Quality Improvement Project: IV Pump Corrective Repairs

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Abstract— **The Ottawa Hospital is a tertiary academic teaching hospital comprised of three campuses and greater than 1,200 care beds. The hospital has more than 1,860 Baxter Sigma Spectrum large volume infusion devices in service. Data analysis of the large fleet revealed approximately 2,100 hours of corrective repair per year at a cost of approximately $200,000 per year in repairs. Corrective repair details also converged upon 3 failure types: AC Adapter, Battery, and Pumping issues. We propose a few quality improvement initiatives focused on the failure types to reduce the number of corrective repairs and provide greater pump reliability and patient safety.**

Keywords— **Quality Improvement, Infusion Pump, Corrective Repairs**

I. Introduction

Infusion pumps (IV pump) are one of the most comprehensive and in-demand medical devices in any hospital. They control the delivery of medication into a patient's body. Any failure of the pump during use could be high risk for the patient. New infusion pump models, called "smart infusion pumps", control infusion rate based on the pump drug library, thereby increasing patient safety. Despite these improvements, regular maintenance should be performed to ensure the reliability of the pump while used on a patient.

The Ottawa Hospital (TOH) is a tertiary academic teaching hospital comprised of 3 campuses, the Civic Hospital, the Riverside Hospital, and the General Hospital. Together these hospitals provide greater than 1,200 care beds. As such, there is an incessant demand for IV pumps. In 2015, TOH partnered with Baxter International (Deerfield, Illinois, USA) to replace the fleet of IV pumps with the Sigma Spectrum (35700BAX2 Version 8) large volume infusion pumps. These pumps are a single pumping channel smart pump equipped with standard drug error reduction library and wireless capabilities. These pumps are used ubiquitously in all care areas of TOH.

A large institution such as TOH with over 1,860 IV pump is in a unique position to see common problems converge on poor design aspects. Herein, we provide a glimpse of some of the observed failures, an assessment of data and our proposed Quality Improvement project with respect to IV pump corrective repairs. The methodology used in this quality project is one of the tools available in Quality Improvement, going through five phases to detail correctly the problem, the action and the results. This tool is called DMAIC for Define, Measure, Analyze, Improve and Control.

II. Define

The challenges at TOH started with noticing many failed batteries due to liquid infiltration and failed AC adapters. The Biomedical Engineering Team have been tracking these failures and it became a daily occurrence to see broken devices on the incoming shelf in the Biomedical shop. This prompted the team to investigate the Computerized Maintenance Management System (CMMS) data to determine how many corrective repairs were done annually, and how these numbers have changed over the years. This investigation also enables a calculation of how much these repairs have cost the organization year over year. Summarizing this data and seeing the upward trend of corrective repairs helped the team contextualized the importance of this subject. It also allowed for the team to see the numbers at an organization level, throughout TOH, instead of at an individual hospital level yielding a clear picture of the evolution of these repairs.

The aim of this project was to look at the available data in our CMMS to find out the most common problem with the IV pumps and try to implement improvements to reduce the number of corrective repairs (See Figure 1).

The objective was that by adapting the way the maintenance is done and by implementing improvements on the fleet of IV pumps, the rate of pump return could be reduced by 50% within two years.

At TOH, IV Pumps are not on a Preventive Maintenance (PM) schedule because of their quantity, the fact that they are hard to find and hard to get access to in clinical areas.

III. Measure

It was observed that a high rate of IV pumps were returning for repair every month and considerable time was spent by technologists fixing them. Nobody had quantified how much time was spent corporately on IV pumps.

Using the data from the Corrective Repairs (CR) in the CMMS we analyzed the work orders on IV pumps corporately to extract three main information:

- Technologist hours: the quantity of time spent to repair IV pump
- Failure Type: the reason why the IV pump is coming for repair
- Costs: the costs related to parts or service

A. Technologist Hours

In 2019, the average time spend per month on Corrective Repair (CR) for IV pumps at TOH was 174 hours. In 2020 until August, this number went up to 244 hours. For 2019, that represents a total of 2,099 hours of CR work on IV pumps (See Figure 1). The forecast of the total number of hours in 2020, with data until August only, will be 2,928 hours, that represents a 40% increase. Using a typical benchmark of 70% technologist productivity [1], that represents approximately 1.81 Full-Time-Employee (FTE) for 2019 and would be forecasted at 2.5 FTE for 2020.

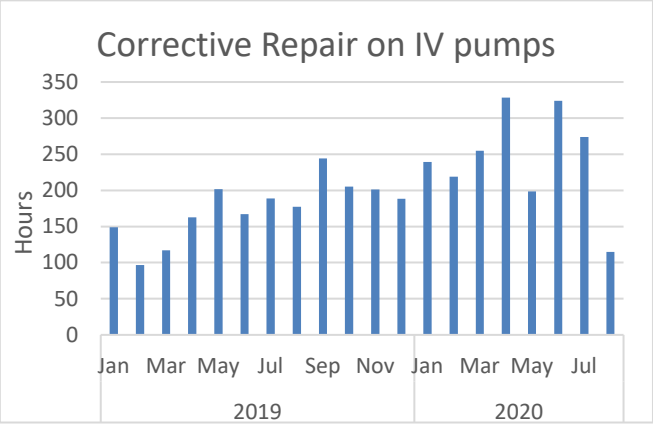

Fig. 1 Corrective Repair Hours by month at TOH

B. Failure Type

Since failure codes are not used to categorize work orders in the CMMS, different failure type had to be found manually by going through each work order. For that reason, the data from the Civic campus of TOH was assessed as a reference. Common failure types in these 1,500 WO, from January 2019 to August 2020, have been categorized into 3 categories (see figure 2):

- AC adaptor: the power adaptor is broken, and the battery cannot recharge
- Pump: any other issue related to the pumping function of the device
- Battery: any issue related to the battery itself, pins, connector, infiltration

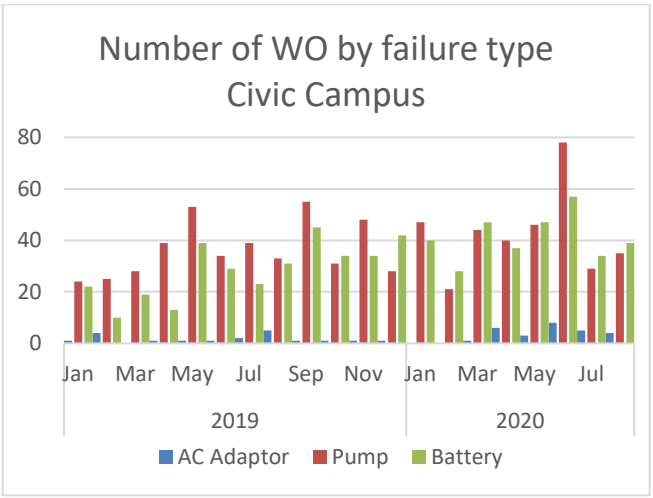

Fig. 2 Count of Civic campus Work Orders by failure type

C. Costs

Even though 2019 and 2020 WOs were analyzed to determine failure types, the yearly costs have been analyzed since 2017 and compiled in Figure 3. It was found that 2 years of data was sufficient to determine failure types conclusively. For the repair costs, 4 years of data clearly shows the increase in the number of problems year over year related to the age of these devices.

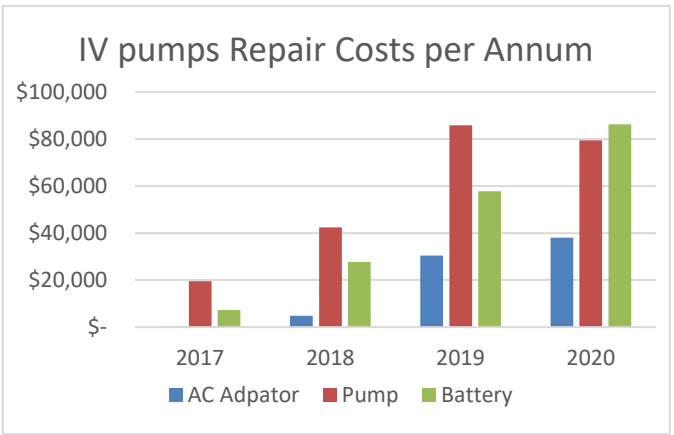

Fig. 3 Repair Costs per Annum by Failure Type at TOH

The type of failure shows an increase over time in the number of work orders directly related to the battery module and the power adaptors. The total cost for parts and external repairs related to these IV pumps in 2019 was $175.000. Costs from January-August 2020 summed $203,000 and the forecast for end of 2020 would be $305,000. In one year, this represents a 75% increase for the repair's costs.

IV. Analysis

The Analysis phase consisted of investigation of the different problems seen as well as the research and testing of different solution.

If PMs were performed on over 1,860 IV pumps, considering an average time of 1 hour per pump, that would add up to over 1,860 hours of PM work per year. In addition to the PM time, there would still be time required for corrective repairs since the PM would not be able to catch all the defect, such as liquid spills or misuse. Considering a repair to PM ratio of 0.25 for this type of pump it would bring the total time spend on IV pumps over 2,300 hours, an equivalent of 2 FTE.

Another strategy could be a modified PM procedure, limiting the PM tasks to the inspection of the pumps focusing on primary failure types observed. Namely inspect and clean batteries, check the connector pins and gasket, control the power adaptor.

Due to limited available resources in the Biomedical Department, a PM strategy has been put to the side. The decision was taken to look at the different possibilities to improve the pump design based on the failure type.

A. Pump

Because of internal repair limitations by the manufacturer related to the pumping function, pumps are sent back to the manufacturer for the majority of the cases where a pumping mechanism failure occurs. A decision was made not to further investigate this category of failure in this quality improvement project since they are not repaired in house. This could be part of a subsequent project evaluating the failures types from the manufacturer's reports.

B. AC Adapter

Broken AC adapter have been inspected and it was found that they tend to break at the exit of the translucent strain relief. Due to the movement of the cable that is not rigid enough and the possibility for the user to pull the plug by the cable making the connection between the plug and the cable the weak spot.

A first solution to minimize cable bending was tested with the addition of heat shrink wrap around the cable to provide greater rigidity at the failure point and restrict bending. This first solution did not yield good results, since it was transferring the problem down the length of the cable and it made it less user friendly for clinical staff having a rigid cable. A decision was made to go with a simpler solution. A loop was made with the cord and was attached to the adapter with a cable tie (aka zip tie) to standardize the curve of the cable.

C. Battery

The battery module revealed a few design problems. The battery module of this IV pump is connected at the back of the pump and clips in at the top of the pump. The battery clip is not waterproof enabling liquid infiltration inside the battery module itself. The battery module case is assembled without any gasket between the 2 halves. The clip retaining the battery against the pump is not tight enough resulting in gap between the battery and pump allowing liquid infiltration between the battery contacts and the pump pins. IV pumps are located right under the IV bags, and any leaks before or during manipulation of the bag result in liquid dripping and spilling on the pump below. If some liquid infiltrated inside the battery case, it could damage the battery itself or the circuit board and result in components burning (See Figure 4).

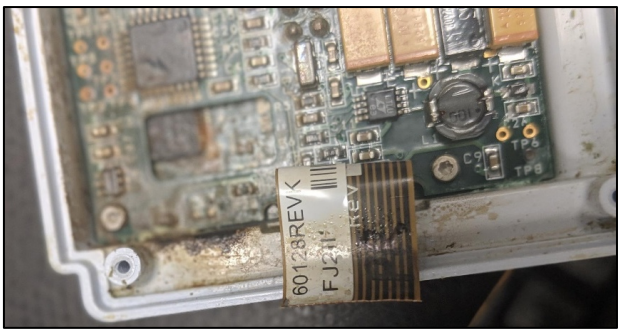

Figure 4 Failed Internal Battery due to liquid infiltration

The battery itself went through at least two improvement projects by Baxter, the first one, implementing a gasket between the 2 halves of the battery module to limit any infiltration. And the second one being released in November 2020, with a new battery module geometry (model 36010) with 2 antennas and a new tighter clip improving the battery contact with the pump case as well as new material for the battery contact to minimize galvanic corrosion. In addition, a transparent rectangular tape was added to cover the clip in an attempt to mitigate liquid infiltration inside the older model of battery module through the clip. If liquid flows between the pump case and the battery module, it can affect the movement of the pump pin making contact between the pump and the battery as well as corroding the contact plates (See Figure 5).

Fig. 5 Fluid Invasion between Pump Case and Battery Module

Originally, a gasket was in place at the back of the pump case around the contact area of the battery to avoid liquid infiltration in this sensitive area. With time, heat and pressure from the battery/pump interface the gasket ends up being completely flat and hard and does not offer a good barrier against fluid anymore. Island Health in Victoria, BC, shared their experience with similar issues on Baxter IV pumps in the CMBES Newsletter of March 2019 [2]. The Biomedical team at TOH contacted them to get further information about the issues they experienced. The suggestion that they made after some testing was to replace the existing gasket at the back of the IV pump with a foam gasket that would offer better resistance and, being slightly thicker would improve the surface contact (See Figure 6).

Fig. 6 Redesigned Island Health gasket (L) and Baxter gasket (R)

Through discussion with Island Health staff it was noticed as well that they use a screw to maintain the battery module tighter to the pump case (See Figure 9). This would prevent any loss of contact from the battery as well as limit liquid infiltration through the gasket.

After some testing with the new gasket and the screw in place there was still a gap between the battery module and the pump case. To limit additional liquid intrusion, a second barrier with similar foam gasket was installed in an angle on the back of the pump case (See Figure 8).

V. Improve

The improvement phase consisted of applying the different solutions to the problems from the Analysis phase to the fleet of pump. Here are the different additional steps taken during an IV pump maintenance at TOH.

A new foam gasket was installed to replace the original one. This one would be installed as high up as possible to ensure proper sealing next to the pins.

Fig. 7 Installation of a new foam gasket

An additional barrier was installed with similar foam gasket higher up on the back of the pump to ensure proper tightness of the battery module to the pump case.

Fig. 8 Installation of a second gasket barrier

A screw was installed on the older model of battery module to keep it tight on the pump case.

Fig. 9 Installation of a screw to lock the battery module to the pump

A rectangular tape cover was installed on top of the battery clip to avoid liquid infiltration inside the battery module.

Fig. 10 Installation of a tape over the battery lock

A loop was made with the AC adaptor cord to control the angle of the cord and limit tension on the weak point.

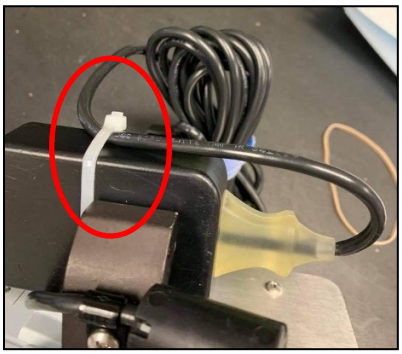

Fig. 11 Installation of a loop in the power cord

VI. Control

The Control phase was not completed at this time for this project. This phase will consist of reviewing the data showed on the Measure phase and compare the trends to asses any changes in the return rate of the IV pump. To be able to see a major impact on the trend, most of the pump would have to have gone through this improvement and we believed it could take TOH up to one year.

VII. Conclusions

The Ottawa Hospital has performed a Define, Measure, Analysis, Improve and Control Quality Improvement Project for the Baxter Sigma Spectrum (35700BAX2 Version 8) large volume infusion pump. We propose a few quality improvement initiatives focused on the 2 main failure types to reduce the number of corrective repairs and provide greater pump reliability and patient safety. Future results will be published after completion of the Control part of the Project.

The next steps that have started to be looked at are how to improve the battery management knowing that most of the batteries are by the end of their life of 5 years/500 cycle.

This project and especially the Measure phase show the importance of repair documentation in a CMMS. Once this data is extracted and analyzed, it is possible to see a problem at a higher level, corporately over 3 campuses, and take action based on the trends.

An improvement in the CMMS that could have helped this project would be to have failure codes entered directly in the Work Orders to determine trends based on the type of failures. This work had to be done manually in this project by seeking the information in each Work Order.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Disclosure

The views, observations and opinions expressed in this article are those of the author alone and do not necessarily represent the views or opinions of Baxter International.

References

1. Mandot, Payal; Ibey, Andrew AM Award-Winning Paper, Journal of Clinical Engineering: 10/12 2020 - Volume 45 - Issue 4 - p E5-E15 doi: 10.1097/JCE.0000000000000434
2. CMBES Newsletter March 2019

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