The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

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Near Miss Identification and Reporting

The strong professional and public emphasis on patient safety during the past decade has led to a clear expectation that any serious medication incident involving a patient will be disclosed, reported, and analyzed. If an incident does not reach a patient, how important is it to report and analyze the details? In general, there may be less impetus to investigate these "near miss" incidents, since many of the factors that drive the analysis of events causing serious harm are not present.[1] Yet several high-profile accidents, including the explosion of the Space Shuttle Challenger in 1986, were foreshadowed by near misses that were ignored. Healthcare organizations that realize that today's near miss could become tomorrow's critical incident are therefore moving toward more proactive analysis of near miss occurrences. Experience outside the field of healthcare indicates that such activities can be expected to lead to measurable improvements in safety performance.[1] This bulletin highlights the value of, and trends for increases in, the identification and reporting of near misses.

The glossary developed by the collaborating parties of the Canadian Medication Incident Reporting and Prevention System (CMIRPS) defines a near miss (or close call) as "an event that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention the event did not reach the patient."[2] The terms 'near hit' and a 'good catch' have similar meanings. It is of interest to compare this definition with those used by other organizations. The 2005 World Health Organization (WHO) document, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems,* defines a near miss or close call as a "serious error or mishap that has the potential to cause an adverse event, but fails to do so by chance or because it is intercepted."[3] Notably, the WHO definition includes events that reach the patient (provided no harm was experienced), whereas the CMIRPS definition for near miss includes only occurrences that do *not* reach the patient. Regardless of the definition used, there is high potential value in establishing a specific process for collecting and analyzing information about near misses. The WHO draft guidelines suggest that understanding the causes of near misses can lead to system changes that will improve safety, stating that "any hospital that is serious about learning will also invite reports of near misses".[3] This statement is equally relevant in other healthcare settings.

Most healthcare professionals will occasionally encounter a near miss that could recur and reach the patient, resulting in serious harm. When our mental alarm bells ring, do we report the near miss and initiate a process to identify and address the underlying causes? The state of "mindfulness" that characterizes high-reliability organizations encourages discovery, stimulates a constant searching for the hazards that can cause error, and discourages the thinking "that would never happen here".[4]

There are several advantages of including near miss reports in incident reporting programs:

- Review and analysis of near misses offers the opportunity to explore factors that could lead to error, unhampered by the pressures and emotions that are often present in the aftermath of a serious event.
- The underlying system failures for near misses can be assumed to be similar to those of incidents that reach the patient.[3] As such, inclusion of near miss reports in reporting programs augments the information available to support quality efforts.
- If a near miss report suggests the potential for a serious event, a full root cause analysis[5] may produce significant learning.
- The examination of near misses can contribute to a culture of safety by clearly demonstrating the organization's commitment to creating a safe environment for patients and staff.
- Near miss reports can help in identifying the need for a proactive risk assessment (such as failure mode and effects analysis[6]) of specific medication-use processes.

Awareness of the importance of near miss reporting systems appears to be growing. In a survey of Canadian hospital pharmacies conducted in 2006,[7] 46% of respondents indicated that their organizations' medication incident reporting systems included prescribing incidents that were detected before dispensing, a substantial increase from only 28% in a similar survey conducted in 2003/2004. Similarly, 64% of respondents reported having systems that included incidents occurring in the pharmacy but detected before the medication left the pharmacy, nearly double the 34% reported for 2003/2004.[7]

The ISMP Canada medication incident database is a national database to which practitioners can submit reports of near misses. These incidents, along with those that reach the patient, are reviewed by ISMP Canada analysts, who employ a prioritization matrix to assess near misses on the basis of their potential harm and the potential frequency of occurrence. This process helps to ensure that all reports are acted upon according to their priority. ISMP Canada's published reports of near misses may include system-based recommendations, as well as outcomes, such as changes to product labeling and packaging.[8,9,10]

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Positive Response from Manufacturer to Your Reports

A number of facilities have reported concerns about the look-alike labelling and packaging of the following parenteral products (Figure 1):

- dimenhydrinate 50 mg/mL, 5 mL vial
- diltiazem 5 mg/mL, 5 mL vial
- flumazenil 0.1 mg/mL, 5 mL vial

The reports submitted to ISMP Canada have documented a variety of problems, including a substitution error in the operating room (flumazenil administered instead of dimenhydrinate) and incorrect storage in an emergency department (diltiazem vials with dimenhydrinate vials).

ISMP Canada has corresponded with Sandoz Canada Inc., the manufacturer of all 3 products, regarding these reports. As a result, the labels for flumazenil and dimenhydrinate will be changed. The new flumazenil label is expected to be in use early 2008 and the new dimenhydrinate label is expected to be in use spring 2008. ISMP Canada thanks Sandoz for their receptiveness to these reports.

In the interim, ISMP Canada suggests the following measures to limit the possibility of error:

- Consider purchasing one or more of these products in a different volume. For example, one hospital switched from the 5 mL (multidose) dimenhydrinate vials to the 1 mL (single-dose) vials.
- Ensure that these products are not stored in close proximity to each other, including in the pharmacy.
- Re-evaluate the need to have more than one of these products as stock in patient care areas.
- Inform all staff of the potential for mix-ups.

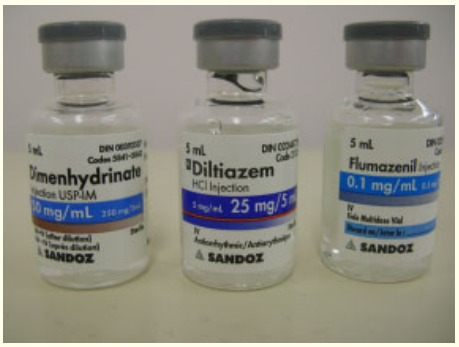

Figure 1. From left to right: dimenhydrinate 50 mg/mL, diltiazem 5 mg/mL, and flumazenil 0.1 mg/mL. The volume of each vial is 5 mL and each vial has a grey cap and a white label with blue bands. (ISMP Canada thanks the reporters who submitted photographs, such as this one, with their online reports.)

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