The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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Medication Incidents Involving Cancer Chemotherapy Agents

This bulletin shares information from medication incidents involving cancer chemotherapy agents that have been reported to ISMP Canada. Some of these incidents have been described in previous issues of the *Safety Bulletin*, along with recommendations for system enhancements.[1-5] The purpose of the current bulletin is to provide an overview of the reported chemotherapy-related incidents, noting the major themes and subthemes that have been identified through interdisciplinary aggregate analysis, and to share insights into areas for system-based improvement opportunities.

Background and Overview of Findings

Medication incidents involving cancer chemotherapy agents have been reported from institutions across the country. For this analysis, all such incidents were extracted from the ISMP Canada medication incident database. A total of 519 incidents involving cancer chemotherapy agents were reported between 2002 and 2009, 96% of which occurred in hospitals. Of these incidents, 40 (7.7%) had an outcome of harm, and 4 (0.8%) had an outcome of death.

Nearly 90% of these incident reports (n = 456) contained sufficient narrative descriptions to allow qualitative analysis; the remaining 63 reports lacked narrative information and were excluded from the overview presented here. The analysis revealed 7 main themes (Table 1). Each theme reflects a high-level process within the medication-use system common to the provision of cancer chemotherapy agents in most patient care settings.

Qualitative Analysis Findings

The following sections present more detail about each of the 7 main themes, including their subthemes, key contributing factors leading to harm or with the potential to cause serious harm, and selected incident examples from the analysis.

Table 1: Overview of Chemotherapy-Related Incidents Reported Voluntarily (2002–2009)*

Main Theme	No. of Incident Reports (n = 456)†	No. of Incident Reports with Adverse Outcome†	
		Harm (n = 38)	Death (n = 4)
Scheduling the patient's visit to clinic for treatment	13	2	0
Prescribing	48	2	1
Order entry or transcription	45	2	0
Clinical assessment and communication of treatment changes	24	3	0
Dispensing	122	1	0
Administration of medication	155	15	3
Monitoring	49	13	0

* Qualitative analysis based on incident reports that provided narrative data.
† Given that the ISMP Canada medication incident database relies on voluntary reporting, it is impossible to infer or project the probability of specific kinds of incidents from these data.

Main Theme: Scheduling the Patient's Visit to Clinic for Treatment

Subtheme	Key Contributing Factors
Incorrect frequency	• System infrastructure that does not adequately support the scheduling of complex (e.g., multiphase) and/or intermittent treatment regimens • Miscommunication of changes affecting multiple treatments that have been scheduled in advance

Incident example: A patient was scheduled to receive chemotherapy on 4 consecutive days at monthly intervals for an unspecified number of months. In the first month of therapy, the treatment was delayed by 1 week because of a low blood cell count. The subsequent month's treatment was inadvertently administered as originally scheduled, instead of being delayed by 1 week.

Comments: For patients with complex chemotherapy regimens and/or intermittent cycles of therapy, it is common practice to schedule treatments in advance. When one of the scheduled treatments must be changed (e.g., because of particular test results), corresponding changes may be required for follow-up treatments. Miscommunications about such changes may lead to error.

Main Theme: Prescribing

Subtheme	Key Contributing Factor(s)
Incorrect frequency	• Reliance on mental approximation to determine dates for dosing schedules
Incorrect chemotherapy regimen or phase of regimen	• Look-alike and/or sound-alike protocol names • Inadequate systems for ensuring that up-to-date predefined order sets are readily available for the increasing number of protocol options • Complexity of chemotherapy protocols (e.g., multiple phases requiring different medications, dosages, and routes)
Incorrect dose	• Miscalculation of patient's body surface area • Lack of easily accessible information about dosing of chemotherapy agents for non-oncology indications
Ordering of a medication to which the patient has previously had a reaction	• Inconsistent and nonstandardized documentation of patient's past reactions to chemotherapy

Incident example: An order for FOLFOX protocol (which includes oxaliplatin) was written, instead of the intended FOLFIRI protocol (which includes irinotecan). The look-alike protocol name was identified as a contributing factor in this case.

Incident example: An order for the protocol Hyper-CVAD 2B was issued instead of the intended Hyper-CVAD 2A. Hyper-CVAD 2B involves intravenous (IV) administration of medications, whereas the protocol for Hyper-CVAD 2A involves both IV and intrathecal administration of medications. This incident illustrates a mix-up of protocol phases.

Main Theme: Order Entry or Transcription

Subtheme	Key Contributing Factor(s)
Incorrect frequency	• Use of dangerous abbreviations
Incorrect medication	• Look-alike medication names
Incorrect dose	• Misinterpretation of order • Lack of knowledge about chemotherapy agents (e.g., related to proliferation of new oral agents)
Duplicate therapies	• Lack of quality checks and/or full medication reviews

Incident example: An order for Aromasin (exemestane) 25 mg ṫ od was misread. The drug was provided as 25 mg TID for about 4 months before the error was detected.

Comment: Eliminating the use of dangerous abbreviations[6] in the communication of medication orders continues to be a challenge.

Main Theme: Clinical Assessment and Communication of Treatment Changes

Subthemes	Key Contributing Factors
Chemotherapy inadvertently given rather than being postponed on the basis of laboratory results; incorrect dose given	• Clinical assessment based on wrong set of blood work results • Chemotherapy delivered to patient care area before verification of blood work results • Lack of a systematic process to ensure independent checks of blood work results • Lack of a systematic process for communicating change orders

Incident example: A dose of cisplatin was administered when it should have been held because of an increase in serum creatinine.

Main Theme: Dispensing

Subtheme	Key Contributing Factor(s)
Incorrect dose	• Incorrect concentration of product selected for order entry or calculation of dosage volume • Incorrect volume of diluent used for reconstitution
Incorrect rate	• Incorrect elastomeric pump selection
Incorrect medication	• Look-alike medication names • Look-alike labelling and packaging
Incorrect IV solution for dilution	• Look-alike packaging

Incident example: A patient with metastatic breast cancer received a refill prescription for Femara (letrozole), an aromatase inhibitor intended to block estrogen production in cases of estrogen-sensitive breast cancer. However, FEM-HRT (an estrogen supplement), a medication with a look-alike name, was dispensed.

Main Theme: Administration of Medication

Subtheme	Key Contributing Factor(s)
Incorrect frequency	• Patient did not receive, or did not understand, education required for self-administration
Incorrect rate	• Information on labels not optimally designed with the end-user in mind (e.g., information about rate of administration not prominently displayed) • Problems with infusion pump • Incorrect programming of pump • Dangerous dose designation on pump display (e.g., display of "05.0" read as "0.5") • Pump malfunction
Incorrect route	• Lack of distinct processes and systems for differentiating chemotherapy intended for different routes of administration
Omission of dose	• Complex clinical trial regimens • Lack of clearly defined roles for multiple practitioners caring for the same patient • Infusion line inadvertently left clamped
Incorrect patient	• Reliance on a single patient identifier

Incident example: Intravenous pump programmed as 626 mL per hour instead of the intended 262 mL per hour for a one hour infusion of docetaxel.

Main Theme: Monitoring

Subtheme	Key Contributing Factor(s)
Leak of medication during infusion	• Lack of systematic process for monitoring • Lack of patient education or patient understanding of risk and actions required
Extravasation	• Early signs of extravasation missed

Next Steps

Reporting is an important component both in identifying opportunities for enhancing medication safety and in monitoring the effects of system changes. The findings of this analysis can be used to support local quality improvement initiatives. The identified key contributing factors leading to harm or potentially causing harm can provide insights into areas for system improvements and implementation of safeguards.

Although guidance documents exist for the safe preparation of chemotherapy medications,[7,8,9,10] more work is needed to identify system-based safeguards and preferred practices. Under the leadership of the International Society of Oncology Pharmacy Practitioners (ISOPP), a cancer chemotherapy self-assessment program is being developed to assist organizations with quality improvements to the medication-use system (refer to the sidebar on page 4 in this bulletin for additional information).

The findings of the analysis reported here have also been reviewed in consultation with the Systemic Therapy Safety Committee of the Canadian Association of Provincial Cancer Agencies (CAPCA) to inform future potential collaborative research and quality improvement projects.

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References

1. Multi-factorial system problems lead to a chemotherapy mishap. ISMP Can Saf Bull. 2002 Jul [cited 2009 Nov 16]:2(7):1-2. Available from http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2002-07Chemotherapy.pdf
2. Chemotherapy error prompts review of medication order processing. ISMP Can Saf Bull. 2003 Aug [cited 2009 Nov 16];3(8):1-2. Available from http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2003-08Chemotherapy.pdf
3. Fluorouracil incident root cause analysis: follow-up. ISMP Can Saf Bull. 2007 Aug 20 [cited 2009 Nov 16];7(4):1-4. Available from http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2007-04Fluorouracil.pdf
4. Incidents of inadvertent daily administration of methotrexate. ISMP Can Saf Bull. 2008 Apr 4 [cited 2009 Nov 16];8(2):1-3. Available from http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2008-02Methotrexate.pdf
5. A near miss involving cyclophosphamide. ISMP Can Saf Bull. 2008 Oct 30 [cited 2009 Nov 16];8(7):1-2. Available from http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2008-07CylophosphamideNearMiss.pdf
6. Eliminate use of dangerous abbreviations, symbols, and dose designations. ISMP Can Saf Bull. 2006 Jul 16 [cited 2009 Nov 11];6(4):1-3. Available from http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2006-04Abbr.pdf
7. Jacobson JO, Polovich M, McNiff KK, LeFebvre KB, Cummings C, Galioto M, et al. American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. J Clin Oncol. 2009;99(ASCO Spec Article):1-7.
8. Hazardous pharmaceuticals (including cytotoxic drugs): guidelines for handling and disposal. Ottawa (ON): Canadian Society of Hospital Pharmacists; 1997.
9. Burroughs GE, Connor TH, McDiarmid MA, Mead KR, Power LA, Reed LD. NIOSH Alert: preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings. DHHS (NIOSH) Publ No. 2004-165. Cincinnati (OH): Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; 2004 Sep [cited 2010 Mar 8]. Available from http://www.cdc.gov/niosh/docs/2004-165/
10. American Society of Health-System Pharmacists, Council on Professional Affairs. ASHP guidelines on preventing medication errors with antineoplastic agents. Am J Health Syst Pharm. 2002;59(17):1648-1668.

Oncology Medication Safety Self-Assessment

The Institute for Safe Medication Practices Canada (ISMP Canada), the Institute for Safe Medication Practices (ISMP; US), and the International Society of Oncology Pharmacy Practitioners (ISOPP) will begin development of a new self-assessment program to help hospitals and ambulatory cancer centres throughout the world to evaluate oncology medication safety.

Chemotherapy 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. The self-assessment will help healthcare organizations to examine their use of these medications by evaluating practices and processes related to patient information, communication, environment, and other key elements of safe medication use.

As with the other medication safety self-assessments (e.g., for hospitals, for long-term care, for community/ambulatory pharmacy, and checklist for the operating room), healthcare organizations will be asked to convene multidisciplinary teams to complete the assessment and invited to submit data through a secure web-based program. Respondents will then be able to compare their findings with aggregate data from demographically similar organizations.

An international group of safety experts will assist with the development, design, and launch of the self-assessment program, which is planned for early 2011.

The oncology medication safety self-assessment is being supported through a grant from ISOPP to ISMP and ISMP Canada. The Clinical Excellence Commission of New South Wales and the Cancer Institute of New South Wales will also provide grant support and expertise to this project. ISOPP received private sector support from Baxter Corporation, ICU Medical, Inc., Pfizer Oncology, and Roche.

For more information, please call ISMP Canada at 1-866-544-7672 or send an email message to info@ismp-canada.org