ARE "SMART PUMPS" PREVENTING MEDICATION ERRORS?

Stephanie Byrne, Quat Manh Do, David Gretzinger and Petr Kresta
Clinical Engineering Program, Winnipeg Regional Health Authority, Winnipeg, Manitoba

Background Information

Intravenous medications delivered through infusion pumps are essential for efficient drug delivery in today's hospital environment. Infusion pumps have the ability to administer multiple complex medications, allowing the nursing staff to tend to other activities.[1] However, as the operation of the pump is manually programmed, a general-purpose infusion pump has the ability to deliver a substantially greater amount than intended, by simply adding an extra zero or forgetting a decimal point. A nurse would stop and think twice about giving a patient 100 pills of certain drug at one time, but this could easily be the case if a pump is programmed incorrectly.

Although there are many variations to the definition, Adverse Events (AE) are unintended injuries or complications that result from health care management, rather than from the patient's existing disease, and these events lead to prolonged hospital stays, disability or death.[2] There have been numerous studies which have analyzed the number of adverse events which occur in hospitals around the world. Baker *et al.* conducted the first Canadian study to analyze the rate of AE's in Canadian hospitals. They determined that 7.5% of patients in the year 2000 experienced at least one AE.[2] This rate is lower when compared to studies conducted in other countries. Based on information from two London hospitals, Vincent *et al.* determined that 10.8% of patients experienced an AE, while Davis *et al.* concluded that 12.9% of patients, based on thirteen New Zealand hospitals, experienced an AE.[3,4] However, in the Harvard Study of Medical Practice, it was determined that an AE occurred in 3.7% of all hospital admissions.[5,6]

A variety of occurrences can result in an AE, although an adverse drug event (ADE) is one of the most common. In a study conducted with 502 patients at the Ottawa Hospital, 64 patients (12.7%) experienced an adverse event. It was determined that ADE's accounted for 50% of these events.[7] A hospital-wide ADE study conducted by Adachi and Lodolce found that incorrect dose errors accounted for 17% of all ADE's. It was further determined that 41% of the wrong dose errors resulted from incorrect programming of the infusion pump.[8]

The Harvard Study of Medical Practice determined that ADE's were the second most common type of event, while in a study conducted by Rothschild *et al.*, programming the pump was the most common stage for errors in the medication process.[5,6] Leape *et al.* reported that 38% of preventable medication errors occurred during the drug administration stage.[9]

While general-purpose infusion pumps have radically changed drug delivery, they have also increased the complexity of the hospital environment and potential for error. Variations in both drug concentrations and dose rate increase the potential for human error. General-purpose infusion pumps have the ability to deliver medications between 0.1-999 ml/hr, a 10,000-fold range, for weights ranging from 600g to over 300kg.[10] Adding an extra zero or missing a decimal point can have disastrous results.

As a result, manufacturers have designed "smart pumps" equipped with dose-limiting software. The intent of this software is to prevent incorrectly programmed doses from being administered by accident. They incorporate advanced technology for storing drug information in a drug library, performing calculations and verifying information entered by the user against dose limits.[1] As the programmed drug library does not contain every drug used in the hospital, the user has the option to either incorporate the dose-limiting software with their infusion, or completely bypass the software and run the infusion in its basic mode. While in the dose-limiting mode, if the user attempts to infuse a drug at a dose outside the predetermined ranges programmed into the pump, the pump provides feedback to the user in the form of an alarm. Infusion will not initiate until the user acknowledges the alarm. The October 2002 ECRI Health Devices Journal evaluated general-purpose infusion pumps. In this evaluation, models which lacked dose error reduction software were rated Not Recommended for new purchases.[11]

A study conducted by Wilson and Sullivan was interested in determining the effectiveness of "smart pump" technology by analyzing data collected from 80 heparin orders. It was determined that 93% of the infusions were in compliance with the dose limits programmed into the infusion pumps.[12]

The February 2002 Institute for Safe Medication Practices (ISMP) Newsletter outlined a case where a nurse accidentally tried to program a continuous dose of heparin at 4000 units/hr, instead of the intended rate of 900 units/hr. The pump's dose-limiting software caught and averted this error.[13]

Approach

This study was interested in analyzing the number of times the user selected and infused a drug from the drug library versus running an infusion without linking to the drug library. Within the number of times the dose-limiting software was incorporated, this study was interested in recording the number of alarms issued to the user, and their response to the alarms. This analysis could potentially reveal averted ADE's.

It was also determined that this study was an excellent opportunity to track the actual utilization time of the pumps. Previous to this research, there has not been a utilization study conducted to justify the allocation of pumps throughout the hospitals. It was anticipated that this analysis could indicate if pump allocation is optimized.

In the Fall of 2005, the Winnipeg Regional Health Authority (WRHA) implemented a region-wide pump replacement. Baxter Colleague CX "smart pumps" replaced existing infusion pumps, with the exception of PCA and enteral feeding pumps. Baxter Colleague CX pumps are equipped with Guardian dose-limiting software. This software enhances the Baxter pump by informing staff when a value entered by the user is outside the pre-programmed dose range for that particular drug. The pump issues a visual and audible alarm to let the user know that the dose value is outside the pre-determined limits. The alarm is a soft warning, as the user has the option to either: 1) obey this warning and reenter new values or 2) override the warning and continue with initial values.

Before implementing the new Colleague CX pumps, internal drug libraries had to be developed to reflect the user's requirements. Seven different Personalities to reflect the needs of various areas within the hospitals were created, each containing its own set of drugs and acceptable dose values. Once the user selects a Personality, they have a limited number of drugs from which they can select.

Baxter Colleague CX pumps record the last 1000 keystrokes and events in a History file stored in the pump. This data is accessible through service menus on the pump or by connecting the pump to a PC and downloading the Event History through the Colleague DL Event History Download program. The download process only takes a couple of minutes. Once the Event History is downloaded onto a PC, data can be copied into an Excel spreadsheet for analysis.

On the front of the Baxter pump, there are four softkeys directly below the display screen, and two arrow softkeys to the right of the screen. As the user proceeds between different menus on the display, the text associated with these softkeys changes to display their current function. Therefore, the operation of the keys continuously changes. When the Event History of the pump is downloaded, it simply records that one of the softkeys has been pressed (i.e.: SOFTKEY #1 press) but it does not relate the softkey to the active command displayed on the screen. Therefore, when biomedical staff is interested in determining the actions of a pump, for example to investigate an occurrence report, staff often have to mimic the Event History on another pump to determine the function of the softkeys. This can be a time-consuming experience.

The program created for this study, written in Access Visual Basic, analyzed the Event Histories of numerous pumps, with the objective to break the code down into specific reoccurring sequences. Using a Master pump to mimic the actions in the Event History, reoccurring sequences were defined, and the program could then accurately track how the user operated the pump.

For the application of this study, the program recorded the number of times the user infused a drug while in the Guardian mode. Based on this information, the program determined how many errors were prevented by Guardian. If the user selected a drug to infuse from the drug library, it was discovered that the same sequence of code appeared. The appearance of this sequence indicated that a drug was selected while in the Guardian mode. The code sequence also displayed the selected drug's concentration and volume. By relating this information to the volumes and concentrations stored in the drug library, the program was able to determine what drug was selected. There were only a few cases when two drugs shared the same values of concentration and volume. In this situation, the program indicated that it was unable to accurately determine the drug.

The program did not record every titration of the drug, but only the initial selection and infusion of the drug. However, if during one of the titrations the user entered a value outside the dose limits, the program recorded this incident.

If a drug was selected using the Guardian dose-limiting software, the program would then check to see if the limits were within the pre-determined dose range. The program determined the values manually entered by the user by comparing the code to several of the defined sequences.

If the dose was outside the pre-defined limits, the program recorded the value initially entered by the user and then whether the user accepted the warning given by the pump and chose to change their dose value or whether the user overrode the warning and continued with their initial value.

The program also analyzed the Event History to determine if the user infused a drug without utilizing Guardian. If Guardian was not incorporated into the infusion, the program would record this activity but it was impossible to determine what drug was being infused by simply analyzing the Event History. To determine this information was beyond the scope of this study. The objective of this study was to determine the frequency of Guardian usage by hospital staff and subsequently how often Guardian issued a warning and potentially caught a programming error.

Finally, this study was an excellent opportunity to track the utilization time of the pumps. To do this, the program recorded the amount of time the pump was turned off during the Event History. As this was the first pump utilization study to be conducted within the WRHA, it was anticipated that results could help determine if the current pump allocation was meeting the needs of the various departments.

Results and Discussion

Technologists from six different hospitals within the WRHA were asked to download the Event History of pumps which were brought in for service. Over a period of three months, 227 Event Histories were submitted for analysis. Within the keystrokes of these 227 pumps, there were 241 (13.2%) Guardian drug infusions, compared with 1586 infusions run without Guardian (86.8%). As illustrated in Table 1, 34 (14.1%) of the Guardian infusions issued a warning to the user. The users elected to override this warning 21 times, while they accepted the warning the remaining 13 times.

To understand the user's operation of the pumps, the 34 warnings issued by Guardian were analyzed in detail. Two of the cases when the user overrode the warning and in one case when the user accepted the warning, the user then immediately turned off the pump without infusing the drug. In another case when the pump issued a warning, the user overrode the warning but then got out of the Guardian mode and infused the drug in the basic mode. One possibility on why the user would immediately turn off the pump or exit the Guardian mode after a warning was issued was that the user was unsure what action the pump would take after the warning. If this was the case, additional education may be required so that staff fully understand the purpose of the dose-limiting software. In the remaining 18 times the user overrode the warning, the user started the infusion with the initial values.

	# of pumps	Infused using Guardian	User override warning	User accepted warning	Infused without Guardian
Site #1	19	23	3	4	132
Site #2	11	2	0	0	99
Site #3	3	1	0	0	8
Site #4	49	51	3	3	284
Site #5	14	3	0	1	130
Site #6	131	127	15	5	933
Total	227	207	21	13	1586
Total	227	241			1586

Table 1: breakdown of infusions by hospital site, and summarized by Guardian usage

Another particular case to note was when a user opted to accept the warning, however when prompted to enter new values, the user entered the same values into the pump and tried to run the infusion again. The pump then issued the same warning to the user. The user tried to enter the same values into the pump again, with the pump issuing the warning a third time, at which point, the user entered a value which complied with the dose-limiting software.

In the remaining accepted warning cases, the user entered a new value for the infusion. The pump accepted the new value and infusion was started.

Within the analysis, two particular circumstances where errors were averted stood out. On one of the pumps in Site #6, the user selected Heparin Sodium while in Guardian mode. The user then manually entered a rate of 135mL/hr using the numeral keypad. The pump calculated this rate to correspond to a dose of 13500units/hr. As the dose range for Heparin Sodium varies from 25 to 2500units/hr, Guardian issued a warning. The user must have then realized

their error, because they accepted the warning and then immediately changed the rate to 13.5mL/hr (corresponding to a dose of 1350units/hr). It appears in this case that the user missed a decimal point in their initial programming of the pump.

In another example at Site #6, the user selected Nitroglycerin in Guardian, and entered 105mcg/kg/min for the dose. As the dose limits for Nitroglycerin vary from 0.1 to 10, Guardian indicated a warning. The user accepted this warning and then immediately changed their dose to 1.5mcg/kg/min. In this case, it appears that the user initially entered a '0' instead of the intended decimal point.

The average utilization time of the pumps by site is illustrated in Table 2. Both single and triple channel pumps are included in this average. For the triple channel pumps, the program records the time that at least one of the channels was active.

	# of pumps	Average pump utilization time
Site #1	19	28.58%
Site #2	11	16.10%
Site #3	3	5.92%
Site #4	49	17.89%
Site #5	14	46.40%
Site #6	131	18.57%
Total	227	22.24%

Table 2: average pump utilization time by site

As this was the first pump utilization study conducted, it was intended to be an initial review. However, the unacceptably low utilization times are significant and warrant additional research into this area.

Conclusion

It is evident from the results of this study that dose-limiting software has the potential to avert ADE's. However, the fact that 86.8% of the analyzed infusions did not incorporate the dose-limiting software needs further analysis. This high percentage could be attributed to the staff's unfamiliarity with this new technology or the drug libraries may need adjustment. A limitation of this study was that it was unable to determine what percentage of drugs infused without Guardian are actually included in the drug library and should have been infused in the Guardian mode. Further studies should be conducted to investigate how often a Guardian drug is infused, but the user opted to not use Guardian.

This study has also revealed significantly low pump utilization throughout the hospitals. Although the results are striking and suggest a possible reorganization of the pumps to optimize their usage, this was a preliminary review and it is suggested that further work into this area be conducted. It is suggested that a long-term utilization study be performed, analyzing each channel of the triple pumps separately and compare with the single channel pumps. Results may indicate the proper allocation of single and triple pumps within the hospital to optimize investments.

---

[1] Larsen GY, Parker HB, Cash J, et al. (2005) *Standard Drug Concentrations and Smart-Pump Technology Reduce Continuous-Medication-Infusion Errors in Pediatric Patients*. Pediatrics 116 (1): 21-25.

[2] Baker GR, Norton PG, Flintoft V, et al. (2004) *The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada*. JAMC 170 (11): 1678-1686.

[3] Vincent C, Neale G and Woloshynowych M. (2001) *Adverse Events in British Hospitals:Preliminary Retrospective Record Review*. BMJ 322: 517-519.

[4] Davis P, Lay-Lee R, Briant R, et al. *Adverse Events in New Zealand Public Hospitals: Principal Findings From a National Survey*. [online] 2001 [cited Feb 13th, 2006] Available from: www.moh.govt.nz/publications/adverseevents

[5] Brennan TA, Leape LL, Laird NM, et al. (2004*) Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I.* Qual. Saf. Health Care 13: 145-151.

[6] Rothschild JM, Keohane CA, Cook EF, et al. (2005) *A Controlled Trial of Smart Infusion Pumps to Improve Medication Safety in Critically Ill Patients*. Crit Care Med 33 (3): 533-540.

[7] Forster AJ, Asmis TR, Clark HD, et al. (2004) *Ottawa Hospital Patient Safety Study: Incidence and Timing of Adverse Events in Patients Admitted to a Canadian Teaching Hospital.* CMAJ 170 (8): 1235-1240.

[8] Adachi W and Lodolce AE. (2005) *Use of Failure Mode and Effects Analysis in Improving the Safety of I.V. Drug Administration*. AM J Health-Syst Pharm 62: 917-920.

[9] Leape LL, Bates DW, Cullen DJ, et al. (1995) *Systems analysis of adverse drug events.* JAMA 274:34-43.

[10] Williams CK and Maddox RR. (2005) *Implementation of an I.V. Medication Safety System*. AM J Health-Syst Pharm 62:530-536.

[11] Health Devices (2002) *General-Purpose Infusion Pumps* 31:353-387.

[12] Wilson K and Sullivan M. (2005) *Preventing Medication Errors with Smart Infusion Technology.* Am J Health-Syst Pharm 61: 177-183.

[13] Institute for Safe Medication Practices. *"Smart" Infusion Pumps Join CPOE and Bar Coding as Important Ways to Prevent Medication Errors.* [online] 2002 [cited Feb 6th, 2006] Available from: www.ismp.org/MSAarticles/Smart.htm