A CASE STUDY: GENTAMICIN HARD LIMIT EVENTS AND FOLLOW-UP ACTIONS IN SMART INFUSION PUMPS

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INTRODUCTION

An infusion pump is a medical device designed to automate delivery of set amounts of drugs or other fluids into a patient over a period of time. Drug administration errors can be related to entering an incorrect dose or infusion time. A report by the Institute for Safe Medication Practices Canada (ISMP) analyzing incidents in pediatric health centers determined that pump programming was a contributing factor in medication incidents, including issues such as decimal misreading, unit confusion, and entering wrong dose [1]. A secondary analysis on MEDMARX data (an adverse drug event reporting system) found that 5.2% of reported errors were due to improper programming of infusion pumps [2]. A report on pediatric error prevention suggested smart infusion pumps and drug libraries as a means for error prevention [3].

Smart infusion pumps, the latest generation infusion pumps, guide users in programming the pump, based on drug libraries. A drug library specifies drug dose and rate ranges that cannot be exceeded (hard limits) and ranges that are not recommended for normal use but may be administered if the user confirms the entered infusion values and overrides the alert (soft limits). Previous studies on smart infusion pumps indicate that drug errors are detectable by the drug library; however, drug error rates were not reduced if users failed to comply with the drug library [4, 5].

The objective of this paper is to highlight the value in a smart pump system, and to find ways to improve its use for reducing hard limit events that may be a contributing factor in compliance. Observing hard limit event parameters and follow-up actions may give insight into factors that cause and lead to hard limit events. As initial work, a drug with a high hard limit rate, gentamicin, was followed for a year (August 2011 to August 2012). Analysis showed that the drug library detected programming errors and that hard limit events may be caused by wrong drug option selection for cases where the drug is listed several times under different labels (slightly modified labels).

BACKGROUND

Smart Infusion Pump at CHEO

Data for this research were obtained from the Children's Hospital of Eastern Ontario (CHEO, Ottawa ON, Canada). In December 2010, CHEO deployed 185 units of Smiths Medical's Medfusion 4000 syringe smart infusion pump (Smiths Medical, St. Paul MN, USA; Figure 1). CHEO is the first site in Canada to adopt the Medfusion 4000. This research was approved by the CHEO Research Ethics Board and Carleton University Research Ethics Board. Currently, infusion devices are not linked to specific patient identifiers or health records.

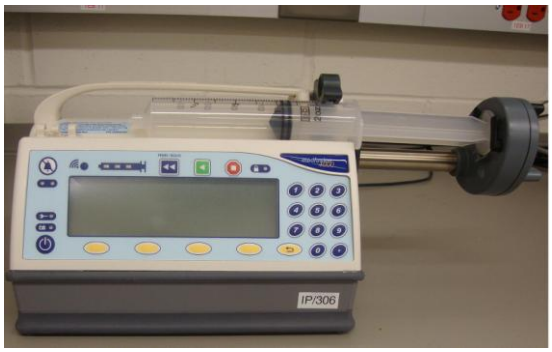

Figure 1: Medfusion 4000 infusion pump

Medfusion 4000 Infusion Pump

The Medfusion 4000 device server is part of the PharmGuard Server software and has report generating capabilities that provide information to clinicians on the usage of the pumps [6]. Safety event reports give information on hard limit and soft limit event counts for every drug in the library. Event history reports present all pump events (e.g., hard and soft limit events, alarms, library updates, and infusions) in chronological order with details (e.g., infusion dose, infusion time, and alarm triggers) associated with the event. The event history report allows a review of pump programming including programming that led to a hard limit. Follow up interventions are also tracked in the event history log.

The drug library at CHEO categorizes all drugs into nine separate profiles, largely based on the departments in the hospital. Profiles make it easier for a clinician to find the drug when setting up an infusion. Profiles also allow pharmacists to set different limits for the same drug in different profiles; for example, narrower drug dosing range limits are programmed for neonatal intensive care.

The "General/Peds Surgery" profile was selected for this study because it had the highest total infusion and total hard limit counts for gentamicin. "General/ Peds Surgery" is the main profile used by CHEO's three largest inpatient units which encompass about 54% of the hospital's total inpatient bed capacity of 167 beds. Gentamicin is an antibiotic used to treat respiratory, urinary tract, soft tissue or hard tissue infections. The main risk of gentamicin administration is vestibular function damage leading to hearing loss and loss of balance. Renal function damage is also a risk, when combined with other drugs. Gentamicin is normally administered three times a day; however, a larger dose can be given once a day. Allowable dosage ranges are lower when it is administered multiple times a day. For this reason, gentamicin is listed twice in the library: 1) "gentamicin 5 mg/mL traditional" and 2) "gentamicin 5 mg/mL once daily".

Analysis of consultations between the registered nurse, pharmacist or physician following a hard limit alert is beyond the scope of this review. Hard limit analysis in this report is evidence-based as it is leveraged by actual Medfusion data from CHEO.

METHODOLOGY

Infusion Details reports were generated from the PharmGuard database server for gentamicin in the "General/Peds Surgery" profile, for the study period from August 2011 to August 2012. Hard limit events were isolated, using Microsoft Excel, along with the associated details on the pump serial number and date and time. For each hard limit, an *Event History* report was generated for the associated pump on the day of the event. The events were categorized based on the actions following the hard limit event.

RESULTS

The total number of PharmGuard infusions in the "General/Peds Surgery" profile within the study period was 36516.

The hard limit events for gentamicin were found to be followed by several types of events that correspond to an action taken by the clinician:

1. *Switched administration mode*: Deliver an infusion with the other drug option. That is, if the hard limit was hit with the "once daily" option, the nurse reprogramming the pump to infuse using the "traditional" option, and vice versa.
2. *Manual mode*: Deliver a manual mode infusion longer than 20 minutes. This includes programming the pump to infuse

a volume over time or a flush infusion outside of the library, or the flush option from the "General/Peds Surgery" profile.

3. *Adjustment*: Input a different value and deliver the infusion
4. *Repeat*: Re-enter the same value and trigger a second hard limit alarm.
5. *Repeat with limit change*: Re-enter the same value and trigger a second hard limit alarm. The hard limit ranges for both events are different from each other, indicating that the user went back one or two steps to change the value of previously set parameters (i.e., changed the weight or dose or both).
6. *Soft limit trigger/override*: Re-entered the dose and triggered a soft limit event. This also indicates that the user went back one or two steps to change the value of previously set parameters (i.e., changed the weight or dose or both).
7. *Other*: the pump was turned off, or another drug was infused.

Table 1 presents the number of times each of these follow up actions occurred.

Table 1: Hard limit event follow up actions

Follow-up Action	**Gentamicin 5 mg/mL**		
	Traditional	***Once daily***	***Total***
Switch Admin mode	17	30	**47**
Manual mode	7	11	**18**
Adjustment	22	21	**43**
Repeat	5	4	**9**
Repeat with limit change	0	5	**5**
Soft limit trigger/override	0	3	**3**
Other	3	4	**7**
Total number of hard limits	54	78	**132**
Total number of soft limit overrides	0	17	**17**
Total infusions	836	670	**1506**

DATA ANALYSIS

Analysis of the details of the hard limit events revealed that the majority of cases were *Switch admin mode*, *Repeat with limit change*, *Soft limit trigger/override* and *Manual mode* categories which are all programming adjustments. Eight cases in the *Adjustment* category were also programming adjustments, as the weight was changed and the same dose that triggered the hard limit event was entered in the delivered infusion.

Three types of errors that led to a hard limit event were identified in the event details:

1. *Selection error*: The "traditional" option was selected instead of the "once daily" option or vice versa. This error is determined by calculating the limits of the alternate drug option based on the entered weight, and checking if the entered dose was within the allowable range for the alternate drug option.
2. *Order entry error*: The wrong key is entered, for example, a zero instead of a decimal point or not entering the value.
3. *Other* error: All other errors caught by the drug library other than selection errors or order entry errors.

Since clinical circumstances and true intent are missing variables in this study, classification is determined by comparing infusion parameters at the hard limit event and parameters of the delivered infusion following the event. The dose that triggered the hard limit event and the delivered dose are exactly the same for a selection error since the clinician adjusted the drug selection or the weight; however, they are different for an order entry error since the clinician adjusted the dose.

Since CHEO's pharmacy department guidelines recommend at least 30 minutes for gentamicin infusion, an infusion time below 30 minutes is either a clinical error or an order entry error; therefore, it is counted as an *Other* error. There were four events where the error appeared to be due to rounding and precision. For example, the dose entered was 150 and the upper hard limit was 149.6. It is possible that the physician ordered the dose, and in that case, it would be a situation that needed a MD

consultant for ordering a dose higher than the limit. These cases are also counted as *Other* errors. The rest of the errors counted as *Other* errors are the events in the *Other* category and three cases where not enough data were available for assessing the event. One of the cases in the *Switch admin mode* category, a completed gentamicin infusion was followed by the hard limit event and a three minute infusion; this suggests that the clinician set up the gentamicin infusion in the place of a flush to clear out the infusion lines. The rest of the *switch admin mode* cases (46 cases) were counted as selection errors. Table 2 presents the number of errors found from analysis of the hard limit events. Note that there are more errors than events because of repeated events associated with one infusion.

Table 2: Hard limit event errors

Error Type	Number of Cases	Percentage
Selection	67	56.8%
Order Entry	13	11.0%
Other	38	32.2%
Total	118	100%

CONCLUSION

Overall, this analysis shows that when setting up a gentamicin infusion in the "General Peds Surgery" profile on the Medfusion 4000 pump, selecting the wrong drug option accounts for more than half of the hard limit events (56.8% of the events). This finding is evidence that smart pumps introduce new types of errors not found in traditional pumps. This analysis also shows that 11% of the hard limit events were order entry errors that the pump was able to catch, which is evidence of the value of the smart pump system.

To reduce hard limit events, increased clinician training and education may be required for the pump with respect to selection of drug program options, such as, on-screen drug option interpretation and the importance of the selection of the proper drug option. Renaming the two drug delivery options is also a possibility to reduce confusion between drug program options that have the same drug name on the on-screen label (e.g., changing "gentamicin 5 mg/mL traditional" to "gentamicin 5 mg/mL three times daily"). This recommendation is relevant to other profiles and to other drugs in the library with more than one option (e.g., tobramycin).

Future work would be a follow-up study after re-education to evaluate the impact of training on drug library non-compliance and selection errors. Linking the pumps to patient health records would provide more information in analyzing the pump data and would allow comparison of infusion with prescription. The device server may contain false data if an improper weight, dose or drug is entered to intentionally bypass the library. Linking pumps to patients and prescriptions would allow one to isolate those cases for further investigation as well as aid in true error classification. Also, tracking cases where there is a clinical need to go outside of the limits would improve analysis of cases of non-compliance. The data would not have revealed prescribing errors, which may have contributed to hard limit events.

ACKNOWLEDGEMENTS

This work was supported in part by Mitacs-Accelerate. The authors would like to thank the Smiths Medical team for all their support.

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