Failure Mode and Effect Analysis™: A Technique to Prevent Chemotherapy Errors

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Promoting a culture of safety involves a philosophical shift from error measurement to proactive assessment of potential harm. Failure Mode and Effect Analysis™ (FMEA) is a prospective risk analysis technique that can be used to examine the chemotherapy administration process. FMEA is a systematic, multidisciplinary team-based approach to error prevention. This article reviews the process of conducting FMEA and provides suggestions on how FMEA can be applied to the chemotherapy administration process. Nurses who are knowledgeable about risk analysis techniques and the process for applying them in clinical practice have the potential to promote a culture of safety for patients receiving chemotherapy.

Chemotherapy used in the treatment of cancer tops the list of high-alert medications, outranking IV potassium chloride and insulin as potential threats to patient safety (Institute for Safe Medication Practices, 2003). Medications are designated as high alert (sometimes referred to as high bazard) when they have a high risk of causing significant patient harm when medication errors or adverse events occur. Chemotherapy agents fall into the category because chemotherapy-related errors not only can cause patient harm but also may be lethal.

Administration of chemotherapy is error prone for many reasons, and even small errors can cause major harm. Chemotherapy, as a classification of medications, is unique in that dosing is individualized and nonstandardized. Doses are computed on the basis of body size or other factors, such as renal function, and require patient-specific calculations. Sometimes dose adjustments are required, which adds second calculations to determine appropriate doses. In addition, most chemotherapy agents require reconstitution and preparation, and several are available in multidose vials in varying concentrations. Therefore, every time a chemotherapy dose is calculated, prescribed, transcribed, prepared, and administered, a multitude of possibilities for error exist.

Complex, multidrug chemotherapy protocols often are used to treat cancer, and the greater the number of medications administered, the greater the potential for error. Some chemotherapy agents are given in various ways (e.g., subcutaneously, via IV) in various doses (e.g., standard versus high) over various periods of time (e.g., bolus, continuous infusions). Each of the variations in how chemotherapy is prescribed and administered has potential for error. The continual introduction of new chemotherapy agents requires nurses to update their knowledge base. Without accessible information, medication errors can result. In addition to the oncology-specific risk factors for error, chemotherapy errors can occur because of other factors, such as understaffing, poor communication, human error, fatigue, and environmental factors (e.g., clutter, noise) (Ogletree, 2001).

Finally, the process of ordering, preparing, dispensing, and administering chemotherapy is highly complex, involving many parts of an organization and requiring handoffs between people of varying clinical backgrounds and experience (including
nonclinicians). The process also is dependant on interaction between often-incompatible information-technology systems and software.

**Failure Mode and Effect Analysis™**

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) expects healthcare organizations to conduct annual, proactive risk management activities for high-risk processes to identify system weaknesses, predict the outcomes of the weaknesses, prioritize the weaknesses, determine why they occur, adopt system changes to minimize the potential for patient harm, and monitor the effectiveness of redesigned processes (JCAHO, 2005a). JCAHO considers chemotherapy administration to be a high-risk process and has issued sentinel-event alerts to identify problem areas, such as vincristine administration errors (JCAHO, 2005b).

A risk management activity that can be used to examine the high-risk process of chemotherapy administration is Failure Mode and Effect Analysis™ (FMEA). FMEA assumes that humans err, that all things have the potential to fail, and that the causes of errors often are beyond individuals’ control (Woodhouse, Burney, & Coste, 2004). FMEA is a systematic, prospective, multidisciplinary team-based risk analysis process that identifies and assesses the effects of potential errors or system failures (Spath, 2003, 2005).

Conducting FMEA does not ensure that a process, such as chemotherapy administration, will be “fail safe.” However, it reduces the likelihood of errors occurring in the process. Following FMEA, teams can take two types of actions: preventing errors from reaching patients and mitigating the effects of errors that reach patients (Spath, 2003).

The following overview of a FMEA process used by the authors is based, in part, on the model developed by the Veterans Health Administration (DeRosier, Stallhandske, Bagian, & Nudell, 2002; Veterans Health Administration National Center for Patient Safety, 2001), personal experience of the authors at various organizations, and FMEA models used in other industries.

**Prior to forming a FMEA team**

1. An organization’s leadership should review the organization’s experience with chemotherapy administration and determine what processes are working well and identify areas that need improvement. The review should include examining incident reports and near misses (“close calls”) and asking staff members whether they would feel comfortable receiving treatment or having family members treated at the facility. Leadership should be involved in executive patient-safety walkabouts, during which they can observe firsthand safety issues being encountered on a daily basis by front-line staff (Frankel et al., 2003).

2. Review healthcare literature about error prevention, general medication-error prevention, and specifically chemotherapy-error prevention. Review current chemotherapy administration guidelines published by various organizations, such as the American Society of Health-System Pharmacists (2002) and the Oncology Nursing Society (Polovich, White, & Kelleher, 2005). Determine whether the organization’s chemotherapy administration safety practices are consistent with best practices described in the literature. Get a sense about where in the chemotherapy process the organization is most vulnerable (subprocesses include procuring, storing, ordering, preparing, dispensing, transporting, administering, monitoring, and disposing of chemotherapy). If a decision is made to examine many subprocesses of chemotherapy, the organization will need to ensure that ample resources are available to support a project of such magnitude.

3. Secure sponsorship from high-level leaders in the organization. The sponsorship should include individuals who can secure funding and necessary resources for FMEA and those who have the authority and capability to remove barriers to successful implementation of recommendations.

**Forming the team and getting to work**

1. Charter a team (see Figure 1). A charter is a written document that clearly defines the scope of a project. Selection of members is a key step. Include representatives from the many disciplines that are part of each chemotherapy subprocess being examined. Typically, a team is composed of four to seven people (Spath, 2003). A team should be composed of staff members who are experts in each subprocess under study. Include staff members with different types of experiences in each process. The team should have a leader and a facilitator. A facilitator’s role is to guide a team through a process. Ideally, the facilitator should be an individual who does not work in the process being examined and is not part of the workflow or process handoffs. If this is the first time an organization has conducted FMEA, consider using an outside consultant or an experienced quality management staff member who has experience conducting FMEA. Conducting FMEA may be challenging for those who are inexperienced, given the complexity of chemotherapy and the narrow room for error in administering the agents.

2. Study all organizational processes, policies, and procedures that apply to the chemotherapy subprocesses under review. A FMEA team should go to the areas where each chemotherapy subprocess is performed to observe the process and talk to staff members.

3. FMEA deals with processes at a higher level. As a result, FMEA flow charts are developed differently than the charts associated with typical continuous quality improvement process flow. Typically, flow charts do not identify every detailed step in a process but instead identify major process steps and handoffs. Begin by devising a flow chart (see Figure 2) that lists all of the steps of the chemotherapy process being examined. Note where actual practice conflicts with written polices and procedures. If a great deal of discrepancy...
exists between an actual process and a process described by organizational policy, consider creating two flow charts, one depicting how the process should be performed and one depicting how the process actually is performed (Spath, 2003). The chart used in generating failure modes must be the chart that depicts the process as it actually is performed. The second flow chart that documents differences between actual practice and policy assists the team in further defining potential failure modes.

4. Conduct a hazard analysis. This step requires consensus by FMEA team members.
   a) Identify the failure modes for each step of a subprocess (see Figure 3). For this step, the team asks “What could go wrong?” Examples include communication, not completing a task, and hand-off issues. Consider not only human error but also equipment failure, missing supplies, and so on. The point is for the team to brainstorm together about what could go wrong. The process may seem subjective, like making “educated guesses,” but based on their own actual experiences, those involved in the work flow know where failures can and have occurred and often have thought about the potential for failure.
   b) Determine the potential effect on patients of each failure mode. Here, the team brainstorms the question “what could happen” if the failure determined earlier actually occurred. During this step, team members may take past adverse events into account (Spath, 2003).
   c) Rank the severity of the failure determined earlier. The team should estimate the severity of the failure using a 1–5 or 1–10 scale, with the highest numbers indicating permanent patient harm and death. FMEA experts recommend a 1–5 scale (Spath, 2003).
   d) Rank the probability of the failure occurring, using the same numeric scale. The determination may be based on history (Spath, 2003) or simply an “educated guess” based on recommendations of the FMEA team’s content experts.
   e) Rank the detectability of the failure. Here the team asks, “What is the chance the failure will reach patients because the failure is difficult to detect?” For example, detecting whether a prescribed chemotherapy dose is in a prepared infusion bag is difficult, but detecting whether a chemotherapy label is missing from a bag is easy.
   f) Identify the areas of greatest concern. This is done by multiplying the severity number by the probability number and then the detectability number. For example, using a 5-point scale, the highest score would be 5 severity x 5 probability x 5 detectability = 125. This score is referred as the risk priority number (RPN) (see Table 1). Kozakiewicz, Benis, Fisher, and Marseglia (2005) addressed all failure modes with an RPN score greater than the mean score.
   g) Between FMEA team meetings, validate the findings of the team with other staff members involved with the processes being examined. This approach can help generate “buy-in” from those who ultimately may need to change their practices and behaviors as a result of FMEA findings.

5. Reduce the possibility of failure by determining what would cause a step in the process to fail. For this step, the root cause analysis (RCA) technique may be of benefit. The RCA team conducts its own literature search of the topic to identify best practices and guidelines published by various organizations.

6. Design the new process. Spath (2003) identified three types of process improvements: those that eliminate the chance for failure, those that make doing the right thing easier, and
those that identify failures quickly and enable people to take action before the failures reach patients.

7. Devise a measurement plan. Before the team pilots the new process, determine how success will be measured. The goal of a proactive approach is cost avoidance, not cost reduction (Spath, 2003), so financial measurements may not apply.

8. Institute a pilot plan. The length of the pilot should be determined during the measurement planning.

9. Measure the change from the pilot.

10. If successful, implement the plan on a larger scale.

Six to 12 months after full implementation

1. Reassemble the FMEA team; survey staff members who are using the revised process and ask whether the new process is working. Determine whether staff members and patients are satisfied with the changes. An additional source of data can be found by reviewing pertinent incident reports and “near-miss” reports.

2. Identify risk management and loss-prevention benefits to the organization. Keep your organization’s insurers informed of positive changes that lower the risk of patient injuries. Some insurers reward improved clinical risk management with reduced professional and corporate liability premiums and provide risk management education credits to providers, further influencing the cost of obtaining coverage.

Lessons learned: what not to do

1. Not having a charter to define the work the team is to complete. Key administrators need to define clearly the part of the chemotherapy process that the FMEA team will examine. Expecting a team to study the entire chemotherapy process from ordering through administration is too large of a task.

2. Not having a leadership sponsor or the correct sponsorship for the FMEA. Without sponsorship, implementation of changes identified through the process may face barriers or lack the necessary resources.

3. Not having the “right people” on the team, that is, a team that is entirely composed of administration staff rather than staff who do the “hands-on” work of the process under study.
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4. Not investing the needed resources to complete the complex process prior to embarking on FMEA. The FMEA process is time consuming and costly. One of the article’s authors recalls that for one FMEA project, five to seven team members met every week for five or six weeks. Meetings were approximately two hours long, for a total of 50–84 staff hours away from their regular work. In addition, secretarial support is needed to record the notes and activities of a FMEA team.

5. Viewing the FMEA process as a guarantee that chemotherapy errors will not occur. FMEA helps identify needed improvements to reduce the potential for error; it is not a guarantee that errors no longer will occur.

6. Using cost savings as a measurement of success for the team. Failure to recognize cost avoidance instead of cost savings can provide an incomplete picture of potential FMEA benefits.

Summary

Complex, multidrug chemotherapy protocols commonly are administered to patients with cancer. At every step of the chemotherapy administration process, from the point that chemotherapy is ordered to the point that it is infused and beyond, potential for error exists. FMEA, a proactive process that promotes systematic thinking about the safety of patient care, is a risk analysis technique that can be used to evaluate the process of chemotherapy administration. Error prevention is an ongoing quality improvement process that requires institutional commitment and support, and nurses play a vital role in the process.

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