determines what can go wrong or what can fail (commonly called the failure modes). The people doing the work every day are in the best position to know what can (and does) go wrong.

This step is similar to a brainstorming session where people generate ideas and come up with solutions to problems. At this point, team members are generating a list of the failures that can occur at each step of the process being analyzed. Below are examples of things that could go wrong during the step of "Physician initiates Coumadin therapy for a resident."

Physician initiates Coumadin therapy for a resident

What Could Go Wrong (failure modes)
1. Order not entered into computer
2. Order not communicated to Pharmacy
3. Wrong dosage ordered
4. Physician unaware Coumadin is contraindicated for this resident

After the possible failures are identified for one step, the team moves on to identifying failures that might occur in the next step. Step 4 is complete when the team is satisfied all possible failures have been identified for each step.

- ✓ **Helpful Tips:**
  - Create an atmosphere where staff participating in the FMEA feel safe talking about process mistakes, or work-arounds that occur. To decrease "protectionism" where staff are reluctant to talk about mistakes made by the peer group they represent, make it clear from the beginning that everyone sometimes makes a mistake and it is not a sign of incompetence; rather most mistakes are the result of a poorly designed process.
  - Do not let this brainstorming session become a finger-pointing exercise. Keep the team members focused on the goal of the FMEA – that is to identify and then reduce or eliminate failures by improving the process.
  - Write the failures on sticky-notes (one per note) and line them up beneath the sticky notes you created for the process steps. When the team members are done identifying failures for each step, they will have a clear visual picture of the entire process and the failures that could occur at each step.
  - Sometimes it is helpful to get additional staff input into this step. Ask team members to gather more ideas as to what can go wrong by sharing the team's preliminary findings with others in their employee group. Bring these ideas back to the next team meeting for discussion and possible addition to the failure lists.

Step 5: Pick which problems to work on eliminating

It is common for project teams to identify several different mistakes that might occur at each step in the process under study. However, changing the process to reduce or eliminate every one of these mistakes is time-consuming, may not be feasible, and often not necessary. Some mistakes rarely happen, some are so obvious that the mistake is easily caught and corrected, and some have little impact on resident safety. In step 5 of the FMEA, the team selects which failures will be the focus of improvement actions.

Selection of the failures to work on eliminating is based primarily on two factors: how likely the failure will actually occur and how the failure will affect the resident should it occur. For each failure, the team decides:

- What could happen should this failure occur? (outcome)
- How serious would the outcome be? (severity)
- How often is this failure likely to occur? (probability)

Determine outcomes

Starting with the first step in the process, the team considers each failure that was identified in step 4 – answering the question, "What would happen if this failure occurs?" Sometimes what would happen is that the resident will experience some type of adverse outcome. Sometimes what would happen is that needed treatment or therapy would be delayed. For example, "What would happen if the physician's order for Coumadin is not entered into the computer?" Team members may agree that this computer entry failure will be caught fairly quickly and corrected, so the resident most likely will not be harmed. In this situation, the outcome for this failure would be a delay in administration of Coumadin.

The team methodically goes through each failure identified during step 4 and determines what would happen if this failure occurs.

Determine seriousness of the outcomes

This decision can be made by the team while they are identifying the outcomes or the seriousness can be determined after all outcomes have been determined. For each outcome, the team must decide how "bad" the particular outcome would be for the resident. This is a subjective judgment made by team members based on their knowledge and experience.

Sometimes facilities use a numeric rating scale to establish the seriousness of the outcome. Below is the rating scale that could be used in nursing homes. The severity rating scale is adapted from the Healthcare Failure Mode and Effects Analysis (HFMEA) model developed by the National Center for Patient Safety of the Veterans Health Administration.

Outcome severity rating scale

Rating	Outcome Category	Description
5	Catastrophic	Resident experiences death or major permanent loss of function (sensory, motor, physiologic, or intellectual),
4	Major	Resident experiences permanent lessening of bodily function (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, or increased level of care for 3 or more days.
3	Moderate	Resident experiences an event, occurrence, or situation which could harm the resident but will not cause permanent injury or lessening of bodily function or require the delivery of additional healthcare services
2	Minor	Resident may experience a minor injury, but most likely would not be affected by the failure and it would not cause any changes in the delivery of care.
1	Near miss	Resident would not experience any injury, changes in delivery of care, or an increased level of care.

Numeric severity rankings are not required to be used in a FMEA. It can be just as effective (and perhaps less intimidating) to have the team rate outcomes using descriptive terms such as:

- Low (minimal resident harm)
- Moderate (short-term resident harm)
- Severe (permanent or long-term harm)
- Fatal (death)

Using a decision-making process such as nominal group technique or multi-voting, the team methodically agrees to a severity ranking for each outcome.

Determine Probability

The team now judges how often each failure is likely to occur.

Rating scales can help to standardize the team members' responses. Below is the probability rating scale adapted from the Healthcare Failure Mode and Effects Analysis (HFMEA) model developed by the National Center for Patient Safety of the Veterans Health Administration.

Failure probability rating scale

Rating	Description	Definition
5	Very high probability: failure is most inevitable	1 failure in 5 attempts
4	High: repeated failures	1 failure in 50 attempts
3	Moderate: occasional failures	1 failure in 500 attempts
2	Low: relatively few failures	1 failure in 5000 attempts
1	Remote: failure is unlikely	<1 failures in 500,000 attempts

Prioritize Failures for Improvement Action

The team goes through the process of identifying failure outcomes and outcome severity and determining failure probability so that priorities for action can be established. If at the outset the team concludes it is important to reduce or eliminate all failures, the exercises described above are not necessary as the team has already set its action priorities. It can move onto step 6 of the FMEA.

More likely the team will find some failures inconsequential – although they do happen every once in a while they do not adversely affect residents. The exercises described above can help the team make this decision.

Which failures should be chosen for action? There are no absolute rules for answering this question. Any failure that is likely to result in catastrophic or major harm to a resident is a good first choice for action. Additionally, any failure that occurs quite often and has the potential for harming a resident should be considered for action. After the team has prioritized the failures that will be the focus of improvement actions, the FMEA moves to step 6.

- ✓ **Helpful Tips:**
  - When defining outcomes that will occur following a failure, choose the most likely outcome not the worst case scenario. Do not forget that outcomes for some failures are delays in treatment or services which may not cause resident harm and may actually go unnoticed by the resident. If the outcome from every failure is classified as catastrophic or major then the team will need to develop improvement actions for every failure.
  - It can sometimes be problematic for team members to judge how often a failure might occur. Sometimes there is a tendency to seek the "right" answer when, without any prevalence data, a correct answer is not possible. In the absence of data, ask the team members to estimate based on their experience and a sense of what happens in the facility. For instance, despite facility policies requiring confirmation of resident identity prior to giving medications, nurses admit that in practice, for a variety of reasons, they fail on occasion to do this safety check. Ask the nurses on the team to estimate how often they think this failure occurs. A more accurate estimate of failure probability might be obtained if management level personnel are not in the room.
  - Setting priorities for improvement is challenging. The team leader and members should openly acknowledge and work to address barriers that can impact the priority-setting process. Watch out for:

- Fears of “winners and losers.” If a team member worries that a change in their area could adversely affect them, they may try to guard their own “turf” by strongly advocating that failures in other areas must be dealt with first.
- Thinking the team can “do it all” and there is no need to prioritize. If people feel uncomfortable admitting that they cannot improve all areas at once, they will resist setting priorities.
- Without a clear leadership commitment to improving resident safety, team members may fear that the group’s priorities will be overturned or go nowhere.

Step 6: Design and implement changes to reduce or prevent problems

In this step the team evaluates each failure chosen for action for the purpose of designing and implementing process changes to reduce or prevent the failure from occurring. This step is similar to the action planning phase in any type of improvement project.

To determine how the process should be changed the root cause of each failure chosen for action must be identified. The team may need to gather additional input from other staff members to help in determining the root causes of failures. For instance, why does a physician order for Coumadin not get entered into the computer? Why is the order not communicated to the pharmacy when it does get entered into the computer? The Five Whys technique is a good way to drill-down to find the root cause of failures. The answer to the first "why" prompts another "why" and the answer to the second "why" prompts another and so on; hence the name the Five Whys.

Once the cause of each failure is clear, the team develops actions to reduce or eliminate the failure. When developing these actions consider questions such as:

- What safeguards are needed to prevent this failure from happening?
- What would have to go wrong to have a failure like this happen? How can we prevent this from going wrong?
- How could we change the way we do things to make sure that this failure never happens?
- If a failure like this happened, how could we quickly catch and correct the problem before the resident ended up being harmed?
- If the resident were harmed by this failure, how could we minimize the effect of the failure on the resident's condition?

Aim for corrective actions with a stronger or intermediate rating, based on the hierarchy suggested by the examples below. Corrective actions which focus on designing controls into the system that do not allow errors to occur and rely less on any one person’s actions are the strongest. The feasibility and costs associated with actions must also be considered.

Stronger Actions

- Change physical surroundings
- Usability testing of devices before purchasing
- Engineering controls into system (forcing function), which force the user to complete an action
- Simplify process and remove unnecessary steps
- Standardize equipment or process
- Tangible involvement and action by leadership in support of resident safety; i.e., leaders are seen and heard making or supporting the change

Intermediate Actions

- Increase staffing/decrease in workload
- Software enhancements/modifications
- Eliminate/reduce distractions
- Checklist/cognitive aid
- Eliminate look alike and sound alike terms
- "Read back" to assure clear communication
- Enhanced documentation/communication

Weaker Actions

- Double checks
- Warnings and labels
- New procedure/memorandum/policy
- Training/in-service
- Additional study/analysis

For example, suppose Coumadin orders do not get entered into the computer because the person receiving the phone order gets busy and forgets to enter the order. The strongest action to prevent this from happening might be to use a Coumadin standing order protocol so that phone orders for this purpose are eliminated or reduced. Decreasing staff workload might reduce the number of orders that do not get entered, although unexpected situations can arise that divert people's attention even when staffing is sufficient. How about something as simple as writing phone orders on sticky paper that can be adhered to the computer screen? This would cause the order to stay visible until someone has time to enter the order. This is an example of a warning or label (sometimes called a visual cue). It is a weak action because the sticky paper can fall off or be taken off by someone in a hurry to access the computer for another purpose. But if no other strong action is available, a weak action is better than none at all.

When designing actions, clearly state what is to be done, by whom, and when. Satisfactory implementation of the actions will be monitored later, so it is important to have clearly defined action plans.

- ✓ **Helpful Tips:**
  - o Do not design actions to prevent failures until the team has a good understanding of what can cause the failures to occur. "Blindly" changing the process in hopes of preventing failures is likely to be unsuccessful and may actually make the process less safe if the changes increase complexity.
  - o The team facilitator should encourage team members to come up with as many intermediate and strong actions as possible. It is helpful to involve supervisory and management staff in the action planning discussions. Designing intermediate and strong actions often requires an understanding of various resident care systems and the facility's resource allocation priorities. Staff members on the team conducting the FMEA may not possess this knowledge.

Step 7: Measure the success of process changes

Concurrent with implementation of action plans, mechanisms are established to gather data that will be used to measure the success of the corrective action. The goal of a FMEA is to reduce the risk of process failures and improve resident safety. What you will measure is how often the process failures identified as high priority to fix (step 5) are still occurring after process changes (step 6) are completed. Plus you will measure the incidence of adverse events related to the process under study (for example, the number of residents on Coumadin that develop a Coumadin-related complication). Some of this data may be available through incident reporting, MDS resident assessments, state survey results, resident satisfaction surveys, and other established sources of performance data. Occasionally a new data collection effort is needed to gather information needed for the results of the FMEA.

Evaluating success of the PIP usually occurs after all process changes have been implemented and will become the responsibility of the person designated to monitor the corrective action/s. The QAA committee is responsible for overseeing all QAPI activities, which includes reviewing data on the effectiveness of all improvement projects.

Ideally, all of the following criteria should be met to conclude the PIP has been successful:

- Measures of effectiveness were monitored over time.
- The goal was attained (fewer failures, better outcomes).
- You are confident that the change is permanent.

FMEA PIP Template

This template can be used to document the completed FMEA including follow-up actions and measures. Revise this template as necessary to meet your needs. Review the Guidance for Failure Mode and Effects before using this template.

Process analyzed:

_____

Team leader/facilitator: _____

Date FMEA started: _____ Date ended: _____

Team members:

Name	Position	Name	Position

Describe your process steps (flowchart): As per the suggested guidance, you might use sticky notes on separate papers.

Identify what could go wrong during each step of the process. You might use sticky-notes indicating what could go wrong for each step. Line these up beneath each process step.

For each item identified that could go wrong, rate each for the seriousness of this outcome (severity) and how often the mistake is likely to occur (probability) (per the suggested guidance and your rating scale preferences). Indicate these ratings on the sticky notes that identify what could go wrong.

Review your ratings and decide on your process failures identified as high priority for improvement actions. List the process failures you will focus on in the table below.

Describe your corrective actions for process failures identified as high priority: Before determining your corrective actions for process failures, consider whether you should conduct a systematic analysis to determine the root cause of each failure chosen for action. If necessary, use techniques such as the five whys, flowcharting, or the fishbone diagram to assist in identifying the root causes. Additional tools are available that guide the use of each of these techniques. It is helpful to keep any of these analyses with your PIP documentation for future reference. In the table below, describe each root cause for each process failure, and then enter your specific actions to reduce or eliminate the failure, your completion timeframe, and the responsible individual or group.

Process Failure	Root Cause of Process Failure	Specific Actions to Reduce or Eliminate the Failure	Completion Time Frame	Responsible Individual/Group

Measures of Success

Corrective Action	Measure(s) of Success (How we will know if this action is successful) (Consider measures of how often the failure is still occurring after process changes and the incidence of adverse events related to the failure)	Reporting Schedule and Individual or Group Responsible for Reviewing Results

Signature of FMEA leader/facilitator_____ Date

_____

Acknowledgement: This guide draws on information from the *VHA National Patient Safety Improvement Handbook* (March 2011), the *Training Toolkit: Failure Mode & Effects Analysis* (Brown-Spath & Associates, 2006) and the *Minnesota Adverse Health Events Measurement Guide* (Minnesota Department of Health, 2010).