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Improving the Safety of Chemotherapy Administration: An Oncology Nurse-Led Failure Mode and Effects Analysis

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Administration of chemotherapy is an important aspect of cancer nursing, and one for which demand has risen sharply since the early 2000s (National Chemotherapy Advisory Group, 2009; Summerhayes, 2003). Treatment regimens typically involve several chemotherapeutic and supportive agents, many of which require individualized dosing (e.g., body surface area, renal function) and are administered by a variety of routes (e.g., orally, IV) and at different rates (e.g., bolus, continuous infusion). Delivery of a regimen at any one administration session can, therefore, take several hours and involve multiple nurses. And, as patients progress through treatment, side effects and toxicity must be monitored and controlled and regimens may change. This complex and dynamic nature of chemotherapy administration makes the process highly vulnerable to errors (Gandhi et al., 2005; Walsh et al., 2009; Weingart et al., 2010). In addition, as patients with cancer often are frail and immunocompromised, and chemotherapeutic agents are high-alert medications, errors in this process can result in serious patient harm and even death (Cousins & Upton, 1994; Institute for Safe Medication Practices [ISMP], 2008; Trinkle & Wu, 1996). Perhaps unsurprising, therefore, is that in a survey of more than 200 oncology nurses, 95% reported “being frightened, scared and anxious” when first working with chemotherapy (Verity, Wiseman, Ream, Teasdale, & Richardson, 2008, p. 244). Although it is impossible to eliminate the risks inherent in health care, taking steps to minimize errors and their consequences is advisable.

Traditionally, efforts to improve the safety of health-care processes have been reactive and generally have entailed focused investigations following particular adverse incidents. However, in addition to intermittent retrospective actions following specific incidents, a need exists for broad, ongoing, proactive efforts to manage risk and improve safety *before* errors occur (Christian

Purpose/Objectives: To assess and improve the safety of hospital-based adult chemotherapy administration.

Design: Prospective, systems-focused clinical risk assessment.

Setting: An adult inpatient and outpatient oncology unit in a large urban hospital in the United Kingdom.

Sample: 8-person nurse-led multidisciplinary team, which included managerial staff and patient safety researchers.

Methods: Failure mode and effects analysis (FMEA), a prospective, systems-focused risk assessment methodology, was undertaken in biweekly team meetings and included mapping the chemotherapy administration process, identifying and numerically prioritizing potential errors (failure modes) for each process step, and generating remedial strategies to counteract them.

Main Research Variables: The analysis aimed to identify chemotherapy administration failure modes and to generate remedial strategies to address them. User feedback on the FMEA process also was collected.

Findings: Several specific chemotherapy failure modes were identified, the majority of which had not previously been recognized, and several novel strategies to counteract them were generated. Many of the strategies were specific, environment-focused actions, which are simple, quick, and inexpensive to implement; however, more substantive, longer-term initiatives also were generated. User feedback generally was very positive, and the process of undertaking the analysis improved multidisciplinary teamwork and communication.

Conclusions: Although time and resource intensive, FMEA is a useful safety improvement tool.

Implications for Nursing: Nurses should be aware of and informed about FMEA as a tool they can use in partnership with management and other disciplines to proactively and collectively improve the safety of high-risk oncology procedures such as chemotherapy administration.

et al., 2006; Senders, 2004; Smith, Boulton, Woods, & Johnson, 2010). In addition to a move toward proactive safety management in health care, a shift away from person-centered views of safety and toward a more

systems-based approach has been seen. A tendency in the past within health care was to assume that the principal causes of errors relate to clinicians' personal failures. However, it now is widely acknowledged that errors result from the failings of complex organizations and systems within which clinicians work (Firth-Cozens & Sanders, 2007; Institute of Medicine, 2000; Reason, 2000).

The prospective systems approach to safety, although relatively new in health care, has been espoused by high-risk industries such as aviation and nuclear power for several decades. As health care gradually has adopted a high-risk industry approach to safety, so too has it adopted industry-based tools for improving safety. One tool that has received considerable attention is the failure mode and effects analysis (FMEA), a risk assessment methodology used to prospectively identify weaknesses in complex, hazardous processes and generate remedial strategies to counteract these weaknesses before they result in adverse events (Chiozza & Ponzetti, 2009; Cohen, Senders, & Davis, 1994; DeRosier, Stalhandske, Bagian, & Nudell, 2002; Paparella, 2007; Sheridan-Leos, Schulmeister, & Hartranft, 2006). Although developed by engineers and originally employed in industrial settings, FMEA is now being used increasingly to assess and improve the safety of healthcare processes, including IV drug administration, blood transfusions, and organ transplantations (Adachi & Lodolce, 2005; Apkon, Leonard, Probst, DeLizio, & Vitale, 2004; Bonfant et al., 2010; Burgmeier, 2002; Chan et al., 2010; Linkin et al., 2005; Steinberger, Douglas, & Kirschbaum, 2009; Wetterneck et al., 2006). Indeed, FMEA now is recommended as a useful safety improvement tool by the ISMP (2001) in the United States and the National Patient Safety Agency (NPSA, 2004) in the United Kingdom.

FMEA typically is undertaken by a multidisciplinary team (MDT) of subject matter experts and, although several variants exist, generally entails (a) mapping the process under evaluation to identify its component steps, (b) identifying failure modes (potential errors) for each process step, (c) numerically scoring the failure modes to prioritize them according to the risk they pose, (d) identifying possible causes for the highest risk failure modes and, based on these, (e) generating remedial strategies to address them. The strategies are then implemented and their effect evaluated using appropriate outcome measures to determine the success (i.e., improved safety) of the redesigned process.

The current study used FMEA to evaluate and improve the safety of adult chemotherapy administration in a large urban hospital in the United Kingdom. Hospital management wanted to assess the safety of the chemotherapy process in its current form and identify where and how safety could be improved. Consultations with onsite patient safety researchers identified FMEA as an appropriate tool to address these aims, and the current study was commissioned. The study

focused specifically on chemotherapy administration, with an emphasis on IV treatment, and was undertaken by a nurse-led MDT. As FMEA is time and resource intensive, the scope should be kept relatively narrow to ensure the analysis is manageable (DeRosier et al., 2002; Stalhandske, DeRosier, Patail, & Gosbee, 2003). Previous studies have demonstrated the applicability and use of FMEA to the chemotherapy treatment process (Bonabry et al., 2006; Kim et al., 2006; Kozakiewicz, Benis, Fisher, & Marsegia, 2005; Robinson, Heigham, & Clark, 2006; Van Tilburg, Leistikow, Rademaker, Bierings, & van Dijk, 2006). However, few studies have focused closely on the administrative step carried out by nursing staff, concentrating instead on the prescribing and dispensing elements conducted by medical and pharmacy staff. Also, most previous studies have been conducted in the United States, and the present study is, to the authors' knowledge, the first to report on the use of FMEA in oncology health care in the United Kingdom.

This article reports the implementation and results of a FMEA to evaluate and improve the safety of chemotherapy administration. The purpose is threefold: (a) to stimulate interest in, and raise awareness of, proactive risk management and the FMEA tool, (b) to disseminate the key weaknesses identified in the chemotherapy administration process and the remedial strategies the authors' generated to counteract them, and (c) to share the authors' experiences of undertaking FMEA within oncology health care and evaluate the use of FMEA as a safety improvement tool.

Methods

Setting

The study was conducted from May 2009 to September 2009 on an adult oncology unit in a large urban teaching hospital in West Yorkshire, United Kingdom. The unit is comprised of a 21-bed inpatient ward and a 10-seat outpatient day care center. The unit has a permanent core team of about 40 staff, including consultant oncologists, registrars, clinical nurse specialists, staff nurses, and a dedicated pharmacist. As the study was commissioned by hospital management, as part of continuous quality and safety improvement activities, and did not involve patients, ethical and governance approvals were not required.

Team

The team was comprised of two managers (the general manager of education and cancer services and the services manager for patients with cancer) and four clinically active nurses (the oncology ward sister, a chemotherapy nurse specialist with more than 20 years' experience, and two more junior but experienced oncology staff nurses). As the analysis focused on chemotherapy administration,

and did not extend to prescribing and dispensing, medical and pharmacy staff were not involved. The team also included two postdoctoral patient safety research fellows (one with an extensive acute care nursing background and previous experience of FMEA and one with a health psychology background). In addition to clinicians who work closely with the process under evaluation, FMEA teams also should contain “outsiders” who are unfamiliar with the process to facilitate the team’s adoption of a critical but unbiased approach (Ashley, Armitage, Neary, & Hollingsworth, 2010; DeRosier et al., 2002; Spath, 2003). The team was led by the health psychology research fellow who briefed the team about FMEA, facilitated the analysis meetings, and documented their output.

Approach

The authors used Healthcare Failure Mode and Effect Analysis™ (HFMEA), developed by the U.S. Veterans Affairs National Center for Patient Safety (DeRosier et al., 2002). HFMEA is an adaptation of the original, industrial FMEA methodology for use in health care (e.g., scale descriptors for failure mode scoring are specific to a healthcare setting rather than a general, industrial context) and has been successfully used in several previous healthcare FMEA programs (Esmail et al., 2005; Habraken, Van der Schaaf, Leistikow, & Reijnders-Thijssen, 2009; Kimchi-Woods & Shultz, 2006; Linkin et al., 2005; Van Tilburg et al., 2006; Wetterneck et al., 2006). The detailed HFMEA methodology and all related materials are publicly available (DeRosier et al., 2002).

Procedure

The analysis was undertaken in five biweekly face-to-face team meetings. In the first meeting, the chemotherapy administration process was mapped out to identify its component steps and substeps. Although the process is governed by official local and national policies, the authors did not automatically map out the process according to policy (i.e., what *should* happen), but, rather, according to current practice (i.e., what *actually* happens). In the second meeting, failure modes were identified for each process step by considering what could possibly go wrong. In the third meeting, the failure modes were scored using the HFMEA scales for their probability of occurrence (ranging from 1 [unlikely] to 4 [likely]) and, should they occur, the likely severity of their consequences (ranging from 1 [minor] to 4 [catastrophic]). The scores were then multiplied to obtain an overall hazard score indicative of the risk posed by the failure mode (i.e., higher scores equal a greater risk). In the fourth and fifth meetings, the HFMEA decision tree was employed to further help prioritize the failure modes, based on their criticality (potential to cause whole system failure), controls (sufficiency of current control measures), and detectability

(likelihood of being detected and prevented). For high-priority failure modes, possible causes were identified and remedial strategies to address them developed. Although the whole team contributed to all activities, as has been the case in other FMEA programs (Apkon et al., 2004; Bonnabry et al., 2006; Ford et al., 2009), only team members closest to the process (i.e., the nursing staff who administer chemotherapy) scored the failure modes. Scores were determined by consensus following group discussion (although, before this, scores were first considered and written down by each individual separately [Ashley & Armitage, 2010]). Outside team meetings, the research fellows sourced and synthesized relevant literature and observed chemotherapy administration on the oncology unit.

User Evaluation

At the final meeting, team members completed an anonymous written evaluation of the FMEA by rating their agreement with a series of statements about the analysis using a five-point Likert-type scale (ranging from 1 [strongly disagree] to 5 [strongly agree]). Items inquired about the experience of participating in the FMEA and its use and value. Open sections for free-response comments were available.

Results

The analysis required five 2.5-hour meetings of the team, and about 10 hours of the research fellows’ time outside each meeting. Therefore, about 150 person-hours in total were used.

Identification and Prioritization of Potential Errors

The chemotherapy administration process was mapped out, from patient arrival to departure, in nine main steps (see Figure 1), each of which comprised numerous substeps. The step “establish patient fitness for chemotherapy,” for instance, comprised three substeps that entailed checking different types of fitness

1. Patient arrives. Check identification.
2. Establish patient fitness for chemotherapy.
3. Check the prescription.
4. Prepare the equipment.
5. Verify patient consent (for the first cycle or following changes to the regimen).
6. Establish an IV line.
7. Administer the drug regimen.
8. Close the IV line.
9. Patient departs.

Figure 1. Main Steps in the Chemotherapy Administration Process

indicators (e.g., blood hemoglobin, patient-reported mucositis). Thirty failure modes were identified and included potential errors such as “an expired drug(s) is administered” and “there is a cytotoxic drug spillage.” Hazard scores assigned to the failure modes ranged from 2–16 (possible range, 1–16), with 17 of the 30 (57%) scores 8 or higher, which, in terms of the HFMEA scoring system, is the start point for failure mode prioritization. The failure modes and their hazard scores are shown in Table 1. Application of the HFMEA decision tree, to further help prioritize the failure modes, proved difficult as the authors found it hard to judge if a failure mode was sufficiently critical to result in whole system failure. The authors eventually discontinued use of the criticality aspect of the decision tree to enable progression with the analysis (although the authors did continue to use the controls and detectability elements in failure mode prioritization). In other words, failure modes were not prioritized if it was deemed that sufficient control measures already were in place or the hazard would be so visible and obvious that it would almost certainly be detected and stopped before it resulted in adverse consequences. For example, the failure mode “a chemotherapy regimen is administered to the wrong patient” was not prioritized because nurses already were required to follow extremely comprehensive official procedures to establish and recheck patient identity. In addition, no evidence existed to suggest that nurses were not following these procedures or that they experienced difficulties or barriers to achieving best practice in this step of the process. Twelve failure modes were deemed high-priority, warranting remedial attention.

Identification of Error Causes and Development of Remedial Strategies

For the prioritized failure modes, the authors brainstormed possible causes and potential remedial strategies. Possible causes for high-priority failure modes included highly specific issues as well as general risk factors. As summarized in Figure 2, a total of 20 remedial strategies were developed, some of which countered specific causes of particular failure modes and some of which addressed general risk factors applicable to multiple potential errors. Illustrative examples of the type and range of process weaknesses identified, and counteractive strategies developed, are detailed later in this article.

The FMEA highlighted a high potential to underdose drugs dispensed in multiple containers—by mistakenly administering only one of them—and a low likelihood of this error being detected and rectified. Identified causes for this error centered on a lack of awareness and, crucially, reminders that drugs may be packaged in multiple parts. As a remedial strategy, it was suggested that pharmacy staff label partial dose syringes, vials,

Table 1. Identified Failure Modes and Related Hazard Scores

Failure Mode	Hazard Score
The patient fails to arrive for his or her appointment and chemotherapy is not given that day (when it should have been).	4
Based on the patient's fitness markers, it is wrongly concluded that he or she is unfit for chemotherapy and it is not given that day (when it should have been).	4
Some of the equipment or drugs are (completely) unavailable and chemotherapy is not given that day (when it should have been).	4
Chemotherapy administration is delayed or prolonged (i.e., the patient's stay in hospital is prolonged).	8*
Chemotherapy is administered to a patient unfit for it (based on the markers of the patient's fitness).	4*
Chemotherapy is administered to a patient who has not consented to it.	2
A drug(s) not on the prescription is administered.	8*
A drug(s) intended for a different patient is administered.	12*
A chemotherapy regimen is administered to the wrong patient.	4
An element(s) of the drug regimen is (wrongly) administered twice (i.e., a double dose is given).	8
An infusion bag is removed before all the contents have infused (i.e., an underdose is given).	4
For a drug whose full dose comes in two or more syringes or bags, only one or some of them are given (i.e., an underdose is given).	12*
The wrong dose of a drug (whose dose is dependent on surface area) is administered.	8*
A patient with a peripherally inserted central catheter is cannulated.	3
Bolus drugs are given as infusions.	4
A bolus drug is administered too quickly.	8
An infusion pump is wrongly programmed (i.e., the drugs are infused at the wrong rate).	9*
An infusion pump stops during the infusion and is not immediately noted and restarted.	8*
A drug(s) from the regimen is omitted (i.e., not administered).	16*
An expired drug(s) is administered.	8*
The drugs that comprise the regimen are not administered in the optimal order.	8*

(Continued on the next page)

* Prioritized failure mode

Note. Scores ranged from 1–16. Higher scores equal more hazard.

Table 1. Identified Failure Modes and Related Hazard Scores (Continued)

Failure Mode	Hazard Score
A chemotherapy drug that needs to be is not protected from light during infusion.	4
The patient has an allergic reaction.	16*
Extravasation occurs.	12
There is air in the IV line.	4
The IV line is flushed with a cytotoxic drug rather than a compatible fluid, such as saline.	4
The IV line is flushed with the wrong compatible fluid (e.g., saline instead of dextrose).	4
Infection is introduced to the patient during the chemotherapy administration process.	8
The cannula site or the peripherally inserted central catheter is not dressed properly at the end of the patient's stay.	16
There is a cytotoxic drug spillage.	12
* Prioritized failure mode	
Note. Scores ranged from 1–16. Higher scores equal more hazard.	

and IV bags with a colored sticker to identify them, for example, as “1 of 2 parts” or “half the full dose.”

Another prioritized failure mode was the administration of multiple drugs in a therapeutically suboptimal order (e.g., vesicant drugs not given first). The analysis highlighted that, other than nurses' knowledge and experience, no controls existed against that error. Identified error causes included a lack of clinician consensus around the matter of optimal drug sequencing and the listing of prescribed drugs for administration at any one session in no particular order. Therefore, as counteractive strategies, it was suggested that the unit establish and integrate into its local policy best practice guidelines on drug sequencing, and that medical staff list prescribed drugs in their optimal administration order.

A potential cause of error, raised in relation to several of the failure modes, was being directly interrupted or distracted by background events when carrying out nursing tasks. Interruptions and distractions are frequent in clinical environments and can be a contributory factor to error (Rivera-Rodriguez & Karsh, 2010). FMEA highlighted the unit's lack of control against interruptions. Notably absent was any quiet space in which to perform cognitive tasks such as interpreting blood test results, double-checking drug doses, and completing patient paperwork. To correct this, the creation of a silent area was proposed—in an office or storeroom—in which it is known and accepted that, unless strictly necessary, nurses working in the area should not be disturbed.

Another general risk factor illuminated by the analysis was poor communication. Communication failures and misunderstandings are leading causes of error (Beyer, Rohe, Nicklin, & Haynes, 2007), applicable to most of the failure modes. Consequently, several remedial strategies were focused on improving unit communication between various parties in a myriad of ways. It was suggested, for instance, that management periodically undertake some form of unit walkrounds, an evidence-based patient safety intervention (Frankel et al., 2003, 2005). By being regularly present on the unit, managers afford clinicians opportunities to communicate their quality and safety issues and initiatives, which they may not if doing so required a trip to management offices outside on-duty hours. By observing on the unit, managers also obtain an empathy with the day-to-day concerns and challenges of practice, which should serve to facilitate and enhance their communications with clinical staff.

User Evaluation of the Experience

The team's anonymous post-analysis feedback was generally very positive. All team members agreed they had “followed and understood each meeting's FMEA activities,” and felt the meetings to have been “interesting,” “enjoyable,” and “useful.” Seven of the eight team members also rated the meetings “inspiring” and “exciting.” Although the whole team was positive about the analysis meetings, five members did note that they were “mentally effortful,” however, just one member found them “tiring,” “anxiety-provoking,” “frustrating,” and “stressful.” No one rated them “irritating” or “boring.” All team members agreed that they had “enjoyed taking part in the FMEA,” and that doing so had been worth their time and effort. Team members also unanimously agreed that they would be willing to take part in other FMEA programs in the future and that they would recommend doing so to colleagues.

In the open sections of the written evaluation form, team members noted that they learned a great deal and valued the opportunity they had been afforded to reflect on and discuss clinical practice in a MDT. Team members commented, for example, that “it was good experience to work closely with management and other colleagues,” that the FMEA provided “opportunity to have time out and reflect on practice,” and that they welcomed being “given the time to discuss our practice, question our practice, and collectively make suggestions to improve our practice.” Team members also noted that participation in the analysis had elevated their awareness of patient safety threats but also had raised their confidence to effectively manage those threats. Team members commented, for instance, that the FMEA had, with respect to chemotherapy administration, “highlighted how dangerous it is” and “identified how easy it is for problems to arise,” but had,

Facility-Based Changes

- Redesign the patient oncology treatment card to make it more intuitive and quicker to use. Improve information consistency, flow, and legibility, and reduce duplication.
- Develop an algorithm or heuristics (rule of thumb) to standardize and guide action following checking and review of patient fitness markers (e.g., toxicity gradings).
- Label drugs whose full dose is dispensed in multiple syringes, bags, or vials as such (i.e., “1 of 2 parts” or “half the full dose”).
- Establish and disseminate a unit policy and procedures on drug sequencing.
- Create a quiet area on the unit where cognitive tasks (e.g., drug-dose checking, interpreting blood results) can be undertaken without interruption or distraction.
- Make the unit stockroom layout permanent (keep the same drug in the same place) and, if changes are made, fully brief all staff about them.
- Employ cognitive memory aids in the unit stockroom to facilitate and expedite equipment preparation and aseptic procedures.
- Procure more calculators for double checking drug doses.
- Procure magnifiers for reading small print drug expiration dates.
- Procure **plug sockets for charging inpatient ward IV pumps overnight**.
- Establish and maintain an electronic diary of patient chemotherapy appointments.

- Gradually replace current IV pumps with a preferred, easier-to-use brand.

Staff-Focused Changes

- List prescribed chemotherapy and supportive drugs in their optimal administration order.
- *Effectively* remind patients of the importance of keeping IV pumps plugged in by verbally highlighting *why* it is important and putting patient reminder notices on pumps.
- *Effectively* remind patients of the importance of promptly communicating IV pump “warning beeps” to staff by verbally highlighting *why* this is important and placing patient reminder notices on pumps.
- Improve staff communication between the unit’s inpatient ward and day care center.
- Train and permit more unit staff members to complete patient chemotherapy consent forms to reduce delay in the treatment process.
- Train and permit more unit staff members to administer bolus chemotherapy to reduce delay in the treatment process.
- Have a designated daily contact among the chemotherapy clinical nurse specialists to whom less experienced nurses can approach with enquires for help and advice.
- Have management undertake periodic patient safety walk-rounds on the unit.

Figure 2. Summary of Remedial Strategies for High-Priority Failure Modes

at the same time, “increased awareness of risk management” and shown that “potential hazards are numerous but manageable.”

Dissemination and Implementation of Outcomes

Since completion of the study, the results have been presented to nursing, medical, and pharmacy oncology colleagues outside the analysis team, and a number of the simpler, inexpensive remedial strategies have been implemented (e.g., procuring and use of plug sockets to charge IV pumps overnight in the ward storeroom). The timeline and financing for implementation of the more substantive recommendations (e.g., creation of a quiet area on the unit) currently are under management review and planning. More of the remedial strategies will be implemented gradually and, over time, their impact evaluated by examining clinical outcomes, patient safety incident reports, and staff feedback.

Discussion

The authors used FMEA to evaluate and improve the safety of chemotherapy administration on an adult oncology unit in a large hospital in the United Kingdom. The authors were keen to assess the safety of the chemotherapy process as it existed and to identify where and how its safety could be improved. The analysis improved the authors’ understanding of the vulnerabilities and strengths in the chemotherapy process, highlighting where risks feasibly could be reduced but

also where little scope for additional improvement existed. Of note, the majority of the weaknesses had not been recognized previously and many were discrete, specific, system-level vulnerabilities (e.g., “part dose” drugs not labeled as such), although more general long-term areas for improvement also were flagged (e.g., staff communication). The authors generated several strategies to counteract the weaknesses, most of which had not previously been considered, and were a novel and direct outcome of the analysis. Many of the strategies were specific, environment-focused actions that are simple, quick, and inexpensive to implement (e.g., procuring magnifiers to read small-print drug expiration dates), although more substantive, longer-term initiatives also were generated (e.g., redesign of the oncology treatment card). An additional valuable output from the study was a detailed step-by-step description of the entire chemotherapy administration process. That had never before been explicitly delineated and documented, and the resulting process map is a lasting resource that can be used for a variety of purposes from audit to training.

The process of undertaking the analysis yielded substantial individual and group benefits for the members of the study team. The FMEA was a rich learning experience, which has contributed to team members’ continued professional development. Because FMEA involved working alongside management and presenting outcomes to medical and pharmacy colleagues, it was an empowering, confidence-building experience for some of the nurses on the team. Indeed, the opportunity to work collaboratively with management was

felt by two nurses to be a real advantage of participating in the FMEA. The many group discussions undertaken during the analysis also increased team members' awareness of each others' different views and perspectives. Indeed, the authors unexpectedly found that team members had very different thoughts and beliefs about the chemotherapy process, despite working together daily on the same oncology unit. Greater understanding and acceptance of those different views, brought about over the course of the study, enhanced the team's communication and collaborative working. The team-building benefits of FMEA have been noted by other analysis teams (Esmail et al., 2005; Steinberger et al., 2009).

Although the outputs and outcomes of FMEA can be considerable, the process is time and resource intensive and, therefore, is a relatively expensive methodology (Habraken et al., 2009). However, FMEA need only be undertaken periodically and for specific high-risk healthcare processes. FMEA does require sustained energy and commitment, and is a significant additional workload on top of clinical practice. The analysis can be time consuming and effortful; however, it also can be very enjoyable (as team feedback shows). FMEA is logistically challenging and it can prove difficult to organize regular analysis meetings with busy clinicians in a hospital environment. With management support, however, undertaking an FMEA is feasible. Some teams also have found elements of the methodology difficult to perform (Day, Dalto, Fox, Allen, & Ilstrup, 2007; Habraken et al., 2009). The authors did find failure mode scoring challenging because of team members' varied viewpoints; however, the only analysis element the authors found problematic was the "criticality" step of the decision tree, which may be caused by inexperience with the tool. A number of guidance articles are available and have offered practical, healthcare-focused advice on managing the setup and analytic steps of FMEA (Ashley et al., 2010; DeRosier et al., 2002; Spath, 2003; Stalhandske et al., 2003).

Despite its numerical component, FMEA essentially is a qualitative methodology based on the knowledge, experience, and opinions of its team members. The outcomes are, therefore, inevitably a product of the analysis team. Consequently, Shebl, Franklin, and Barber (2009) questioned reliability and argued that "healthcare organizations should not solely depend on FMEA findings to improve patient safety" (p. 86). FMEA does not produce objective data, although it does harness the carefully considered views and opinions of local, multidisciplinary subject matter experts, who are an important strand of information. FMEA is, therefore, a useful addition to an organization's multi-method safety improvement toolkit.

FMEA is a team-based, proactive systems approach to safety, which recognizes the inevitability of error,

engages staff in open communication about safety concerns and initiatives, and promotes a shared perception of organization vulnerabilities and strengths. Use of this tool may, therefore, help to foster "error wisdom" among staff (in terms of readiness and vigilance for error occurrence) and purposeful, intelligent risk assessment and prevention (Reason, 2004). Indeed, several of the authors' team members spontaneously noted, in the post-analysis feedback form and subsequent informal discussions, that the analysis had elevated their awareness of the high-risk nature of chemotherapy administration and increased their knowledge and confidence in risk management. More broadly, FMEA is highly consistent with, and may help to promote, a positive safety culture within the wider organization, characterized by a shared prioritization of patient safety and an open, non-punitive approach to safety-incident reporting and analysis (Vincent, 2006).

Implications for Nursing Practice

FMEA is recommended by the ISMP and NPSA and is increasingly used worldwide to improve the safety of complex, high-risk healthcare processes. Oncology nurses should be aware of and informed about FMEA, which can be used to improve the safety of high-risk oncology procedures such as chemotherapy administration. As this study demonstrated, proactive safety tools can be used by clinical teams to identify specific chemotherapy process weak spots and to generate local remedial strategies that may not otherwise have been developed until after an administration error had occurred. As FMEA uses a MDT, it allows nurses to work in firm partnership with management and other disciplines to improve patient safety. In addition, as FMEA now is supported by a growing and widely accessible literature, nurses are in a position not only to participate in such analyses, but to proactively initiate and lead them.

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