SMART PUMPS: MAXIMIZING SAFETY THROUGH EFFECTIVE DESIGN AND TRAINING

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ABSTRACT

Objective: To assess the impact of smart pump design and training on nurses' ability to safely administer intravenous (IV) medications.

Methods: Two lab studies were conducted in a high fidelity simulated clinical environment. The first study was a within group experiment that compared the impact of three commercially available smart pumps on nurses' performance. The second study was a mixed factor experiment that compared the impact of traditional vendor training to human factors and education-informed training on nurses' performance.

Results: Nurses' ability to safely deliver IV medications was significantly affected by smart pump design. However, no significant difference in ability to avoid errors was found between training curricula.

Conclusions: The acquisition of a smart pump that includes design features that have been shown to augment safety (e.g., workflow that encourages users to employ the drug library, informative and salient limit alerts) is more likely to promote safe IV infusions than optimized smart pump training.

INTRODUCTION

Medication errors, and in particular intravenous (IV) errors, are a significant cause of medical injuries[1-4]. While infusion pumps have greatly improved the accuracy and continuity of IV infusions, they are involved in 35-60% of the estimated 770,000 Adverse Drug Events (ADEs) that occur each year [5-8]. Most of these errors are the result of nurses manually inputting incorrect settings or parameters into the pump [5,8,9].

Smart infusion pumps have the potential to reduce medication administration errors by alerting users to potential dosing errors. However, despite a cost of three to four times more than traditional infusion pumps, achieving the safety benefits of smart pumps has been challenging for many hospitals.

At the request of the Ontario Ministry of Health and Long Term Care (MoHLTC) and the Ontario Health Technology Advisory Committee (OHTAC), the University Health Network's (UHN's) Healthcare Human Factors (HHF) team conducted a series of studies to collect evidence on the safety benefits of smart infusion pumps and develop strategies for Ontario hospitals to improve implementation of smart pump systems.

An initial report was completed in early 2009[10]. Overall, HHF found that smart infusion systems can improve medication safety, but their effectiveness is limited and dependent on hospital implementation[10]. The report found that smart pump system implementation must be viewed as a patient safety initiative rather than a stand-alone pump replacement initiative[10]. A broad interdisciplinary approach is required to[10]:

- Develop a smart pump strategy to achieve incremental benefits through system integration (e.g., bar coding capabilities)
- Standardize drug concentrations and dosing units
- Plan for routine drug library updates and log analyses; make every effort to implement a wireless network
- Support users for the cultural shift required to use smart pumps effectively (e.g., use dose rate field)

Without consideration of these factors, it is unlikely that the full benefits of smart pump technology will be achieved[10].

The authors have subsequently completed a supplementary report, which is the focus of this article, based on studies whose goal was to assess the impact of pump design and training on nurses' ability to safely administer IV medications (expected release in spring 2010).

BACKGROUND

Smart pumps are the next generation of IV infusion pumps, which incorporate comprehensive, hospital defined drug libraries with built-in safeguards, to alert users to potential programming/dosing errors.

Figure 1 provides a general overview of the workflow for programming a smart pump. A user programs a smart pump by first selecting the Clinical Care Area (CCA) and entering into its dose error reduction system (DERS). A user will then select a drug name and concentration from the drug library and enter the infusion parameters (e.g., dose rate, volume to be infused). When the infusion parameters are entered, the pump software checks to ensure the dosage values are within pre-determined dosage ranges set by the institution in the DERS. If not, nurses are prompted with either a *soft* limit warning, which can be overridden, or *hard* limit warning, which cannot be overridden.

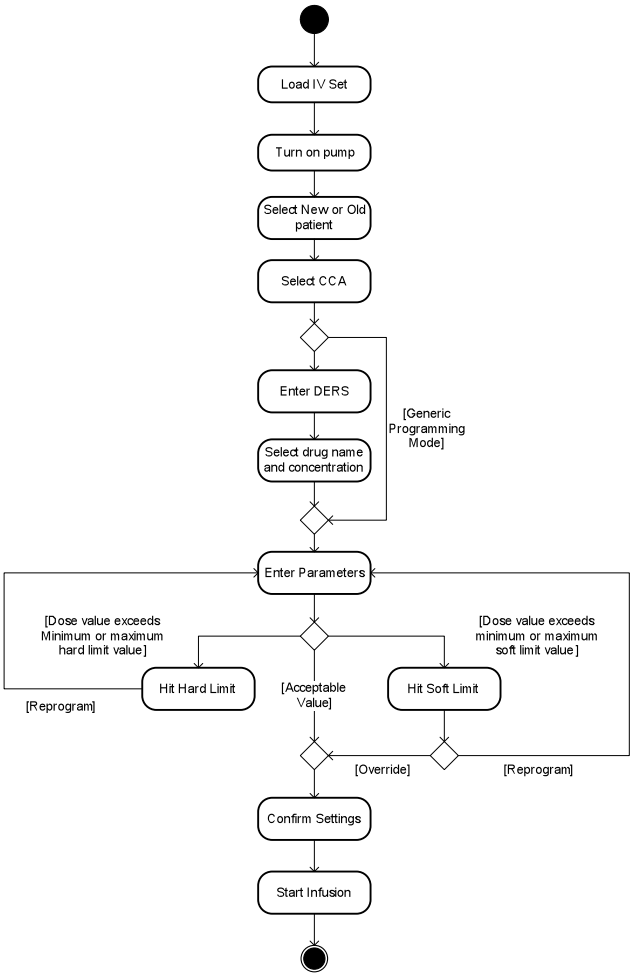

Figure 1: Generalized Smart Pump Programming Workflow: Primary/First Infusion

METHODS

Two separate, but related, laboratory studies were conducted to evaluate smart pump design and training, which are described further below. Research Ethics Board (REB) approval was obtained.

Smart Pump Design

A within-group study was conducted that compared three different commercially available smart pumps. Twenty-four nurses recruited from UHN delivered seven IV infusions on each of three smart pumps. Thus, the experimental design was a 3 (pump model) x 7 (infusion scenario) repeated measures design. The order of the pumps and infusion scenarios were counterbalanced to avoid carry-over effects.

The infusion scenarios were completed in a high fidelity simulated clinical environment containing patient beds, mannequins, drug labels, IV poles, IV bags and IV tubing (see Figure 2). Nurses received infusion drug orders in the same format as their typical practice. That is, physician orders were presented on an integrated computer physician order entry (CPOE) and electronic medication administration (eMAR) system to mirror current nursing practice at UHN. For some unique drugs, paper orders are still used at UHN, and in these cases, the standardized form was used instead of CPOE/eMAR to reflect current practice.

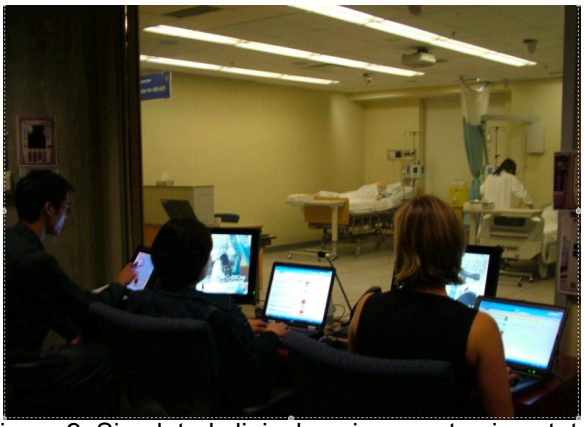

Figure 2: Simulated clinical environment using state of the art digital usability labs

Smart Pump Training

An experimental study was conducted in which the type of training was manipulated. A mixed factors design was used. Forty-seven nurse participants were recruited from UHN. The first twenty-four nurses received a shortened form of traditional vendor based training (VBT). The remaining twenty-three nurses received training designed with modern education principles and human factors analysis of the errors observed with the VBT group. This second training protocol was called human factors and education informed training (HFET). Participants in each group were asked to complete the same set of seven IV infusion scenarios in the same simulated environment as the smart pump design study, but participants only had to complete the tasks on one pump (the same pump was used between the two training groups).

Therefore the between group variable was the training protocol, and the within subject variable was the infusion scenario.

RESULTS

Smart Pump Design

Smart pump designs were compared and evaluated by pump programming subtask (see Figure 1). Infusion subtask success rate was defined as the proportion of nurses that successfully completed the subtask. Subtask failure was the result of either the infusion not being started; the infusion being started with parameters different from those on the medication order; and/or the nurse requiring explicit instructions on how to continue (minor hints were allowed).

Overall statistical differences were recorded between pump designs (see Table 1). That is, key smart pump design features were found to augment safety.

Table 1: Programming Subtask Completion Success Rate -- Statistical Differences Between Designs

Smart Pump Programming Subtask	Statistical Difference Between Designs in Subtask Success Rate*?
Loading IV set	No (but strong impact on subtask completion time)
Starting-up the pump and entering DERS	No
Selecting the drug and concentration	No
Accessing generic programming	Yes (p<0.001)
Entering parameters and starting the infusion	Yes (p=0.05) for intermittent infusions only
Accessing secondary infusion programming	Yes (p<0.001)
Entering secondary infusion parameters	Yes approaching significance (p<0.06)
Responding to soft limit alerts	Yes (p<0.001)
Responding to hard limit alerts	No

* = Cochran Q was used

Smart Pump Training

The training protocols were analyzed by comparing failed infusion rates (defined as in the smart pump design study). In particular, failed infusions were grouped into four categories (see Table 2).

No significant differences were found between training methods overall, or in any failure category (see Table 2). That is, users performed no better after focused educational training based on observed errors (HFET) than users who received general training (VBT). Therefore, training was not found to be effective in remediating errors associated with smart medication systems.

Table 2: Failed Infusions -- Statistical Differences Between Training Protocols

Failed infusions: Failure Mode	Statistical Difference Between Training Protocols*?
Entered wrong parameters	No
Incomplete infusions or instructions required	No
Incorrect handling of limits	No
Selected wrong drug or programmed in generic mode	No

*4 (Failure Mode) x 2 (Training Group) repeated measures analysis of variance (ANOVA) was conducted with repeated measures on the first factor.

DISCUSSION

The study results present two key ideas that contribute to an effective smart pump implementation.

1. Prioritize Design Oriented Safety Strategies

Nurses' ability to safely deliver IV medications was significantly affected by smart pump design. However, no significant differences in safety were found between training curricula; training was not able to compensate for the safety issues posed by poor pump design. These results reinforce the notion that error prevention strategies that change the system (i.e., design oriented) are more effective than those that rely on human vigilance and memory (i.e., people oriented). Therefore, the acquisition of a well-designed smart pump is more likely to promote safe IV infusions than comprehensive training programs. As such, hospitals should focus on the acquisition of a well- designed smart pump to maximize its intended safety benefits.

It is important to note that effective error prevention requires a well-rounded approach and that training remains a valuable tactic. However, training should not be used as the primary response to error prone systems. Error reduction through the use of system changes (e.g., smart pump workflow that encourages, or even forces, DERS use) is likely to achieve better outcomes.

2. Acquire Design Features that Encourage Safe Infusion Programming

Overall, there is no perfectly designed smart pump commercially available that meets the needs of each organization's medication processes. As such, each organization should evaluate and acquire smart pumps based on their unique needs. However, the study

results highlight key general smart pump design features that can statistically augment safety. Consequently, organizations will benefit from smart pumps that utilize these features, some of which are summarized below:

1. Smart pumps must encourage users to use the dose error reduction system (DERS). A workflow that defaults users into the DERS is ideal. By automatically placing users in the DERS, hospitals maximize use of the drug library and therefore increase both safety and efficiency.

2. Smart pump default programming parameters (e.g., dose rate, volume to be infused) should match the information provided to the end-user (e.g., drug order, bag label) and be presented in the same order. This will help eliminate error-prone unit conversions. Given the wide variation of prescribing practices, this may not be feasible in all circumstances, but is highly recommended when possible.

3. Smart pump limit alerts should be informative and salient. Limit alerts should prudently use colour and audio to draw attention to the alert. They should also include clear text explanations of what has happened, the value of the limit that was violated, and intuitive user options.

4. Smart pumps should ensure secondary infusion mode is easily accessible and the infusion mode (i.e., primary or secondary mode) should be clearly visible. In addition, smart pumps should ensure that users can intuitively switch between modes as this further reinforces the understanding of which mode is currently being accessed.

These recommendations highlight the need for further collaboration between pump manufacturers, healthcare providers and end users. Further collaboration will help enhance smart pump system designs and training programs, resulting in more effective and safe implementations.

HHF will continue to research the safety of smart pump systems with an added focus on the administration of multiple concurrent and sequential IV infusions. Multiple infusions increase the complexity and risks of administration due to the high number of pumps, channels, IV bags and tubing combinations that must be properly coordinated. Research in this area is particularly relevant for intensive care areas where multiple infusions are common.

CONCLUSION

In summary, the acquisition of a well-designed smart pump (e.g., workflow that encourages users to employ the drug library) is more likely to promote safe IV infusions than optimized training curricula. Therefore, health care organizations should prioritize the acquisition of a smart pump that contains basic design features that have been shown to augment safety. Training should not be used as the primary response to address IV errors. This reinforces the notion that design oriented error prevention strategies that change the system (e.g., pump programming workflow) should be prioritized over people oriented strategies (e.g., training).

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REFERENCES

[1] Leape LL, Brennan TA, Laird NM, et al.. The nature of adverse events in hospitalized patients: results from the Harvard Medical Practice Study II. NEngl J Med;324:377-84, 1991.

[2] Kinnealey E, Fishman G, Sims N, Cooper J, DeMonaco H. Infusion pumps with “drug libraries” at the point of care – A solution for safer drug delivery; 2003.

[3] Ross LM, Wallace J, Paton JY. Medication errors in a paediatric teaching hospital in the UK: Five years operational experience. Arch Dis Child; 83(6):492-7, 2001.

[4] Kaushal R, Bates DW, Landrigan C. Medication errors and adverse drug events in pediatric inpatients. JAMA;285:2114-20, 2001.

[5] Reeves J. "Smart pump" technology reduces errors. APSF;18(1):1-16, 2003.

[6] Tourville J. How technology is helping Children's Medical Center of Dallas reach zero-error tolerance. U.S. Pharmacist; 28: 80-86, 2003.

[7] Eskew JA, Jacobi J, Buss WF, Warhurst HM, Debord CL. Using innovative technologies to set new safety standards for the infusion of intravenous medications. Hosp Pharm;37:1179-89, 2002.

[8] Adachi W, Lodolce AE. Use of failure mode and effects analysis in improving the safety of IV drug administration. Am J Health-Syst Pharm;62(9):917-20, 2005.

[9] Murdoch LJ, Cameron VL. Smart infusion technology: A minimum safety standard for intensive care?. Br J Nurs;17(10):630-6, 2008.

[10] Healthcare Human Factors. Smart medication delivery systems: Infusion pumps. Toronto. 2009. Available: http://www.ehealthinnovation.org/files/SmartMedicationDeliverySystems_FullReport.pdf.