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Are We Making Smart Pumps Smarter?

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Are We Making Smart Pumps Smarter?

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ABSTRACT

Background: Medication errors comprise a significant proportion of medical errors, and are abundant, costly, and associated with causing harm to patients via adverse drug events. The most serious medication errors often involve IV medications. Smart pumps were developed to improve patient safety by reducing medication errors. While some studies have found that smart pumps do not decrease medication errors, most have found they are effective to some degree. It is believed that routinely analyzing data on smart pump alerts, making corresponding adjustments in the drug libraries, and analyzing those adjustments can reduce alarm fatigue, which may then decrease medication errors by resulting in less smart pump users overriding the alerts and utilizing workarounds of smart pump safety features.
Objective: The objective of this study is to assess if changes made to the Indiana University Health system smart pump drug library decreased nuisance alerts by comparing the actions taken in response to alerts before and after the changes were made.
Methods: For a given change made to the Indiana University Health smart pump drug library on April 1, 2016, actions taken in response to alerts corresponding to that change three months prior to and three months after the change were analyzed. The primary outcome was the percent of total alerts that were overrides. Using data from the smart pumps, the number of overrides, reprograms, cancels, and total alerts for each drug in the first and second quarter were recorded. The percentage of total alerts that were overrides, the percentage of total alerts that were reprograms, and the ratio of overrides to reprograms for each quarter were calculated.
Results: Analysis was conducted on 8 drugs: carboplatin, fentanyl PCA, hydromorphone PCA, morphine PCA, morphine PCA 10-24kg, morphine PCA >40kg, naloxone, and octreotide. From the first quarter to the second quarter, the percent of overrides increased for 3 drugs, but for all 3, the number of overrides and total alerts decreased. Of the 5 drugs that had a decrease in the percent of overrides, 3 had an increase in the number of overrides and total alerts. Only 2 drugs had a decrease in the percent of overrides and the number of overrides and total alerts. Statistical significance was achieved only for hydromorphone PCA and morphine PCA. The difference between the first and second quarters in the all the measured outcomes varied between the drugs.
Conclusions: Forming any definitive conclusions was difficult due to the results containing a significant amount of variation. The literature suggests methods to improve smart pump usage, and improve medication safety by extension. These methods are interfacing smart pumps with computerized physician order entry, clinical decision support systems, electronic medical record/electronic medication administration record, pharmacy information systems, bar-coded medication administration, and laboratory data, as well as improving smart pump safety features compliance through education of smart pump users, leadership support, including/consulting smart pump users in drug library design, and routinely using the event log data as a component of a continuous quality improvement program. These methods are all in line with the current, trending belief that the best method for preventing medication errors is making changes to the medication use system as a whole to correct underlying systems failures instead of addressing a single point, such a smart pump alerts.

BACKGROUND

The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer."[1,2] Medication errors comprise a significant proportion of medical errors, and are abundant, costly, and associated with causing harm to patients via adverse drug events (ADEs).[1,3-5] It is well known that ADEs are a leading cause of medical injury and costly from a variety of perspectives.[5-7] Due to varying definitions and methods of detecting them, the exact incidence of medication errors and ADEs, as well as the incidence of medication errors that cause ADEs, are difficult to accurately measure and therefore controversial and unclear.[1,2,6] Most medication errors occur in the ordering and administration stages of the medication use process.[1-3,6,8] The most dangerous medication errors are those that occur during the administration phase because they result in the most patient harm and are the least likely to be intercepted.[2,8] Intravenous (IV) medications, along with high-risk medications (ex. insulin, heparin, morphine), which are so named due to their high risk of causing severe patient harm, are commonly associated with medication errors.[1,8,9] The most serious medication errors (resulting in the most severe harm to patients) often involve IV medications.[1,8]

One technology developed to improve patient safety by reducing medication errors is smart pumps. In the literature, the term "smart pump" describes infusion pumps and/or devices which incorporate software programs that provide customizable drug libraries containing limits on doses, concentrations, volumes, and administration rates

specific to different medications and particular care areas/units in the facility.[1,2,8-11] When the user turns on the smart pump, they must first choose a particular clinical area (ex. ICU).[1,10] The pump is then automatically configured to meet the requirements of that specific clinical area.[1,10] When infusions are programmed outside the preprogramed limits, alerts are generated, and users can reprogram the infusion to be within the preprogrammed limits, override the alert (and continue medication administration as originally programmed) when allowed, or cancel the infusion.[8,9]

Several studies and literature reviews have been conducted that examine the efficacy of smart pumps at increasing patient safety by preventing medication errors. While some studies have found that smart pumps do not decrease medication errors, most have found they are effective to some degree. [1,2,11] However, all the studies found that smart pumps can only detect and prevent errors related to incorrect smart pump programming when the drug library limits are exceeded, and that ability is severely limited by noncompliance with the smart pumps' safety features.[1,2,11] Noncompliance includes actions such as smart pump users not selecting drugs from the drug libraries (and therefore bypassing the pump's safety features) and/or ignoring the smart pump's alerts and alarms [1,11]

Smart pumps record/capture an extensive amount of detailed programming and alert data on every infusion in their event logs, so reports for analyzing and evaluating drug libraries and clinical practice trends can be generated from that data.[7-10] By increasing compliance with smart pump safety features via refining drug libraries, these reports guide quality improvement as well as increase medication safety.[1,7-11] This is because it is believed that routinely analyzing data on alerts, making corresponding

adjustments in the customizable drug libraries, and analyzing those adjustments can reduce alarm fatigue/minimize alerts that are perceived as "nuisance alerts", which may then result in less smart pump users overriding the alerts and utilizing workarounds of smart pump safety features.[8,9] Voluntary incident and/or error reporting systems inherently have reporting bias, but smart pump event log data provides an objective way to calculate and/or analyze how often smart pumps prevent errors.[1,2,5,6,11] Both the Carolinas HealthCare System (CHS) and University of Pittsburgh Medical Center (UPMC) health systems have experienced decreased smart pump alerts by consistently analyzing smart pump event log data, and then using that data to evaluate and refine drug libraries as part of a continuous quality improvement (CQI) program.[7,8]

Infusion Pump Informatics (IPI) is a members-only, web-based analytics system for conducting in-house evaluations and cross-facility comparisons of smart pump alert data.[9] Data available from the analytics program includes, but is not limited to drug, profile (unit/clinical care area), facility/hospital, amount or percent exceeding limits, and actions taken in response to alerts.[9] Patient data is not captured by the analytics system, and no records that are capable of linking back to individual patient records are collected.

The objective of this study is to assess the efficacy of changes made to the Indiana University (IU) Health system (an IPI member) smart pump drug library at decreasing nuisance alerts by comparing the actions taken in response to alerts before and after the changes were made. The results will positively impact medication safety at IU Health by providing a valuable objective, metric analysis that will further promote the growth and sustainability of smart-pump initiatives across the IU Health system.

METHODS

Study Design

This is a before-and-after study of actions taken in response to alerts as a result of changes made in the IU Health smart pump drug library in April 2016. The IU Health system has a standardized smart pump drug library across 15 hospitals in Indiana. Several changes were uploaded to the drug library of all the smart pumps in the system on April 1, 2016. For a given change, actions taken in response to alerts corresponding to that change three months prior to (in the first quarter/January-March 2016) and three months after (in the second quarter/April-June 2016) the change were analyzed.

Exclusion Criteria

Drugs with a change to their drug library were excluded from analysis if they did not have data from both quarters, no change was made to the limits in the drug library, or the intent of the change was not to reduce the number of overrides and total alerts (ex. standardization of the drug library across all the units).

Outcomes

The primary outcome was a surrogate of smart pump user behavior defined as the percent of total alerts that were overrides. This percent should be lower in the second quarter if the drug library changes resulted in less overrides/alerts that are perceived as nuisance. Secondary outcomes were categorizing good catches and missed catches of errors as noted by actions taken in response to a given alert. Good catches were represented by reprograms, while missed catches were a result of overrides. The percent of total alerts that were reprograms and the ratio of overrides to reprograms were used to measure the secondary outcomes.

Data Collection

All the changes made to the IU health smart pump drug library, including to which drug the change was made, were recorded in an Excel file. Using data from the IPI analytics program, two Excel files (one file containing data from the first quarter, and one containing data from the second quarter) were generated for each drug with a change made to its smart pump library. From this data, the number of overrides, reprograms, cancels, and total alerts for each drug for each quarter were recorded in a Word document, and the percentage of total alerts that are overrides for each quarter were calculated and also recorded in the Word document. In order to enter the data into Statistical Package for Social Sciences (SPSS) for statistical analysis, it had to be converted into a number format that SPSS can read and analyze. To do this, another Excel file was created that contained 1 table for each drug (see Example Table 1). Each table recorded how many overrides, reprograms, and cancels occurred in each profile an alert for the drug occurred in according to quarter. The actions were recorded as numbers (1=override, 2=cancel, 3=reprogram), and each profile was listed twice in each table, with a one at the end of the profile's name indicating first quarter data, and a two indicating second quarter data. This data was then entered into SPSS.

Statistical Analysis

The before and after groups (first vs. second quarter data) were compared using dependent sample chi-square tests for categorical data. A 2-sided *p* value of less than 0.05 was considered statistically significant, and statistical analysis was conducted using Statistical Package for Social Sciences version 13.0 (SPSS Inc., Chicago, IL). The

percent of total alerts that were overrides, the percent of total alerts that were reprograms, and the ratio of the number of overrides to the number of reprograms were calculated.

RESULTS

Drugs Analyzed

A total of 10 drugs that had a change made to their drug library in April 2016 had data for both the first and second quarters. Analysis was conducted on 8 of those drugs (carboplatin, fentanyl PCA, hydromorphone PCA, morphine PCA, morphine PCA 10-24kg, morphine PCA >40kg, naloxone, octreotide), and 2 of them (IV fluid [IVF] potassium and valproate) were excluded. The change made to IVF potassium's drug library was standardizing the limits across all of the profiles, which was done to deduce how to best build the drug library, and not to reduce the number of overrides and total alerts. Therefore, IVF potassium was excluded. Valproate was excluded because the change made to its drug library was adding features/limits, so no existing limits were actually changed.

Percent of Total Alerts That Were Overrides (table 2)

Table 1 displays the number of overrides, cancels, reprograms, and total alerts and the percent of total alerts that were overrides (the data recorded in the Word document) for each drug according to quarter. From the first quarter to the second quarter, the percent of overrides increased for three of the eight drugs analyzed (fentanyl PCA, morphine PCA >40kg, naloxone), but for all three, the number of overrides and total alerts decreased. Of the five drugs that had a decrease in the percent of overrides, three of them (carboplatin, morphine PCA, octreotide) had an increase in the number of overrides and total alerts. Only two drugs (hydromorphone PCA and morphine PCA 10-24kg) had a decrease in the

percent of overrides and the number of overrides and total alerts, and both were narcotics. Statistical significance was achieved only for hydromorphone PCA and morphine PCA. The difference in the percent of overrides between the first and second quarters varied between the drugs.

Percent of Total Alerts That Were Reprograms (table 3)

There was an increase from the first to the second quarter in the percent of total alerts that were reprograms for four of the drugs (hydromorphone PCA, morphine PCA, morphine PCA 10-24kg, octreotide). A decrease in the percent of reprograms occurred for the other four drugs (carboplatin, fentanyl PCA, morphine PCA >40kg, naloxone). Variation existed between the drugs in the difference between the two quarters in the percent of reprograms.

Ratio of the Number of Overrides to the Number of Reprograms (table 4)

The ratio of the number of overrides to the number of reprograms increased from the first quarter to the second quarter for three of the drugs (carboplatin, fentanyl PCA, naloxone) and decreased for two of the drugs (hydromorphone PCA, octreotide). All three of the remaining drugs (morphine PCA, morphine PCA 10-24kg, morphine PCA >40kg) were morphine and had zero reprograms in either the first or the second quarter. A ratio of overrides to reprograms could therefore not be calculated for one of the two quarters, so a difference in the ratio between the first and second quarters could not be determined for those drugs. Between the drugs for which a difference in the overrides to reprograms ratio between the two quarters could be determined, that difference varied.

DISCUSSION

Ideally, the number of overrides and total alerts, the percent of overrides, and the ratio of overrides to reprograms would decrease, while the percent of reprograms would increase for each drug. Hydromorphone PCA was the only drug that had ideal results for all of the measured outcomes. For the other 7 drugs, the number of outcomes with ideal results varied. The variation, together with the inconsistencies between all the drugs in the difference in the outcomes between the first and second quarters confer a high degree of variability to the results overall. Therefore, it is difficult to form any definitive conclusions from the results.

The actions taken in response to alerts were not analyzed based on profile, and the data on type of limit violated (dose, infusion duration, concentration, volume, administration rate, etc.), facility, or amount by which the limit was exceeded was not utilized. This is a limitation of the study because those variables are potential confounders, and if the actions taken in response to alerts had been analyzed based on those subgroups, some concrete conclusions may have been able to be formed. A second limitation of the study is the small sample size/number of drugs analyzed. If a longer time frame had been examined, trends in the data may have been found due to the potential for having more drugs to evaluate. Since IPI does not provide access to any patient-specific information or information about why the smart pump users took the actions they did, it was impossible to distinguish between nuisance alerts and non-nuisance alerts. Not distinguishing between nuisance and non-nuisance alerts is another limitation of the study because its objective was to assess the efficacy of changes made to the IU Health drug library at decreasing nuisance alerts due to drug library inaccuracies. Also, the reasoning

behind the study's objective is to help achieve the clinical practice goal of increasing medication safety by decreasing the number of nuisance alerts, so alarm fatigue will decrease/less non-nuisance alerts will be overridden and more errors will be intercepted. Essentially, the actions taken in response to alerts were used as a surrogate for smart pump user behavior, and we had no data that directly pertained to the reasoning behind that behavior.

Previous research has shown that smart pumps are still vulnerable to medication errors, mainly due to noncompliance with their safety features and the limited types of errors they can detect or prevent.[1,2,10,11] Methods to improve medication safety via improving smart pump usage suggested by the literature are interfacing smart pumps with computerized physician order entry (CPOE), clinical decision support systems (CDSs), electronic medical record (EMR)/electronic medication administration record (eMAR), pharmacy information systems (PIS), bar-coded medication administration (BCMA), and laboratory data/results, as well as improving compliance with the smart pumps' safety features through education of smart pump users, leadership support, including/consulting smart pump users in drug library design, and routinely using the event log data as a component of a CQI program.[1,2,7-11] By interfacing smart pumps with other electronic systems, they may be able to prevent more types of errors, such as wrong drug, wrong dose, and wrong patient errors. Increasing compliance with smart pump safety features (via the previously mentioned methods) may enhance smart pumps' ability to detect or prevent not only the incorrect programming errors, but also the errors interfacing with other systems would enable them to prevent.

Future studies on the efficacy of smart pumps at decreasing medication errors should look at a time frame that is at least a year or two long, include a method to incorporate data that indicates the reasoning behind the behavior of smart pump users, and utilize subgroup analyses based on drug type, facility, profile, etc. A study could also compare smart pumps interfaced with other medical technologies (ex. CPOE, CDSs, EMR/eMAR, PIS, BCMA, lab data) with smart pumps that have not been interfaced regarding their efficacy at reducing medication errors.

Due to evidence showing that errors are usually due to system failures/faulty system design that cause breakdowns at various points throughout the system, it is believed that making changes to the system as a whole/correcting the underlying systems failures will prevent errors.[3-6] Evidence has also shown that that belief applies to medication errors because they can occur at any stage of the medication use process, and a single proximal cause can result in a variety of errors, and an error may result from several proximal causes.[1-7,11] All of the previously mentioned methods to improve medication safety via improving smart pump usage involved changes made to the overall medication use system, and are therefore in line with the belief that correcting the underlying systems failures is the best method to prevent medication errors.

CONCLUSION

Forming any definitive conclusions was difficult due to the results containing a significant amount of variation. The literature suggests methods to improve smart pump usage, and improve medication safety by extension, are interfacing smart pumps with CPOE, CDSs, EMR/eMAR, PIS, BCMA, and laboratory data, as well as improving smart pump safety features compliance through education of smart pump users, leadership

support, including/consulting smart pump users in drug library design, and routinely using the event log data as a component of a CQI program. These methods are all in line with the current, trending belief that the best method for preventing medication errors is making changes to the medication use system as a whole to correct underlying systems failures.

REFERENCES

1. Hertzel C, Sousa VD. The use of smart pumps for preventing medication errors. *J Infus Nurs* 2009;32:257-267.

2. Husch M, Sullivan C, Rooney D, et al. Insight from the sharp end of intravenous medication errors: implications for infusion pump technology. *Qual Saf Health Care* 2005;14:80-86.

3. Kaushal R, Shojania K, Bates D. Effects of computerized physician order entry and clinical decision support systems on medication safety: a systematic review. *Ann Intern Med* 2003;163:1409-1416.

4. Leape L, Bates D, Cullen D, et al. Systems analysis of adverse drug events-ADE prevention study group. *JAMA* 1995;274:35-43.

5. Resar R, Rozich J, Classen D. Methodology and rational for the measurement of harm with trigger tools. *Qual Saf Health Care* 2003;12:ii39-ii45.

6. Bates D, Cullen D, Laird L, et al. Incidence of adverse drug events: implications for prevention-ADE prevention study group. *JAMA* 1995;274:29-34.

7. Mansfield J, Jarrett S. Using smart pumps to understand and evaluate clinician practice patterns to ensure patient safety. *Hosp Pharm* 2013;48:942-950.

8. Skledar SJ, Niccolai CS, Schilling D, et al. Quality-improvement analytics for intravenous infusion pumps. *Am J Health-Syst Pharm* 2013;70:680-686.

9. Catlin AC, Malloy WX, Arthur KJ, et al. Comparative analytics of infusion pump data across multiple hospital systems. *Am J Health-Syst Pharm* 2015;72:317-324.

10. Snodgrass RD. Smart pump technology. *Biomed Instrum Technol* 2005;39(6):444-446.

11. Ohashi K, Dalleur O, Dykes PC, Bates DW. Benefits and risks of using smart pumps to reduce medication error rates: a systematic review. *Drug Saf* 2014;37:1011-1020.

Example Table 1: Actions Taken In Response to Alerts In Each Quarter According to Profile

Fentanyl PCA			
	Action Taken		
Profile	**1**	**2**	**3**
Hem/Onc 1	22	0	1
Hem/Onc 2	0	0	0
Adult Med/Surg 1	55	3	4
Adult Med/Surg 2	21	2	1
Adult ICU 1	40	5	2
Adult ICU 2	15	1	0
L&D 1	0	0	1
L&D 2	0	0	0

Table 1: Number of Overrides, Cancels, Reprograms, and Total Alerts and Percent of Overrides According to Quarter

Drug	Overrides	Cancels	Reprograms	Total Alerts	Percent Overrides
Carboplatin					
1st Quarter	160	9	3	172	93% (160/172)
2nd Quarter	197	14	1	212	92.9% (197/212)
Fentanyl PCA					
1st Quarter	117	8	8	133	88% (117/133)
2nd Quarter	36	3	1	40	90% (36/40)
Hydromorphone PCA					
1st Quarter	1115	55	81	1251	89.1% (1115/1251)
2nd Quarter	29	3	9	41	70.7% (29/41)
Morphine PCA					
1st Quarter	88	6	0	94	93.6% (88/94)
2nd Quarter	112	5	15	132	84.8% (112/132)
Morphine PCA 10-24kg					
1st Quarter	18	1	0	19	94.7% (18/19)
2nd Quarter	6	1	1	8	75% (6/8)
Morphine PCA >40kg					
1st Quarter	23	0	1	24	95.8% (23/24)
2nd Quarter	2	0	0	2	100% (2/2)
Naloxone					
1st Quarter	30	8	10	48	62.5% (30/48)
2nd Quarter	10	2	3	15	66.7% (10/15)
Octreotide					
1st Quarter	127	27	23	177	71.8% (127/177)
2nd Quarter	158	41	43	242	65.3% (158/242)

Table 2: Percent of Overrides

Drug	1st Quarter	2nd Quarter	Chi-Squared	P Value
Carboplatin	93% (160/172)	92.9% (197/212)	1.774	0.412
Fentanyl PCA	88% (117/133)	90% (36/40)	0.859	0.651
Hydromorphone PCA	89.1% (1115/1251)	70.7% (29/41)	15.689	<0.001
Morphine PCA	93.6% (88/94)	84.8% (112/132)	11.918	0.003
Morphine PCA 10-24kg	94.7% (18/19)	75% (6/8)	3.02	0.221
Morphine PCA >40kg	95.8% (23/24)	100% (2/2)	0.087	0.768
Naloxone	62.5% (30/48)	66.7% (10/15)	0.115	0.944
Octreotide	71.8% (127/177)	65.3% (158/242)	2.286	0.319

Table 3: Percent of Reprograms

Drug	1st Quarter	2nd Quarter
Carboplatin	1.74% (3/172)	0.47% (1/212)
Fentanyl PCA	6.02% (8/133)	2.5% (1/40)
Hydromorphone PCA	6.47% (81/1251)	22% (9/41)
Morphine PCA	0% (0/94)	11.4% (15/132)
Morphine PCA 10-24kg	0% (0/19)	12.5% (1/8)
Morphine PCA >40kg	4.17% (1/24)	0% (0/2)
Naloxone	20.8% (10/48)	20% (3/15)
Octreotide	13% (23/177)	17.8% (43/242)

Table 4: Ratio of Overrides to Reprograms

Drug	1st Quarter	2nd Quarter
Carboplatin	53.3 (160:3)	197 (197:1)
Fentanyl PCA	14.6 (117:8)	36 (36:1)
Hydromorphone PCA	13.8 (1115:81)	3.2 (29:9)
Morphine PCA	(88:0)	7.5 (112:15)
Morphine PCA 10-24kg	(18:0)	6 (6:1)
Morphine PCA >40kg	23 (23:1)	(2:0)
Naloxone	3 (30:10)	3.3 (10:3)
Octreotide	5.5 (127:23)	3.7 (158:43)