



WIRELESS SMART INFUSION PUMPS: A PROPOSED CONTINUOUS QUALITY IMPROVEMENT DATA ANALYSIS PROCESS

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INTRODUCTION

Infusion pumps are examples of a medical device that are used to administer fluids, nutrients and medications into a patient's body in a controlled manner.¹ They are affiliated with medication errors that can lead to severe harm or death and increased costs to the health care system.² According to data collected from 850 US hospitals in 2008, 58% of parenteral medication errors occurred during their administration, and 79% of harmful errors happened when medication was administered intravenously.³ Moreover, the FDA received 56,000 reports of adverse events between 2005 and 2009 associated with the use of infusion pumps across several brands and models, including numerous injuries and deaths.⁴

In February 2014, a tertiary care hospital in Ontario, Canada replaced its pump technology, Colleague CXE volumetric infusion pumps (Baxter), with the Spectrum Generation 2 Infusion System (Baxter) across all clinical care areas (CCAs) throughout the hospital as the currently used technology was approaching the obsolete phase. Prior to the go-live date of the new pump system, nurse educators were responsible to ensure that all nurses were trained, and they were the point of contact following the training sessions. The Biomedical Engineering Department also received service training from the manufacturer.

The Spectrum smart infusion pumps have Wi-Fi capability, creating the ability to update drug libraries and associated limits, and providing utilization data that can be uploaded onto a data server wirelessly.⁵ These data typically are referred to continuous quality improvement (CQI) data. The Pharmacy Department initially created the master drug library (MDL) in an interdisciplinary fashion and continues to maintain the MDL. The MDL is a software tool where the hospital pharmacy stores information on all IV and epidural drugs, as well as associated CCAs and infusion parameters for each drug entry.⁶

The main objective of our study was to design a CQI data analysis process to monitor dose error reduction system compliance and identify drugs with a high frequency of hard limits attempted. Soft limits prompt users to reconsider a predetermined drug dosage but permit them to select the dosage, whereas hard limits prevent users from proceeding with a dosage outside of the hard limits.⁷

METHODS

Our design of the CQI data analysis process was based on the Define, Measure, Analyze, Improve, Control (DMAIC) Principles. The DMAIC principles is a Six Sigma continuous improvement methodology designed to define objectives, gather data, conduct the appropriate analysis and investigation, identify corrective or improvement actions, implement

improvements and continue to monitor the process.⁸ This process can be adapted to assess DERS compliance and MDL effectiveness with the intent to improve clinical practice and MDL content.

The hospital's Safe Medication Practice Committee (SMPC) members agreed to review the Dose Error Reduction Software (DERS) compliance and the frequency of the hard limits attempted on a quarterly basis. A DERS compliance of less than 95% would trigger an investigation to determine the cause and identify and implement corrective actions to increase the compliance for the next cycle. Also, the committee was interested in the top five drugs with highest number of hard limits attempted compared with the total number of hard limits attempted across the hospital and for each CCA.

RESULTS

CQI Data Analysis Process to Monitor Performance of the Wireless, Smart Infusion Pumps

The proposed CQI data analysis process framework was adapted from the DMAIC principles⁸ to help inform the performance assessment of the new wireless, smart infusion pump system. Elements of the framework consist of defining the hospital standards for DERS compliance across all CCAs (i.e., 95% or greater) and identifying the top five drugs with the highest frequency of hard limits attempted, a review and analysis of the CQI data reports, investigating and developing corrective action plans, follow-up with the CCA(s) to ensure the implementation of the action, and regular monitoring of the data.

Figure 1 outlines the steps in the CQI data analysis process to assess the performance of the new wireless smart infusion pump system at the hospital.

The Biomedical Engineering Department would produce the CQI reports on a quarterly basis, and the Pharmacy Department then would review them to evaluate the DERS compliance and the frequency of hard limits attempted overall and by CCA. If DERS compliance is

below 95% in any of the CCAs, the Pharmacy Department would commence an investigation on the cause(s) of low compliance with the most appropriate stakeholder (e.g., nurse educator, physician, etc.) followed by the development and implementation of corrective actions in the CCA. The top five drugs with the greatest number of hard limits attempted per CCA also would trigger an investigation and appropriate actions. These actions can consist of education sessions for the pump users or an update to the parameters of specific drugs in the MDL that more accurately reflects clinical practice. The Pharmacy Department then would send the updated MDL to the Biomedical Engineering group to be uploaded wirelessly on all pumps in use. Biomedical Engineering would then monitor pump MDL receipt confirmation level through the pump application software. Pumps that are not showing confirmation of new MDL receipt can be easily identified and located to ensure that the new MDL was downloaded onto the pump.

This process would allow users to reflect on the results and communicate their insights on the daily ease of use to the nurse educators and the Pharmacy Department. A closed loop flowchart with a feedback system can facilitate the continuous monitoring of the CQI data and to implement required changes to improve the performance of the pump, as well as any adjustments to the CQI data analysis process, as required.

Planned Evaluation of the CQI Data Analysis Process

Following the implementation of the CQI data analysis process, a study is planned to measure its effectiveness on monitoring the DERS compliance and top five drug with the highest frequency of hard limits attempted the hospital and by CCA, and to assess the acceptability of the CQI data process by the hospital staff.

We plan to conduct a pre- and post-study to measure the effectiveness of the CQI data analysis process to monitor the DERS compliance and the frequency of hard limits attempted for specific drugs at the hospital. In addition, we will interview the staff in the Pharmacy and Biomedical Engineering

Departments, nurse educators, and physicians to inquire about their perception of and experiences with the CQI data analysis process and solicit information about suggestions for improvement.

We will use descriptive statistics to present the monthly DERS compliance for the pre-implementation and post-implementation periods. As well, we will calculate the proportion of hard limits attempted by drug over the total number of hard limits attempted across the hospital and by CCA for the study period using the McNemar test for paired data. Logistic regression analyses will be conducted to measure the association between specific factors with the proportion of frequency of hard limits attempted per drug versus the total number of hard limits attempted.

Interviews with hospital staff, who participate in the process, will solicit their acceptance of the process and their suggestions for improvement. The analysis of their responses will focus on a detailed description of emerging themes to identify the overall impression of, the strengths and challenges with, and strategies to enhance the CQI data analysis process to support its sustainability at the hospital.

DISCUSSION

The new wireless smart infusion pump system incorporates a comprehensive MDL and captures CQI data stored on the data server as part of the hospital's information system. Routine reviews of the CQI reports can guide the education sessions and MDL updates to enhance their clinical applicability and DERS compliance.³ Importantly, the smart pump technology automatically captures data on alerts, the medication administered, the initial dose programmed, and the user actions, the CCA, physical location of the pump, and the date and time of each action. These data are sent through the wireless connectivity to the Sigma Gateway Server that resides on the hospital's information system network.⁹ The information provided in pre-formatted reports can help to identify high risk practices, compliance with the drug library limits, medications with the highest occurrences of errors, the number of averted errors by

identifying near misses, and dosing limits that are not aligned with clinical practice.⁹ The identification of incorrect safety limits can help to inform the drug library updates and to assess their utilization and usefulness in averting errors.¹⁰ With the previous Colleague pumps, MDL updates were completed manually by a biomedical technician, which was a very challenging task given that these pumps were mobile and were hard to locate.

One important challenge with the CQI data analysis process is the lack of information on the patient profile. The hospital has not implemented yet the Positive Patient Identification technology for drug infusions. The individual drug dosage limit alerts, therefore, cannot be linked back to specific patients, so there is no patient context within the CQI data to supplement the analysis.^{11,12} An integration of the wireless pump system into the hospital electronic medication administration record would allow the programmed dose to be compared to the patient's prescription and help to investigate if an adverse drug event occurred.³ Moving forward, data captured in the new pumps will facilitate the close monitoring of compliance and soft and hard limits events by CCA and drug in the future. Data analyses at the hospital needs to be prioritized, but the Biomedical Engineering Department currently lacks the human resources dedicated to this task

Future iterations of the proposed CQI data process can incorporate a review of the top five drugs with the highest frequency of soft limit events by CCA. Data on the user experience can guide the design, purchase and appropriate use of the medical device.¹³ Research that incorporates a human factors evaluation would also help to better understand any risks in undermining the benefits demonstrated in this study if users choose to opt-out of the drug library. Interviews with the users or observational analyses to watch the user behaviors can provide valuable insights on why differences in DERS compliance exist in some CCAs. Further investigation is required to understand the reasons for user behaviors and how best to address them to achieve a culture of safety among the users.¹¹

CONCLUSIONS

CQI data can provide insights on MDL updates necessary and education opportunities to improve and maintain compliance and reduce the frequency of soft and hard limit events. The success of both the implementation of the new technology and the proposed CQI data analysis require open communication and detailed coordination in numerous departments across the hospital, including the CCAs and the Pharmacy and Biomedical Engineering Departments.

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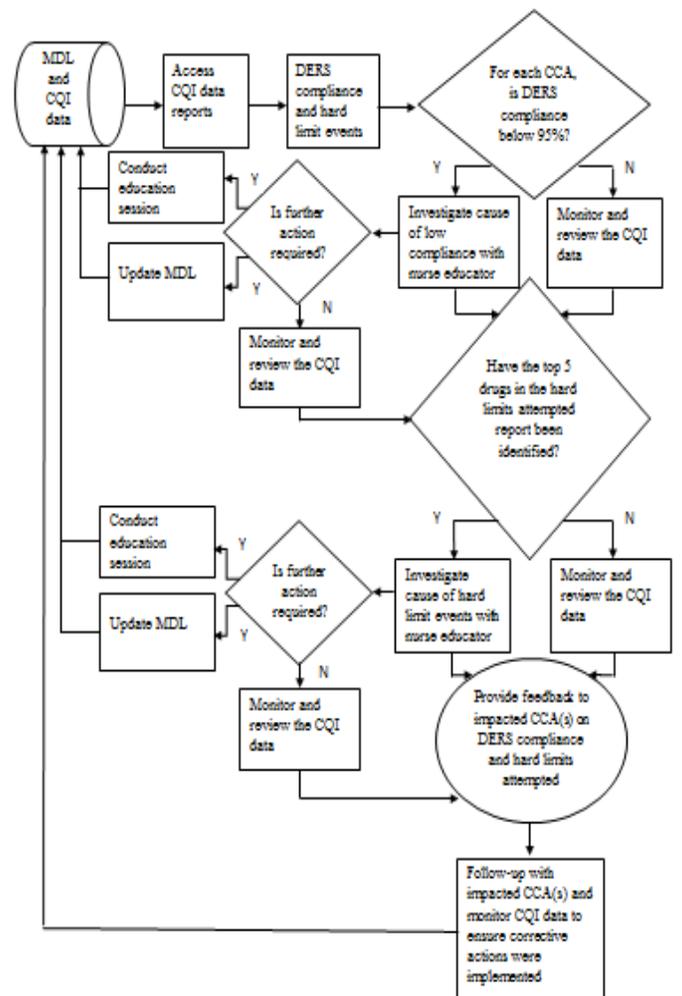


Figure 1: CQI data analysis process to monitor the performance of wireless, smart infusion pumps