

# TOPICS

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## **FMEA: A Proactive Resident Safety Technique** **Patrice L. Spath, MA, RHIT**

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Caring for nursing home residents has become more complex as the case mix acuity of those being served increases. Maintaining a safe environment for residents can be challenging. Nursing homes must be proactive in preventing adverse events. This article describes how risk assessment methods such as failure mode and effects analysis can be used to eliminate or control resident safety hazards in nursing homes.

A nursing home resident falls and fractures her hip. The incident is investigated and steps are taken to prevent something similar from happening again. A few months later a resident receives the wrong dose of Coumadin and suffers life-threatening complications due to excessive bleeding. The incident is investigated and steps are taken to prevent something similar from happening again. Rather than wait for an accident to happen before deciding what safety improvements are needed, nursing homes must begin to proactively prevent incidents, especially when the potential outcome may be catastrophic for a resident. Although nursing home staff may be skillful and careful there is always the possibility of human error or mechanical failure.

A number of high risk industries such as aviation, aerospace, and nuclear power use proactive risk analysis techniques to reduce the likelihood of failures. Coupled with other high reliability practices, these industries now experience few catastrophic accidents.<sup>1</sup> There is a growing awareness and application of risk analysis techniques in healthcare to improve clinical and

administrative processes. Starting in 2001, The Joint Commission required its accredited facilities to conduct periodic proactive risk assessments of high-risk, problem-prone patient and resident care activities.<sup>2</sup> The 2003 Institute of Medicine (IOM) report, *Patient Safety: A New Standard of Care*, recommended research on application of proactive risk analysis techniques.<sup>3</sup> While the CMS Nursing Home Quality Assurance & Performance Improvement (QAPI) requirements do not call for proactive risk assessments explicitly, initiatives that result in improved resident safety qualify as performance improvement projects – which are required.<sup>4</sup>

### **FMEA Model**

There are a number of different methods for conducting a proactive risk assessment. The most common model used to improve clinical activities in healthcare organizations is failure mode and effects analysis (FMEA). This model involves three phases: identify, analyze, and act. During the *identify* phase, the process being evaluated is defined and people involved in the process identify what can go wrong (the failures). During the *analyze* phase, the likelihood each failure will occur and failure consequences are evaluated. In the *act* phase, process changes that will eliminate failures or reduce the severity of consequences are formulated and implemented. Finally, the success of actions is evaluated. If these phases sound familiar it is because a FMEA project is similar to the Plan-

Do-Study-Act model used for performance improvement projects.<sup>4</sup>

There are several variations of the basic FMEA model used in healthcare, including a version created by the Department of Veterans Affairs.<sup>5</sup> Because FMEA was initially developed for use in other industries many of the models are more complex and rigorous than may be necessary to improve clinical safety in healthcare organizations. For example, FMEA models often involve numeric scoring of the probability and severity of failures to create a risk priority number or criticality score for each one.<sup>2</sup> Failures receiving high scores are prioritized for action – which means process changes are focused on preventing just these failures. While prioritizing the failures most in need of being prevented is important, in healthcare organizations the scoring process may be more subjective than quantitative. A study of the failure scoring mechanisms during FMEA projects involving medication administration found “considerable variability in individual team members’ opinions on scores.”<sup>6</sup> The FMEA process described in the next section uses less exacting prioritization methods such as structured brainstorming and multi-voting to identify failures most in need of prevention. Some nursing homes may choose to use numeric failure scoring systems in the analyze phase.

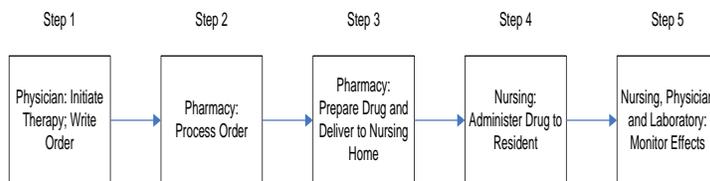
### Identify Phase

Like all improvement projects, a FMEA project is initiated because of the desire to improve performance. The goal of a FMEA project is to prevent catastrophic problems by reducing the risk of failures that could cause these problems. FMEA projects often are conducted on high-risk or problem-prone resident care activities identified through routine incident reporting. Another way to identify processes that would benefit from proactive risk assessments is to ask staff where the next adverse resident event is likely to happen. FMEA projects also can be conducted for administrative activities such as insurance billing or building maintenance, although such projects may not meet the resident-focused quality and safety improvement intent of the Joint Commission standards and CMS QAPI requirements.

Senior leaders charter the FMEA project team which is comprised of people most familiar with the process chosen for risk assessment. The

FMEA project starts with a clear definition of the process under review. It is helpful to create a high-level flowchart of the process so everyone on the team agrees on the process steps. Figure 1 is an example of a high-level flowchart for the process of providing anticoagulant therapy to residents. This process will be used to describe how a FMEA project is done, although anticoagulant therapy may not be a high-risk activity in some nursing homes.

Figure 1: High-Level Flowchart of Anticoagulant Therapy



An entire system, such as shown in Figure 1, can be analyzed or the team may choose to conduct the risk assessment on only those steps known to be problematic. Once team members agree on the process steps to be analyzed, they describe what could go wrong at each step. For instance, at step 1 the physician might fail to order the right dose for a resident. At step 2, the pharmacy might lose the order. At step 3, the pharmacy might mislabel the medication vial. And so on. Often a step has more than one possible failure. For instance, at step 4 the nurse could give the anticoagulant to the wrong resident or might miss giving the medication as prescribed. The people personally involved in the process are in the best position to know what can (and occasionally does) go wrong. Identifying failures should not be a “blame-game.” People must be encouraged to honestly and openly talk about what goes wrong so the team can work on reducing the risk of these failures.

### Analyze Phase

Team members will probably identify several process failures that might happen. Some are more likely to actually occur than others. Some failures will have more catastrophic results than others. Some are more apt to be discovered and corrected before a resident is harmed. During the analyze phase the team selects the high priority or critical failures – those most in need of being prevented. To set these priorities the team considers the frequency of each failure, e.g., does it happen every day, once a week, once a month, more than

one a month, etc.? The team also considers the severity of the consequences of each failure should it actually occur. Consequences can range from “none because the failure will be corrected before it reaches the resident” to “severe resident disability or death.” Just by discussing frequency and consequences for each failure, the team may be able to reach consensus on which failures should be prevented. If there are differing opinions, it can be helpful to use a nominal group decision making process. For instance, team members can privately vote on which failures to work on preventing. The votes are tallied and the failures receiving the highest number of total votes are considered the most important to prevent.

There are no absolute rules for selecting high priority failures. The team should consider taking corrective actions for a failure if the consequences are severe (potentially serious failures) no matter how often the failure occurs or if the consequences are moderate to severe and the failure happens often. In some situations, team members may believe that all failures need to be prevented but this option is often not reasonable given the limited resources in nursing homes. By focusing the team’s attention on preventing high priority failures the FMEA project is more likely to achieve its improvement goals.

### Act Phase

At this point the FMEA project team has selected the critical failures requiring action. Now the team devises actions aimed at preventing these failures. Before determining what needs to be done the team must first investigate what causes the critical failures to happen. For instance, what would cause a physician to order the wrong dose of anticoagulant for a resident? Is this failure due to a simple oversight or does the physician lack pertinent clinical information about the resident that is needed to calculate dosages? Why might a nurse fail to administer the medication as required? Do nurses get distracted? Are they understaffed? Are residents often unavailable during medication rounds? The FMEA project team may benefit from the input of other staff members when determining the cause of critical failures. Before deciding how best to prevent each high priority failure, the cause must be understood.

Actions directed at correcting the cause of critical failures fall into one of three categories: eliminate the chance for failures, make it easier for people to do the right thing, make it easier to identify failures quickly and take appropriate action. In Table 1 are examples of improvement actions in each action category. Efforts to catch failures before they occur or block them from causing resident harm ultimately will be more fruitful than ones that seek to somehow create flawless caregivers.

Table 1: Actions to Prevent or Reduce the Likelihood of Failures

Action Category	Improvement Actions
<b>Eliminate the chance for failures</b>	<ul style="list-style-type: none"> <li>• Restructure tasks so the error prevalent step is no longer performed</li> <li>• Automate the process to change the role of human involvement</li> <li>• Purchase error-proof equipment</li> </ul>
<b>Make it easier for people to do the right thing</b>	<ul style="list-style-type: none"> <li>• Create visible displays of acceptable actions (e.g., checklists, computer-alerts, instructional posters)</li> <li>• Conduct pre-use inspections, such as double-checks prior to administration of high risk medications</li> <li>• Reduce the number of process steps, thus reducing the chances for an error</li> <li>• Standardize the process steps to improve consistency of performance</li> <li>• Make ergonomic changes (e.g., improve lighting, reduce workplace clutter)</li> <li>• Maintain equipment according to manufacturers' recommendations (e.g., regularly monitor compliance with routine maintenance schedules)</li> <li>• Limit the number of people who are permitted to do a critical task</li> </ul>
<b>Identify failures quickly and take appropriate action</b>	<ul style="list-style-type: none"> <li>• Human intervention (e.g., train people to better recognize and deal with unusual situations)</li> <li>• Response teams (e.g., specialized teams that are prepared and coordinated to deal with predefined consequences)</li> <li>• Backups (e.g., provision of equipment and/or human intervention to mitigate the consequences of the adverse event)</li> <li>• Automation (e.g., visual/auditory feedback of "off-normal" situations)</li> </ul>

Input from staff outside of the FMEA project team and best-practice suggestions from the literature also are helpful when designing actions to prevent failures. This information will not only broaden the team's understanding of the needed system changes but also improve acceptance of the actions by the people being asked to do something differently.

Once actions are implemented, the success of these actions must be evaluated. This evaluation involves measuring compliance with process changes and measuring the expected end results to determine if the frequency of critical failures has been reduced.

### **Conclusion**

Rather than waiting for something to go wrong and then investigating why it happened, proactive risk assessment techniques such as FMEA can be used to identify what *could* go wrong so potential problems can be averted before causing resident harm. These assessments do not need to be complex or rigorous to achieve desired safety goals. Start by identifying process failures, analyzing which failures are most in need of being prevented, and then take action to prevent these critical failures. We must strive to create a safe environment for our residents and proactive risk assessments can help achieve this goal.

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### **References**

1. Weick KE, Sutcliffe KM. *Managing the unexpected: Assuring high performance in an age of complexity*. San Francisco: Jossey-Bass; 2001.
2. Spath PL. Using failure mode and effects analysis to improve patient safety. *AORN Journal*, 2003; 78:16-37.
3. Aspen P, Corrigan JM, Wolcott J, et al. *Patient safety: achieving a new standard of care*. Washington, DC: The National Academic Press; 2003.
4. Centers for Medicare and Medicaid Services (CMS). QAPI at a glance: A step by step guide to implementing quality assurance and performance improvement (qapi) in your nursing home. 2013. Retrieved from: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/QAPIAtAGlance.pdf>
5. DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using health care failure mode and effect analysis: The VA National Center for Patient Safety's prospective risk analysis system. *Jt Comm J Qual Improv*. 2002;28:248-67.
6. Ashley L, Armitage G. (2010). Failure mode and effects analysis: An empirical comparison of failure mode scoring procedures. *J Patient Saf*, 2002; 6: 210-5.