Do Smart Pumps Actually Reduce Medication Errors?

Sonia Pinkney, Patricia Trbovich, Mark Fan, Sarah Rothwell, Joseph A. Cafazzo, and Anthony Easty

There is growing evidence that medication errors are prevalent in healthcare, with one estimate that there is at least one medication error per hospital patient per day.[1] This is partly due to the complexity of the medication process. Unfortunately, its intricacies are mirrored in the daunting list of potential interventions (e.g., improve medication labeling, implement double check procedures, create training programs and/or implement new technologies). As a result, healthcare providers are currently grappling with how best to proceed.

A framework for intervention design was presented in a "Medication Safety Alert!" bulletin published by the Institute for Safe Medication Practices (ISMP) to help prioritize effective changes for safe medication use.[2] This is commonly referred to as the hierarchy of effectiveness, and it categorizes interventions into six levels, with the most effective at preventing errors at the top and the least effective at the bottom. Figure 1 provides further information regarding each level of the hierarchy, but the top three levels can be described as design-oriented strategies and the bottom three levels as person-oriented strategies.

While effective error prevention often requires the use of strategies at all levels of this hierarchy, generally strategies that change the system (i.e., design-oriented) provide more effective and longer lasting safety benefits than those that rely on the vigilance of people (i.e., person-oriented). That is, the hierarchy suggests that interventions aimed at correcting user behavior (e.g., relying on training personnel) are often not effective because they do not address the underlying systemic issues that lead to errors. As shown in Figure 1, tools that remove the potential for an error to occur are ideal. Failing this, tools that change the system to minimize, or ideally remove, the reliance on human weaknesses, such as memory and communication of complex information (e.g., illegible hand writing, communicating verbatim), are preferred. Tools that rely too heavily on users' attentiveness, complicated processes and systems, or people detecting their own or others' errors are usually less effective.

ABOUT THE AUTHORS

Sonia Pinkney is a clinical engineer working within the healthcare human factors team at the Centre for Global eHealth Innovation at the University Health Network. *Email: sonia.pinkney@uhn.on.ca*

Patricia Trbovich, PhD is academic research lead for the healthcare human factors team at the Centre for Global eHealth Innovation at the University Health Network.
Email: patricia.trbovich@uhn.on.ca

Mark Fan is a human factors analyst with the Healthcare Human Factors team based at the University Health Network.
Email: mark.fan@uhn.on.ca

Sarah Rothwell is a clinical engineer at Massachusetts General Hospital.
Email: srothwell@partners.org

Joseph Cafazzo, PhD is lead for the Centre for Global eHealth Innovation and director of healthcare human factors at the University Health Network.
Email: joe.cafazzo@uhn.on.ca

Anthony Easty, PhD, CCE is chair of the management committee for the Centre for Global eHealth Innovation and senior director at University Health Network. *Email: tony.easty@uhn.on.ca*

Healthcare providers often employ person-oriented interventions because they can be easier and faster to implement than design-oriented ones.[2] This is also true for health technology designers, who often do not adequately consider the strengths and limitations of their end users prior to product launch, resulting in an overreliance on person-oriented strategies (e.g., manuals, training) when managing the resulting postmarket product issues.

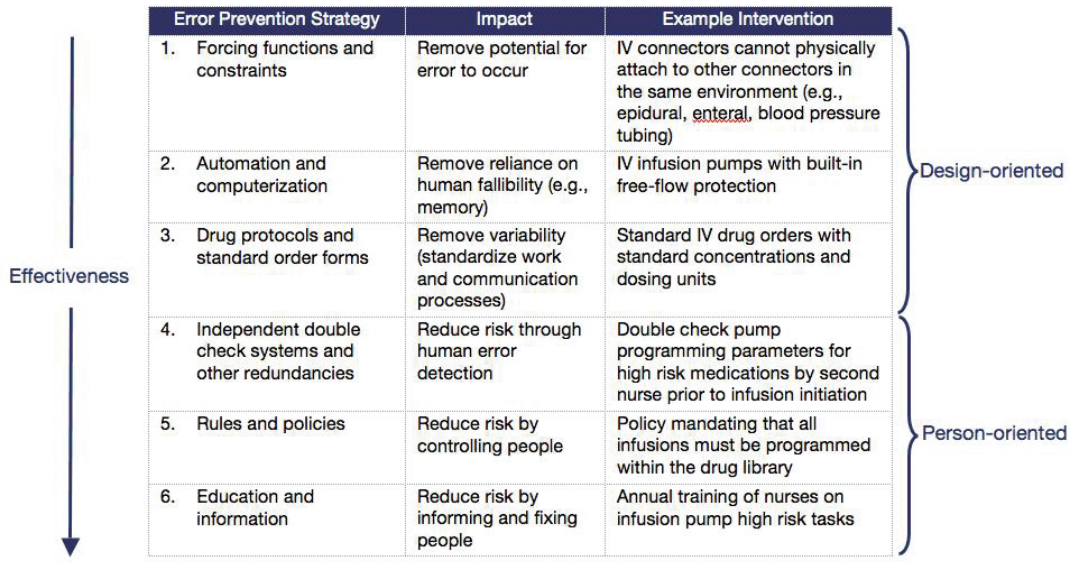

Figure 1. Medication Error Prevention Hierarchy of Effectiveness[2]

Smart infusion pumps are one intervention healthcare providers are implementing in an attempt to design out intravenous (IV) medication errors, particularly pump programming errors. Unlike traditional infusion pumps, which have a wide range of acceptable programming parameters, smart pumps include hospital-defined drug libraries with dosing limits to alert users to potential programming/dosing errors. Nurses are prompted with either a "soft" limit warning, which can be overridden, or "hard" limit warning, which cannot be overridden. Some smart pumps are also starting to incorporate bar coding capabilities, which can verify additional patient medication rights (e.g., right patient, right route, right time, right drug). However, research to date has shown varying impacts of smart pumps, with some studies claiming a reduction in errors[3,4,5,6] and others suggesting minimal to no impact.[7,8,9] These conflicting results, combined with their heavy price tag, beg the question: are smart pumps actually effective at preventing medication errors?

As part of its ongoing focus on medication safety, the Ontario Health Technology Advisory Committee (OHTAC) requested that Healthcare Human Factors (HHF) at the University Health Network (UHN) help answer this question by completing a series of empirical tests in a simulated environment with smart general purpose infusion pumps.[10,11,12] This article focuses on reviewing the key results from these studies through the lens of the hierarchy of effectiveness.

Studies

We conducted three separate but related studies using our usability labs where we simulated an inpatient unit. Nurses were asked to program various IV infusions in realistic scenarios (with planted errors) while human factors experts observed behind a one-way glass (Figure 2). The three experiments were conducted to quantify the impact of the following on nurses' ability to safely deliver IV medications and fluids:

1. Infusion pump type (i.e., comparison of a traditional pump, smart pump, and smart pump with bar coding capabilities)[10,12]
2. Smart pump design (i.e., comparison of three different commercially available smart pumps)[11]
3. Training (i.e., comparison of two different training curricula, one which was representative of typical vendor training and another focused on known smart pump issues using human factors and adult education principles)[11]

Findings

Overall, smart infusion systems were found to statistically decrease the rate of medication errors, and in particular, ensure that patients receive the right dose.[10,12] However, their effectiveness was limited and dependent on pump design, configuration, and implementation.[10,11,12] This finding is primarily due to the fact that in their current form, smart pumps are still heavily dependent on person-oriented error prevention.

Alerts and Their Limits

One key finding was that soft limit warnings had no significant impact on preventing errors.[10,12] Nurses simply overrode these alerts even when clinically inappropriate. While their effectiveness was found to be dependent on design (e.g., prudent use of color and audio, clear text explanations of what has happened, the value of the limit that was violated, and intuitive options on how to proceed),[11] nurses frequently overrode the alerts.[10,12] This finding is not surprising since soft limit alerts can be viewed as a person-oriented error prevention strategy because they essentially act as a double check, and rely on human intervention to detect and correct an error. Also, it is interesting to note that the experimental results provided no conclusive evidence that the use of a confirmation screen, another person-oriented intervention, increased safety during parameter entry.[11]

Figure 2. Usability lab, Centre for eHealth Innovation, UHN. Human factors experts observe nurse participants as they deliver IV infusions with smart infusion technologies in a high-fidelity simulated environment.

In contrast, in our lab studies when nurses hit a hard limit they were forced to reprogram the infusion, which prevented wrong dose medication errors.[10,12] This is particularly interesting because many hospitals are implementing no, or very few, hard limits due to the lack of authoritatively endorsed best practice dosing standards and variability in workflows and practices. However, based on our study data, hard limits should be more liberally used by hospitals as they are an excellent example of a forcing function that prevents an error from occurring.

An Engaging and Up-to-Date Drug Library

Smart pumps are only effective if users program infusions within the safety that the drug libraries can provide. In our lab studies, users programmed almost all infusions within a drug library when the pump workflow either defaulted them into the drug library or prompted them to use the drug library.[10,11] This is a remarkable finding because most hospitals struggle to ensure high drug library compliance. Approximately half of the surveyed Ontario hospitals that currently use smart pumps reported that nurses in their institution were not using the drug library at all or only minimally.[10]

One contributing factor for the difference between the lab and survey results may be that most smart pumps in use in Ontario require users to actively engage the drug library; the default pump workflow is to program infusions generically rather than default the user into the drug library. Therefore, a smart pump that relies on users actively engaging the drug library is less preferable to one that encourages, or even requires, nurses to enter into the drug library.[10,11] Supporting and constraining users to follow the preferred workflow (i.e., program infusions within the drug library) is a design-oriented solution that helps ensure users employ the safety features of the smart pump.

Another reason users may not employ drug libraries in the field is that they must be comprehensive and up-to-date or nurses will become frustrated and revert to generic programming.[10] Healthcare organizations can help avoid this behavior by ensuring that comprehensive standardized concentrations and dosing units are synchronized throughout the medication system (e.g., drug orders match drug library options). This requires that drug libraries be dynamic as they must be coincident with changing clinical best practices and drug formulary. Wireless networks are essential to routinely update drug libraries, to maintain and even increase the intelligence of the smart infusion system over time.[10] This is an example where automation and standardized work processes—design-oriented solutions—can help augment smart pump effectiveness.

No Math Please

Our lab studies also highlighted that smart pump effectiveness is statistically decreased when nurses have to derive pump input parameters from doctor's orders, which involves error-prone calculations.[10,11,12] These errors occurred across all smart pumps evaluated, with less than half of them being caught by the nurse or smart pump (errors were within soft limits).[11]

Nurses should be presented clear, exact, and unambiguous input parameters required to program the infusion pump.[10,11] Smart pumps help support this practice by readily providing nurses with programming fields that match medication orders (e.g., dose, dose rate, duration), unlike traditional pumps, which require nurses to calculate flow rate or use dose/duration-rate calculators buried in submenus. However, old practices die hard: in our experiments, some nurses preferred to continue programming smart pumps using flow rate, which remains an option on most smart pumps, resulting in calculation errors.[10,11] Therefore, further collaboration between pump designers and end users is required to optimize pump programming.

Experimental results suggest that these types of errors can be designed out of the system by providing infusion-specific default programming fields that match parameters provided to nurses on medication orders and IV bag labels.[10,11] This may, for example, require different parameter input screens for continuous versus intermittent infusions or perhaps be drug specific. This is in keeping with the hierarchy of effectiveness by constraining and supporting users to desired workflows. Ultimately, the best practice solution will involve an integrated medication administration system where the elements of different systems (e.g., computerized physician order entry, bar code administration management, and positive patient identification systems) are in sync and used to automatically program smart pumps (see "the closed-loop medication management dream" below).

It's In the Tubing, or Is It?

We found that all tested smart pumps failed to address some of the known risks associated with infusion therapy, particularly regarding the physical setup of pumps.[10,11,12] Smart infusion pumps have no "smartness" to ensure the correct fluid is being administered to the correct patient access site. This is particularly an issue for secondary "piggyback" infusions, where a high rate of physical setup errors was observed across all pump types (i.e., traditional pump, smart pump, and smart pump with bar coding enabled).[10,12] Observed physical setup issues included bag misalignment, tubing mix-ups, and failing to open the secondary clamp.[10,12]

> "Smart pumps hold much more potential to help reduce medication errors when integrated with other components of the medication process."

Smart pumps in their current form do not design out these issues. They rely on training and hospital policies and procedures—person-oriented solutions—to ensure pumps are pulling fluid from the correct bag and pumping it to the correct access site. It is hypothesized that these issues are further compounded in acute environments where multiple pumps/channels are common and the potential for confusion from multiple tubing and pumps is increased. This issue is currently being studied further by HHF.

Training is Not the Answer

While training is important to orient users to a new technology, our lab results revealed that training has limited effectiveness in remediating errors associated with smart medication delivery systems.[11] Specifically, users that had focused educational training based on observed errors performed no better than those that received general training.[11] This reinforces the notion that poor design cannot be compensated by person-oriented strategies, such as training.

The Closed-Loop Medication Management Dream

As discussed herein, smart pumps on their own are, at best, a limited medication safety strategy because they only focus on potential dosing errors using a mix of design and person-oriented strategies. However, smart pumps hold much more potential to help reduce medication errors when integrated with other components of the medication process (e.g., computerized physician order entry, bar code administration management, and positive patient ID systems).

When fully integrated into a closed-loop medication management system, a nurse may scan a barcode on the patient's wristband, IV bag label, his/her ID badge, and pump (vendor-specific implementations may vary). The scanned bedside information is then compared with the information upstream (e.g., physician order). If all elements match, the smart pump's programming parameters

are automatically populated and reviewed and confirmed by the nurse prior to administration. Once the infusion is running, the information is charted in the medication administration record (MAR).

This sort of integrated system holds potential because it is primarily a design-oriented medication error prevention strategy that can help verify all five patient medication rights: the right drug and dose by the right route at the right time for the right patient. It uses forcing functions, constraints, and automation to minimize the reliance on human memory, data entry, and communication, thereby increasing infusion safety and providing automated documentation.

The unfortunate reality is that most hospitals and vendors are not ready for this kind of integration. It requires the synchronization of many complex workflows and systems which are currently disparate and interact in a multitude of ways with tremendous variability. We encourage hospitals to work methodically toward this goal.

In 2008, we wanted to test a closed-loop medication management system in our labs to quantify its impact on nurses' ability to safely administer IV medications and fluids, but at that time no vendor licensed in Canada was able to provide us with a market-ready system. As a result, we could only test a compromise solution, which could detect if the infusion was being administered to the correct patient, but could neither verify that the scanned information matched the initial order nor auto-populate the complete drug order into the pump (see Figure 3).

Our lab results revealed that the automatic patient identification verification on the barcode-enabled smart pump significantly increased nurses' resolution of wrong patient errors.[10,12] This finding reinforces the potential for a fully closed-loop medication management system and the validity of designing out these system issues. However, in its current form, it is susceptible to the same person-oriented issues as smart pumps, such as a high rate of soft limit overrides and wrong drug, wrong route, and wrong time errors.[10,12] Therefore, while smart pumps with barcoding hold promise and help prevent certain errors that standard smart pumps could not address (i.e., wrong patient errors), our findings show that until hospitals achieve system interconnectivity, barcode-enabled smart pumps will continue to allow errors to reach the patient (e.g., physical setup errors, wrong drug).[10,12] In addition, further research may be required to optimize barcode-enabled smart pumps given that it introduces new workflow requirements (e.g., scanning issues).

Conclusions and Recommendations

Most hospitals must bridge the gap between traditional infusion pumps and the fully integrated closed-loop medication management system described above. Therefore, healthcare providers are left with the question: How do I optimize smart pump implementations now to minimize medication errors?

Our lab studies have shown that reliance on training alone is not the answer. Rather, the answer lies further up the hierarchy of effectiveness. Healthcare providers, together with vendors, can optimize smart pump implementation by focusing on the following three design-oriented solutions:

First, smart pumps must be designed with features that have been shown to augment safety. Our study results highlight key general smart pump design features that can statistically augment safety. Consequently, healthcare providers will benefit from acquiring smart pumps that utilize these features. Some of these features are summarized above (e.g., salient and informative limit alerts, workflows that encourage or force the use of drug libraries, default programming fields that match orders),

Figure 3. Nurse scans an IV bag drug label containing the patient name, drug name and concentration. This information is compared to the patient name scanned on the patient armband and if it matches, the drug and concentration are automatically selected during pump programming.

but more information including detailed recommendations is available in our report *Smart Medication Delivery Systems: Infusion Pumps*, 2009,[10] and associated documents, which are available at: http://www.ehealthinnovation.org/?q=node/365. Vendors must work with their end users and design teams to ensure their products include these basic design features, if not already included, as well as mitigate the residual risks associated with IV infusions (e.g., secondary piggyback infusions).

Second, smart pump implementation must be viewed as part of a larger medication safety initiative and not as a pump replacement project. Design-oriented solutions should not be focused just on the technology itself, but also on the redesign of associated workflows and environments to optimize smart pump implementation, for example, standardizing drug dosing concentrations and units, which are synchronized and used throughout the medication process from the initial drug order to administration (i.e., pump programming). Other workflows will be new to smart pumps and consequently require development and support, for example, ensuring smart pump drug libraries are comprehensive (i.e., all drugs, fluids, boluses and hard limits) and frequently updated. In addition, downloaded pump logs can be used to review and optimize clinical practice.

Third, while most hospitals and vendors are not ready for a fully closed-loop medication management system, it is critical that they start planning and designing for it. Only then will we be able to close the gap between the potential full benefits of smart infusion technology and our existing reality.

All these results and recommendations highlight the need for further collaboration between smart pump manufacturers, healthcare providers (e.g., end users), and regulatory and advisory bodies to systematically design out the underlying issues that lead to IV medication errors through a combination of technical, workflow, and environmental interventions. This reinforces the fundamental notion presented in the hierarchy of effectiveness that successful and long-lasting improvements to IV medication administration safety will only be achieved by eliminating the potential for error to occur rather than trying to correct end user behavior. ■

Acknowledgements

The authors gratefully acknowledge the Ministry of Health and Long-Term Care of Ontario (MoHLTC), particularly Dr. Leslie Levin and Dr. Birthe Jorgensen of the Medical Advisory Secretariat (MAS) for supporting this work. We also acknowledge the involvement of the hospital staff at the University Health Network (UHN). The authors thank Eliza To for her help with the pharmacy requirements of this project and for her valuable insights. We would also like to thank Jennifer Jeon, Alvita Chan, Melissa Griffin, Rachel Zhang, NiiOkai Alcide, and Andrew Shantz for their help in the execution of the experiments.

This research was funded by Ministry of Health and Long-Term Care of Ontario (MoHLTC) and conducted at the request of the Ontario Health Technology Advisory Committee (OHTAC). The opinions in this paper are those of the authors and do not necessarily reflect the sponsor's official position.

References

1. Institute of Medicine. Preventing Medication Errors: Quality Chasm Series. 2006. Available at: http://www.iom.edu/Reports/2006/Preventing-Medication-Errors-Quality-Chasm-Series.aspx. Accessed April 28, 2010.
2. Institute for Safe Medication Practices. Medication error prevention "toolbox." ISMP Medication Safety Alert! 1999 (June 2). Available at: http://www.ismp.org/newsletters/acutecare/articles/19990602.asp. Accessed April 28, 2010.
3. **Kinnealey E, Fishman G, Sims N, et al.** Infusion pumps with "drug libraries" at the point of care—A common solution for safer drug delivery. 2003. Available at: http://www.npsf.org/download/Kinnealy.pdf. Accessed April 28, 2010.
4. **Murdoch LJ, Cameron V.** Smart infusion technology: A minimum safety standard for intensive care? *British Journal of Nursing.* 2008;17(10):630-36.
5. **Larsen GY, Parker HB, Cash J, et al.** Standard drug concentrations and smart-pump technology reduce continuous-medication-infusion errors in pediatric patients. *Pediatrics.* 2005;116(1):21-5.
6. **Maddox RR.** ICU sedation—An analysis of intravenous dose limit overrides. In: Schneider PJ (ed) Measuring Medication Safety with Smart IV Systems: Proceedings from the Fourth Conference. Cardinal Health Centre for Medication Safety and Clinical Improvement, San Diego, CA. 2004:37-40.
7. **Husch M, Sullivan C, Rooney D, et al.** Insights from the sharp end of intravenous medication errors: Implications for infusion pump technology. *Qual Saf Health Care.* 2005;14:80–6.
8. **Rothschild JM, Keohane CA, Cook EF, et al.** A controlled trial of smart infusion pumps to improve medication safety in critically ill patients. *Crit. Care Med.* 2005;33(3):533-40.
9. **Nuckols TK, Bower AG, Paddock SM, et al.** Programmable infusion pumps in ICUs: An analysis of corresponding adverse drug events. *J General Intern Med (Suppl 1).* 2008;23 Suppl:141-45.
10. Healthcare Human Factors Group. Smart medication delivery systems: Infusion pumps. Toronto. 2009. Available at: http://www.ehealthinnovation.org/?q=node/365. Accessed April 28, 2010.
11. Healthcare Human Factors Group. Smart medication delivery systems: Infusion pumps. Supplementary Report: Evaluation of Effective Smart Pump Design & Education Strategies. Toronto. 2009. Available at: http://www.ehealthinnovation.org/?q=node/365. Accessed April 28, 2010.
12. **Trbovich PL, Pinkney S, Cafazzo J, et al.** The Impact of Traditional and Smart Pump Infusion Technology on Nurse Medication Administration Performance in a Simulated Inpatient Unit. Accepted at *Qual Saf Health Care 2009.* Available at: http://qshc.bmj.com/content/early/2010/04/27/qshc.2009.032839.full.pdf. Accessed April 28, 2010.