

# **Failure Modes and Effects Analysis of the Alaris Medley Infusion System**

Anthony Angelo  
University of Connecticut Health Center  
Clinical Engineering Department  
263 Farmington Avenue  
Farmington, CT 06030-1015

Healthcare facilities strive to provide a safe environment for patients and staff. Each hospital does what it can to improve patient safety. Though, even in the safest hospitals, adverse events can occur. It is the hospital's responsibility to take an active role in the prevention of adverse events. There are specific methods used by healthcare facilities to analyze a process and identify modes of failure. Failure Modes and Effects Analysis (FMEA) is one of those more widely used.

Failure Modes and Effects Analysis is a proactive approach in the prevention of unanticipated adverse events. The goal of FMEA is to identify ways in which a process can fail and redesign it to prevent or minimize the effects of such failures from reaching a patient. Root Cause Analysis (RCA), another method for analyzing adverse events, is used to identify the underlying cause of an incident that has already occurred. Rather than reacting to an adverse event, FMEA is a method used to identify and weed out problems before an event occurs.

Failure Modes and Effects Analysis can be broken into five steps. First, the topic of the FMEA must be identified and clearly defined. It is important that the analysis have a narrow scope such that managing the project does not become too complex. Topics may arise from issues experienced on the hospital floors or even by adverse events that were caught by clinicians before they reached the patient, also known as "good saves". Second, a multidisciplinary team must convene to perform the analysis. It is important that all parties that are involved or invested in the process be present. The third step is listing all of the steps in the process being analyzed. It is suggested to graphically describe the process. A flow diagram of all steps in the process and any sub-processes can be used to help the committee narrow the scope of the FMEA. Once completed, the committee could verify that all steps involved in the process being examined are represented.

The fourth step of the process is to conduct a hazard analysis. First, the committee must identify all modes of failure which can occur at each step in the process. Once the team has identified all the failure modes, they must score each under three categories: severity, probability, and detectability. Different forms of FMEA use different scales; some use a 1-4 scale while others use a 1-10 scale. The severity score examines the potential seriousness if a specific failure mode were to occur; the more serious the potential outcome, the higher the severity score. The probability score identifies the likelihood such a failure mode will occur; the more likely the failure mode is to occur, the higher the score. The detectability score signifies how easy it is for the specific problem to be identified; the harder it is to detect the problem, the higher the detectability score.

Once each of the failure modes have been scored, the values in each of the three categories are multiplied together to create the Risk Priority Number (RPN). This number represents the overall risk of the failure modes. The committee must then determine the criteria for which failure modes are serious enough to warrant corrective actions. Such criteria include any RPN score over a designated score or simply examining the top ten or highest scoring failure modes.

The final step in the FMEA process is the creation of preventative actions plans. The action plans are designed to either prevent the failure mode from occurring, institute safeguards to prevent the failure from reaching the patient, or to minimize its consequences. Actions plans should also include an individual or party, agreed on by the committee, who will be responsible for implementing any suggested changes in the process. Each action plan should be given a timeline or implementation date so that changes are made in a timely manner. Lastly, the committee must agree on a means to measure the effectiveness of the action plans. This typically results in a census or form of data collection to determine the level of compliance with the redesigned process.

The University Of Connecticut Health Center (UCHC) is required by The Joint Commission to perform at least one FMEA per year. The purpose behind this is to promote an active role in improving patient safety in accredited hospitals. The Alaris Medication Infusion System was chosen as one of their FMEA projects due to a number of reasons that have put the Alaris pumps in the spotlight. First, there is a planned software upgrade to the pumps. The new software allows for more reporting features as well as upgrades to the drug library itself. There has also been an interest in upgrading the system to possess wireless capabilities and to begin the use of secondary tubing sets. In all these cases, the clinicians would have to begin new rounds of training on the Alaris pumps. The author's involvement in the FMEA was to act as the team leader and coordinator.

The scope of the FMEA was limited to the medication delivery procedures of the Alaris infusion pump. The process included the setup and loading of required disposables, through the programming of the pump, and up to the removal of the IV tubing from the patient. Steps and procedures of medication ordering and patient verification before tubing setup were excluded from the FMEA. These processes are not directly related to use of the pump setup.

The committee chosen to examine the Alaris Infusion System included representatives from a variety of different departments. To provide expertise in the clinical use of infusion pump, three nursing representatives were present. Two were clinical nurse specialists, from Critical Care and Medical/Surgery areas, and a Critical Care nursing administrator. Also represented at the FMEA discussion were the Pharmacy, Nursing Administration, Nursing Education and Clinical Engineering. The representatives comprised all the necessary foundations required in the use of the Alaris system: training, clinical use and service.

Once the committee was formed, a list of the process steps was created. The steps included three sub-processes. The first sub-process is the set up of IV tubing for infusion, which involves spiking the medication bag, priming of the line, connecting to the patient and installing the tubing into the pump chamber. The next sub-process was the programming of the pump. This process divided into two separate paths. The pump instructs the user to decide if he/she wants to perform a basic infusion or a Guardrail infusion. A Guardrail infusion incorporates the smart pump safety features programmed into the pump by the Pharmacy, while basic infusion does not. The Pharmacy will program specific soft and hard limits for medications. If a clinician programs the pump outside a soft limit, it asks for a confirmation, and allows the clinician to override the alert. If a hard limit is broken, the pump will not allow an infusion until it is programmed within the limits set by the Guardrails drug library. The programming steps differ between these two paths. It was decided that the steps involved in each path should be separate and both should be examined. The last sub-process is the removal of the IV tubing from the patient after medication delivery has been completed. The steps in the process were reviewed by the clinical nurse specialists to verify their clinical accuracy.

The use of secondary tubing sets was also included in the FMEA in anticipation for their upcoming use. Currently, all infusions done at UCHC are through primary tubing lines. The use of secondary lines connected to primary lines for medication delivery would significantly decrease the cost spent on disposables annually. The incorporation of secondary lines has been put on hold until the Guardrails drug library can be updated to include this feature.

Once the process steps were agreed upon, the different failure modes had to be identified. The committee created a preliminary list by considering each step of the process and imagining how the step could fail. Some examples included the inability to locate a pump, programming incorrect infusion values with and without Guardrails, and possible free flow. Next, we examined the current training material used by Nursing Education for incoming employees. Failure modes identified from those materials included failure to prime the line and improper installation of primary and secondary tubing.

Potential mechanical failures were developed by Clinical Engineering. Such failures include rate inaccuracy, connector short-circuits, and sensor failures. The FDA Manufacturer and User Device Experience (MAUDE) database was examined to identify failure modes experienced at other hospitals. The search was limited to reports from the last three years. This search identified two failures: unexplained pump shutdowns and unanticipated infusions when the unit was turned off. Also identified in the FDA search was an important shortcoming of the system. One hospital experienced an event which the pump was unable to sense an engaged roller clamp on a secondary line. Failing to do so prevented any of the secondary medication to be infused, yet the pump had indicated the secondary infusion was complete. All of the preliminary failure modes were reviewed and agreed upon by the committee.

The committee then continued to score each of the failure modes on their possible severity, probability, and detectability using a one to ten number scale. Using the FMEA process, the severity score is scaled such that a score of one meant there would be no significant impact on clinical outcome. A score of three equals a mild impact, a five equals a moderate impact, a seven equals a significant impact, and a ten would mean the whole system would fail. The probability scale is scored by the frequency an incident would occur. A one means once in 100 years, three equals once every five years, five equals once every year, seven equals once a month, and a ten equals multiple times a day. The detectability scale is scored by how noticeable the failure is. A one equals very visible, three equals fairly easy, five equals moderately detectable, seven equals moderately difficult, and a ten means the failure is extremely difficult to detect or invisible.

The probability of failure modes relied mainly on the clinical nurse specialists who had front line experience with the pumps. Due to the range of medications infused, clarification into the severity section had to be made. If a patient did not receive a medication or was given an amount not intended by the physician, the severity of such a failure would depend on what medication was being infused. Some medications might not be critically important to the patient (i.e. fluids) and/or would not cause an adverse event if infused at an unanticipated way. Yet, in the cases of critical drugs, such events could mean injury or death. For the severity section, it was agreed upon by the committee to assume that medications being infused were condition critical and any under or over infusion could lead to adverse events.

After all of the failure modes were scored, the committee multiplied the three scores to reach each failure mode's RPN score. Action plans were to be created for the top ten highest scoring failure modes. The top ten highest scoring failures were: 1) failure to select correct pump channel (mix up of drug line and pump module), 2) selecting incorrect drug or dosage

from the drug library, 3) improper set up of secondary tubing, 4) mechanical rate inaccuracy, 5) confirming incorrect values under Guardrails, 6) infusion while the unit is off, 7) programming incorrect values without Guardrails, 8) secondary medication not delivered, 9) free flow, and 10) wrong patient connection site.

Once the top ten failure modes were identified, action plans were drafted to prevent or minimize their consequences. It was decided that one of the failure modes, mechanical rate inaccuracy, required no action plan. Clinical engineering currently performs preventative maintenance to all pump modules annually; the manufacturer's recommended interval. The action plan to prevent a wrong patient connection site involved both nursing and the pharmacy. Nursing will encourage the verification of a medication's correct patient connection site prior to infusion. Pharmacy will begin to use warning labels on non-IV delivered medications. Currently, they have begun to label epidural or intrascaline drips with "NOT FOR IV USE" stickers. Clinical Engineering will also coordinate another FMEA specifically on tubing misconnections.

Other than the previously mentioned cases, the action plans for the other eight highest scoring failure modes fell into two major categories: training and Guardrails. With the upcoming software upgrade as well as the incorporation of secondary tubing, Nursing Education was planning to educate the staff on the pumps new features as well as review procedures for secondary tubing. The failure modes related to free flow involve 1) infusion while the unit is off or paused and 2) free flow due to a failure of the tubing safety clip. The action plans for these failures require Nursing Education to emphasize the use of the roller clamp at key procedural steps. Engaging the roller clamp during paused infusions will prevent the free flow of medication into the patient, preventing possible overdoses. Clinicians are given the Cardinal-Alaris training materials when learning to use the pumps. To further promote following proper procedure, Clinical Engineering plans to purchase Cardinal-Alaris "Quick Guides". These laminated cards are attached to each pump and list the same procedural steps taught to the clinicians upon their initial training.

Nursing Education will also extensively train staff on the proper installation and programming of secondary infusion lines. Currently, the clinical staff have been given an in-service on the proper steps to set up a secondary line according to Cardinal-Alaris' training materials. Two of the failure modes relate to improper set up of secondary tubing (improper secondary line set up and pumps inability to sense occlusion on secondary). Prior to the software conversion training, Nursing will develop a standard procedure for secondary line installation. In-service training will be provided periodically for incoming staff. The procedural steps for secondary lines are also referenced in the laminated "Quick Guide" cards. In addition, Clinical Engineering will investigate the effects on flow of the secondary medication when the secondary bag is lower than the primary, when the line is occluded and when the roller clamp is engaged.

The last action plan is to prevent the mix up of drug lines and pump modules. During the upcoming training following the software upgrade, Nursing Education will remind clinicians of inherent safety features that prevent chamber mix up. These features include the fact the user is required to push a button on the desired pump chamber to select it for programming rather than using only the central keyboard. Also, the name of the medication being delivered will scroll across the pump when using Guardrails. The recommended implementation date for all training related action plans as well as the reeducation of the staff by Nursing Education will coincide with the software upgrade and will take place Spring 2008. The follow up measurements for the training related action plans will be done through walkthrough audits.

The three remaining failure modes are all related to the Guardrail system. Programming incorrect infusion values into the pump while not using Guardrails could have serious consequences depending on the drug. The purchase of the Alaris Guardrail system was made to improve patient safety. Without the use of the Guardrails, the Alaris pump has no added safety features. Nursing must encourage staff to use Guardrails for all infusions performed. With the upcoming software conversion, training must be done to educate the clinical staff on the new features available with the software. Clinical Engineering will hold training sessions for super users in the Pharmacy, Nursing as well as others in Clinical Engineering. The sessions will feature the new Alaris software's capabilities. To monitor the compliance of Guardrail usage, the Alaris pumps are to have their alert logs downloaded quarterly by Clinical Engineering. The alert logs contain data on the number of infusions with and without Guardrails.

As part of the action plan to encourage Guardrail usage, the author will fabricate a special cart to facilitate the manual downloading of Guardrail alert data by Clinical Engineering. Currently, pumps are brought to Clinical Engineering for download. The cart will allow pumps to be downloaded onsite, decreasing transport time and time away from the floors. Also, a new review process will ensure that the alert data for the hospital and specific key areas are monitored. The hospital's Medication Safety Group has agreed to spearhead the review of the Guardrail alert data along with the Nursing Administration Committee.

Pharmacy will be performing a revision of the drug library as part of an action plan. They will add any absent medications and distribute the proposed list to the front line clinicians to confirm that those limits match how drugs are administered. Also, the newest software version to be installed along with the updated drug library includes a section for fluids. The Guardrail alert data review will also act as a measure of how accurate the drug library is, through the number of basic infusions, overrides and reprogrammed infusions. As part of the software upgrade, newer medications will be added to the drug list and the limits programmed for medications will be congruent to how they are used on the floors. Certain areas perform many fluid infusions, which are not part of the drug library.

The last failure mode, confirming incorrect values, is also related to the accuracy of the drug library. If a nurse programs the pump with values outside the limits set by Guardrails, an alert page will be displayed. If the displayed values do not conform to the limits set in the Guardrails, the pump asks the user to confirm that the programmed values are accurate. If the Guardrail limits are not congruent with how the medication is used, the nurse may simply override the alert. The clinically inaccurate values programmed into Guardrails will eventually cause "Alert Fatigue" and the nursing staff will simply confirm alerts they receive without reviewing the data. This is a dangerous habit. Consequently, a user may input infusion values that will cause an adverse event, the alert page will be displayed, but the nurse will confirm it without looking because "it always happens". The library upgrade will be completed by the Pharmacy; it will be checked by front line clinicians for accuracy; and the software installation will be performed by Clinical Engineering. Since the FMEA committee's meeting, nursing managers have begun to encourage the use of Guardrails prior to the software upgrade.

In summary, the action plans to prevent the top ten failure modes identified by the FMEA committee revolve around in-service user training and the Guardrail system. Nursing administrators will encourage the use of Guardrails during all infusions. Nursing Education will begin a new round of user training on the Alaris pumps highlighting their new features and reviewing proper use. The training shall include the use of secondary lines and emphasize the use of the roller clamp in the prevention of free flow. The Pharmacy will work to update the

drug library to include all new medications and edit Guardrail limits to be as clinically accurate as possible. All action plans will be implemented by Spring, 2008 when the software upgrade shall be installed by Clinical Engineer. The author will fabricate the download cart to facilitate alert log downloads. The alert review process shall be managed by the hospital's Medication Safety Group along with the Nursing Administration Committee. The super user training coordinated by Clinical Engineering will take place before Nursing Education initiates their general user training.

A goal of every hospital is to provide a safe environment for its patients and employees. Performing an annual FMEA is an effective way of analyzing processes to identify shortcomings and areas of improvement. It shows that the hospital wishes to improve the environment of care by preventing adverse events from occurring rather than performing damage control retrospectively. Also, it is important to involve all parties invested in the FMEA process. Involving a multidisciplinary group allows all aspects of process to be reviewed from different points of view. The use of the FMEA process in healthcare facilities greatly improves patient safety and is a thorough and credible method in the proactive prevention of adverse events.