Adopting Failure Modes and Effects Analysis in the Healthcare Setting

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A MISTAKE IN THE WORKPLACE may not be a big deal in some professions, and often the mistake may only affect the person who committed the error. Some mistakes, however, can be far-reaching and can have potentially harmful outcomes. For example, central service/sterile processing department (CS/SPD) employees in healthcare facilities play a critical role in the facilitys infection prevention program, and any workplace errors in their environment can have serious repercussions throughout the facility.

When a mistake is made in a hospital CS/SPD, the typical response is to conduct a swift investigation, identify the person(s) responsible, initiate corrective action, perhaps conduct a brief training or retraining session, and then get back to business as usual. Depending on the error, this process may be sufficient; but when patient safety is in jeopardy, a different approach and a thorough review of current quality improvement processes may be necessary.

Yuma Regional Medical Center (YRMC) in Yuma, Ariz. is an exception to the rule. Our 328- bed hospital is the primary healthcare provider within a 180-mile radius. Having no competition in the area, one might expect that YRMC would have a somewhat relaxed attitude toward quality processes. This assumption would be wrong, however, because over the past 12 months, our medical center has initiated an extensive effort to incorporate Failure Modes and Effects Analysis (FMEA) methodology into our daily activities as a means to improve quality and reliability throughout the facility, and specifically to improve the quality of our patient care.

What is an FMEA?

FMEA is not new and has been used extensively worldwide. The methodology was developed by the National Aeronautical and Space Administration (NASA), where it was used to identify potential risks in programs and devices being developed. FMEA was later adopted by other industries, most notably the automotive industry, and is now a globally recognized critical step in the design and control of processes. In the healthcare manufacturing industry, FMEA is required by the Food and Drug Administration in the design and manufacture of all medical devices, pharmaceuticals, and contract sterilization. For example, a medical device would require FMEA to be performed in the manufacturing process, the actual use, and the application of the device. In recent years FMEA has become more widely used by Six Sigma practitioners and is being adopted in many industries.

FMEA can be performed in various ways and for various purposes, but it applies a consistent method, which is a systematic approach to identifying and analyzing what can go wrong, the probability of it going wrong, and the effect when it does go wrong. This way, events that can go wrong or can result in a serious outcome can be identified and prevented. FMEA focus areas fall into the following categories:

* System global system functions
* Design components and subsystems
* Process manufacturing and assembly processes
* Service service functions
* Software software functions

Recently, the YRMC Central Service/Sterile Processing Department (CS/SPD) had the opportunity to be actively involved in an FMEA process following an incident involving the release of items for patient care that did not successfully complete a steam sterilization cycle. Although this incident did not have any patient care consequences, the staff recognized that this type of error could be devastating to a department and could have serious short-term and long-term effects.

From a patient care perspective, an error of this type could result in a surgical site infection, or worse. From a department perspective, this error immediately results in the lost productivity, waste and expense necessary to retrieve and reprocess the effected items. Potential long-term effects would take the form of a loss of confidence by internal customers and a reputation tainted by the perception of poor quality service. Because the consequences of such an error can be complex and widespread, the CS/SPD staff wanted to ensure that this type of incident didnt happen again.

Conducting the Analysis

With the close guidance of our quality services department, which had been overseeing quality improvement processes in other direct patient care areas of the hospital, the FMEA process was initiated and carried out in the CS/SPD over a six-month period.

Phase One: Development of the Flow Chart

Phase One consisted of a 45-day process and was spent developing a flow chart of the entire YRMC instrument processing workflow, including a complete list of all activities within each area of the workflow. The flow chart began as a simple diagram, and evolved into an extremely detailed model that included all the steps involved with each activity in the workflow process.

At this stage in the process, all sterile processing staff members attended a one-hour weekly meeting that was dedicated to this project**.**

Phase Two: Development of the Failure Mode Model

After mapping out the instrument process workflow, the next 30 days were spent in Phase Two, which required identifying workflow areas where there was a potential for something to go wrong. In phase two, in order to identify these potential failure points, a more in-depth analysis of each point in the workflow was performed and a list of risk points (potential failure points) were identified and documented in a Failure Mode Model spreadsheet. Since each potential failure point in the instrument processing workflow could be associated with very different levels of concern and weight, the failure points had to be scored to determine their potential impact. Each failure point was scored in three separate categories according to the severity of the failure, the probability of a failure, and how detectable a failure would be. A score of 1 to 4 was assigned to each risk point identified in each of the three categories to determine the risk priority number (RPN). For each category, scores were determined based on the following criteria:

Severity   
1 = No problem (not severe)   
2 = Small problem slight concern   
3 = Problem concern   
4 = Very severe Probability   
1 = Remote (0-25 percent)  
2 = Uncommon (25-50 percent)  
3 = Occasional (50-75 percent)   
4 = Frequent (75-100 percent) Detection   
1 = Detection always occurs (75-100 percent)   
2 = Detection often occurs (50-75 percent)   
3 = Detection rarely occurs (25-50 percent)   
4 = Detection never occurs (0 -25 percent)

After each risk point was scored, the RPN was determined by multiplying the numbers in each category; S x P x D. The RPN could range anywhere from 3 to 64, depending on the risk level. The risk priority number was then used to set priorities and determine the action level of each potential failure mode.

Phase Three: Development of Action Plan

During Phase Three, the intensive process improvement work was set into action. Over a six-month period, the FMEA focus group narrowed from weekly meetings with the entire department to a team of five key team leaders. In order to ensure that all failure points were appropriately addressed, the team worked diligently to prioritize each failure point based on its risk priority number. Any failure point with an RPN score of 12 or less was addressed in routine in-service education programs. Failure points with scores greater than 12 were placed in the Action Items Follow-up document.

Once in the follow-up document, each action item was prioritized and the responsibility for each action item was assigned to one of the five team leaders. The team leaders then set target completion dates and were responsible for all activities involved with their assigned action items.

At the conclusion of activities for each action item, the team leader was also responsible for documenting measurements of effectiveness as part of the action items follow-up document.

FMEA in Action

The immediate area of concern that led to the initiation of the FMEA process was the steam sterilization workflow and protocol. In focusing on potential failure modes in this area, several were identified with risk priority numbers higher than 24. The action items within this area included:

1. Changing the sterilization load record to add documentation space for identifying implantable devices in the load and space to document if a biological indicator was included in the load.

2. Developing a load protocol for sterilizers (product mix, load contents, product sterilization parameter requirements and implant content, for example).

3. Reviewing staff scheduling for the second shift (from 2:30 to 11 p.m. at YRMC this is also the last shift of the day) to ensure that the last steam sterilization load of the day is started by 9:45 p.m., and initiating a process to ensure that a staff member is present to remove that last load when its complete.

4. Reviewing sterility assurance products currently available for use as a safety net to provide the sterilizer operator with an additional visual assurance that the sterilization cycle was successful.

Another interesting discovery during the FMEA process was in identifying instrument sets that the CS/SPD staff wanted to label as Priority One sets. These would include any set that contained an implantable device or any one-of-a-kind set. Surprisingly, the staff discovered that 224 out of 356 sets routinely processed belonged in the Priority One category. A decision was made to label these sets with permanent labels to alert staff members that these sets must be processed first. This change had such a visual impact that even surgeons began to inquire about the Priority One labels. Now the staff has an extremely helpful tool that they did not have before to ensure that they process these instruments before any others.

By making these simple work practice alterations, our medical centers CS/SPD has achieved a high level of assurance that the process failure they previously experienced will not reoccur.

The added benefit of using FMEA to address quality issues has been that the entire instrument processing workflow has been thoroughly analyzed and many process improvement initiatives have been implemented as a result. Although this analysis was conducted as a quality improvement project, FMEA has now become an ongoing work-in-progress and has firmly established a new quality process mind set for all CS/SPD staff members at YRMC.

Conclusion

Sterile processing professionals are committed to doing their part in providing quality patient care. The CS/SPD professionals at YRMC have taken their work to the next level; they have raised the bar with their efforts to find better methods to identify every possible scenario in which their processes could fail, developed solutions to eliminate these potential failures, and provided education or altered current processes to meet their quality improvement goals. The use of FMEA in the healthcare setting is a proven process and an invaluable quality improvement tool that should be considered by any sterile processing department committed to improving their processes.

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References

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