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ADVERSE INCIDENT REPORTING AND STAFF VIGILANCE LEADS TO EARLY IDENTIFICATION OF MEDICAL EQUIPMENT PROBLEMS

Mario R. Ramirez, P.Eng, M.A.Sc., CCE, Eric Niles, Navtej Virdi CBET(C) , Rocky Yang, and Greg Patterson, CBET(C), The Hospital for Sick Children, Toronto, Ontario, Canada

BACKGROUND

Adverse Incident reporting has become a standard of practice for many hospitals. At the Hospital for Sick Children in Toronto, we have a practice that when staff experience an event that could cause patient harm they are encouraged to create an Incident Report in our electronic Safety Reporting System. Once the incident report is entered, it generates a series of e-mails to people who need to be aware of the incident, and in some cases, take action. When a piece of medical equipment is suspected to be involved, Medical Engineering receives a copy of the Incident Report. In addition to the Incident Report, staff are asked to clearly identify the device that is suspected to be involved and set it aside so that Medical Engineering can assess the device. In August 2015, we received two incident reports where a Syringe Module stopped working while delivering a critical drug and gave a channel error message in the Paediatric Intensive Care Unit (PICU). Testing of the Syringe modules indicated that the module and system were working properly. A third incident occurred in the PICU and the QA leader for the PICU contacted Medical Engineering Team leader to review the three incidents and to identify possible trends with the syringe modules in other areas. During the investigation, it was determined that the Channel Error was only being experienced in the PICU. We received a fourth incident report with the same problem. Our Biomedical Engineering Technologists decided to perform extended testing by simulating similar infusion as reported by the PICU nurse. It was during this extended testing that the Technologists duplicated the Channel Error and decided to further investigate the root cause of the error. Upon opening of the casing of the Syringe Module and a thorough inspection, the Technologists discovered some traces of oxidation/rust in the drive mechanism that were the possible root cause of the syringe module failure. During the month of August, we continued to receive more incident reports with the syringe module Channel Error failure. This paper will cover the results of the investigation on the Channel Error, our findings of oxidation/rust on the drive train, the company's response and action plan to inspect and correct over 800 Syringe modules

INTRODUCTION

The Hospital implemented the Carefusion Alaris IV therapy system in 2008. Over 2,100 modules were placed in service: Alaris PC Units, large volume, syringe modules and PCA modules. In addition, we also implemented the Alaris Drug Error Reduction System (DERS). Changes to the drug libraries are sent wirelessly to the PCUs. The Medical Engineering department put the IV Pumps on a Preventative Maintenance program and performs the out of cycle repairs as needed. Over the past four years, Medical Engineering has not seen an unusual increase of repairs on the IV modules (Large volume or syringe modules).

PROBLEM IDENTIFICATION

In August 2015, Medical Engineering received a couple of syringe modules from the Paediatric Intensive Care Unit (PICU) indicating that they had stopped infusing while delivering a critical drug and gave an error message. The technologists proceeded to check the devices but were unable to duplicate the error. Functional checks were performed and a pm as indicated by the manufacturer. The syringe

modules would pass the inspection and be placed back in service. In the same month, a third incident occurred in the same unit and the QA leader for the PICU contacted Medical Engineering Team leader to review the three incidents and to identify possible trends with the device in other areas. During the investigation, it appear that the Channel Error was only being experienced in the PICU. We received a fourth incident with the same reported problem and our Biomedical Engineering Technologists performed not only the manufacturers recommended check, but also decided to perform extended testing by simulating similar infusion as reported by the PICU nurse. It was during this extended testing that the Technologists recreated the Channel Error and decided to further investigate the root cause of the error.

The Technologists opened the syringe module casing and upon thorough review of the internal components, they discovered that some elements of the drive train were showing signs of oxidation/rust which was the possible cause of the channel error message. Meetings with the QA leader of the PICU were held and it was agreed that further monitoring of the syringe modules was required. Nurses were alerted of the possibility of infusions stopping in the middle of infusions and were asked to report and isolate syringe modules that exhibited the channel error message. Every syringe module reported with the channel error message was inspected internally. While the extent of oxidation/rust was not the same with all the modules, they all showed signs of rust and hence the need to replace the drive train assembly.

PROBLEM RESOLUTION

Medical Engineering contacted the Canadian manufacturer representative and explained the problem encountered with the modules. The Canadian manufacturer contacted their headquarters in USA, and they indicated that no similar problems had been seen in other institutions. However, the Canadian manufacturer did express concern and offered to assist the hospital to determine the cause of the problem. To this end, they requested to send a few of the syringe modules that presented the channel error and they were going to investigate the possible cause in their labs.

In parallel of the review of the syringe modules by the manufacturer, our department placed an order for the Lower Housing Assembly (LHA), which is the part that was needed to replace the drive train component that exhibited the rust. We were informed by the Canadian representative that the LHA was in back order and they did not have a possible arrival date.

Meetings with the senior management of the manufacturer were held, to determine why there was a back order of the LHA, and we found out that the manufacturer was about to issue a recall of syringe modules that had been manufactured between March 2014 to July 2015. The manufacturer had initiated the recall because they had identified that the LHA supplied by a new company was not meeting their standards of manufacturing. As a consequence, they were not able to supply us with the requested LHA as they were being used to replace those IV modules affected by their recall.

At the Hospital, we also had internal meetings with clinical staff and senior management as there was an urgency to determine the extent of the problem, i.e., the number of syringe modules with the rust problem. We had over 800 syringe modules and all were used across the hospital. While not an unreasonable request, it placed Medical Engineering in a dichotomy. On the one hand, we could determine how many syringe modules were affected, but in the other hand, we were not able to repair them due to the back order of the main component. Regardless, it was decided that it was better to know the extent of the rust problem so that we could determine the best action plan.

Testing Phase

Once the decision was made that all 800 syringe modules had to be tested, the Medical Engineering team created an action plan that ensured testing of all the modules in the most efficient and short possible time. IV equipment is centralized and it is distributed to the floors when needed. They are cleaned by our Central

Services Department (CSD). Once the IV devices are cleaned, they are taken to Transport services for distribution throughout the hospital as needed. Meetings were held with Nursing Informatics, clinical representatives, CSD, transport and Medical Engineering to devise a plan to bring the syringe modules to Medical Engineering for testing. The Medical Engineering team assigned three technologists to perform the testing of the modules.

The manufacturer had produced their report of the syringe modules sent for their inspection, and confirmed the existence of rust in the internal components. They indicated that it was caused by fluid ingress that might have been used during the cleaning phase. Some of the modules exhibited a white powder-like residue due to fluid ingress. The manufacturer emphasized the proper cleaning techniques approved by the company.

With the manufacturer's information and our own findings, the technologists were asked to inspect the internal components of the syringe module. If there were no signs, or very minimal signs of fluid ingress, and the module passed the manufacturer's recommended PM procedure, they were to label the modules with a Green Dot. If the module showed signs of fluid ingress and passed the PM procedure they were to label the module with an Orange Dot.

The labeling of the syringe modules proved beneficial from the clinical point of view. Nursing personnel were instructed to use Green Dot - syringe modules, for critical medication infusions. Other medications were to be infused with the Orange Dot modules.

Testing of the modules revealed that on average 17% of the syringe modules were able to be labeled with Green Dots and the rest of the units were Orange Dot.

Collaboration

Conducting the testing of the modules for 800 units while at the same time having them being used on the wards, is a big challenge. A small task force was formed consisting of the following people:

- Nursing Informatics
- Clinical representatives
- Medical Engineering
- CSD
- Transport Services

The task force met every week to review the status of the testing, collection of modules and distribution of the modules to the wards. At the same time issues related to proper module cleaning and transporting of modules was discussed. Regular communication was held with the clinical leaders and Senior Management

The Canadian manufacturing representative for the infusion devices was very helpful and assisted the Hospital by providing loaner units and arranging for training personnel to come and teach our CSD personnel the proper cleaning techniques. Similarly, they were very helpful in advocating for the hospital for the prompt delivery of the LHA units that were back ordered.

As there were a large number of syringe modules that exhibited major ingress of fluid and the hospital could not obtain the LHA, it was decided that the Hospital had to acquire new syringe modules. Three orders were placed for a total of 325 new syringe modules. In mid-October the company expanded the recall of the syringe modules to include all modules including those that had been purchased earlier than 2014 [1]. Working together with the manufacturer we were able to obtain some of the LHA parts that were back ordered. At the same time we had to arrange for the company to come and perform their inspection and remediation of the recalled devices. The majority of the remediation by the manufacturer was completed by December, however, we still had a couple of days in January when the manufacturer's technologists came to continue the remediation process.

CONCLUSION

Early identification of potential failure trends with the syringe module was pivotal in ensuring that patient care was greatly unaffected. Working together with the clinical team, nursing informatics, CSD, Transport and Medical Engineering, the Hospital was able to address an issue that affected all units across the hospital. Effective collaboration with the manufacturer proved beneficial as they were great hospital advocates within their organization. The collaboration helped us in obtaining further training for CSD and transport personnel. Furthermore, this collaboration ensured delivery of the parts that were back ordered and prompt intervention to address the subsequent recall of syringe modules.

The number of safety reports was greatly decreased after the remediation process was completed as can be seen in figure one below.

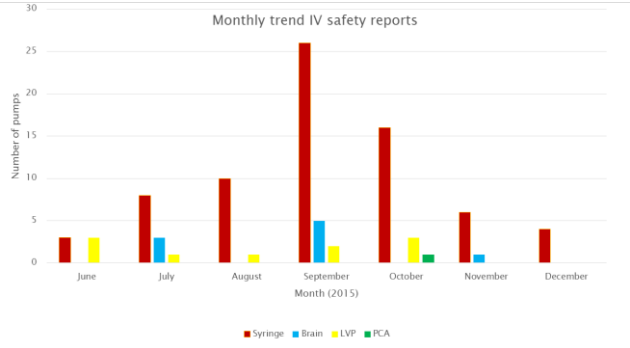

Figure 1: Monthly Safety Reports for IV Devices

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REFERENCES

[1] CareFsion, Urgent: Medical Device Recall Notification, Alaris Syringe Module (Model 8110), Oct 19, 2015.