

Medication Incidents Reported to and Reviewed by the ICRC:

A TREND ANALYSIS BY ISMP CANADA

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In a collaborative effort to promote safe medication practices in community pharmacy, the Institute for Safe Medication Practices Canada (ISMP Canada) reviews medication incidents reported to the Inquiries, Complaints, and Reports Committee (ICRC) at the Ontario College of Pharmacists on a regular basis. ISMP Canada reviewed 100 medication incidents reported to the ICRC between January 1 2009 and December 31, 2010. A previous analysis reviewed 78 medication incidents

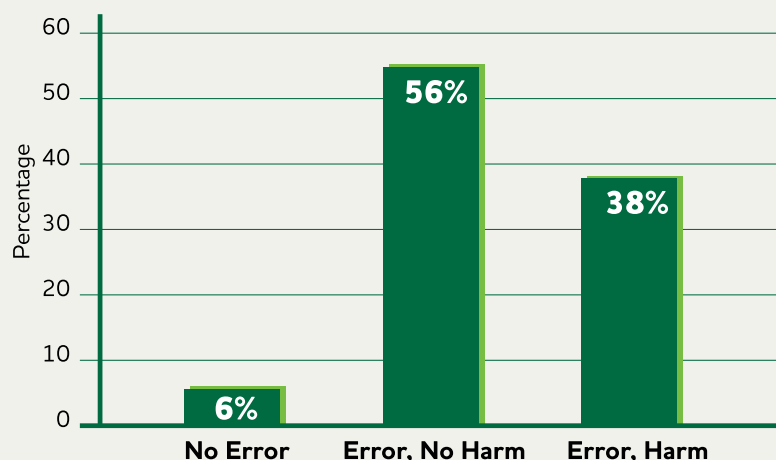
reported to the ICRC between January 1, 2007 and December 31, 2008.¹ The purpose of this review is to search for trend information that may help in recognizing potential flaws in the medication-use system, highlight areas of interests and concerns in community pharmacy, and develop recommendations for enhancing medication safety. The information gathered from these incidents provides ISMP Canada and OCP with deeper understanding towards the development of patient safety

strategies in order to prevent future occurrences of medication incidents in community pharmacy practice.

This report highlights the most significant findings from a quantitative analysis of 100 medication incidents (reported to the ICRC between 2009 and 2010) with a main focus on:

- Degree of harm to patient due to incident
- Type of medication incidents
- Common medications reported
- Medication system stages involved in the incident
- Possible contributing factors
- Areas of concern in community pharmacy practice

FIGURE 1. **DEGREE OF HARM TO PATIENT DUE TO INCIDENT**



No Error	Near misses
Error, No Harm	Medication was dispensed to the patient, but no symptoms were detected and no treatment was required
Error, Harm	Mild, moderate or severe harm

A similar result was observed from the previous report¹ with 42.3% of the errors causing "harm" to patients. Although most of the medication incidents from the two recent reviews were not associated with patient harm or death, the proportion of events associated with harm does illustrate the importance of implementing system-based safeguards and consequently preventing similar incidents from happening in the future. Furthermore, it is possible that extra healthcare recourses associated with the "harm" events would have been required, in particular, the grief and suffering caused to patients and their family members.

TYPE OF MEDICATION INCIDENTS

The three most common types of incidents reported were:

1. Incorrect dose/frequency/strength/concentration (26%)
2. Incorrect drug (26%)
3. Omitted medication/dose (11%)
4. Expired medication (7%)

Compared with the previous analysis¹, similar types of incidents were noticed with the exception of incidents related to "omitted medication/dose" and "expired medication". The increasing number of errors associated with "omitted medication/dose" and "expired medication" could be due to inadequate education for patients and healthcare providers as well as lack of quality control or independent double checks. Additionally, other factors could have contributed to the medication incidents listed above, including look-alike/sound-alike drug names, use of dangerous abbreviations and crowded storage spaces in the pharmacy.

ISMP Canada has conducted incident analyses which suggest medication system improvement strategies for enhancing patient safety through the Safety Bulletin (available at <http://www.ismp-canada.org/ISMPCSafetyBulletins.htm>). For example, "Aggregate Analysis of Dose Omission Incidents Reported as

Causing Harm" can be retrieved from http://ismp-canada.org/download/safetyBulletins/2013/ISMPCSB2013-02_Dose_Omission_Incidents.pdf.

COMMON MEDICATIONS REPORTED

The medications most frequently involved in reported events were different between these two analyses.¹ The medications below are commonly prescribed and/or dispensed within a community pharmacy setting. Due to the small sample size of these two analyses, we were unable to determine if these medications are truly high-risk or red flags to community pharmacy practice. Further analysis with a larger sample size of medication incidents is required in order to provide a better understanding of high-risk medications in community pharmacy. However, it is important to know that warfarin, methadone, and oxycodone have been recognized as high-alert medications in community or ambulatory care settings.²

MEDICATION SYSTEM STAGES INVOLVED IN THE INCIDENT

Within this analysis, the majority of medication incidents occurred during the prescription order entry stage and prescription preparation/

dispensing stage. A similar trend was noticed from the previous analysis on medication incidents reported to the ICRC from 2007 to 2008.¹ One possible explanation for this pattern is that these stages are the two most common processes within the medication-use system in community pharmacy practice. Since most of these incidents were discovered and reported to the ICRC by patients and/or their caregivers, other stages within the medication use system, such as prescribing, administration, and monitoring might not be as easily recognized.

POSSIBLE CONTRIBUTING FACTORS

The most common causes associated with these medication incidents were:

- Drug name, label or packaging problems (35%);
- Environmental factors (i.e. poor lighting, cluttered work spaces, and distractions in the pharmacy), staffing or workflow problems (23%);
- Staff education problems (18%); and
- Lack of quality control or independent check system (12%).

Similar types of contributing factors were noticed from the previous review with slightly different frequencies.¹ It is important to know that a medication incident

TABLE 1: **COMPARISON BETWEEN COMMON MEDICATIONS REPORTED TO THE ICRC FROM 2007-2008¹ AND FROM 2009-2010**

Common medications reported to the ICRC from 2007-2008 ¹		Common medications reported to the ICRC from 2009-2010	
Synthroid®	(8 of 78 cases)	Methadone	(5 of 100 cases)
Amlodipine	(5 of 78 cases)	Oxycodone	(4 of 100 cases)
Clindamycin	(3 of 78 cases)	Lipitor®	(2 of 100 cases)
Warfarin	(3 of 78 cases)	Sertraline	(2 of 100 cases)

may have multiple contributing factors. Therefore, it is not possible to conclude that the contributing factors mentioned above are the only ones causing medication incidents. However, analysis of medication incidents does provide us a good indication for potential areas of focus to enhance medication safety.

AREAS OF CONCERN IN COMMUNITY PHARMACY PRACTICE

Look-alike/Sound-alike:

A 19-month-old child was given Chloral Hydrate instead of the prescribed Lactulose. As a result of this error, the child was hospitalized and monitored for 24 hours. According to the patient's mother, the child continued to experience night terrors and has had ongoing visits to her physician's office. It was noted by the pharmacist that the two bottles were stored closely together on the shelves. The bottles look similar in appearance, and both labels start with the prefix "PMS".

Look-alike/sound-alike medication incidents accounted for 12% of the incidents reviewed. ISMP Canada has received other reports regarding look-alike/sound-alike drug names and conducted an analysis on these medication incidents.³ In community pharmacy practice, these errors can occur at any point in the medication-use system, including prescribing, order entry, dispensing, administration and/or monitoring. Alerts should be incorporated into the pharmacy computer systems to flag potential mix-up during drug selection processes.³

Wrong Patient:

Patient was prescribed clarithromycin 250 mg for a 10-day course of treatment. However, she was

dispensed a medication vial labelled and intended for a different patient, which contained lorazepam 2 mg. Patient did not notice the error until she took her second dose. She was experiencing dizziness and vomiting during the first dose already. Patient took the medication back to the pharmacy. The dispensing pharmacist recalled that the correct prescription vial was in the basket at that time, but somehow during the checkout procedure another patient's prescription was bagged and dispensed to the patient.

Errors involving incorrect patients accounted for 11% of incidents reviewed. Medication errors related to incorrect patients can occur for a variety of reasons at any point in the patient encounter. Thus, a patient verification process using at least two identifiers (e.g., birth date, address) is needed throughout the medication-use process.⁴

Expired Medication:

The patient attended the pharmacy to fill a prescription for Elocrom[®] cream. When she returned home, she removed the prescription label and noticed that the medication would expire in the same month. Three days later she returned to the pharmacy to notify them of the error. The pharmacist apologized and gave her a new tube with a better expiration date. The patient has lost trust in the pharmacy and is worried about the expiration of all the other medications that are not dispensed in their original vials.

Errors involving expired medication accounted for 7% of incidents reviewed. All products in a community pharmacy should be properly stored under the conditions specified by the manufacturer. The expiry date of each product should be checked on a regular basis; the product with near expiry date must be flagged and

identified properly. All expired drugs and medical products must be collected, labeled clearly as expired items, and kept in a separate place for proper management or disposal. Furthermore, all pharmacy staff should practice independent double checks of the expiry date of the product prior to dispensing.

METHADONE:

A relief pharmacist dispensed the wrong dose (10-fold overdose) of methadone to six patients. The pharmacist dispensed methadone to several patients that day using stock solution already made in the pharmacy. However, additional stock solution was required and prepared by the relief pharmacist. The relief pharmacist consulted the compounding log and recalled reading 25 g of methadone powder required to compound the stock solution. However, the correct dose was 2.5 g of methadone powder.

Errors associated with methadone accounted for 5% of the incidents reviewed. Pharmacies are encouraged to adopt a workflow that allows independent double checks to verify proper order entry, dispensing, and administration (in the case of methadone).⁵ The ideal model for methadone maintenance treatment (MMT) is one which allows a 3-way integration of patient, pharmacist, and physician within the community to ensure availability and accessibility of MMT for patients requiring such care.⁵

LIMITATIONS OF ANALYSIS

The findings in this analysis are based on medication incidents submitted to the ICRC by patients or their caregivers. Therefore, it cannot be used to obtain a true estimate of high-alert medications or the probability of specific

incidents in a typical community pharmacy. However, it does suggest that there is a potential to reduce preventable patient harm by focusing on several or specific high-risk medication-use areas. Some of the limitations of this analysis include:

- Under-reporting of incidents in community pharmacy is a considerable concern, and in most cases patients would not report incidents if they were not likely to complain.
- Due to the small sample size of this analysis, it is impossible to conclude that the results would truly reflect current community pharmacy practice. Since no statistical analyses were done within this review, it is impossible to completely rule out “chance” from our explanations.
- Similarly, due to the small sample size and the fact that the most frequently reported medications are commonly prescribed or dispensed medications, it is impossible to determine if those medications are truly high-risk to community pharmacy practice. Therefore, a qualitative data analysis of the incidents’ description and the investigation reports will be beneficial for further verifications.

RECOMMENDATIONS

1. All healthcare practitioners are encouraged to report medication

incidents and near misses or good catches to ISMP Canada Medication Incident and Near Miss Reporting Programs (available at https://www.ismp-canada.org/err_index.htm) to identify early opportunities for enhancing medication safety.


2. Community pharmacists are encouraged to adopt ISMP Canada Community Pharmacy Incident Reporting Program (available at <http://www.cphir.ca>) which facilitates community pharmacies for continuous quality improvement.
3. Patients are also encouraged to report medication incidents via the ISMP Canada Consumer Reporting portal at <http://www.safemedicationuse.ca/report/>.
4. Other ISMP Canada medication safety initiatives and continuous quality assurance (CQA) programs for community pharmacies include:
 - Medication Safety Self-Assessment® for Community/Ambulatory Pharmacy™ (available at <http://www.ismp-canada.org/amssa/>), which helps identify system improvement opportunities proactively within your own pharmacy.
 - Root Cause Analysis (RCA) (available at <http://www.ismp-canada.org/rca.htm>) which provides a standardized approach to the retrospective analysis of critical incidents and near-miss events in health care.

- Failure Mode and Effects Analysis (FMEA) (available at <http://www.ismp-canada.org/fmea.htm>) which is a proactive assessment of work environment, equipment, and procedures to identify, improve or correct system-based problems.

CONCLUSION

Continuous quality improvement in community pharmacy practice is motivated by lessons learned from past mistakes. Collaboration with ISMP Canada would assist in identifying high-risk medications and analyzing possible contributing factors that may lead to errors in the medication-use system.⁶ Through the analysis of incidents and sharing of findings, healthcare practitioners can learn from reported incidents and implement system-based safeguards. Ultimately we can create a culture of patient safety and prevent similar medication incidents from occurring in the future.

ACKNOWLEDGMENT

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