Why is Critical Incident Reporting and Shared Learning Important for Patient Safety?

Reporting on Critical Incidents Related to Medication / IV Fluid

Ontario Hospital Association Video and Webcast

Toronto, Ontario

August 24, 2011

Institute for Safe Medication Practices Canada

Overview

1. Introduction to ISMP Canada
2. Examples of Ontario Leadership
3. Value of Reporting

ISMP Canada Home
ISMP Canada Safety Bulletins
Report A Medication Incident
News
CMIRPS
Products & Services
Publications
Current Projects
About Us
Contact Us
Education Events
Media
Related Links
Privacy
Definitions of Terms
Disclaimer

Advancing safe medication use

The Institute for Safe Medication Practices Canada is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

CMIRPS
Supported by Health Canada

MedRec

SafeMedicationUse.ca
Supported by Health Canada

Reporting and Prevention Systems

REPORT
a Medication Incident

Medication Incident and Near Miss Reporting Programs for:

- Practitioners
- General Public
  SafeMedicationUse.ca

MOHLTC Supported Initiatives

- Ontario Antimicrobial Stewardship Project
- Operating Room Medication Safety Checklist©
- Multiple IV Infusions Project
- Medication Reconciliation
- Medication Safety Support Service (MSSS)
- Safer Medication Use in Older Persons

Multi-Stakeholder Projects

Safer Medication Use in Older Persons

Canadian Pharmaceutical Bar Coding Project

Upcoming ISMP Canada Events

Webinars	Wednesday, September 7, 2011 (at 12 noon ET)	CPOE/eMAR: Measuring the Impact on Clinicians, Quality, and Safety
	Wednesday, September 21, 2011 (at 12 noon ET)	Exploring Medication Safety in an Acute Care Hospital: Nurses, Pharmacists, and Pharmacy Technicians link Medication Safety to Patient Safety and Quality Patient Outcomes
	Wednesday, October 5, 2011 (at 12 noon EDT)	Knowledge Translation: What is it and what does it mean to you and the patients we care for?
Workshops	October 13, 2011	Root Cause Analysis (RCA) Workshop for Pharmacists
Patient Safety Workshop Series	September 28-30, 2011	Montreal (French)
	October 26-28, 2011	Halifax

ISMP Canada Board

Barry McLellan, MD President and CEO, Sunnybrook Health Sciences Centre

Beverley Orser, MD, FRCPC, PhD Associate Professor of Anesthesia and Physiology, University of Toronto

Eleanor Morton, CCHRA(C), Hons BAS, Risk Management, previously Healthcare Insurance Reciprocal of Canada

Emily Lap Sum Musing, RPh, BScPhm, MHSc, ACPR, FCSHP, CHE Executive Director of Pharmacy, Patient Safety Officer, Director of Clinical Risk and Quality, University Health Network

John Senders, PhD Scientific Consultant to ISMP, Professor Emeritus, University of Toronto

Michael Cohen, MS, RPh President, ISMP US

Ruth Wilson, MD, CCFP Department of Family Medicine, Queen's University

Tom Paton, PharmD, Director of Pharmacy, Sunnybrook & Women's Health Sciences Centre

W. Morley Lemon, FCA, CPA Professor Emeritus, University of Waterloo

Medication Incident Analysis

1. Shared learning from medication incidents helps identify system improvement opportunities
2. Solution development involves consultation and collaboration

Globe & Mail – June 12, 2002

Wrong injection causes death

BY GRAEME SMITH

A drug used to execute death-row prisoners was mistakenly injected into an elderly woman, whose death in a Peterborough, Ont., hospital will be examined in a coroner's inquest.

Bonita Porter, Ontario's deputy chief coroner of inquests, announced yesterday that a jury will look at why Frances Marie Tanner, 84, died at the Peterborough Regional Health Centre on Jan. 21.

The cause of Ms. Tanner's death is already known: Somebody injected a dose of potassium chloride into her vein. Small quantities of the drug can cure potassium deficiencies, but larger amounts are poisonous.

At least three other Canadians have died after receiving the same drug, sometimes from nurses who thought it was a different medicine.

Some doctors blame these accidents on manufacturers who sell potassium chloride in plastic ampoules and vials that closely resemble containers of sterile water, saline solution, and other harmless solutions.

Others say hospitals need stricter controls over potentially deadly substances. Ontario's chief coroner sent a memo to hospitals last year specifically warning them that potassium chloride has been wrongly administered in the past.

After the latest death, however, the coroner's office decided it was time to emphasize the danger.

"It was felt that an inquest might be the best way to get the information out," Dr. Porter said.

The medical community knows surprisingly little about its own errors. A newsletter published last month by the Institute for Safe Medication Practices Canada recorded five cases in which patients were accidentally given potassium chloride; three died, and two were considered "near misses."

More cases could exist, said the institute's president, physician David U. While many hospitals have removed potassium chloride from nursing stations, he said, some doctors still demand to have it on hand, particularly in intensive-care units. And the drug manufacturers have a financial interest in maintaining their products' uniform packaging.

"The companies have just one assembly line, so they all look the same," he said. "It's an accident waiting to happen."

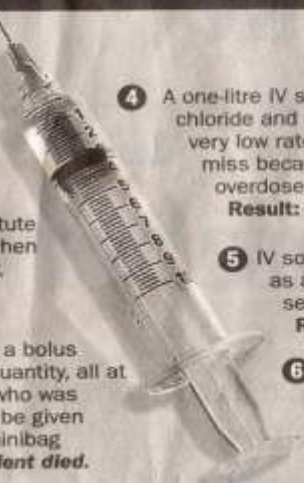
Researchers have suggested that perhaps 5,000 to 10,000 Canadians die because of medical error in hospitals every year.

The estimate is extrapolated from just one American study, however. A Canadian study was launched last month.

Litany of errors

Incidents involving potassium chloride in Canada:

1. Potassium chloride (KCl) was administered via direct IV when the intended action was to flush an intravenous line with diluted sodium chloride. **Result: *Patient died.***
2. KCl concentrate was used to reconstitute a drug for parenteral administration when the intended diluent was sterile water. **Result: *Error was noted before administration.***
3. KCl concentrate was administered as a bolus injection – an injection given in high quantity, all at once – by a health-care professional who was unaware that KCl concentrate cannot be given as a bolus but must be diluted in a minibag and given as an infusion. **Result: *Patient died.***
4. A one-litre IV solution was prepared with potassium chloride and although it was administered at a very low rate, the incident was felt to be a near miss because of the potential for accidental overdose. **Result: *Error was noted during administration.***
5. IV solutions containing KCl were administered as a fluid replacement in a patient requiring several litres of fluid in a short time frame. **Result: *Hyperkalemia, patient died.***
6. Frances Marie Tanner, 84, received an intravenous injection of potassium chloride at the Peterborough Regional Health Centre on Jan. 21, 2002. **Result: *Patient died.***



SOURCE: INSTITUTE FOR SAFE MEDICATION PRACTICES REPORT, MAY, 2002 IMAGE: PHOTODISC

THE GLOBE AND MAIL

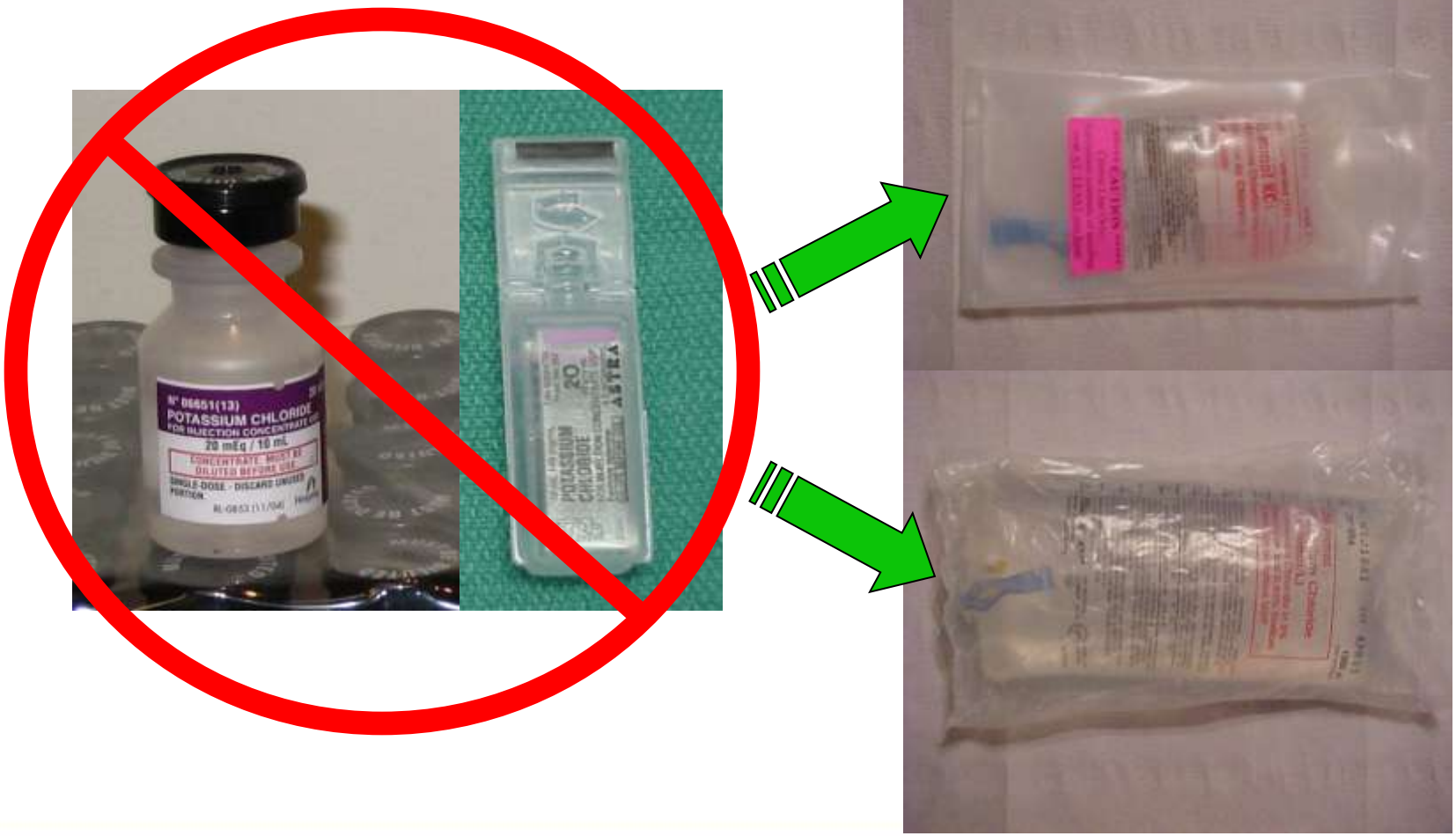
Initiative to eliminate concentrated potassium chloride from patient care areas was supported by MOHLTC

Similar packaging and storage contributed to fatal errors

Provincial Advisory Committee

- Ontario Ministry of Health and Long-Term Care
- Ontario Hospital Association
- Registered Nurses Association of Ontario
- Registered Practical Nurses of Ontario
- Ontario Medical Association
- Ontario Pharmacists' Association
- Quality Health Network
- College of Nurses of Ontario
- Canadian Society of Hospital Pharmacists – Ontario Branch
- College of Physicians and Surgeons of Ontario
- Ontario College of Pharmacists
- Institute for Safe Medication Practices Canada

Province-wide effort



CMIRPS

Canadian Medication Incident Reporting and Prevention System (CMIRPS) Program

REPORT
a Medication Incident

Practitioners:
Healthcare Professional - (e.g., nurse, pharmacist, physician)

ISMP CANADA

ISMP Canada:
Institute for Safe Medication Practices Canada

SafeMedicationUse.ca
Supported by Health Canada

General Public:
Preventing harm from medication incidents is a responsibility of health professionals. **Consumers like you** can also play a vital role.

SHARE

ISMP Canada Activities for the CMIRPS:

- Reporting Systems for Medication Incidents
- A consumer medication safety reporting and learning program: SafeMedicationUse.ca
- Safety bulletins and alerts by ISMP Canada about medication incidents and prevention strategies
- Medication Safety Self-Assessment programs
- Root Cause Analysis workshops and frameworks
- Failure Mode and Effects Analysis workshops and frameworks
- Responding to queries on medication safety (email or telephone)
- Medication safety workshops and webinars

The key partners in the development and implementation of CMIRPS are Health Canada, ISMP Canada, Canadian Institute for Health

CMIRPS Web site

ISMP Canada is pleased to announce that CMIRPS Web site has been officially launched.

This new Web site is now available with information on the Canadian Medication Incident Reporting and Prevention System (CMIRPS), a collaborative program to reduce and prevent harmful medication incidents in Canada.

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) are partnering to contribute information, tools and expertise in the prevention of harmful medication incidents.

Visit the new CMIRPS Web site today for more information about the program and its partners.

Read the News Release - PDF

Strategic Partners

- Accreditation Canada
- Canadian Patient Safety Institute
- Canadian Institute for Health Information
- Health Canada
- Healthcare Insurance Reciprocal of Canada
- Healthcare Professional associations
- Healthcare Professional colleges
- Provincial Ministries
- Provincial Quality Councils
- International Medication Safety Network
- World Health Organization

Results

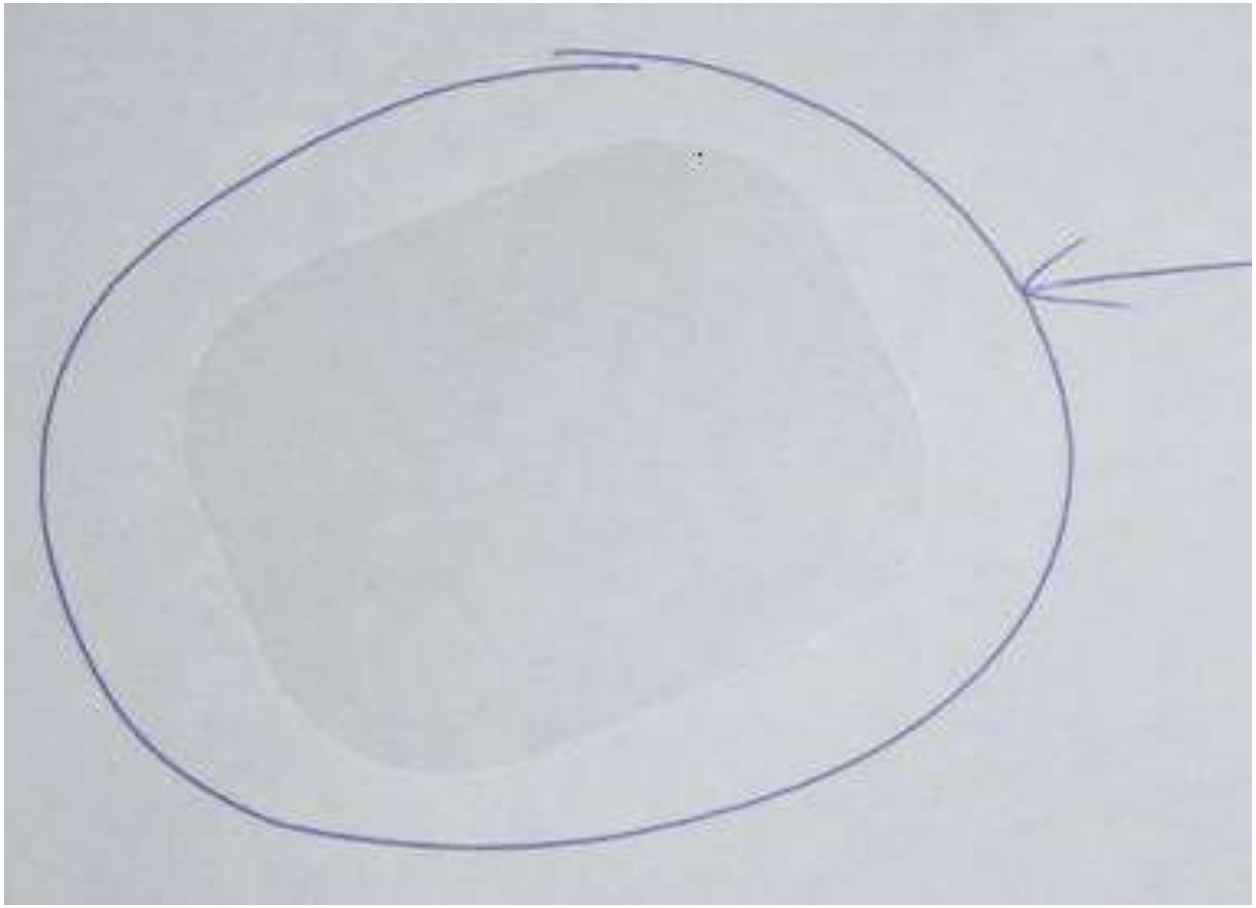
A 2004 independent national survey reported 96% of Ontario hospital respondents had removed KCl concentrate from patient care areas.

"Ontario most successful province in this safety initiative"[1]

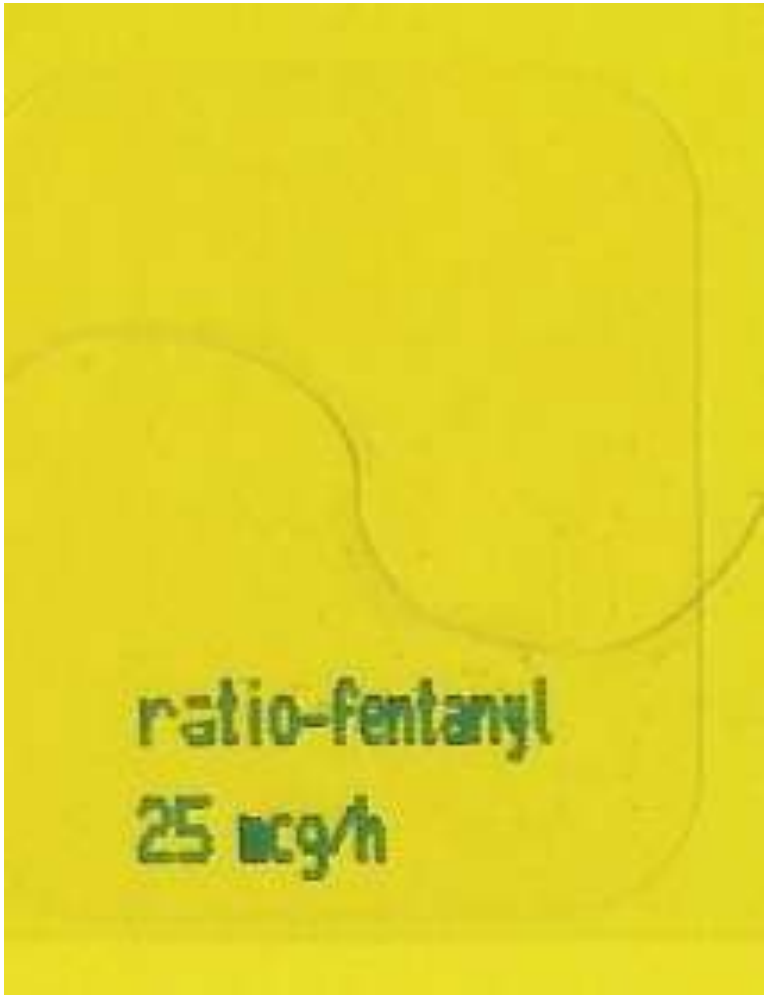
Work informed Accreditation Canada standards development.

1 McKerrow R, Johnson N, Hall KW, Roberts N, Salsman B, Bussieres JF, Macgregor P, Lefebvre P, Harding J. (Eds.). 2004. "2003/2004 Annual Report, Hospital Pharmacy in Canada: Medication Safety" [15tth Hospital Pharmacy in Canada Survey]. Eli Lilly Canada. P;. 55-57. Retrieved March 9, 2007. <http://www.lillyhospitalsurvey.ca/hpc2/content/rep_2004_toc.asp

Report: Transdermal Fentanyl Patch Not Visible after Application



Result: Product Change Implemented



Report: Dose Calculation Difficulty

Result: Label Change Implemented

- Concentration now expressed in g per total volume, and mg per mL
- Manufacturer logo removed to give prominence to critical information
- CEO called to express appreciation for improvement recommendation

Reports involving Neuromuscular Blocking Agents

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.

Volume 6, Issue 2

ISMP Canada Safety Bulletin

April 25, 2006

Neuromuscular Blocking Agent Labelling and Packaging Initiative

A collaborative meeting of representatives of pharmaceutical manufacturers of neuromuscular blocking agents was convened by ISMP Canada in Toronto on February 27th, 2006. The foremost outcome was agreement among the attending stakeholders on the "ideal features" for packaging and labeling of neuromuscular blocking agents:

1. Red cap with white lettering: "Paralyzing agent" or "Warning: Paralyzing Agent"
2. Red ferrule with white lettering: "Paralyzing agent"
3. Red lettering on the product label: "Paralyzing agent" or "Warning: Paralyzing Agent"
4. Peel-off label, using the colour scheme and content information recognized by the ASA/CAS recommended standards, for application to a prepared syringe (ASA = American Society of Anesthesiologists (www.asahq.org); CAS = Canadian Anesthesiologists' Society (www.cas.ca)
5. Space on the product label for bar code application
6. Development of a universal symbol for neuromuscular blocking agents and proposal for global use: placement of this symbol (e.g., on the label), to be determined
7. Review of potential benefit of using TALL-man lettering for generic names of neuromuscular blocking agents

Participating manufacturers (Sandoz Inc, Hospira, Organon, and Abbott) are evaluating the feasibility of incorporating some or all of these features.

Result: Package and Label Changes

Moving Forward

All manufacturer's now include a warning:

Branding

Global Impact

Original Carton Label

Canadian Initiated Over-label (April '04)

New Global Carton Label

Knowledge Transfer

Work has informed Health Canada's Draft Guidance Document - Labelling of Pharmaceutical Drugs for Human Use

- Designed to facilitate compliance with regulated labelling requirements.
- Supports safe and effective use of drugs

Available from: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/index-eng.php

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.

Volume 8, Number 3

ISMP Canada Safety Bulletin

May 19, 2008

Drug Interaction Incident with HIV Post-exposure Prophylaxis

The regimens for post-exposure prophylaxis (PEP) against human immunodeficiency virus (HIV) consist of combinations of antiretroviral medications. These medications are taken for a period of 4 weeks to reduce the risk of HIV infection in people who may have been exposed to the virus, either through occupational exposure (e.g., needle-stick injuries) or non-occupational exposures (e.g., sexual assault).[1,2] They must be started as soon as possible (preferably within hours of exposure);[1,2,3] therefore, if the person is deemed a suitable candidate for prophylaxis, an HIV PEP "starter kit" is often provided in the emergency department or other ambulatory setting to ensure prompt initiation. The process for supplying the balance of the HIV PEP medication varies. The medications may be dispensed by a community pharmacy or may be provided during follow-up clinic visits. When providing HIV PEP, a systematic approach for identifying possible drug interactions may be lacking.

Certain antiretroviral medications are known to be involved in numerous drug interactions through their inhibition of the

- The clinically significant drug interaction between ritonavir and fentanyl was not identified.

Ritonavir is a potent inhibitor of the CYP 3A4 enzyme which is responsible for metabolizing fentanyl.[6] A study evaluating the interaction between ritonavir and intravenous fentanyl found that fentanyl clearance was reduced to one third when ritonavir 200 mg, given three times per day, was added. The authors conclude that ritonavir treatment results in an approximately three-fold increase in fentanyl concentrations,[7] an interaction of major clinical significance.[8] Administration of Kaletra for HIV PEP delivers a ritonavir dose of 100 mg twice per day. Studies of the increase in fentanyl concentration occurring as a result of an interaction with a lower dose of ritonavir (as in the HIV PEP protocol) have not been published. Of interest, the product monographs for the fentanyl patch (e.g., Duragesic)[9] do list ritonavir as an interacting drug. However, the ritonavir product monographs (Kaletra,[10] Norvir,[11] and Norvir SEC[11]), do not include fentanyl in the

To download the bulletin: http://www.ismp-canada.org/download/ISMPCSB2008-03HIVPEP.pdf

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.

Volume 5, Issue 3 **ISMP Canada Safety Bulletin** March, 2005

Heparin-Induced Thrombocytopenia — Effective Communication Can Prevent a Tragedy

An otherwise healthy 63-year-old patient was admitted to hospital for elective mitral valve replacement surgery. Unfractionated heparin (UFH) was administered according to protocol during the surgical procedure, and full-dose UFH was administered intravenously for several days afterward, until a therapeutic international normalized ratio (INR) was attained with oral warfarin. The platelet count was 96 x 10^9/L (normal range 150-400 x 10^9/L) immediately after surgery and rose to 142 x 10^9/L by the fifth postoperative day. Over the next two days the platelet count fell to 54 x 10^9/L. Because of the decline in the platelet count, the physician ordered an assay to detect for the presence of the antibody responsible for heparin-induced thrombocytopenia (HIT). On the following day, the positive results of the HIT antibody assay were posted in the laboratory section of the electronic patient record (EPR). As well, a paper copy of the laboratory report was sent to the ward; however, the patient had been discharged earlier that day, and the report was placed with other materials to be sent to the health records department for filing.

Approximately one week later, the patient presented to the emergency department of the same hospital complaining of shortness of breath. The differential diagnosis included pleural effusion and pulmonary embolus.

approximately 3% of patients who receive UFH and less than 1% of patients who receive low-molecular-weight heparin (LMWH). The diagnosis is based on the following three criteria: (i) current or recent exposure to heparin, (ii) unexplained fall in platelet count (usually a fall of 50% or more, even if the platelet count nadir remains above 150 x 10^9/L) with or without thrombosis, and (iii) laboratory evidence of HIT antibodies. The fall in platelet count usually begins 5 to 10 days after heparin is initiated but may occur more abruptly in patients with recent exposure to heparin. When HIT is diagnosed (or strongly suspected), all heparin must be discontinued, including UFH and LMWH by any route. In addition, the use of an alternative, HIT-safe anticoagulant (e.g., argatroban, lepirudin, or danaparoid) should be carefully considered.

> … problems can ensue when there is no coordinated system to ensure communication and documentation of critical test results and drug allergy information.

The devastating case of HIT described above illustrates some of the problems that can ensue when there is no coordinated system to ensure communication and documentation of critical test results and drug allergy information. Although this patient received appropriate platelet count monitoring and detection of HIT antibodies during the original hospital admission, the failure to adequately communicate and document this information led to inappropriate re-administration of UFH, with a catastrophic

Available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2005-03HIT.pdf

ISMP Canada Home
ISMP Canada Safety Bulletins
Report A Medication Incident
News
CMIRPS
Products & Services
Publications
Current Projects
About Us
Contact Us
Education Events
Media
Related Links
Privacy
Definitions of Terms
Disclaimer

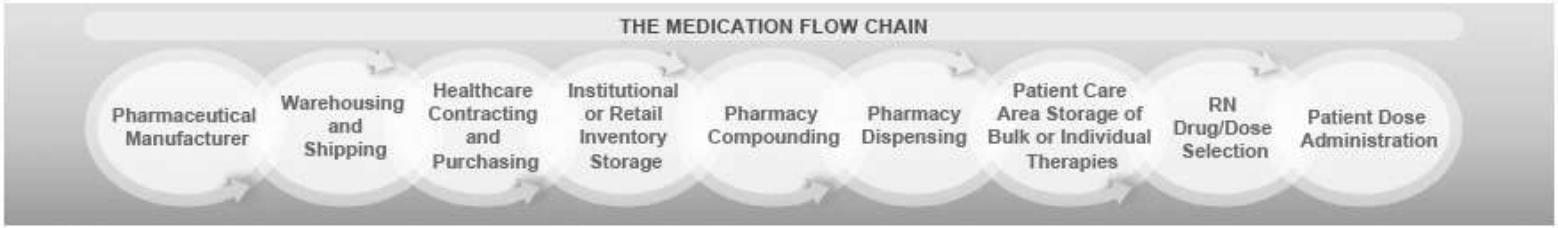
Financial Support has been provided by:

Canadian Pharmaceutical Bar Coding Project

About the Project Strategy, Collaboration, and Next Project Steps | **Downloads** News Release, Brochure, Endorsement ... | **Supporters** Financial Supporters, Implementation Advisory Committee, Technical Task Force, Endorsements | **Contact Us** Become a Supporter | **Français**

SHARE

About the Project



Designing a National Strategy for Healthcare

In an effort to increase patient safety, members of the healthcare industry are collaborating to implement standardized bar codes on all aspects of pharmaceutical labelling.

Headed jointly by the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI), the initiative is guided by a national Implementation Committee and being developed with assistance from a 34-member Technical Task Force (TTF), representing six identified healthcare sectors.

ISMP Canada and CPSI jointly endorsed the adoption of the GS1 global standard for automated identification (e.g., bar coding) of pharmaceutical products in Canada.

The multiphase project has developed draft technical requirements

Find out who is endorsing standardized Pharmaceutical Barcoding Practices

FINANCIAL SUPPORT HAS BEEN PROVIDED BY:

- Medbuy Corporation
- HealthPRO Procurement Services Inc
- Healthcare Insurance Reciprocal of Canada (HIROC)
- Baxter Corporation

Pharmaceutical Bar Coding Project

Major Objectives:

- To develop a pan-Canadian strategy for bar coding of commercial pharmaceutical products.
- To select a common product database for standardized product data
- To facilitate clinical information systems development which utilizes automated identification and data capture at each point of the medication chain
- To create a national environment for automated identification implementation within each identified healthcare sector.

Endorsements

Canadian Adverse Events Study

"Efforts to make patient care safer will require leadership to encourage the reporting of AEs, continued monitoring of the incidence of these events, the judicious application of new technologies and improved communication and coordination among caregivers."

Baker GR, Norton PG, Flintoft V, et al. CMAJ. 2004;170(1):1686. Available online at www.cmaj.ca

Distinction between Adverse Drug Reactions and Medication Incidents

Adverse Drug Reaction Reporting	Medication Incident Reporting
Adverse Drug Reaction Reports (Canada Vigilance) inform the risk:benefit ratio inherent with drug use (properties of the medication).	Medication incidents are preventable and inform medication system improvement.

Health Canada | Santé Canada

Your health and safety...our priority. | *Votre santé et votre sécurité... notre priorité.*

Canadian Adverse Reaction Newsletter

Volume 18 • Issue 3 • July 2008

www.healthcanada.gc.ca/carn

In this Issue

Fentanyl transdermal patch and fatal adverse reactions 1

Atomoxetine and suicidal behaviour: update 2

Twinject auto-injector and device malfunctions 3

Summary of advisories 4

Scope

This quarterly publication alerts health professionals to potential signals detected through the review of case reports submitted to Health Canada. It is a useful mechanism to disseminate information on suspected adverse reactions to health products occurring in humans before comprehensive risk–benefit evaluations and regulatory decisions are undertaken. The continuous evaluation of health product safety profiles depends on the quality of your reports.

Reporting Adverse Reactions

Canada Vigilance Program
Phone: 866 234-2345
Fax: 866 678-6789
Online: www.healthcanada.gc.ca/medeffect

Did you know?

To receive the Newsletter and health product advisories free by email, subscribe to the MedEffect e-Notice at www.healthcanada.gc.ca/medeffect

Fentanyl transdermal patch and fatal adverse reactions

The fentanyl transdermal system is indicated for the management of moderate to severe chronic pain that cannot be managed by other means such as opioid combination products or immediate-release opioids.[1] The safety of this system is contingent on its use according to the conditions recommended in the Canadian product monograph.[1] The fentanyl transdermal system has been marketed in Canada under the brandname Duragesic since 1992. In July 2006, 2 generic products were introduced: Ratio-Fentanyl and Ran-Fentanyl transdermal systems.

Health Canada continues to monitor reports of serious adverse reactions (ARs) suspected of being associated with fentanyl transdermal patches. Fatal outcomes were previously described in this newsletter involving opioid-naive adolescents and adolescents who abused this medication.[2,3] The Canadian product monograph for Duragesic was revised in 2005 to emphasize safety information following reports of death related to inappropriate use of this product. Related advisories were issued in September 2005.[4,5] Numerous publications have highlighted safety issues related to the use of fentanyl patches.[6-9]

From Jan. 1, 1992, to Dec. 31, 2007, Health Canada received 105 reports of ARs suspected of being associated with fentanyl transdermal patches wherein a fatal outcome was reported. Twenty-seven of the reports were received after the last Health Canada risk communications.[4,5] As part of the ongoing monitoring of AR reports, the data were analyzed to identify potentially preventable incidents and to increase awareness regarding the safe use of this product. In 33 of the 105 reports, the cause of death was reported to be unrelated to the fentanyl transdermal patches; in 20 cases, insufficient information was provided in the report for evaluation. The remaining 52 reports are summarized in Table 1.

Health care professionals are reminded to follow the directions in the product monographs for fentanyl transdermal patches.[1] Guidance on the safe use of this product is essential for patients, caregivers and their families, including the safe storage of fentanyl patches to prevent their accessibility for abuse and prevention of accidental overdose.

Marielle McMorran, BSc, BSc(Pharm); Maria Longo, BScPharm, Health Canada

Acknowledgement: Health Canada acknowledges the collaboration with Sylvia Hyland, RPh, BScPhm, MHSc (Bioethics), of the Institute for Safe Medication Practices Canada (ISMP Canada) and member of the Expert Advisory Committee on the Vigilance of Health Products, in the analysis of this data and preparation of this article.

Core Principles of Reporting

- Reporting must be safe - individuals who report incidents must not be punished or suffer other ill-effects from reporting. Reporting is only of value if it leads to a constructive response.
- The most important function of a reporting system is to use the results of data analysis and investigation to formulate and disseminate recommendations for system improvements.
- A reporting system must produce a visible, useful response to stimulate improvement and continued reporting.

Why is Reporting Important?

- Learning from experience can prevent harmful mistakes from recurring. Safety is enhanced by learning from failures.

- Meaningful analysis, learning, and system improvement requires collaboration at all levels.

Discussion

- ? Questions
- ? Feedback
- ? Opportunities

Sylvia Hyland, VP and COO
Institute for Safe Medication Practices Canada

shyland@ismp-canada.org
416-733-3131 ext. 222