Institute for Safe Medication Practices Canada
REPORT MEDICATION INCIDENTS
Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

ISMP Canada Safety Bulletin

Volume 13 • Issue 6 • July 23, 2013

Preliminary Results from the International Medication Safety Self Assessment for Oncology

Chemotherapy and biotherapy agents used in cancer treatment are considered to be "high-alert" drugs, which are more likely to cause patient harm when involved in an error. A root cause analysis completed by ISMP Canada in 2007 identified the need for an assessment tool to assist oncology practitioners in identifying areas of risk particular to this specialized field.[1] To meet this need, ISMP and ISMP Canada collaborated with an international panel of oncology practitioners to develop the ISMP International Medication Safety Self Assessment® for Oncology (https://mssa.ismp-canada.org/oncology). This online assessment is intended to help organizations providing chemotherapy (including chemotherapy, biotherapy, and treatment-related drugs) to assess their medication management safety practices and processes, identify opportunities for improvement, and compare their findings with those of similar organizations both nationally and internationally. Development of the assessment was made possible through a grant from the International Society of Oncology Pharmacy Practitioners, with additional funding from the Clinical Excellence Commission of New South Wales and the Cancer Institute NSW, both in Australia. Private sector support was received from Baxter Corporation, ICU Medical, Inc., Pfizer Oncology, and Roche. Support provided to develop the assessment allowed for a 6-month complimentary "snapshot" period of open enrolment. This bulletin shares selected findings from the completed assessments submitted during that period and provides insight into system vulnerabilities related to dispensing of intravenous (IV) vinCRIStine, use of oral chemotherapy, and management of overfill when preparing IV chemotherapy. A detailed report of aggregate results is being prepared for submission to a peer-reviewed publication.

Participants

More than 350 oncology practice sites from 13 countries submitted results between April and October 2012. There were 271 respondents from the United States, 42 from Australia, 18 from Canada, and 21 from other sites representing Brazil, China, Italy, Jordan, Malaysia, New Zealand, Qatar, Saudi Arabia, Spain, and the United Arab Emirates.

The majority of responding sites were located in urban areas (defined as having a population of 50,000 or more). Forty percent of participants indicated that their sites had an academic affiliation, and 76% participated in research. Thirty percent were state or nationally designated cancer treatment centres. The majority of chemotherapy was provided on an outpatient basis, with 80% of respondents indicating that inpatient chemotherapy made up less than 25% of the chemotherapy workload.

Selected Findings

WHO Recommendations for Intravenous VinCRIStine and Other Vinca Alkaloids

In 2007, the World Health Organization (WHO) recommended that IV vinCRIStine (and other vinca

alkaloids) should be prepared and administered only via minibags.[2] Despite repeated warnings, such as those issued by the WHO,[2] ISMP,[3,4] and ISMP Canada,[5] vinCRIStine intended for IV use is known to have been mistakenly administered intrathecally 55 times in a variety of settings around the world since 1968. Most of these incidents have caused the patient's death, and those patients who survived have experienced devastating neurological effects, such as quadriplegia.[6]

The oncology self assessment includes 4 items related to these WHO recommendations. These items were also included in a 2005 ISMP survey on IV vinCRIStine use.[7] Responses received from participants in the 2012 assessment suggest that improvements in processes for IV vinCRIStine are being made (see Table 1). It is concerning, however, that nearly 50% of US respondents reported that they do not always provide vinCRIStine in minibags: 35% of these respondents indicated that this safeguard either had not been discussed, or had been formally discussed but not implemented. Eighty-three percent of Canadian respondents indicated full implementation of this safeguard (although the sample size for Canadian respondents was much smaller).

Another worrisome finding was that only 61% of Canadian respondents reported routine implementation of a simple safeguard, the use of auxiliary labels with the WHO's recommended wording, a much lower rate than found for the United States (92%) and for all countries combined (89%).

Assessment of Safeguards for Oral Chemotherapy

Concerns about the safe use of oral chemotherapy agents prompted the inclusion of assessment items specifically addressing known areas of risk for these agents. The availability and use of oral chemotherapy agents is increasing. Oral agents can offer convenience for patients as the medications can be managed independently at home. There is a misperception, however, on the part of practitioners and patients that oral chemotherapy agents are safer

Table 1: Results for Core Characteristic 8 (WHO Recommendations on vinCRIStine)

Core Characteristic 8 **:** *Your organization/practice setting follows the safety strategies recommended by the World Health Organization (WHO) for vin*CRIS*tine (and other vinca alkaloids as applicable).*

		% OF RESPONDENTS WHO HAVE *FULLY IMPLEMENTED* THE ASSESSMENT ITEM*			
Item No.	**Assessment Item**	2005 ISMP Survey Results (n = 409)[7]	All Countries (n = 352)	United States (n = 271)	Canada (n = 18)
76	VinCRIStine is dispensed in a minibag of a compatible solution (e.g., 25 mL for pediatric patients and 50 mL for adults). VinCRIStine doses are never dispensed and/or administered using a syringe.	23%	61% (215/352)	54% (147/271)	83% (15/18)
77	VinCRIStine is dispensed with a prominent warning label that reads: FOR INTRAVENOUS USE ONLY–FATAL IF GIVEN BY OTHER ROUTES.	93%	89% (315/352)	92% (249/271)	61% (11/18)
78	The presence of vinCRIStine is prohibited in areas where intrathecal medications are administered and/or stored.	38%	65% (175/270)	64% (136/213)	58% (7/12)
79	Confirmation that the administration of any prescribed intrathecal medications has been completed is required before dispensing vinCRIStine.	42%	54% (140/260)	54% (112/207)	45% (5/11)

* Where the denominator is less than the total number of respondents, missing data represent organizations that do not provide intrathecal chemotherapy

than parenteral agents. A 2006 survey of US cancer centres found that only 1 in 4 centres had standard prescribing safeguards for oral chemotherapy and fewer than 1 in 5 had safeguards related to administration and monitoring.[8] An international survey conducted in 2008 assessed general medication safety practices in oncology, including management of oral chemotherapy.[9] Almost one-third of 377 respondents from 34 countries thought that oral chemotherapy did not require the same safety measures as parenteral therapy.

In a study of medication errors involving oral chemotherapy agents, the most common errors were related to the wrong dose or an extra dose, the wrong drug, the wrong number of days of therapy supplied, and omission of doses.[10] Although most of the errors reported were in fact near misses or close calls, a surprising finding was that the greatest percentage of events causing harm involved supplying the drug for the wrong number of days (39.3%).

More than 80% of respondents in the 2012 assessment indicated that they provided oral chemotherapy. Only half of Canadian respondents and a smaller proportion of those from the United States and all countries combined had implemented safety-related processes for oral chemotherapy

Table 2: Results for Assessment Items Related to Management of Oral Chemotherapy Agents

		% OF RESPONDENTS WHO HAVE *FULLY IMPLEMENTED* THE ASSESSMENT ITEM†		
Item No.	**Assessment Item**	All Countries (n = 352)	United States (n = 271)	Canada (n = 18)
73	The processes used to ensure the safety of orders for oral and other non-parenteral dosage forms of chemotherapy/biotherapy are the same as those in place for parenteral dosage forms.	43% (153/352)	41% (112/271)	50% (9/18)
75	For intermittent treatment with oral chemotherapy/ biotherapy drugs, the quantity of drugs prescribed and dispensed for ambulatory patients (e.g., number of tablets/capsules) is the exact quantity required by the patient for a specified timeframe.	67% (162/241)	68% (114/167)	69% (11/16)
81	All chemotherapy/biotherapy drugs (oral and parenteral) are dispensed with auxiliary labels, on the primary container and the transport container, (e.g., "Chemotherapy") so that it is easily identified and understood as being cytotoxic.	84% (294/352)	83% (226/271)	78% (14/18)
90	Chemotherapy/biotherapy (both oral and parenteral) is safely stored in a separate designated area of the pharmacy with appropriate signage to warn of hazards and refrigerated chemotherapy/biotherapy medications are segregated from other medications.	79% (278/352)	79% (214/271)	83% (15/18)
128a	Oral chemotherapy/biotherapy that needs to be manipulated from its original form (e.g., crushed, split, opened, or dissolved) is first checked against a published reference.	74% (262/352)	76% (205/271)	72% (13/18)
128b	If the chemotherapy/biotherapy drug is to be manipulated, this is always done in a controlled environment, such as a biological safety cabinet/isolator and using appropriate personal protective equipment (PPE).	78% (273/352)	82% (221/271)	72% (13/18)

† Where the denominator is less than the total number of respondents, missing data represent organizations that do not dispense oral chemotherapy for patients to self-administer at home.

similar to those employed for parenteral chemotherapy (see Table 2). These results suggest that many organizations and healthcare professionals still do not appreciate the risks associated with oral chemotherapy agents. As such, more safety strategies and practices for prescribing, dispensing, administering, and monitoring oral chemotherapy need to be developed and implemented.

Management of Overfill in Chemotherapy Preparation

In early April 2013, attention was drawn to the management of overfill volume in the context of chemotherapy preparation in Canada. It was revealed that more than 1,100 patients in 2 provinces had been affected by a miscommunication leading to unintended underdosing of cyclophosphamide and gemcitabine.[11,12] An expert panel has been convened to review related processes. Preliminary information shared to date indicates that communication of product concentration on the label and methods of recording overfill may have been contributing factors to the incidents. Responses to an assessment item related to management of overfill for compounded IV chemotherapy highlight the need for improvements in labelling (see Table 3).

Using the Oncology Self Assessment in Your Organization

Organizations providing oncology services are encouraged to use the ISMP International Medication Safety Self Assessment® for Oncology to identify areas of vulnerability in their own practice settings and to monitor their progress over time.

A printable version of the assessment is available at: https://mssa.ismp-canada.org/oncology/page/12. A fee-based program is now available for organizations that wish to enter their data online, score their results, and receive comparable aggregate data from other organizations. For more information, contact mssa@ismp-canada.org.

Organizations that participated and returned their results during the open enrolment period can access their own results and comparative data at: https://mssa.ismp-canada.org/oncology (password required).

Table 3: Results for Assessment Item 84 (Overfill Volume)

		% OF RESPONDENTS WHO HAVE *FULLY IMPLEMENTED* THE ASSESSMENT ITEM		
Item No.	**Assessment Item**	All Countries (n = 352)	United States (n = 271)	Canada (n = 18)
84	There is a standard process to identify the overfill volume on the pharmacy label for compounded IV chemotherapy/ biotherapy solutions.	53% (186/352)	51% (137/271)	67% (12/18)

References

1. Fluorouracil incident root cause analysis. Toronto (ON): Institute for Safe Medication Practices Canada; 2007 May 22 [cited 2013 Jul 16]. Available from: http://www.ismp-canada.org/download/reports/FluorouracilIncidentMay2007.pdf
2. Information Exchange System Alert No. 115. Hong Kong: World Health Organization; 2007 Jul 18 [cited 2013 Jul 15]. Available from: http://www.who.int/patientsafety/highlights/PS_alert_115_vincristine.pdf
3. Accidental administration of IV meds intrathecally. ISMP Med Saf Alert. 1998 [cited 2013 Jul 15];3(19):1. Available from: http://www.ismp.org/newsletters/acutecare/articles/19980923.asp
4. Pain, paralysis, and knowledge of impending death marks intrathecal vincristine. ISMP Med Saf Alert. 2000 [cited 2013 Jul 15];5(7):1. Available from: http://www.ismp.org/newsletters/acutecare/articles/20000405.asp
5. Published data supports dispensing vincristine in minibags as a system safeguard. ISMP Can Saf Bull. 2001 Oct 3 [cited 2013 Jul 15]. Available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2001-10Vincristine.pdf

6. Burgess N. High-risk medication alert for vincristine injection. Appendix 3: Literature review. Collingwood (Australia): Society of Hospital Pharmacists of Australia Federal Secretariat; 2005 Dec [cited 2013 Jul 15]. Available from: http://www.safetyandquality.gov.au/wp-content/uploads/2012/02/vlitera2.pdf
7. IV vincristine survey shows safety improvements needed. ISMP Med Saf Alert. 2006[cited 2013 Jul 15];11(4):1-2. Available from: http://www.ismp.org/newsletters/acutecare/articles/20060223.asp
8. Weingart SN, Flug J, Brouilllard D, Morway L, Partridge A, Bartel S et al. Oral chemotherapy safety practices at US cancer centres: questionnaire survey. BMJ. 2007;334(7590):407-9.
9. Johnson PE, Chambers CR, Vaida AJ. Oncology medication safety: A 3D status report 2008. J Oncol Pharm Pract. 2008;14(4):169-180.
10. Weingart SN, Toro J, Spencer J, Duncombe D, Gross A, Bartel S et al. Medication errors involving oral chemotherapy. Cancer. 2010;116(10):2455-64.
11. Patients being informed of chemotherapy drug underdosing in four hospitals. Cyclophosphamide and gemcitabine purchased from drug manufacturer [news release]. Toronto (ON): Cancer Care Ontario; 2013 Apr 2. [Cited 2013 Jul 15] Available from: https://www.cancercare.on.ca/cms/One.aspx?portalId=1377&pageId=271334
12. The Saint John Regional Hospital informs patients of chemotherapy drug underdosing [news release]. Miramichi (NB): Horizon Health Network; 2013 Apr 3. [Cited 2013 Jul 15] Available from: http://horizonnb.ca/home/information-news/news-releases/the-saint-john-regional-hospital-informs-patients-of-chemotherapy-drug-underdosing.aspx

Upcoming Multi-Incident Analysis Workshops Can Help You Learn More About Your Medication Incidents

Multi-incident analysis is a qualitative medication incident analysis technique described in the Canadian Incident Analysis Framework.[1] Analysis is conducted on a group of medication incidents involving a common factor (e.g., practice setting, drug class), a process that constitutes an efficient method to reveal trends or patterns of contributing factors that were not previously perceptible.

ISMP Canada developed a workshop to teach this medication incident analysis technique and recently presented it at two fully attended sessions. This full-day interactive workshop is designed to teach a stepwise process for conducting a multi-incident analysis. To evaluate the effectiveness of the workshop (for participant uptake of the presented technique), a 10-question multiple-choice test, based on the key concepts of the multi-incident analysis technique, was developed. The test was administered at the beginning and the end of each workshop presentation. A paired t-test was used to compare the mean scores between the pre- and post-workshop tests.

The 16 attendees from the first 2 presentations of the workshop came from diverse professional backgrounds and included nurse managers, pharmacy directors, pharmacy technicians, and quality improvement officers. Sixteen pairs of pre- and post-workshop test scores were obtained and analyzed. The mean pre-workshop score was 38.8%, and the mean post-workshop score was 73.8% ($p < 0.001$), representing a significant improvement in the understanding of the key concepts of the multi-incident analysis technique. The evaluation results indicated that the workshops were effective in teaching the key concepts and facilitating the application of this important medication incident analysis technique.

Another multi-incident analysis workshop will be held in Toronto on September 12, 2013. For details, please visit http://www.ismp-canada.org/education/workshops/2013/Sept_12_2013_MIARegistrationDocuments.pdf or contact ISMP Canada at 416-733-3131.

For more information about this workshop and how the multi-incident analysis technique can be adapted to your organizational practice, please contact ISMP Canada by email at education@ismp-canada.org, by phone at 416-733-3131, or toll-free at 1-866-544-7672.

Reference

1. Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework. Edmonton (AB): Canadian Patient Safety Institute; 2012 [cited 2013 Mar 28]. Incident Analysis Collaborating Parties are Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety Canada (a patient-led program of CPSI), Paula Beard, Carolyn E. Hoffman and Micheline Ste-Marie. Available from: http://www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20 Framework.PDF

ImagineNation Challenge Highlights the Impact of Digital Health in Canada

From drug information systems to electronic medication reconciliation, the continued development of digital health is changing the way healthcare providers deliver care – and it's making healthcare safer for Canadians. Acknowledging the difference that digital health is making, Canada Health Infoway is asking Canadians to share their first-hand accounts of how these changes are helping them.

Canada Health Infoway, a federally funded organization, recently launched the *ImagineNation* Challenges, a series of awards that focus on the impact that digital health is having across Canada in careers, organizations, and patients' lives.

Career Impact Challenge (up to $6000 in awards for professional development): Participants are asked to describe, in no more than 250 words, the impact that public investments in digital health have had, directly or indirectly, on their career, in terms of training, professional development opportunities, leadership, collaboration, or time saved.

Business Impact Challenge (up to $6000 in awards to be donated to postsecondary educational institutions): Participants are asked to describe, in no more than 500 words, the impact that public investments in digital health have had on their businesses and organizations.

Patient Impact Challenge (up to $6000 in awards to individuals): Participants are asked to describe, in no more than 250 words, the impact digital health has had on their experiences as patients or caregivers for friends and family.

The *ImagineNation* Challenges close on July 31, 2013. Visit www.imaginenationchallenge.ca to enter the Challenge.

CMIRPS SCDPIM
Canadian Medication Incident Reporting and Prevention System
Système canadien de déclaration et de prévention des incidents médicamenteux

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

HIROC

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

ISMP CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

Report Medication Incidents

(Including near misses)

Online: www.ismp-canada.org/err_index.htm
Phone: 1-866-544-7672

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

Sign Up

To receive this publication or other medication safety publications sign up at:

www.ismp-canada.org/subscription.htm

Contact Us

Email: cmirps@ismp-canada.org
Phone: 1-866-544-7672