

Medication Safety Alerts

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Patient safety requires culture change and system improvement. Hospital pharmacists are in the best position to orchestrate system changes to improve medication safety. After all, they are in the unique position of understanding medication-use processes and their safety components from A to Z. Although challenges and barriers have repeatedly inhibited our ability to move forward with new thinking and to dare the health care system to make daunting system design changes, Canada is home to champions whom we can applaud and learn from. ISMP Canada has recently learned about medication safety initiatives at the Children's and Women's Health Centre of British Columbia in Vancouver, which are described here by the pharmacy staff. —David U, column editor

CLINICIAN-BASED DESIGN OF PATIENT SAFETY SYSTEMS

Like other health institutions, Children's and Women's Health Centre of British Columbia (C&W) has experienced patient safety challenges, which have included the most severe consequence, patient harm. These challenges, and the occasional absence of commercial safety devices, have motivated our staff to venture boldly into system and technology design.

Our institutional motivation is not profit, but rather the introduction of patient safety designs to the market, so that they will be made broadly available at reasonable cost. Should any profit be realized, it will be used to reimburse the hospital's financial commitment and to support additional endeavours in safety design. In some cases, an existing vendor partner undertakes much of the burden of design and marketing expense through an R&D partnership arrangement. In areas where we do not have existing partners, we have ourselves pursued technical design and ownership (through patent application).

This review of our current projects is intended to demonstrate the type of clinician designs that are possible and to provide an appreciation of the elements of partnership and support that are necessary for success.

Spinal Injection Safety System

Inadvertent administration of the wrong drug by the spinal or epidural route, often with catastrophic results,

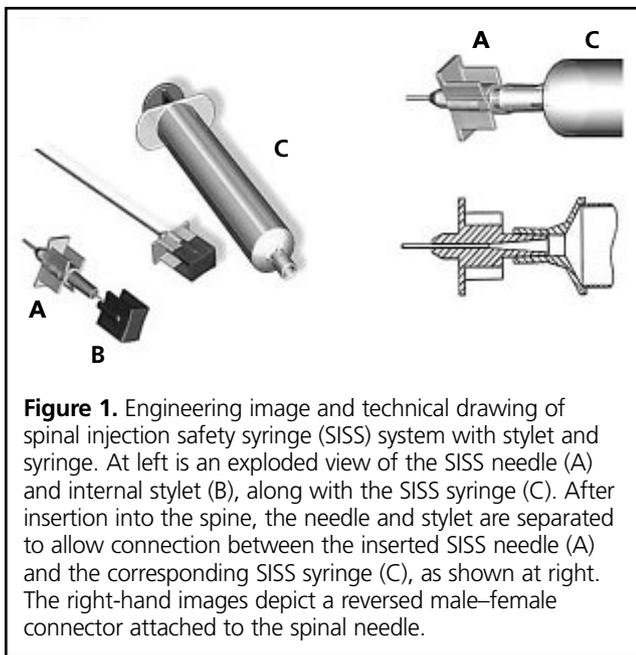
continues to occur in oncology and anesthetic practices.¹ Positions expressed by health regulatory and professional bodies have indicated the need for a designed solution to prevent inadvertent injection of a high-alert drug by the wrong route.^{2,4}

In an effort to improve patient safety, the Canadian Anesthesiologists' Society has recently revised its *Guidelines to the Practice of Anesthesia, 2002 edition*, to include the recommendation that "Until a specific connection system is devised for neuraxial use, both sides of all Luer connections should be labeled".⁵ Yet spinal, epidural, and IV injection errors are not uncommon and arise in part because of the ubiquitous use of Luer connectors for a wide range of medical devices.⁶

Although there is disagreement among some experts about the value of undertaking a major design change of existing medical devices to ensure incompatibility of equipment intended for different routes of injection (e.g., spinal or epidural rather than intravascular),⁷⁻¹¹ we have designed and patented a modified syringe and needle system that we feel addresses the need for such as device. The system was developed in collaboration with the Health Technology Division of the British Columbia Institute of Technology (BCIT).

The design of our spinal injection safety syringe (SISS) (Figure 1) is based on a "forced function" principle, and the unit will not cross-connect with currently marketed IV systems (Figure 2). This incompatibility was achieved by redesigning the



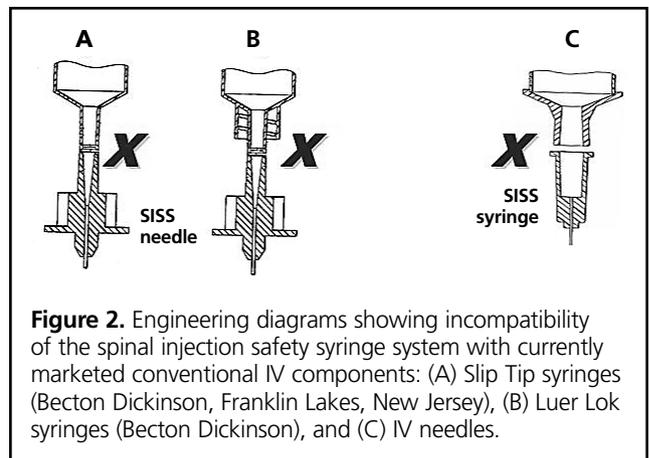


connections, using a resized and modified male–female end. If the system is adopted as the sole spinal injection system within an institution, connection of Luer Lok or Slip Tip IV syringes (both Becton Dickinson, Franklin Lakes, New Jersey) to spinal needles will be entirely prevented. This design also prevents medication that has been drawn up into the spinal syringe from being administered intravenously by direct connection to any peripheral IV site. It thereby reduces the potential for other identified crossover errors such as spinal bupivacaine given intravenously.¹²

The SISS is currently in the prototype stage, having received Canadian and US patent approval in early 2003. Plans are being developed for limited production of the system and for human trials. Although the first phase of our efforts has been directed at reducing spinal injection errors, use of the same connection design in subsequent phases will allow expansion of the product design for application with spinal and epidural infusions, which may be of particular interest to anesthesiologists responsible for pain management.

Centricity-Admin Point-of-Care (Bedside) Dose Verification by Nurses

Point-of-care bar code verification systems can reduce nurses' bedside errors by as much as 87%.¹³ Several versions of this technology are commercially available. However, in many cases the hospital must use the vendor's provided hardware; furthermore, the systems may be additional to (rather than integrated into) the hospital's existing and future mobile equipment. If



several such technologies are used simultaneously, nurses may need to carry multiple devices and may consequently express dissatisfaction with the technologies.

In conjunction with GE Medical Systems (formerly BDM Information Systems), Saskatoon, Saskatchewan, and Providence Health Care (specifically, the Pharmacy Department of St Paul's Hospital, Vancouver), C&W has co-developed a bedside verification system for use by nurses. The system is based on bar code scanning of patients and drug doses at the point of drug administration. It uses real-time radio frequency technology to verify the accuracy of each patient dose, by comparing the scanned patient and dose bar codes with active medication profile data maintained within the pharmacy computer system. Two years in design, this system is an alternative to the standalone systems currently available. It gives the hospital flexibility in its hardware planning, ensures patient confidentiality, and offers a variety of functions to the nursing staff.

The system uses a multifunctional, personal digital assistant (PDA). Our hospital selected a Symbol PDA (model 8846; Symbol Technologies, Holtville, New York), but different models might be chosen by other hospitals, as long as they meet certain baseline standards. The software functionality resides not within the PDA itself but within the hospital intranet and is accessed through the on-board PDA Internet browser.

Because the software and patient data do not reside within the PDA, they do not consume valuable internal memory, and the PDA is available as a multipurpose tool for the nurse. Also, because patient data are never downloaded to the PDA, there are no patient confidentiality concerns should the device be mislaid. A single PDA device, chosen by the hospital (rather than dictated by the technology), becomes a tool for integrating multiple safety, information, and communication tasks.

The Centricity-Admin software performs basic medication dose safety checks (right patient, right drug, right dose, and right time), but it is also intended to go beyond basic safety to improve other aspects of the medication system. It provides a real-time system for medication administration records (MARs). It allows electronic documentation by the nurse of dose administration, either as a standalone post-event MAR system or interfaced with electronic health records. It helps the nurse to organize patient care by automatically scheduling activities and will link to other drug or policy information sources available through the hospital's intranet. Safety warnings and dose reminders reduce the potential for administration error. In the future, the system will be linked to warnings generated by increasingly complex clinical logic modules, defined by clinical pharmacists. It is also anticipated that the system will be linked with laboratory systems and nutrition services to facilitate bar code checking for other products (such as blood products and breast milk) or tests.

The first version of the system underwent trial within our Oncology Programme, beginning in December 2003. The trial has been a success, and GE Medical began marketing the device under the brand name Centricity-Admin in early 2004. Texas Children's Hospital in Houston has begun a trial, and that institution and C&W hope to expand use of the product to all acute care pediatric (and obstetric) patients within the next year (2004/05).

Other Initiatives

As a result of the success of the initiatives described above, other design projects have been initiated. Some design activities have gone beyond medication safety into the related area of parenteral therapy safety.

Infusion Calculators for Nurses

Examples of the plug-in modules for the bedside verification tool described above include dosage infusion calculators for nurses. These calculators help nurses to accurately calculate and admix complex IV solutions, when necessary. These mobile intranet-based calculators will be accessible through either mobile PDAs or any computer within the ward unit. The first of these is being developed by our neonatal clinical pharmacist and can be used in 2 ways: as an infusion bag "recipe" calculator for neonates with fluid overload when the flow rate has been set by physician order or as a rate calculator when a fixed amount of drug is being mixed into a fixed fluid volume.

Prevention of Tubing Entanglement

In July 2002, Health Canada issued a hospital alert on the risk of strangulation of infants by IV tubing and monitor leads,¹⁴ recommending that all children who might become entangled in a lead or tubing while in hospital should be continuously observed by an adult or connected to a monitor. This recommendation was recognized as operationally challenging, so C&W once again worked with BCIT to develop 3 prototypes that should significantly reduce the possibility of strangulation in young infants and cognitively impaired children.

The first phase of this project is complete, and 3 prototypes have been presented to nurses for feedback. Our next step will be to further develop the top 2 designs identified through the on-site nursing evaluation. We will produce 1000 units of each device for evaluation purposes and will thereafter attempt to attract business partners to bring the products to the health care market.

Mobile Assessment of Vascular Access Lines

An intranet-based PDA tool for mobile assessment of vascular access lines is being developed predominantly by nurses, under the authority of the chief of nursing practice and the hospital Safe Medication Administration Committee. The goal is to develop a mobile system through which each patient care area can record and monitor vascular access lines and their daily conditions. The resultant database will be centrally stored, for use in several ways, including outcome quality improvement, statistical trending, and related assessments of nursing staff.

Elements of Design Support

In any area of patient safety, we learn from earlier experiences, and design is no different. We quickly discovered that ideas do not easily progress from paper to production. A successful enterprise relies on supportive partnerships with nontraditional as well as traditional partners, often a different one at each stage of the project.

If your institution wishes to undertake design projects, we recommend that you consider the following key elements:

- Align with commercial partners with whom you have already developed relationships. Be willing to work cooperatively and combine your clinical expertise with their design and marketing know-how.
- Be flexible in design concepts and project timelines.
- Learn failure modes and effects analysis, and apply the principles to your design.
- Partner with health care technology designers within academic and technical institutions such as the BCIT.



- Develop a departmental relationship with your hospital's business development director.
- Ask your hospital lawyer to provide legal advice on various agreements (e.g., service contracts and nondisclosure agreements) and, perhaps, patent applications.
- Seek encouragement and advice from various safety organizations.
- Correspond directly with individuals who are safety pioneers, and seek their advice.
- Attend and contribute to health care safety meetings.
- Involve academic researchers, who know where research money can be obtained and who know how to write effective grant applications.
- Ask other institutions and outside colleagues to join the enterprise.
- Add your ideas to the agenda of the hospital safe medication committee. Seek the committee's support and formal endorsement.
- Seek design ideas from clinicians in all disciplines in your hospital. Introduce an element of fun by presenting "idea awards" and holding fairs for prototype assessments.
- Promote the idea that future profits will offset earlier hospital or grant expenses and lead to further design opportunities.
- Most importantly, work with a forward-looking executive within your organization, one who is also dissatisfied with status quo and who will be willing to promote your initiatives within the organization.

Conclusions

We recommend that pharmacists consider the design of safety systems as an integral part of their professional scope of practice. C&W has undertaken several clinician-based design projects, arising from our concern about the lack of availability of safety systems in the marketplace or from our desire to develop devices specific to unique patients' needs both within our institution and for use by those institutions with similar patient populations.

We have learned that the path to change and systems development is challenging, but clinician-based design is a positive process and results in significant safety benefits. Not only can it provide wide benefit to many patients and institutions, especially those with specialized problems, it also helps to create a positive culture for other safety developments.

We have provided a list of key strategies to enhance success, and encourage pharmacists to consider undertaking such multidisciplinary design activities. We also recommend that professional and regulatory groups align strategically to more effectively influence the health device marketplace.

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