CHALLENGES WITH THE PERFORMANCE OF FAILURE MODE AND EFFECTS ANALYSIS IN HEALTHCARE ORGANIZATIONS: An IV Medication Administration HFMEA™

Tosha B. Wetterneck[a], Kathleen Skibinski[b], Mark Schroeder[c], Tanita L. Roberts[d] and Pascale Carayon[e]

[a] Department of Medicine, University of Wisconsin Medical School
[b] School of Pharmacy, University of Wisconsin, Madison
[c] Department of Anesthesia, University of Wisconsin Medical School
[d] University of Wisconsin Hospital and Clinics
[e] Center for Quality and Productivity Improvement and the Department of Industrial Engineering, University of Wisconsin, Madison, WI

The value of performing prospective analysis before technology implementation is well known to the chemical, nuclear and aviation industries. The performance of a failure mode and effects analysis (FMEA) is now required by healthcare organizations accredited by JCAHO as part of their patient safety standards. However, most healthcare organizations have little experience with applying human factors engineering techniques to process or technology evaluation and the procedure of how and when healthcare organizations should perform FMEA is not well described. This paper describes the method and challenges of performing a process and design FMEA to prepare for the implementation of a new intravenous infusion pump at a University Hospital. Recommendations are made for the performance of a process and design FMEA for new technology implementation in healthcare organizations.

INTRODUCTION

Failure mode and effects analysis (FMEA) is a human factors engineering technique used to define, identify, and eliminate known and/or potential failures, problems, and sources of error from the system, design, process, and/or service before they reach the customer. Both the IOM report, *To Err is Human: Building a Safer Health System* and the AHRQ Evidence Report/Technology Assessment Number 43, *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*, recommend using human factors techniques to evaluate medical devices before purchase and on an ongoing basis after implementation because technology can introduce new errors, even when its purpose is to prevent them (Kohn, 2000; Wachter, 2001). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also required the performance of a yearly proactive risk assessment (e.g., FMEA) of a process or technology in 2001, to encourage patient safety efforts in healthcare organizations. Typical applications for FMEA in healthcare organizations include preventing technology or device defects, improving patient care processes for high risk procedures (blood transfusion, MRI scanning) and identifying potential safety issues both to patients and care providers (Stamatis, 1995). Recently, the Veterans Administration National Center for Patient Safety developed a Health Care FMEA (HFMEA™), intended to be easier to apply to healthcare situations. This model includes concepts from the industry FMEA model, the hazard analysis and critical control point model from food safety, and a modified hazard matrix scoring system based on health care outcomes (DeRosier, 2002). The widespread use of FMEA by healthcare organizations and its effectiveness to improve quality of care and safety has not been well studied or discussed. However, there are reports about the considerable time and resource commitment required by organizations to perform the task (Burgmeier, 2002; ECRI, 2002) and with problems applying the FMEA model to health care settings (Capunzo, 2004). This paper describes our organization's undertaking of a process and design FMEA for the implementation of a new technology, an intravenous infusion pump or "Smart pump" which has a preprogrammed drug library with dosing limits. Challenges identified by the team during and after the FMEA are discussed and recommendations are made for healthcare organizations to guide their planning and execution process for using FMEA.

BACKGROUND

The decision to consider the purchase of new intravenous (IV) infusion pumps with a preprogrammed drug library designed to decrease pump programming errors was made in late 2002 by Hospital leadership as a

fail-safe solution for IV medication administration errors, specifically pump programming errors leading to patient harm. A multidisciplinary team evaluated the existing IV infusion pump technologies based on desired and ideal function criteria developed by the team. The Alaris Medley Medication System with Guardrails® pump technology was chosen for purchase and a Return on Investment (ROI) proposal was developed based on cost of implementation versus cost avoidance from reduction in medication errors. At the time of the purchase agreement, the organization's Patient Safety Committee chose the introduction of the new technology as the next FMEA to be performed by the organization. The organization had performed one previous FMEA that evaluated the existing safety of MRI use. The IV Pump FMEA team started its work 3 ½ months before implementation of the new technology was planned. The timing of implementation was delayed to allow the team to complete its work and operationalize solutions for high priority failure modes to improve safety during implementation. The team's final report was ready one week before technology implementation, during which time end-users were undergoing training on the new technology. Overall, the team felt the FMEA process was useful and identified appropriate solutions for prioritized failure modes.

METHODS

To understand the process and challenges encountered by the FMEA team, information was collected through a variety of mechanisms including: open forum discussion by team members at the end of the FMEA, recording of the personal experiences of the FMEA facilitator and team leader, review of meeting minutes, and post-FMEA structured interviews with FMEA team members.

RESULTS

Challenges and recommendations were identified and grouped into the following areas: personnel, team leadership, definition of team charge, FMEA execution and organizational factors.

Personnel

A multidisciplinary team including Pharmacy, Nursing administration and end-users, Anesthesia, Medicine, Biomedical Engineering, Anesthesia Engineering, Safety, and Quality Improvement was assembled with an anesthesiologist as team leader and a Pharmacy graduate student and Quality Improvement analyst chosen to co-facilitate the group. The multidisciplinary nature of the FMEA team was identified as a key strength by 9 of the 14 FMEA team members interviewed upon completion of the FMEA process. However, the substantial time commitment for individual team members and the significant personnel investment for the organization were not recognized at the start of the FMEA. In total, twelve to fifteen hospital personnel attended over 46 hours of meetings over the four and a half month time period to complete the FMEA. Most members were familiar with aspects of the medication use process involving the pump, however, only half of the FMEA team members were end-users of the pump, and therefore significant time was spent familiarizing the team with the process of programming both the current and new pumps. There were problems with end-user attendance at the meetings due to patient care responsibilities. Nurses on disability leave were then utilized as team members to overcome difficulties with finding staff nurses from varied care areas to attend the meetings. In addition, to supplement gaps in end-user participation, team members performed direct observations of the IV medication administration process and interviewed end-users.

Team Leadership

The team realized at the first meeting that an experienced facilitator was necessary to guide them through the FMEA exercise. The organization did not have such an expert on staff and a human factors-trained pharmacist with FMEA experience from an affiliated School of Pharmacy was asked to join the team in this role. In response to an open-ended question on strengths of the FMEA process, 7 of the 14 interviewees indicated that the facilitator was a strength of the process.

Defined Team Charge

The team's charge from the Patient Safety Committee did not include a specific process to analyze nor did it define the scope of the team and which processes the team should or should not analyze; therefore, the first meeting was spent for this purpose. The team chose to analyze the medication use process. Also, the team made the decision to perform both a process FMEA of the current system and a design FMEA of the new process with the new technology. This added considerable time to the entire FMEA process, but was necessary to understand the changes in the process that needed to occur and the process vulnerabilities that would not be fixed with the addition of new technology.

FMEA Execution

Training for the FMEA team members was provided through a half-day seminar on FMEA and human factors engineering concepts and an hour-long lecture on HFMEA™. Only one team member had prior experience with a process and design FMEA. In the interviews conducted upon completion of the FMEA process, 6 of the 14 members interviewed indicated that they did not have a good understanding of FMEA at the inception of the team. The team determined that the medication use process had six overall process steps: patient assessment, prescription, transcription, preparation/dispensing, administration, and monitoring. Five of the process steps (excluding administration) had a total of 22 sub processes identified. The administration process was much more complex with 3 major sub process steps (prepare medication for infusion, program pump, run infusion) that required the development of 5 further processes for primary, secondary and continuous infusions due to variation in IV medications and pump programming possibilities. The team repeated the administration process mapping for the new IV pump. Significant variations of practice were noted in many of the process steps based on the many different patient care areas (e.g., general care, ICU, pediatrics) and the team mapped only the most common variations due to time considerations.

The identification of failure modes was also time-consuming and challenging. One of the challenges was the availability of data to objectively evaluate the new IV pump and pump process. Data reviewed by the team to assist in completing the failure mode determination included internal information: pilot study data and medication error incident reports, as well as external information: ECRI data, list serve discussions (which needed to be verified), biomedical engineering quality assurance data and the product specification document. The level of detail in the failure modes and number of failure modes to consider was debated. Team members had concerns with listing failure modes that were not thought to have occurred, and considerable time was spent discussing solutions during the failure mode process, due to the action oriented health care team. Areas in the new process that were highlighted as high priority, problem areas included the appropriate placement of and correct use of the IV tubing, the infusion description display, pump usage during code situations and reprogramming the pump when transferring patients from the operating room or intensive care unit to the general floor.

The HFMEA™ hazard scoring system was used to assess failure modes (Table 1). Severity and probability were assessed to arrive at a hazard score. Each failure mode then proceeded thru the HFMEA™ decision tree to review criticality, control measures and detectability to decide which failure modes needed further action. Probability and severity were scored on a 4-point scale based on HFMEA™ definitions for the current process. A low-medium-high scoring system was used for the new process steps involving the new technology, as there was little to no information available to guide the team. In HFMEA™, detectability is scored differently than traditional FMEA; rather, it is answered yes/no as part of the decision tree analysis. The large number of medication administrations per day in the organization (about 10,000 per day) led to high scores for probability. The scoring of probability, with the top score of 4 representing failures that occur several times in one year, did not allow the team to differentiate scoring for failures that occur multiple times daily, daily, weekly, or monthly. Likewise, the dangerous nature of IV medications delivered incorrectly to a patient led to high severity scores. Therefore, most failure modes had high hazard scores (8, 9, 12, and 16) and most were not eliminated by the decision tree. All failure modes and causes that were not eliminated by the decision tree were moved to action and outcomes, the last step in HFMEA™. Identical process step failure modes that appeared in both process and design FMEAs were evaluated together.

Approximately 200 failure modes and related causes were evaluated. The team used the subgroups of training, policy and procedure, technology, environment and people to further categorize causes of the failure modes, which guided the team to solution building, eg. Causes of improper insertion of the tubing into the new pump were identified as lack of knowledge of proper insertion because of a different technique for insertion in the new technology (training), which led to a short-term training solution focused on exact insertion of the tubing top fitment (Table 2). The team also noted with this failure mode that the new technology 'allowed' for improper insertion of the tubing, something that the current pump did not allow, and identified a technology change solution as a long-term solution. Whenever possible, the team sought technology redesign solutions as a long-term solution with better reproducibility and duration of outcomes as well as recommending short-term systems change and end-user training. Recommendations for systems change were summarized and presented to Hospital leadership. Technology redesign solutions were shared with the vendor. The team was empowered to begin short-term solutions as soon as possible and also took advantage of hospital committees already in place to help with systems change and education (Nursing Practice Committee, Bar Code Technology committee, etc).

Organizational Factors

Many of the challenges described above relate to the newness of the FMEA process to healthcare organizations. The Patient Safety Committee chose the implementation of new technology for prospective risk analysis based on expert opinion that technology could lead to new errors in the system. However, it was not realized that the FMEA process would be so time-consuming and the original planned technology implementation date did not allow our team time to make process changes before technology training occurred. Also, even though the decision to purchase the new technology was made based on desired functioning, it was done before the FMEA which meant that the team could not consider a variety of technologies available on the market as solutions to particular failure modes and weigh which technology would be best suited for our processes in place to promote patient safety.

DISCUSSION

Due to the substantial time commitment and significant investment of time and resources needed, FMEA should be considered only on the healthcare organization's highest priority processes. Based on our experience performing a complex process and design FMEA involving technology, the following recommendations are made to guide other healthcare organizations as they perform these FMEAs.

The people and time resources committed to the FMEA process should be considered as important as the investment in the technology. Therefore, a complex FMEA should only be performed with experienced team members and a defined scope. Organizations should develop FMEA experts and an expert team facilitator. Super-users should be dedicated to the FMEA process. Ideally, the implementation schedule of the new technology should not be determined until the entire FMEA process is completed or near completion and the team should have authority to halt or delay the implementation based on their findings. Thus, the team should have a direct link for feedback to organizational leadership.

The VA HFMEA^{TM} process defined criteria to evaluate potential failure modes, however, these criteria may be viewed as a disadvantage because of their rigidity. In the problem prone, high risk IV medication administration process, the HFMEA^{TM} scoring method did not allow for minute differentiation of probability, severity and detectability scores and therefore made prioritization of failure modes and ability to follow the hazard score over time for improvement difficult. However, the goal of FMEA is to err on the side of safety and prevent or eliminate risk potential. The reality of healthcare processes remains. We have loosely coupled system designs with substantial variation in processes that contribute to numerous failure modes. Before the team scores failure modes, the scales used for the hazard score (HFMEA^{TM}) or risk priority number (traditional FMEA) should be reviewed and evaluation criteria should be established by team consensus.

Many authors recommend limiting the number of process steps in the FMEA, hence, limiting the number of failure modes and eventual action items (DeRosier, 2002; ECRI, 2002), however, the implementation of new technology in a process did not lend well to such limitations in the medication use process and despite the limiting of our FMEA to mostly the IV administration process, hundreds of causes were generated for over 50 failure modes.

Potential solutions to failure modes should explore alternative technology or technology redesign. In this case, it is essential to have biomedical and human factors engineers as an active part of the FMEA team to be involved with product design as well as to perform quality assurance and user interface and product safety testing on the technology.

ACKNOWLEDGMENTS

This research is funded by AHRQ Grant # 1 UC1 HS014253-01 (PI: Pascale Carayon, co-PI: Tosha Wetterneck). Tanita Roberts is currently affiliated with Ben Taub General Hospital, Houston, Texas.

REFERENCES

Burgmeier J. Failure mode and effect analysis: an application in reducing the risk of blood transfusion. *Joint Commission Journal on Quality Improvement.* 2002;28:331-339.

Capunzo M, Cavallo P, Boccia G, Brunetti L, Pizzuti S. A FMEA clinical laboratory case study: how to make problems and improvements measurable. *Clinical Leadership and Management Review.* 2004;37-41.

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. *Joint Commission Journal on Quality Improvement*. 2002;28:248-267.

ECRI. An introduction to FMEA. Using failure mode and effects analysis to meet JCAHO's proactive risk assessment requirement. *Health Devices*. 2002;31:223-226.

Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: building a safer heath system. Committee on Quality

of Health Care in America. Institute of Medicine. Washington, D.C.:National Academy Press;2000.

Stamatis DH. Failure mode and effects analysis – FMEA from theory to execution. Milwaukee, WI:ASQC Quality Press, 1995.

Wachter RM, Shojania DG, Duncan BW, McDonald KM (Eds.), Making health care safer: a critical analysis of patient safety practices. Washington, DC: Agency for Healthcare Research and Quality, 2001. AHRQ Publication 01-E0

Table 1. HFMEA™ Step 4 – Hazard Analysis of IV Medication Administration, Programming Pump

Failure Modes E: Administration E2: Program Pump E2b: Primary continuous infusion, using manual calculation	SCORING			DECISION TREE ANALYSIS			
	Severity[a]	Probability[b]	Hazard Score	Single Point Weakness	Control Measure	Detectable	Proceed?
Turn pump on – E2b(1)							
Battery dead	1	4	4	N	—	—	N
No power	4	1	4	Y	Y	—	N
Pump self-checks – E2b(2)							
Electrical mechanical failure	1	4	4	N	—	—	N
Push options button – E2b(3)							
Perform manual calculation – E2b(4i)							
Inaccurate calculation	3	4	12	—	N	N	Y
Incomplete process – no double check	3	4	12	—	N	N	Y
Incorrect weight	3	4	12	—	N	N	Y
No calculator	1	1	1	N	—	—	N
Enter rate – E2b(5i)							
Push incorrect key pads	4	4	16	---	N	N	Y
Misread order	4	4	16	---	N	N	Y
Enter volume – E2b(6i)							
Adjust volume based on assumptions – too much	2	2	4	N	—	—	N
Adjust volume based on assumptions – too little	3	3	9	—	Y	—	N
Push incorrect key pads	4	4	16	—	N	N	Y
Misread order	4	4	16	—	N	N	Y
Enter rate (instead of volume)	4	2	8	—	N	N	Y
Push "run" after verifying data entered – E2b(7i)							
No activation – "run" not pushed	1	4	4	N	—	—	N
Misread display	4	4	16	—	N	N	Y

[a] Severity: ranked on 1- 4 scale where 1= minor, no injury; 4 = catastrophic, death or permanent loss of function

[b] Probability: ranked on 1 - 4 scale where 1= unlikely, occurs once in 5 to 30 years; 4 = likely, happens several times in 1 year

Y = Yes, N = No

Table 2. FMEA New IV Pump – Preparation of Medication for Infusion, Loading Tubing into Pump

Step	Failure Modes	Severity	Probability	Score	Detectable	Proceed?	CAUSES						ACTIONS					
							Training	Policy & Proc	Technology	Environ	People	Notes	Training	Policy & Proc	Technology	Environ	People	L= long-range Others = short-term
Insert top fitment	Collar too high	H	H	H	Y	Y	X		X			Know what to look for	X		X			Highlight in training, including pictures
	Collar cocked	H	H	H	Y	Y	X		X			Know what to look for	X		X			Posters on units
													X	X				Rounds to check placement
															X			L – different colors for tubing sections
															X			L – technology to stop incorrect placement

H = High, Y = Yes