ISMP Canada Safety Bulletin

The WHO Provides Guidance to Incident Reporting Programs

Earlier this year, the World Health Organization (WHO) published *The Conceptual Framework for the International Classification for Patient Safety* (ICPS).[1] The framework is intended to standardize definitions of and relationships among important safety concepts to which existing local, regional, and national classifications can be aligned. It supplements previously published guidelines highlighting the importance of adverse event reporting.[2]

ISMP Canada has advocated for the development of a worldwide taxonomy* so that medication incident data collected at local levels can contribute to international learning at the aggregate level.[3] The absence of an internationally recognized classification system for incident reporting programs has limited the potential to aggregate information collected in different countries for the purposes of global learning. Reporting systems need a common language to facilitate the sharing of statistics, descriptive studies, and evaluative research. Importantly, the guidance from WHO will enable the comparison of incident information received from different jurisdictions and will support the early detection and identification of emerging global patient safety issues.

The WHO defines a "patient safety incident" as "an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient."[1] In Canada, a national program has been established for collecting and analyzing information about medication incidents. The Canadian Medication Incident Reporting and Prevention System (CMIRPS)† collects reports of *preventable* medication-related events. The CMIRPS program is comprised of the National System for Incident Reporting developed by the Canadian Institute for Health Information and the

Individual Practitioner Reporting component developed by ISMP Canada. CMIRPS stakeholders participated in and contributed to the development of the conceptual framework for the ICPS, and this Canadian involvement has helped to ensure alignment of Canadian data sets with the ICPS.

The conceptual framework for the ICPS consists of 10 high-level classes (described in detail, with examples, in the framework):
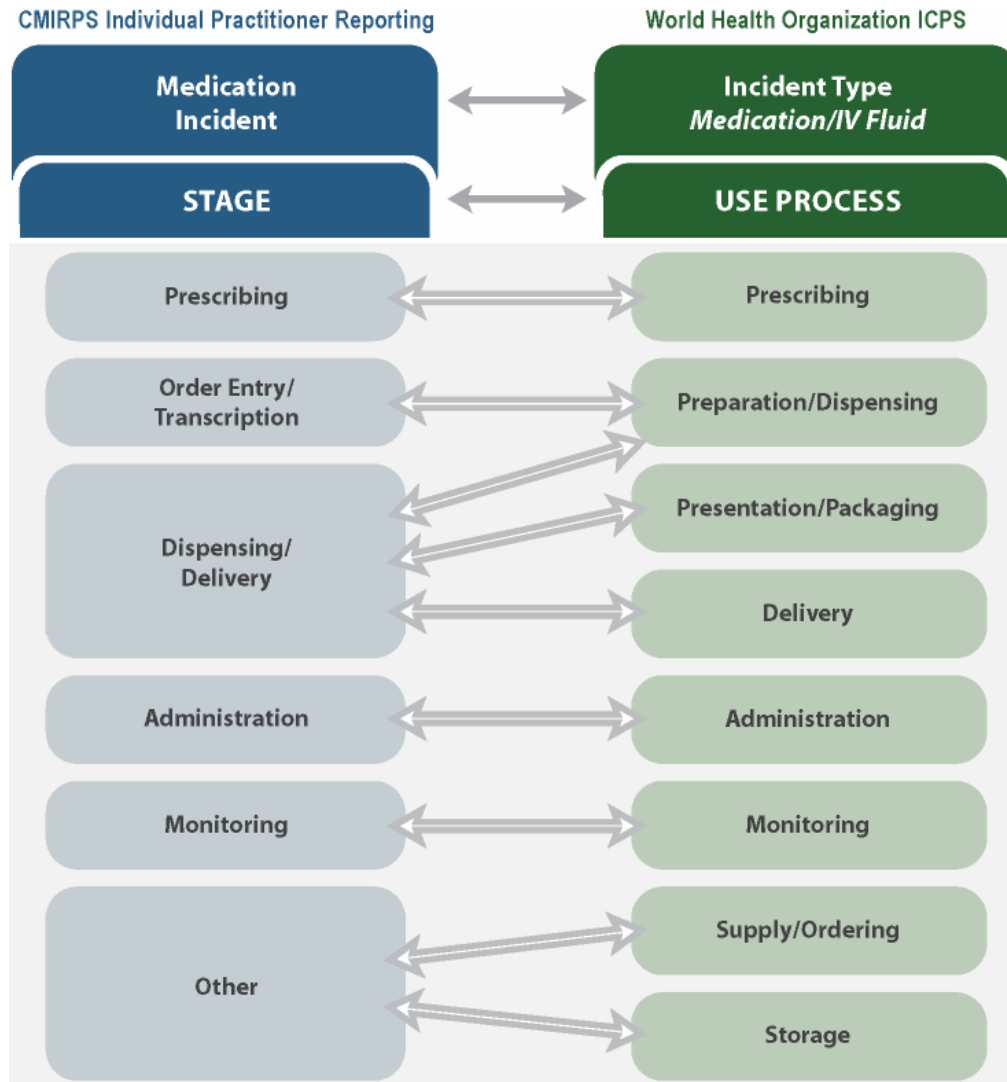
1. Incident Type
2. Patient Outcomes
3. Patient Characteristics
4. Incident Characteristics
5. Contributing Factors/Hazards
6. Organizational Outcomes
7. Detection
8. Mitigating Factors
9. Ameliorating Actions
10. Actions Taken to Reduce Risk

Figure 1 (page 2) illustrates the congruence between the CMIRPS Individual Practitioner Reporting component and the conceptual framework for the ICPS, comparing the CMIRPS medication use "Stage" and the ICPS "Medication/IV Fluid Use Process". Continuous improvement efforts for the CMIRPS program will include refinements to the data set to optimize alignment with the ICPS, and this will be done in consultation with stakeholders.

Patient safety efforts fundamentally require reporting of incidents. Each incident report offers value by identifying sources of risk that might otherwise go unnoticed. Alignment of reporting programs by means of an internationally recognized classification system will facilitate the sharing of information, including the findings from incident analyses and actions taken to reduce risk. The WHO conceptual framework for the ICPS represents progress toward coordinated patient safety efforts and global learning.

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* The WHO conceptual framework provides definitions for the term "taxonomy", including "System for naming and organizing items into groups that share similar characteristics."

† http://www.ismp-canada.org/cmirps.htm

Figure 1. Alignment of CMIRPS Individual Practitioner Reporting with the WHO conceptual framework for the International Classification for Patient Safety (ICPS), for incident type "Medication/IV Fluid".

References

1. World Health Organization. The Conceptual Framework for the International Classification for Patient Safety. Final technical report. Version 1.1. Geneva (Switzerland): World Health Organization; 2009 [cited 2009 Jul 8]. Available from http://www.who.int/patientsafety/taxonomy/en/
2. World Alliance for Patient Safety. WHO draft guidelines for adverse event reporting and learning systems: from information to action. WHO/EIP/SPO/QPS/ 05.3. Geneva (Switzerland): World Health Organization; 2005 [cited 2009 Nov 6]. Available from http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf
3. Fluorouracil incident root cause analysis [Internet]. Toronto (ON): Institute for Safe Medication Practices Canada; 2007 May 22 [cited 2009 Nov 20]. Available from http://www.cancerboard.ab.ca/NR/rdonlyres/2FB61BC4-70CA-4E58-BDE1-1E54797BA47D/0/FluorouracilIncidentMay2007.pdf

Reported Look-Alike Concerns with Labelling for Sodium Chloride 0.9% and Hypertonic Sodium Chloride IV Solutions Lead to Change

ISMP Canada received a near-miss report where sodium chloride 5% was inadvertently used in a pharmacy for admixing a medication instead of the intended sodium chloride 0.9% (i.e., normal saline). Fortunately, the error was caught before the admixtures were dispensed.

The reporter also identified a need to better differentiate the sodium chloride 3% product from the sodium chloride 0.9% product (Figure 1).

Figure 1. From left to right: 250 mL sodium chloride 0.9% (normal saline), sodium chloride 3%, and sodium chloride 5% solutions. All information on the labels is printed in black type.

Sodium chloride 0.9% is an isotonic solution that is frequently used for parenteral hydration, whereas sodium chloride 3% and 5% are hypertonic solutions used only for specific indications (e.g., the treatment of hyponatremia). The inadvertent administration of a hypertonic sodium chloride solution could lead to patient harm.

ISMP Canada notified Baxter Canada about the report. After consulting with its customers, Baxter Canada redesigned the labels for sodium chloride 3% and 5%, and sent copies of these soon-to-be-released labels to ISMP Canada (Figure 2).
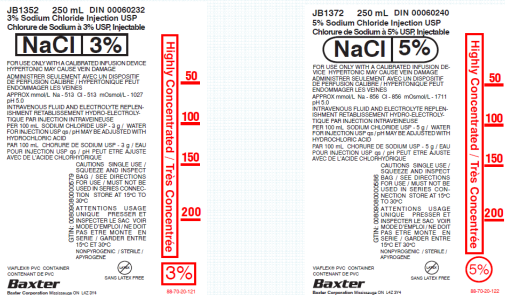
Figure 2. From left to right: soon to be released labels for sodium chloride 3% and sodium chloride 5%. *Red colour* **is used to give prominence to critical information.**

Working with Consumers to Prevent Medication Incidents

ISMP Canada is developing a consumer-focused medication safety website (www.SafeMedicationUse.ca) that will provide a mechanism for consumers to report medication incidents. The site will also offer information to support consumers in the prevention of harmful medication incidents. Watch for more information on this new component of the CMIRPS program in an upcoming bulletin.

ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.
Medication Incidents (including near misses) can be reported to ISMP Canada:
(i) through the website: http://www.ismp-canada.org/err_report.htm or (ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.
ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System