## **ISMP** Canada

### To Err is Human, To Share is Divine

By Christine Koczmara, RN, BScPsy, Carol Dueck, RN, BScN, MCE and Valentina Jelincic, RPh, BScPhm

#### Information about the authors

Christine Koczmara, RN, BScPsy, is a staff member at ISMP Canada. She also holds a casual position as a bedside nurse in the Intensive Care Unit (ICU) at St. Joseph's Health Centre, Toronto.

Carol Dueck, RN, BScN, MCE, is the ISMP Canada Project Leader for the Analyze-ERR<sup>®</sup> software program that assists hospitals and other health care settings to use a non-punitive, non-blame approach to tracking and analyzing medication incidents.

Valentina Jelincic, RPh, BScPhm, is a pharmacy and management consultant and medical writer, with varied experience in the private and public sectors and with professional and non-profit associations.

#### Abstract

Front-line health care practitioners are often safety nets preventing errors from reaching patients. Nurses in critical care environments commonly deal with high-risk patients, high-alert medications and extreme conditions, placing themselves and medication systems under greater pressures. Human error cannot be eradicated. However, the systems in which practitioners work and interact can be made safer and more fault-tolerant. When errors occur, nurses are in a unique position to provide valuable insights. Practitioner reporting and sharing of incident information internally and externally can enhance patient safety by helping to prevent recurrence of similar events.

Medication errors have been recognized as a major category of hospital adverse events in Canada and in other countries (Baker et al., 2004; Leape et al., 1991; Thomas et al., 2000; Wilson et al., 1995). Many articles have specifically highlighted the occurrence of medication errors in the critical care setting (Andrews et al., 1997; Bracco et al., 2001; Calabrese et al., 2001; Cullen et al., 1997; Leape et al., 1999; Parshuram et al., 2003; van den Bemt et al., 2002). Critical care units commonly provide care to high-risk patients who have reduced physiological capacity and ability to recover from an error. This vulnerable patient population often

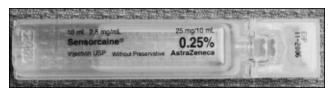


Figure 1: Manufacturer labelling of product *without* generic drug name. (Used with permission from ISMP Canada.)

requires high-alert medications to promote homeostasis and recovery and yet these same medications have a higher probability of causing harm when an error occurs (ISMP, 2003 December 18).

Error reporting systems have been identified as an integral component in improving safety in many industries (Barach & Small, 2000). In particular, documentation of near misses, identified as occurring up to 300 times more frequently than adverse outcomes, can provide an effective and proactive source of information for reducing errors (Barach & Small, 2000). Furthermore, reporting of near misses (i.e., where harm was avoided) has fewer cultural and psychological barriers and can facilitate a blame-free approach to error reporting in general. Although hospitals have incident reporting mechanisms, near misses are much less commonly reported (Burdeau, Crawford, van de Vreede, & McCann, 2006). Studies on error reporting, including those focused on critical care environments, identify a variety of factors required to increase voluntary error reporting including increasing reporting of near misses, eliminating a punitive culture/moving towards a culture of safety, multidisciplinary reporting, timely feedback and follow-up that address improvements, and leadership commitment to patient safety (Bion & Heffner, 2004; Force et al., 2006; Ricci et al., 2004; Stump, 2000).



Figure 2: *Before* – 0.9% sodium chloride injection, left, and sterile water for injection, right, in Viaflex<sup>®</sup> bags. (Used with permission from ISMP Canada.) *After* – Colour photo of sterile water for injection available at: www.ismp-canada.org/download/ISMPCSB2003-06Sterile Water.pdf Health care professionals at the "sharp end" (i.e., providing direct patient care and closest to the error) are commonly nurses. Error reports received reflect how practitioners on the sharp end can suffer feelings of great responsibility and failure. Comments such as "I should have been more careful", "I should have read the label carefully", or "This has never happened before and will never happen again" are common. Practitioners not directly involved may pass judgment on those who have made errors. A culture of blame, however, does little to enhance systems and prevent errors from recurring. Organizations may also focus on individual practitioners, noting strategies such as "spoke with the nurse" or "education of nurse", in the hope of preventing incident recurrences. Unfortunately, this approach serves to perpetuate the myth that humans can be taught to perform flawlessly and compensate for shortcomings that commonly exist in the medication use system. This also leads organizations to overlook multiple factors remote from the individual that continue to exist and will likely lead others to make a similar error. Even when "education" is identified as a necessary component in incident follow-up, there can be failure to recognize the need to be proactive to educate all practitioners and to further identify effective strategies to bring the crucial information to the point of care delivery where it is required.

Classifying the cause of an incident as "human error" will not lead to effective error-prevention strategies as humans can never achieve perfection, nor can they be expected to. Health care processes and systems should alleviate the pressures to perform perfectly and help lead us down the correct path of action. Vicente (2003) highlights the progress of other organizations in which errors can lead to catastrophic events. Vicente discusses how error analysis in the aviation industry evolved into the discipline of human factors engineering (HFE). He notes that in one particular kind of plane, controls for the landing gear and the flaps were identical in shape and placed side-by-side, which led to crashes and deaths due to pilots misidentifying the levers during take-off. Reports indicating "human error" did little or nothing to change recurrences until a more in-depth analysis was conducted with the few pilots who survived these crashes. Vicente notes that this led to a change in the shape of the controls (landing gear



Figure 3: *Before* – Packaging for morphine 2 mg/mL and morphine 10 mg/mL ampoules. (Used with permission from ISMP Canada.)

controls became round and flaps became triangular in shape; providing more intuitive, immediate tactile feedback) resulting in an immediate elimination of the error. In health care, anesthesia is a discipline that has achieved successes in error reduction through the application of HFE principles. One example is the elimination of mix-ups between anesthetic gases and oxygen by changing the fittings, making the connections between oxygen and anesthetic gases incompatible.

Reports of errors and near misses from any health care environment can provide impetus for effective change when the underlying factors are identified. ISMP Canada believes in error reporting that promotes reciprocal trust. It relies on voluntary practitioner/organization reports of medication-related sentinel events or risks. Practitioners/organizations rely on ISMP Canada to act on their report in a variety of ways, such as increasing national awareness by publication and distribution of safety bulletins, and assisting in effecting system-based medication enhancements to prevent incident recurrence. Examples of the reports received and responded to by ISMP Canada discussed in published bulletins and resulting in improved safety applicable to the critical care environment, include:

1. Recall of AstraZeneca's Sensorcaine<sup>®</sup> polyamps<sup>®</sup> after three anesthesiologists reported their concerns regarding the missing generic drug name, considered to be critical information on the label (Refer to Figure 1). Concerns for inadvertent confusion and potential intravenous administration of bupivacaine (cardiotoxic if given intravenously) were relayed to the manufacturer and Health Canada, and a bulletin (ISMP Canada, 2005 July 21) was distributed nationally leading to a recall of the product.

2. Three reports of patient harm as a result of mix-ups between sterile water for injection and IV solutions. (Sterile water is not isotonic and, if infused intravenously, can lead to rapid red blood cell hemolysis, kidney failure and death.) An ISMP Canada bulletin with multiple recommendations was issued (ISMP Canada, 2003 June). ISMP Canada also worked with the manufacturer to have the look-alike packaging of the sterile water product (Figure 2) changed to better differentiate it from IV solutions: red lettering, capitalization of "WATER", "NOT FOR DIRECT INFUSION" clearly and prominently noted. Staff in critical care areas is encouraged to review these bulletins and other information sources (e.g., ISMP, 2003 September 18) for the applicability of their recommendations and to review the use of all sterile water products in a bag format, such as Viaflex® (e.g., if used for ventilator humidification; if used with hyperthermia kits; if used as a base solution in continuous renal replacement therapy [CRRT]).



Figure 4: *After* – Packaging of morphine 2 mg/mL and morphine 10 mg/mL ampoules. (Used with permission from ISMP Canada.)

3. Two error reports were received involving the mix-up of morphine 2 mg/mL and 10 mg/mL ampoules resulting from substitution errors with look-alike packaging (Refer to Figure 3). One patient required treatment with naloxone and the other required additional monitoring. ISMP Canada alerted the manufacturer who subsequently made changes in their packaging (ISMP Canada, 2004 November) (Refer to Figure 4).

4. Reports of near misses and actual mix-ups involving neuromuscular blocking agents have also resulted in a number of recommendations (ISMP Canada, 2002 December; ISMP Canada, 2004 July; ISMP Canada, 2005 April). As a starting point towards standardization, ISMP Canada and pharmaceutical manufacturers of these products have collectively agreed on "ideal" labelling and packaging enhancements (ISMP Canada, 2006 April 25) (Refer to Figure 5).

Currently, there are approximately 12,000 voluntarily reported medication incidents in the ISMP Canada database (ISMP Canada, 2006 April 26). ISMP Canada receives medication incidents through a variety of voluntary reporting mechanisms, including a web portal for individual reports or batch reporting from Analyze-ERR® (ISMP Canada errorreporting software program), mail, fax, e-mail and telephone. Reports vary regarding the impact of the incident on patients, ranging from severe harm (i.e., death or permanent disability) to the majority, where no patient harm occurs. Less often, error reports highlight near misses (good catches) before they reach the patient, or hazardous situations in which concerns for error potential exists (e.g., look-alike packaging, poorly labelled products). One study showed nurses were responsible for intercepting 86% of all medication errors made by physicians, pharmacists and others before the error occurred (Leape et al., 1995). Reporting of near misses provides a tremendous opportunity for insight into needed changes for avoiding patient harm. All reports provide an opportunity for consideration of system enhancements. Thus, energy can be directed towards repairing underlying system failure points that continuously rely on individual vigilance to prevent errors from reaching patients.

Two types of analysis are performed from error reports:

- 1. Aggregate analysis to provide a high-level overview of all errors in the database (e.g., medications most often involved in harm, stages of the medication use process that are involved: prescribing, transcribing, dispensing, administration and monitoring); and
- 2. Select analysis of a single report for a detailed understanding of circumstances contributing to the error.

ISMP Canada Safety Bulletins commonly examine the latter. The bulletins focus on medication-related sentinel events defined as "an unexpected occurrence involving death or serious physical or psychological injury or risk thereof." (JCAHO, 2003, p. 21). These bulletins are distributed across Canada in an effort to raise awareness, to share valuable learning that often reflects common system weaknesses, and to provide recommendations that indicate opportunities for enhancing the medication use processes along the health care continuum (e.g., facilities, pharmaceutical manufacturers). At a national level, the need for an integrated, voluntary non-punitive reporting

system has been identified as an essential step in advancing patient safety in Canada (RCPSC, 2002). ISMP Canada is working collaboratively with Health Canada and the Canadian Institute for Health Information in the Canadian Medication Incident Reporting and Prevention System.

Moving beyond the expectation that all health care practitioners must always perform perfectly and flawlessly will take time and effort on the part of individuals, hospitals and other facilities, as well as provincial and national organizations. Moving towards a culture of safety (eliminating the blame and shame of errors and of practitioners who report them) has been identified as a crucial strategy to increase voluntary reporting (Force et al., 2006; Stump, 2000). Promoting a culture of safety recognizes that well-intentioned, caring and competent practitioners can and do make errors - good people make bad mistakes. Attitude shifts in how we view errors/incidents are needed for effective and sustainable change. Reporting of errors, near misses and hazardous situations requires that care is taken not only in how and what information is collected, but also that reporting is reciprocated with feedback regarding identified system-based failures and corresponding improvements (Force et al., 2006; Ricci et al., 2004; Stump, 2000). The sharing of error reports by nurses and other frontline critical care practitioners (e.g., clinical pharmacists, physicians, registered respiratory care practitioners) beyond the bedside can lead to system enhancements.

The critical care nurse can "sound the alarm" on actual errors, near misses or potentially risky situations to promote system enhancements before a medication error occurs by taking a few minutes to begin a reporting sequence within the organization, in addition to reporting incidents to ISMP Canada.

# How to report an incident/error to ISMP Canada

ISMP Canada has a national voluntary medication incident and 'near miss' reporting program for the purpose of sharing learning experiences from medication errors. Implementation of preventive strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in health care is our collaborative goal.

To report a medication error to ISMP Canada: (i) visit the website, www.ismp-canada.org, or (ii) e-mail info@ismp-canada.org, or (iii) phone 1-866-544-7672 (1-866-54-ISMPC).



Figure 5: Examples of the variety of labelling/packaging of neuromuscular blocking agents in Canada. (Used with permission from ISMP Canada.)

ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in publications.

#### **References**

- Andrews, L.B., Stocking, C., Krizek, T., Gottlieb, L., Krizek, C., Vargish, T., et al. (1997). An alternative strategy for studying adverse events in medical care. **The Lancet**, **349**, 309-313.
- Baker, G.R., Norton, P.G., Flintoff, V., Blais, R., Brown, A., Cox, J., et al. (2004). The Canadian Adverse Events Study: The incidence of adverse events among hospitalized patients in Canada. Canadian Medical Association Journal, 170, 1678-1686.
- Barach, P., & Small, S.D. (2000). Reporting and preventing medical mishaps: Lessons from non-medical near-miss reporting systems. British Medical Journal, 320, 759-763.
- Bion, J.F., & Heffner, J.E. (2004). Challenges in the care of the acutely ill. The Lancet, 363, 970-977.
- Bracco, D., Jean-Baptiste, F., Bissonnette, B., Wasserfallen, J.B., Revelly, J.P., Ravussin, P., et al. (2001). Human errors in a multidisciplinary intensive care unit: A one-year prospective study. Intensive Care Medicine, 27, 137-145.
- Burdeau, G., Crawford, R., van de Vreede, M., & McCann, J. (2006). Taking aim at infusion confusion. Journal of Nursing Care Quality, 21, 151-159.
- Calabrese, A.D., Erstad, B.L., Brandl, K., Barletta, J.F., Kane, S.L., & Sherman, D.S. (2001). Medication administration errors in adult patients in the ICU. Intensive Care Medicine, 27, 1592-1598.
- Cullen, D.J., Sweitzer, B.J., Bates, D.W., Burdick, M.S., Edmondson, A., & Leape, L.L. (1997). Preventable adverse drug events in hospitalized patients: A comparative study of intensive care and general care units. Critical Care Medicine, 25, 1289-1297.
- Force, M.V., Deering, L., Hubbe, J., Andersen, M., Hagemann, B., Cooper-Hahn, M., et al. (2006). Effective strategies to increase reporting of medication errors in hospitals. The Journal of Nursing Administration, 36, 34-41.
- Institute for Safe Medication Practices. (2003, September 18). How sterile water bags show up on nursing units. **ISMP Medication Safety Alert!**, 8(19), 1-2.
- Institute for Safe Medication Practices. (2003, December 18). ISMP's list of high-alert medications. **ISMP Medication Safety Alert!, 8**(25), 3. Retrieved May 20, 2006, from http://www.ismp.org/msaarticles/highalert.htm
- Institute for Safe Medication Practices Canada. (2002, December). Neuromuscular blocking agents: Time for action. **ISMP Canada Safety Bulletin**, **2**(12), 1-3. Retrieved May 31, 2006, from http://www.ismp-canada.org/ publications.htm
- Institute for Safe Medication Practices Canada. (2003, June). Enhanced sterile water label paves way for national standard. **ISMP Canada Safety Bulletin, 3**(6), 1-2. Retrieved May 31, 2006, from http://www.ismp-canada.org/ publications.htm
- Institute for Safe Medication Practices Canada. (2004, July). "Paralyzing" mix-ups in the operating room: Opportunity to improve safety with neuromuscular blockers. **ISMP Canada Safety Bulletin, 4**(7). 1-2. Retrieved May 31, 2006, from http://www.ismp-canada.org/publications.htm
- Institute for Safe Medication Practices Canada. (2004, November). Morphine ampoule look-alike packaging alert. ISMP Canada Safety Bulletin, 4(11), 1-2.

- Institute for Safe Medication Practices Canada. (2005, April). Report of near miss with succinylcholine warrants action. ISMP Canada Safety Bulletin, 5(4), 1-2. Retrieved May 31, 2006, from http://www.ismp-canada.org/publications.htm.
- Institute for Safe Medication Practices Canada. (2005, July 21). Bupivacaine injection: Check your supplies. **ISMP Canada Safety Bulletin**, **5**(5), 1. Retrieved June 4, 2006, from http://www.ismp-canada.org/publications.htm
- Institute for Safe Medication Practices Canada. (2006, April 25). Safety strategies for potassium phosphates injection. Neuromuscular blocking agent packaging and labelling initiative. **ISMP Canada Safety Bulletin, 6**(2), 2. Retrieved May 31, 2006, from http://www.ismp-canada.org/ publications.htm
- Institute for Safe Medication Practices Canada. (2006, April 26). ISMP Canada Medication Error Database.
- Joint Commission on Accreditation of Healthcare Organizations. (2003). **Root cause analysis in healthcare: Tools and techniques** (2nd ed.). Oakbrook Terrace, IL: Joint Commission Resource.
- Leape, L.L., Cullen, D.J., Clapp, M.D., Burdick, E, Demonaco, H.J., Erickson, J.I., et al. (1999). Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. **The Journal of the American Medical** Association, 282, 267-270.
- Leape, L.L., Brennan, T.A., Laird, N., Lawthers, A.G., Localio, A.R., & Barnes, B.A. (1991). The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. The New England Journal of Medicine, 324, 377-384.
- Leape, L.L., Bates, D.W., Cullen, D.J., Cooper, J., Demonaco, H.J., Gallivan, T., et al. (1995). Systems analysis of adverse drug events. Journal of the American Medical Association, 274, 35-43.
- Parshuram, C.S., Ng, G.Y., Ho, T.K., Klein, J., Moore, A.M., Bohn, D., et al. (2003). Discrepancies between ordered and delivered concentrations of opiate infusions in critical care. Critical Care Medicine, 31, 2483-2487.
- Ricci, M., Goldman, A.P., de Leval, M.R., Cohen, G.A., Devaney, F., & Carthey, J. (2004). Pitfalls of adverse event reporting paediatric cardiac intensive care. Archives of Disease in Childhood, 89, 856-859.
- Royal College of Physicians and Surgeons of Canada. (2002). National Steering Committee on Patient Safety. Building a safer system – A national integrated strategy for improving patient safety in Canadian health care. Retrieved May 20, 2006, from http://rcpsc.medical.org/publications/ building\_a\_safer\_system\_e.pdf
- Stump, L.S. (2000). Re-engineering the medication errorreporting process: Removing the blame and improving the system. American Journal of Health-System Pharmacists, 57(24, Suppl. 4), S10-S17.
- Thomas, E.J., Studdert, D.M., Burstin, H.R., Orav, E.J., Zeena, T., Williams, E.J., et al. (2000). Incidence and types of adverse events and negligent care in Utah and Colorado. **Medical Care, 38,** 261-271.
- van den Bemt, P.M., Fijn, R., van der Voort, P.H., Gossen, A.A., Egberts, T.C., & Brouwers, J.R. (2002). Frequency and determinants of drug administration errors in the intensive care unit. **Critical Care Medicine**, **30**, 846-850.
- Vicente, K. (2003). The human factor: Revolutionizing the way people live with technology. Toronto, ON: Random House.
- Wilson, R.M., Runciman, W.B., Gibberd, R.W., Harrison, B.T., Newby, L., & Hamilton, J.D. (1995). The Quality in Australian Health Care Study. Medical Journal of Australia, 163, 458-76.