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What does your IV Smart Pump Infusion Data tell you about IV Clinical Practice and Patient Safety?

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Abstract

SMART pumps can provide retrospective data which, when interpreted in collaboration with clinician users, can provide valuable insight into IV medication practices, compliance with Dose Error Reduction Software (DERS), resource utilization of infusion pumps, and intercepted medication errors and can assist in the promotion of a culture of patient safety. An evaluation of the value the Colleague Infusion Pump with GUARDIAN DERS brings to clinical practice at the University of Ottawa Heart Institute (UOHI) was undertaken through the quantitative analysis of infusion pump data. Interpretation of these reports in collaboration with nurses assisted in identifying various issues impacting best practice. Targeted approaches to practice changes, protocol redesign and further education were identified.

Background/Rationale

Adverse events (AEs) result in 9,000 – 24,000 preventable deaths in Canada each year (Baker, Norton, et.al, 2004). Although surgical procedures were found to be the most common type of AE in the Canadian Adverse Events Study, the second most common AEs were associated with drug- or fluid-related events. Adverse drug events (ADE) specifically focus on the delivery of medication to patients and represent a significant vulnerability for patients in hospitalized settings. In addition, ADEs place a financial burden on the healthcare system through an increased length of stay and the implementation of treatment plans to mitigate the injury (Classen & Pestonik, 1997; Rodriguez- Monguio, Otero & Rovira, 2003).

In 2004, Health Canada issued a Notice to Hospitals warning of the risks associated with intravenous infusion pumps. Between 1987 and 2003 Health Canada received reports of 425 separate incidents involving infusion pumps. Of these 425 incidents, 23 resulted in deaths, 135 resulted in injury and 127 could have potentially led to injury or death. Of the 23 deaths, 20 were suspected to be the result of pump technology or user error. All 135 injuries were attributed to pump technology or user error (Health Canada, 2004). As a result of these findings, Health Canada recommended a number of safety steps to be implemented in healthcare to protect against infusion device medication errors including the recommendation that hospitals use infusion devices with safety features such as software that provide safeguards against dosing and infusion related errors. These devices are commonly known as "SMART Pumps" (Wilson & Sullivan, 2004). Upper and lower dosing limits are developed in conjunction

with hospital clinical and pharmaceutical protocols and programmed into the pump. Should a clinician program an infusion medication dose outside of those limits considered safe, the pump will alert the clinician to this potential error. The clinician may then choose to accept their choice (since occasionally in clinical practice scenarios the dosing limits must be overridden) or they may recognize a programming error and cancel the dose before the infusion has commenced.

The Canadian Adverse Events Study suggested that as many as 37 to 51% of adverse events (AE) in healthcare are preventable (Baker et.al, 2004).. Other studies have shown preventable AE rates as high as 51% (Brennan, Leape, et al, 1991). Although most patients who experienced and AE recovered, many experienced an increased length of stay in hospital or temporary disability and a number of them died as a result of their injury. Costs have been estimated at approximately $8,000.00 per ADE in the US (Rodriguez-Monguio, Otero, Rovira, 2003; Brennan, Leape, et al, 1991; Malashock, Gould & Shull, 2004; Bates, Spell, et. al, 1997) and this estimate does not include the additional costs associated with litigation, malpractice insurance premiums and injury related costs such as lost income or family hardship.

It is reasonable to suggest that acuity levels in Canada are rising as the population ages. It is also reasonable to suggest that complex infusion therapy usage will also rise creating a greater potential for infusion errors (Rex, Turnbull, Allen, Vande Voorde & Luther, 2000). Nursing workforce shortages place additional burdens on clinicians who

must do more with less, increasing the potential for human error (Milligan, 2003; Wilkins & Shields, 2008; Reason, 2000). Increasingly, those responsible for the delivery of healthcare services understand that individual clinicians are rarely singularly responsible for an adverse event rather, recognizing that the clinical environment is complex and many factors can contribute to errors (Balas, Scott & Rogers, 2004).. Within the context of a "just culture" environment, health care providers have been shown to be a reliable source of information about the nature and conditions giving rise to medication errors (Reason, 2000, Neale, Woloshynowych & Vincent, 2001).

Escalating healthcare costs in Canada result in hospital administrators having to make difficult decisions about resource allocation and infrastructure upgrading. Efficient use of current technology allows limited funds to be redirected towards more pressing shortfalls. SMART pumps have been shown to intercept potentially costly medication errors, thereby demonstrating their usefulness (Classen et al, 1997). One such device, Baxter's Colleague CXE with GUARDIAN Dose Error Reduction Software (DERS), was implemented throughout the University of Ottawa Heart Institute (UOHI), in Ottawa, Ontario, Canada. The University of Ottawa Heart Institute (UOHI) is Canada's largest and a highly reputable cardiovascular health centre dedicated to understanding, treating and preventing heart disease. The UOHI has three clinical floors (116 beds) offering specialized cardiac care, including cardiac life support, a 90,000-square foot Research Centre, a Prevention and Rehabilitation Centre, a Diagnostic Centre, and the Cardiac Reference Centre. The Institute serves more than 1.5 million residents from Eastern and Northern Ontario, and Western Quebec, and has the largest artificial heart program in Canada (UOHI, n.d.).

This paper provides an overview of the efficacy of Baxter's Colleague CXE with GUARDIAN DERS in the clinical setting of UOHI.

Methodology

In August, 2007, data from 199 Baxter Colleague CXE infusion pumps at the UOHI was downloaded, representing 73.4 hours, or approximately 3 days, of infusion pump activity. Several quantitative reports were generated from this data including:

1. Unit specific medication error intercepts
2. Medication error intercepts and associated time of day
3. Unit specific data of infusion starts using dose error reduction software
4. Management of high risk infusion medications
5. Infusion pump battery management
6. Asset (infusion pump) utilization

These reports were presented to UOHI Nurse Educators, Unit Managers and Biomedical Engineering Services Department members for qualitative feedback. Individual interviews were conducted and recorded. Additionally, 3 focus groups with end users were conducted in December 2007 and audio-recorded. A total of 52 users participated in the focus groups. The reports were presented without interpretation, and users were asked to interpret the findings and comment on their relevancy to clinical

practice and error prevention. Field notes were taken. Audio tapes were transcribed and coded to generate themes. Correlation between themes generated by focus groups, individual interviews and group presentation responses was sought.

Results

The download of data from the 199 infusion pumps translates to approximately 3 days of typical pump activity.

The COLLEAGUE GUARDIAN DERS feature allows clinicians to administer intravenous infusions within the institution's pre-defined safety limits. These safety limits are determined in collaboration with Pharmacy, Medicine and Nursing and programmed into the GUARDIAN drug library. If the clinician programs a drug infusion outside of the defined limits, an alert message provides the user with two options that are defined as follows:

a) Accept the dose that was entered (**OVERRIDE**)

b) Cancel the dose that was entered and re-enter the correct dose (**NEAR MISS**)

During the three-day time frame, 14 medication errors were intercepted through use of GUARDIAN. Figure 1 demonstrates the drug type and dosage of medication errors that were intercepted.

DRUG	LOW DOSE LIMIT	HIGH DOSE LIMIT	INCORRECT DOSE ENTERED	CORRECTED DOSE
Heparin 25000 units/250 mL	100 units/hr	1500 units/hr	**14,000 units/hr**	1400 units/hr
			70,000 units/hr	700 units/hr
			12 units/hr	1200 units/hr
			11 units/hr	1100 units/hr
			1600 units/hr	1500 units/hr
			2000 units/hr	500 units/hr
Nitroglycerin 50 mg/250 mL CCU	15 mcg/min	100 mcg/min	**1000 mcg/min**	100 mcg/min
			1000 mcg/min	100 mcg/min
			10 mcg/min	100 mcg/min
			333 mcg/min	50 mcg/min
Nitroglycerin 50 mg/250 mL CSU	0.5 mcg/kg/min	4.9 mcg/kg/min	**0.242 mcg/kg/min**	0.25 mcg/kg/min
Norepinephrine 8 mg/250 mL	0.005 mcg/kg/min	1 mcg/kg/min	**2.22 mcg/kg/min**	0.741 mcg/kg/min
			0.004 mcg/kg/min	0.022 mcg/kg/min
Vasopressin 100 units/100 mL	0.5 units/hr	2.4 units/hr	**0.1 units/hr**	changed drug to nitroprusside

Figure 1: Drug Type and Dosage of Intercepted Errors

This data was further stratified by time of day. Figure 2 demonstrates the chronogram illustrating specific time of day when errors were intercepted.

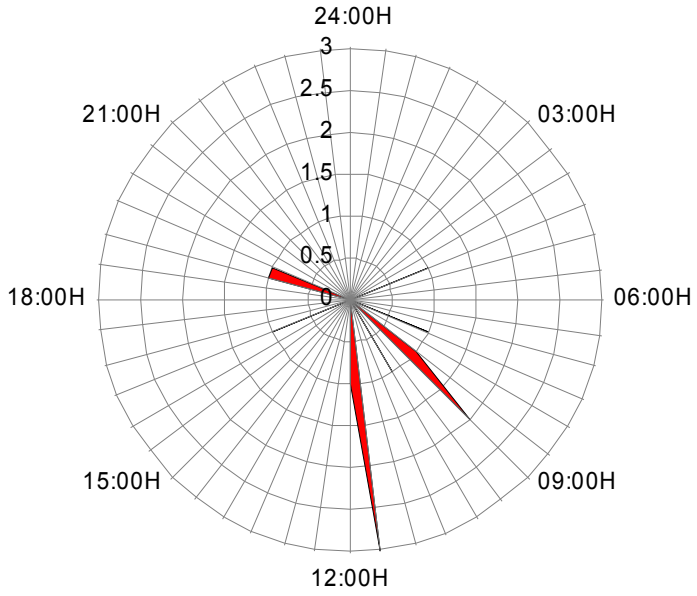

Figure 2: Chronogram of Intercepted Errors

Interpreting this data in conjunction with clinician users allowed for the examination of clinical practice and other routine duties. For example, nurses commented that 09:00H was the time when they were typically occupied with reporting activities and on rounds with Physicians, transcribing medications, etc. 11:30H was the time when the first group of nurses generally take their lunch break (and the remaining nurses are particularly short staffed, busy and hungry!) and 19:00H was evening change of shift time for 12-hour shifts.

"These are all "rushing times"….you know 9:00, we're putting out our pills, orders are being done, 11:30 …well, here we are, we're all rushing to go to first break….and 7:30 in the evening is change of shift and that can be really hectic with people coming and going."

Clinicians were particularly surprised at the strong clustering of intercepted errors at these times. Although they could quickly account for the intercepted errors in terms of what activities were taking place in the clinical environment, they remained concerned that these times were resulting in such striking patient vulnerability.

"We're surprised at what we're seeing….people are tired…stuff happens, but the feature is working as it's intended to… you can trust it…you don't need to check the higher and lower limits…."

The GUARDIAN DERS captured 67 Overrides in the three-day time frame. The most commonly overridden drugs are illustrated in Figure 3.

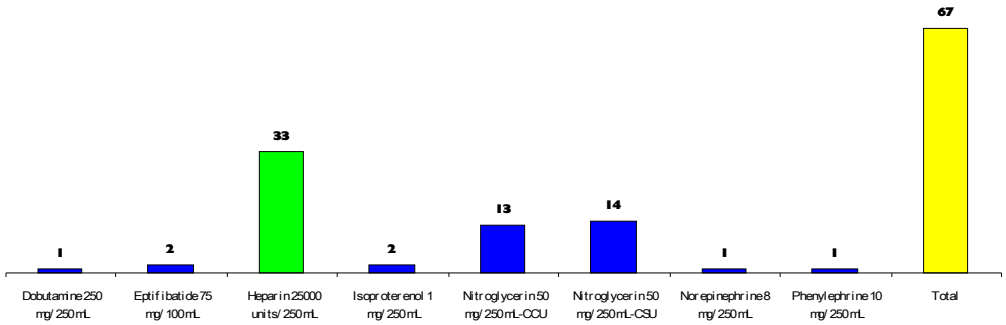

Figure 3: Most Commonly Overridden Drugs

This information can be used to determine appropriateness of pre-set hospital protocols in light of current practice, or alternatively, can be used to examine current practice in light of safe medication management goals.

"We are always overriding ni-pride…it gets annoying for the patient…the limits don't seem to be working for us."

It is interesting to note in this particular example that despite the perception that "We are always overriding ni-pride…" in fact, nitroprusside was not a commonly overridden drug in these 3 days. The quantitative data may also assist in supporting or refuting commonly held perceptions. Regardless, the collaboration between nursing, pharmacy, medicine and industry suppliers to develop drug libraries that support best clinical practice can only serve to improve patient safety.

In the three-day time frame, the majority of infusion starts were in "rate-volume" (that is, not started within the GUARDIAN DERS) – Figure 4.

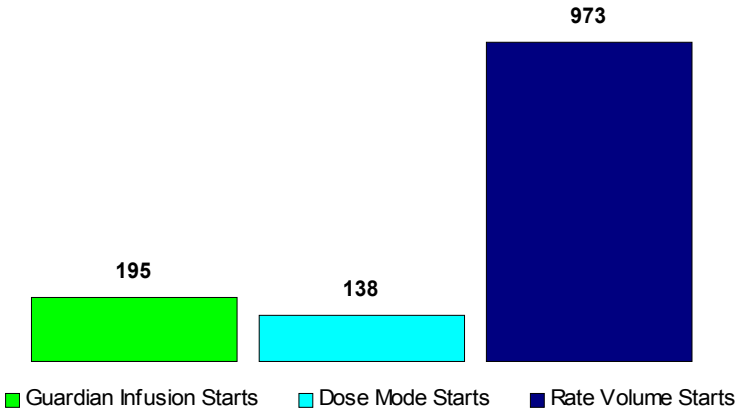

Figure 4: Infusion Start Methods

The data downloaded provided unit specific information regarding clinical practice and usage of the GUARDIAN safety system. This information, interpreted in conjunction with clinical practice common to specific units, allowed for evaluation of the appropriate level of GUARDIAN usage per unit and assisted in the identification of gaps in education. Clinical Nurse Educators commented that the quantitative data provided by Baxter's Clinical Informatics program had given them the evidence they needed to target education for practice change within specific units. Figure 5 depicts the breakdown of infusion start methods per unit. Hospital protocol dictates that high-risk medications should always be started within GUARDIAN. Quantitative data combined with clinical observation suggested that this was not always the case. Nurses confirmed this in the focus groups.

"I've known some people that once they've hit the rate sometimes they say "Forget It"…get out of it and just use rate volume because they don't have time to fuss. It's not OK….it's asking for a mistake. Especially for heparin!"

Department	Guardian Starts	Dose Mode Starts	Rate Volume Starts
BED BAY UNIT	22	8	79
CARDIAC CATH LAB	9	14	62
CARDIAC CT SCAN	3	8	18
CARDIAC DAY UNIT	2	3	21
CARDIAC SURGICAL - H3	7	7	66
CARDIOLOGY - H4	4	5	33
CARDIOLOGY - H5	19	15	46
CCU	37	46	161
CSICU	36	64	157
OR-PACU	24	23	35
PET-LAB		1	4
REFERENCE CENTRE	13	10	44
OTHER*	19	19	247
TOTAL	**195**	**138**	**973**

Figure 5: Infusion Method Starts by Unit

- Other = pumps that were located at a neighbouring hospital

The data provided by the Clinical Informatics download also provided insight into the management of infusion pump batteries. Figure 6 depicts the breakdown of discharged batteries by unit. Discharged batteries are less capable of maintaining their charge for the full capacity of the battery, thereby posing the risk of unanticipated cessation of infusion therapy to the patient. Fully charged batteries can be counted on to maintain infusion therapy during those times when the pump must run on battery, such as during some diagnostic tests or transport. Nursing users identified that simply plugging

the pump in whenever possible can assist in maintaining the health (and safety) of infusion pump batteries. Highlighting areas with poor battery management practices allows for targeted education as well as additional review of biomedical maintenance programs. In some cases, there are insufficient and/or inaccessible plugs and this, too can be addressed with the specific data provided.

"Sometimes you worry that you'll injure your back trying to get at those plugs….and then we don't want our patients opening up their sternotomy reaching under their bed for a plug!"

Department	Total Pumps	Discharged Batteries	% Discharge
BED BAY UNIT	12	7	58.33 %
CARDIAC CATH LAB	7	2	28.57 %
CARDIAC CT SCAN	5	0	0.00 %
CARDIAC DAY UNIT	2	0	0.00 %
CARDIAC SURGICAL - H3	13	5	38.46 %
CARDIOLOGY - H4	8	1	12.50 %
CARDIOLOGY - H5	12	3	25.00 %
CCU	32	5	15.63 %
CSICU	39	6	15.38 %
OR & PACU	16	4	25.00 %
PET LAB	2	0	0.00 %
REFERENCE CENTRE	9	4	44.44 %
OTHER*	42	17	40.48 %
TOTAL	**199**	**54**	**27.14 %**

Figure 6: Breakdown of Discharged Batteries by Unit

Finally, the reports provided information about infusion device utilization. When determining the number of infusion devices required by an institution, administrators

must find the balance between providing sufficient devices for periods of high usage and ensuring that scarce healthcare dollars are not spent on unnecessary equipment. Figure 7 depicts UOHI's infusion pump utilization. Of note, one of the days on which data was collected was a statutory holiday with lower patient volumes. Staff expressed satisfaction that sufficient pumps were available during higher usage times, thereby enhancing the provision of safer patient care. This information further provides clinicians and administrators with the opportunity to review their mix of both single and triple channel pumps, in light of their patient profile and demands for infusion therapy.

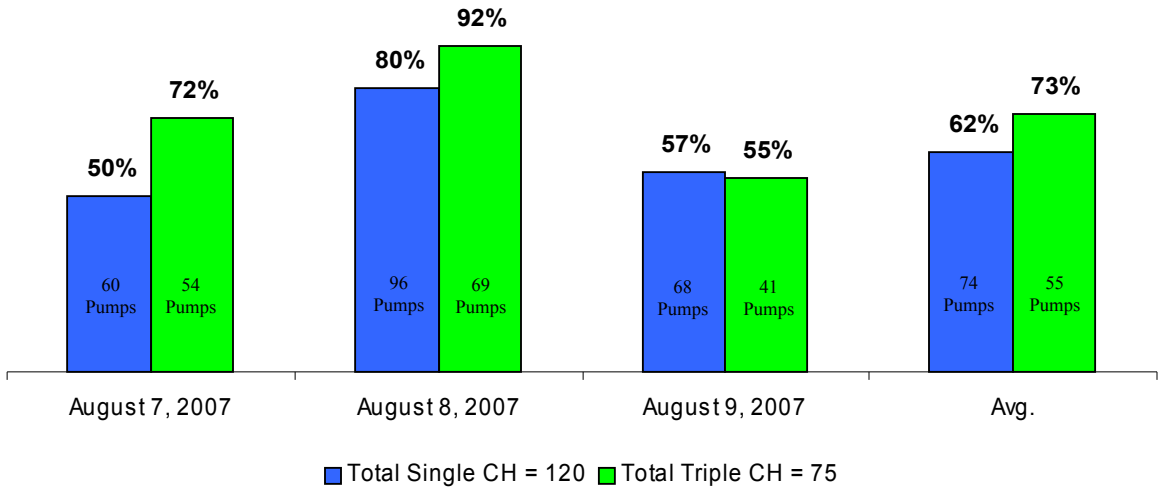

Figure 7: UOHI's Infusion Pump Utilization

The infrastructure required to support this technology is readily available in hospitals in Canada. A number of SMART pumps require wireless connectivity. However, older physical structures, remote areas and/or shrinking budgets often result in wireless connectivity not being an option and/or a priority in terms of spending. As a

result the case could be made for utilizing SMART pumps that do not require wireless connectivity in these instances. Timothy Zakutney, UOHI's Manager of Biomedical Engineering, suggested,

"Wireless connectivity to infusion pumps may be a great benefit to facilitate updating pharmacy profiles in infusion pumps but should not be treat3ed as a prerequisite to implementing SMART pumps. The value of this type of protective software in terms of reducing patient risk and improving patient care outweigh the added value of wireless connectivity."

Conclusion

Medication delivery errors add to the challenges of delivering healthcare in Canada. Since as many as 51% of AE in healthcare are considered potentially preventable (1), it is incumbent upon healthcare providers and administrators to investigate methods of reducing these avoidable errors. One approach involves collaboration with industry providers to implement technology that can contribute to a safer Canadian healthcare environment. SMART pumps are an easily implemented infusion system proven to intercept medication errors before they can cause harm to the patient. In the 3 day time frame evaluated at UOHI, 14 medication errors were intercepted. If the average cost per ADE is estimated to be $8,000.00 (6), one can easily see how a SMART pump system might quickly provide return on investment.

Initial evaluation by clinicians using the system indicates that clinicians recognize the value this system brings to the clinical setting. Since the reports generated do not specify which individual clinician is responsible for which intercepted error, clinicians felt that the Clinical Informatics reports could effectively contribute to the promotion of a safer culture through targeting units or areas that require further education rather than blaming individual clinicians. Discussions regarding potential practice and/or protocol changes that can improve safety in infusion therapy further support a just culture through the inclusion of practitioners in the development of strategies, a "grass-roots" approach to the reduction of adverse drug events.

Future Directions

Initial evaluation of Baxter's Colleague CXE Infusion Device with GUARDIAN DERS indicates that clinicians and administrators alike find value in the investment in terms of providing safer patient care and promoting a culture of safety. Future directions include a follow up download of data from infusion pumps to validate the efficacy of practice and protocol changes that have been implemented in response to the feedback provided by the Baxter Clinical Informatics team with the goal of improving GUARDIAN utilization in the practice setting.

Accreditation Canada (AC) has outlined Required Organizational Procedures (ROPs) for managing medications. SMART pumps addresses ROP 21.0, "The organization has a coordinated risk management program to reduce medication related errors and sentinel events", 21.2, "The organization's error prevention strategies target

the system, not the individual (emphasizing shared accountability)", and 21.3, "The organization uses a drug use evaluation (DUE) process for medications with heightened error potential" (18).

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Glossary of Terms:

A SMART pump is an infusion device, which includes both hardware and Dose Error Reduction
software (DERS).

Dose Error Reduction Software (DERS) is software integrated into the pump which allows clinicians to incorporate their best practice guidelines into infusion therapy through dosing limits.

Adverse Event (AE) is an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay and that is caused by health care management rather than by the patient's underlying disease process. (*Canadian Adverse Events Study)*

Adverse Drug Event (ADE) is any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems including: prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. *(Institute for Safe Medication Practices)*

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