Reporting Canadian Medication Incidents: What Can We Learn?

E-Medication Management Conference
May 2015
Overview

- Distinctions
- Drivers
- Barriers and Facilitators
- Available Reporting Mechanisms
- What’s Next?
Distinctions

**Medication Incident/Error**
- Preventable
- May cause inappropriate medication use or patient harm
- While medication is in the control of the healthcare professional, patient, or consumer
- May be related to:
  - professional practice, drug products, procedures, and systems
- May occur at any point along the drug use continuum

**Adverse Drug Event:**
- Injury from a medicine or lack of an intended medicine.
- Includes adverse drug reactions and harm from medication incidents.

Adapted From: CMIRPS Collaborating Parties
http://www.ismp-canada.org/definitions.htm
Adverse Reactions

- Undesirable effects of health products
- May occur under normal use conditions of the product.
- Within minutes or years after exposure to the product
- Range from minor reactions to serious and life-threatening events
- Not preventable or ameliorable

May initially be considered unexpected when the effects of medication are incompletely known

Often can be prevented once increased knowledge is obtained:

Thus, reporting and information sharing on ADRs are important to medication safety.

Adapted from: Health Canada Website
http://www.hc-sc.gc.ca/dhp-mps/medeff/advers-react-neg/index-eng.php#a1
MEDICATION INCIDENT REPORTING DRIVERS
CSHP Standards of Practice

OFFICIAL PUBLICATIONS

STANDARD 1 - Professional Accountability and Continued Competence

1.8 Responds to and reports situations which may be adverse for the client and/or health care providers

From: Professional Hospital Pharmacy Practice: Standards (2003)

http://www.cshp.ca/members/dmsgetfile.asp?file=%7BB1E12CF6F-FE2C-4BD3-9309-9A8124B2A353%7D
Model Standards of Practice

Pharmacists respond to safety risks.

Pharmacists regardless of the role they are fulfilling:
10. manage errors, incidents and unsafe practices (2.6)
11. promptly disclose alleged or actual errors, incidents and unsafe practices to those affected and in accordance with legal and professional requirements (2.6)
12. record and report alleged and actual errors, incidents and unsafe practices in accordance with legal and professional requirements (2.6)
13. adhere to applicable laws, regulations and policies applicable to pharmacy practice (3.1)

Pharmacists, when providing patient care:
14. report the occurrence of adverse events and close-calls*** (2.6)

Pharmacists, when managing a pharmacy:
15. review errors and incidents to determine patterns and causal factors that contribute to patient risk (2.6)
16. develop and implement policies and procedures that minimize errors, incidents and unsafe practices, including supporting staff in their obligation to report adverse events and close-calls (2.6)

From Model Standards of Practice for Canadian Pharmacists
http://napra.ca/Content_Files/Files/Model_Standards_of_Prac_for_Cdn_Pharm_March09_Final_b.p df

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Practice Standards for Nurses

Safety

Nurses promote safe care, and contribute to a culture of safety within their practice environments, when involved in medication practices.

Nurses:
- seek information from the client about their medication, as needed
- provide education to the client regarding their medication
- collaborate with the client in making decisions about the plan of care in relation to medication practices
- promote and/or implement the secure and appropriate storage, transportation and disposal of medication
- promote and/or implement strategies to minimize the risk of misuse and drug diversion
- take appropriate action to resolve or minimize the risk of harm to a client from a medication error or adverse reaction
- report medication errors, near misses or adverse reactions in a timely manner, and
- collaborate in the development, implementation and evaluation of system approaches that support safe medication practices within the health care team.

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Required Organizational Practice

ADVERSE EVENTS REPORTING

The organization establishes a reporting system for adverse events, sentinel events, and near misses, including appropriate follow-up. The reporting system is in compliance with any applicable legislation, and within any protection afforded by legislation.

From: 2015 ROP handbook    http://www.accreditation.ca/rop-handbooks
## Legislated/Mandatory Reporting

<table>
<thead>
<tr>
<th>Region</th>
<th>Reporting Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta Health Services</td>
<td>Reporting of Clinical Adverse Events, Close Calls, and Hazards</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>SK Critical Incident Guidelines</td>
</tr>
<tr>
<td>Manitoba</td>
<td>The Regional Health Authorities Amendment and Amendments to the Manitoba Evidence Act</td>
</tr>
<tr>
<td>Ontario</td>
<td>Excellent Care for All Act</td>
</tr>
<tr>
<td>Quebec</td>
<td>Registre national des incidents et accidents survenus lors de la prestation de soins de santé et de services sociaux (RNIASSSS)</td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>Department of Health Serious Reportable Event Policy</td>
</tr>
<tr>
<td>Health PEI</td>
<td>Patient Safety Incident Reporting Policy</td>
</tr>
</tbody>
</table>
Public Focus on Adverse Events

Inside Canada’s secret world of medical error: ‘There is a lot of lying, there’s a lot of cover-up’
Published Data Supports Dispensing Vincristine in Minibags as a System Safeguard
Table 1: Results for Core Characteristic 8 (WHO Recommendations on vinCRISitine)

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

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Assessment Item</th>
<th>2005 ISMP Survey Results (n = 409)</th>
<th>All Countries (n = 352)</th>
<th>United States (n = 271)</th>
<th>Canada (n = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>76</td>
<td>VinCRISitine is dispensed in a minibag of a compatible solution (e.g., 25 mL for pediatric patients and 50 mL for adults). VinCRISitine doses are never dispensed and/or administered using a syringe.</td>
<td>23% (157/665)</td>
<td>61% (215/352)</td>
<td>54% (147/271)</td>
<td>83% (15/18)</td>
</tr>
<tr>
<td>77</td>
<td>VinCRISitine is dispensed with a prominent warning label that reads: FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.</td>
<td>93% (315/352)</td>
<td>89% (315/352)</td>
<td>92% (249/271)</td>
<td>61% (11/18)</td>
</tr>
<tr>
<td>78</td>
<td>The presence of vinCRISitine is prohibited in areas where intrathecal medications are administered and/or stored.</td>
<td>38% (175/442)</td>
<td>65% (175/269)</td>
<td>64% (136/213)</td>
<td>58% (7/12)</td>
</tr>
<tr>
<td>79</td>
<td>Confirmation that the administration of any prescribed intrathecal medications has been completed is required before dispensing vinCRISitine.</td>
<td>42% (140/333)</td>
<td>54% (140/260)</td>
<td>54% (112/207)</td>
<td>45% (5/11)</td>
</tr>
</tbody>
</table>
Medication INCIDENT REPORTING:

SELECTED LITERATURE/ PUBLICATIONS
Research
Recherche

The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada


[CMJA] • MAY 25, 2004; 170 (11) 1679
# Hospital Pharmacy in Canada

## Table G-1. Reporting System for Medication Incidents 2007/08

<table>
<thead>
<tr>
<th></th>
<th>Bed Size</th>
<th>Teaching Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All (n=161)</td>
<td>Non-Teaching</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Teaching</td>
</tr>
<tr>
<td>A medication incident reporting</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>system is in use</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td>Medication incidents are reported</td>
<td>74%</td>
<td>53%</td>
</tr>
<tr>
<td>to an external reporting program</td>
<td>47%</td>
<td>45%</td>
</tr>
<tr>
<td>(n=159)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication incident reports can be</td>
<td>18%</td>
<td>16%</td>
</tr>
<tr>
<td>used during an individual health</td>
<td>11%</td>
<td>13%</td>
</tr>
<tr>
<td>care provider’s performance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>assessment (n=160)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information regarding the</td>
<td>61%</td>
<td>45%</td>
</tr>
<tr>
<td>institution’s medication incidents</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>is broadly communicated to hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>and physicians (n=158)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information regarding published</td>
<td>95%</td>
<td>71%</td>
</tr>
<tr>
<td>medication incidents is broadly</td>
<td>59%</td>
<td>58%</td>
</tr>
<tr>
<td>communicated to hospital staff and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>physicians (n=160)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 54% report to a health region program
- 40% report to ISMP Canada
- 34% to a provincial program
- 7% to “other” program

From: Lilly Survey 2007-2008
http://www.lillyhospitalsurvey.ca/hpc2/content/Reports3.asp
Reporting captures the tip of the iceberg

- 2007 study at large UK National Health Service hospital
- Examined 1006 admissions
- 110 admissions had at least one patient safety incident resulting in harm

Case Review

- Case review detected all 110 admissions in which patient suffered harm

Incident Reporting System

- Detected only 5% of 110 admissions in which patient suffered harm

Sari et al, 2007: http://www.bmj.com/content/334/7584/79
The Tip of the Iceberg

- Incident reports: 0.01-0.05%
- Prescription order review: 0.3%
- Observation: 15-20%
Original Research

Understanding the attitudes of hospital pharmacists to reporting medication incidents: A qualitative study

Steven D. Williams, M.Phil.\textsuperscript{a,b,*}, Denham L. Phipps, Ph.D.\textsuperscript{b}, Darren M. Ashcroft, Ph.D.\textsuperscript{a,b}

Focus groups involving 17 pharmacists from 4 hospital sites in Northwest England

\textit{Williams SD, Res Soc Admin Pharm, 2013}
Focus group findings

Barriers

• The high prevalence of medication errors

• Impact on inter-professional working relationships with doctors and nurses

• Reporting forms considered too cumbersome and time consuming to complete

Facilitators

• Severity of any patient harm was the primary reporting driver

• More confident to report if there had been previously witnessed positive feedback and system change following an error
# Reporting, Learning and the Culture of Safety

**TABLE 1.**

Important success factors for effective reporting systems

<table>
<thead>
<tr>
<th>Organizational</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Generative approach toward information processing (Westrum 2004)</td>
</tr>
<tr>
<td>• Just culture (not a blame-free culture) (Reason 1997)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Design of the system</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Voluntary and confidential</td>
</tr>
<tr>
<td>• Easy to use</td>
</tr>
<tr>
<td>• Focus on the story (Morath and Turnbull 2005)</td>
</tr>
<tr>
<td>• Emphasis on close calls (near misses) (Morath and Turnbull 2005)</td>
</tr>
<tr>
<td>• Acknowledgement and feedback given to reporter</td>
</tr>
<tr>
<td>• Analysis by clinicians and someone able to analyze human factors and organizational issues (Vincent 2007)</td>
</tr>
<tr>
<td>• Visible action taken to mitigate important risks identified in reports</td>
</tr>
</tbody>
</table>

*From: Flemons WW et al., Healthcare Quarterly 2012*
What are barriers or facilitators to incident reporting in your organizations experience?
MEDIICATION INCIDENT REPORTING MECHANISMS
NATIONAL REPORTING MECHANISMS
The Canadian Medication Incident Reporting and Prevention System

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.

Reporting, sharing and learning about medication incidents will help to reduce their reoccurrence and help create a safer healthcare system. Find out how you can report and share learning about medication incidents.

Featured resources:

- Reporting is everyone’s responsibility
CMI RPS Characteristics

- Health Canada
- ISMP Canada
- Canadian Institute for Health Information
- Canadian Patient Safety Institute
- Stakeholder networks

Collaborative program

- Protocol changes
- Product changes

Reporting and Learning systems

- Healthcare professionals, institutions, consumers and patients
- Identify problems, analyze information and share solutions

Initiate and Support System Level Change

Knowledge Transfer Program

- Sharing information, tools and expertise
CIHI data...

Working to prevent medication incidents

NSIR Registered Facilities

250 registered hospitals
~30% of Canadian hospitals submitting to NSIR

Over 20,000 incidents submitted to NSIR from the 5 jurisdictions

Slide adapted from CIHI slide
How Data Providers are Using NSIR
Saskatoon RHA

http://www.cihi.ca/land/Article/Data+In+Action/cihi010203
Reporting to ISMP Canada - Individual Practitioners
ISMP Canada Individual Practitioner Reports – By harm/error classification

Based on reports received since January 2013

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Examples of Sharing and Learning from CMI RPS

WHAT HAVE WE LEARNED?
Outputs

ALERT: Look-Alike Labelling and Packaging for Diphenhydramine and Phenylephrine

A facility reported concerns regarding the look-alike labelling and packaging of parenteral diphenhydramine and phenylephrine products.

Preventable Death Highlight: Management of Known Drug Interactions

Medication regimens are becoming increasingly complex, with many patients taking several medications concurrently to treat multiple conditions. With this increase in the number of medications by individual patients has come an increase in the potential for drug–drug interactions. Drug–drug interactions can result in preventable adverse events due to changes in the pharmacologic or clinical response to one or both of the drugs involved, for example, a reduction in efficacy or an increase in the risk of adverse effects.

Labelling and Packaging: An Aggregate Analysis of Medication Incident Reports

The information presented on the inner and outer labels of health products and the design and layout of this information constitute an important mechanism of communication to end users, both healthcare practitioners and consumers. Since ISMP Canada began accepting voluntary incident reports in 2000, reporters have repeatedly identified issues related to labelling and packaging of health products as a concern. Some of these incidents have been described in detail in previous ISMPCanada Safety Bulletins.

http://www.ismp-canada.org/ISMPCSafetyBulletins.html
Collaboration to Sustain Practice Improvements

• More than 50 recommendations adopted by Accreditation Canada into Standards and Required Organizational Practices (ROPs)
Reported incidents inform Labelling and Packaging Improvements

Before

After
PATIENT REPORTED MEDICATION INCIDENTS
## Incident Report:

**NOTE:** Red Asterisks (*) indicate which fields are REQUIRED.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Date the incident occurred</td>
<td>month, year</td>
</tr>
<tr>
<td>2. Province or Territory</td>
<td></td>
</tr>
<tr>
<td>3. What type of medication incident are you reporting? *</td>
<td></td>
</tr>
<tr>
<td>4. Where did the incident happen? *</td>
<td></td>
</tr>
<tr>
<td>5. At what stage(s) of the medication system did the incident occur? (Choose all that apply.) *</td>
<td>Prescribing, Documentation/computer entry, Preparation/dispensing, Administration, Monitoring, Other, I don't know</td>
</tr>
</tbody>
</table>
Outputs

Know When You Know

It is important to know when you are taking a medication for a long period of time. Other mistakes can be made when a medication is being taken for a period of time. The length of time can be a factor in determining whether or not a medication is being taken properly. The reason you are taking the medication can also be a factor in determining whether or not a medication is being taken properly. It could even happen that a medication is being taken without any adverse effects. It could even happen that a medication is being taken without any adverse effects.

Tips for Practitioners

- Children are particularly vulnerable to the consequences of a medication error. Additional safeguards should be put in place when prescribing, dispensing, and administering medications for children. Consider using tools such as checklists and computerized dose checks to support safe practices.
- When prescribing or dispensing a medication for a child, always ask for the child’s age and current weight. A child’s weight can change quickly with normal growth. Take care to record the unit of the weight correctly on the pharmacy profile, e.g., kilograms (kg) versus pounds (lb).
- Make sure the prescribed dose is appropriate for the child’s weight. Verify dose calculations and other details against an approved reference for pediatric dosing.
- Counsel the child’s caregiver on how to administer the medicine. For liquid medicines, provide an oral syringe or other suitable measuring device. Demonstrate how the dose should be measured accurately, and then have the caregiver show you how he or she would measure the dose. Make sure the caregiver knows how frequently the medicine is to be given.

Found at: www.safemedicationuse.ca

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Learning can be shared with Patients
Global Patient Safety Alerts

• Database for sharing evidence informed alerts, advisories and recommendations.
  • 26 contributing organizations
  • Hundreds of searches every month
  • Supported by the World Health Organization

• Includes:
  • CMI RPS bulletins and alerts for practitioners
  • CMI RPS newsletters and alerts for consumers
  • Alberta…
  • Manitoba…
  • Ontario Critical Incident Learning Bulletins
PROVINCIAL/TERRITORIAL REPORTING AND COLLABORATION
British Columbia

- Web-based patient safety event reporting, learning and management tool used by care providers across all healthcare organizations in BC.

- Rollout began in 2008 (first system of its kind in Canada)
Health Quality Council of Alberta

Collaborative projects to transfer learning into practice

Available from www.HQCA.ca
Manitoba Institute for Patient Safety

Collaborative project to transfer learning into practice

Key Points

Below is a list of medications that have the potential to result in complications. For your presentation, choose to include all, some or none of these medications.

Although these medications have been proven to be safe and effective, they can cause serious injury if they are taken incorrectly. When a patient is on a high alert medication, they need to:

- check with their pharmacist or doctor before taking any non-prescription medication or natural health products.
- inform a new physician or pharmacist that they are on these medications.


Medication Safety: A Guide for Pharmacists

Learn to be Safe –
Appendix D – Supplemental Topic: High Alert Medications
October 15, 2013

Available from www.MIPS.ca
To advance the patient safety agenda, in August 2011 the Ontario Ministry of Health and Long-Term Care issued a directive that hospitals must report critical incidents involving medications and intravenous fluids to the Canadian Institute for Health Information National System for Incident Reporting (NSIR). A critical incident is an "unintended event that occurs when a patient receives treatment in the hospital that results in death, or serious disability, injury or harm, and does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing treatment".

ISMP Canada has been identified as the lead organization for analysis of the reported incidents. A multidisciplinary team reviews each submitted critical incident report to ensure effective identification of the contributing factors. In addition, ISMP Canada will periodically conduct aggregate analysis of reported incidents to provide a more in-depth assessment of events involving a particular medication or care setting. On the basis of these analyses, ISMP Canada will develop and disseminate outcome-directed recommendations, with an emphasis on high-leverage actions that take into account human factors engineering principles and the need to design systems with integrated safeguards.

Available from www.ISMP-Canada.org
Outputs

Smart Pumps Need Smart Systems
The availability of programmable infusion pumps has contributed to the precision of the administration of parenteral medications. Smart infusion pumps incorporate drug administration software (DEIS) or dose limit functionality, but the specific limits must be programmed by the user. While DEIS limit programming can be enabled or disabled, many limits are hard-coded and beyond the user's control. Hard-coded limits prevent the user from customizing them to the environment of care. Various incidents with smart pumps can occur when the programmer is not used to their full capability or when the limits are not set to optimal values.

Call to Action for Hospitals
Make medication safety a strategic priority:
- Prioritize capital purchase of infusion pumps with DEIS that support simultaneous prescribing systems.
- Make an organizational commitment to fully operationalize the DEIS in all areas and work toward an overall goal of improving and automation of smart pumps. Become part of a closed-loop medication system.

Make system-based changes to enhance safety:
- Ensure that programming of smart pumps is consistent in all areas of the hospital.
- Program all necessary drug sets for high-risk medications, i.e., override overrides are not allowed.
- Ensure that high-alert medications, given by continuous infusion, are programmed to patient care units with appropriate level of staff. Staffing limits, and monitoring equipment.
- Incorporate medications for which electronic drug libraries are not available or do not match the drug and concentration ordered because there is no independent double-check process and a newer mechanism is implemented pump programming.

Sustain high-quality practices:
- Ensure that staff have the supporting resources needed to use and maintain and update pumps.
- Regularly audit infusion pump libraries and ensure compliance with alerts by performing pump testing.
- Actively solicit feedback from pump users as part of continuous quality assessment.
- Support incident reporting and to patient safety organizations, such ISMP Canada.

Ontario Hospital Critical Incidents Related to Medications or IV Fluids
Analysis Report
January to December 2013

Submitted to the Ontario Ministry of Health and Long-Term Care
Health Quality Ontario
Formatted for posting July 2014

©2015 Institute for Safe Medication Practices Canada (ISMP Canada)

Found at: http://www.ismp-canada.org/oci/
WHAT’S NEXT?
White Paper Project

- Environment Scan to identify all types of reporting systems that could provide medication incident data to contribute to sharing and learning
  - Identify Gaps and Overlaps

More data
Greater likelihood of identifying potential risk and sentinel events
More information to learn from
More knowledge to share
Greater likelihood of prevention of patient harm from Medication Errors
Linkages Across Data Sources

How can we work together and create links?

Linking data sets, making connections

In all likelihood via solutions

What might be your contribution?
Unintentional Acetaminophen Overdoses

CIHI
National System of Incident Reporting

Poison Control Centres

Coroners and Medical Examiners

Others
Insurers, Regulatory Authorities, Manufacturers, and More

Health Canada
ADR Reports

ISMP Canada
Individual Practitioner Reporting, SafeMedicationUse.ca

Unintentional Acetaminophen Overdoses

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Other sources?

• What other potential sources exist?

• Please e-mail me if you have information or ideas to support this project:
  
kgraham@ismp-canada.org
In Summary...

**Levers**
- Regulation and Practice Standards encourage medication incident reporting

**Barriers**
- Cultural and Structural barriers still persist

**Reporting Systems**
- CMIRPS offers several reporting systems in Canada: Practitioners, Institutions, Consumers

**Knowledge Translation**
- Many provincial examples of how the outputs are used to enhance safety and quality of care

**What’s next?**
- Linking many data sets across silos to better identify potential risks and prevent patient harm from medication incidents