

Aggregate Analysis of Dose Omission Incidents Reported as Causing Harm

The omission of one or more doses of prescribed medication, which can occur at almost any stage of the medication-use process,¹ is among the most commonly reported types of medication incident across different hospital care settings.¹⁻⁴ Dose omission incidents, including inadvertent discontinuation of a medication, can have clinically insignificant effects; however, some incidents of this type have contributed to patient harm, emergency room visits, hospital admissions, and death.^{1,2,5} This bulletin focuses specifically on dose omissions reported to have caused harm, as submitted to the National System for Incident Reporting (NSIR).^{*} An aggregate analysis of these incidents, performed by ISMP Canada, is presented here, with emphasis on the medications most frequently involved in harmful dose omissions, along with the major themes, subthemes, and contributing factors identified by the analysis.

Methodology and Findings of the Quantitative Analysis

Reports of incidents involving “dose omission” with a reported severity of “harm” or “death” were extracted from the NSIR.^{6,7} In total, 159 incidents met these criteria and were included in the quantitative analysis to identify the medications most frequently involved in this type of incident. The data reviewed

for this analysis spanned a period of about 2.5 years (September 2008 to March 2011). During this period, most of the data were submitted by acute care facilities. The reported incidents were associated with mild or moderate harm (Table 1); no cases of severe harm or death were reported. Insulin and heparin sodium were the top 2 medications associated with harm because of dose omissions (Table 2).

Eighty-two of the 159 incidents were associated with the medications listed in Table 2. Each of these 82 incidents was then reviewed in detail, with 3 incidents being excluded from subsequent analysis because of insufficient detail. Therefore, a total of 79 incidents remained for the qualitative analysis.

Table 1: Reported Severity of Outcomes of Medication Incidents

Severity	No. of Incidents [†]
Mild harm	109
Moderate harm	50
Severe harm	0
Death	0
Total	159

[†] It is recognized that it is not possible to infer or project the probability of incidents on the basis of a voluntary reporting system.

* The NSIR (provided by the Canadian Institute for Health Information) is a component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS) Program. More information about the NSIR is available from: <http://www.cmirps-scdpim.ca/?p=12>

Table 2: Medications Most Frequently Involved in Reported Dose Omission Incidents Associated with Harm

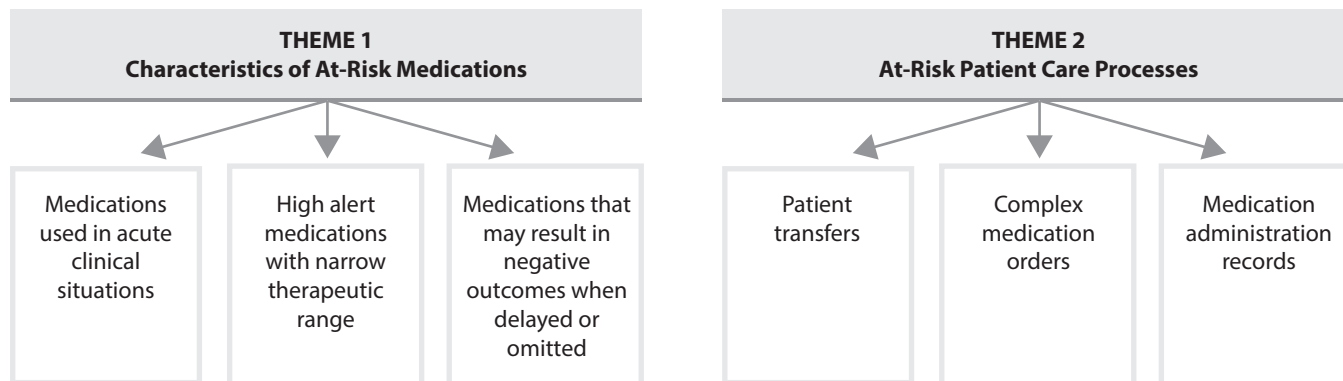
Rank	Medication	No. (%) of Incidents (n = 159)‡
1	Insulin	30 (18.9%)
2	Heparin sodium	21 (13.2%)
3	Potassium chloride	13 (8.2%)
4	Metoprolol tartrate	8 (5%)
5	Acetylsalicylic acid (ASA)	6 (3.8%)
5	Hydromorphone hydrochloride	6 (3.8%)
6	Metformin hydrochloride	5 (3.1%)
6	Warfarin sodium	5 (3.1%)

‡ Only medications involved in 5 or more incidents are listed. In accordance with the privacy and confidentiality guidelines of the Canadian Institute for Health Information, small cells of data (<5) are suppressed. Some of the incidents involved more than one medication. This table includes 3 cases that were later removed from the qualitative analysis.

Findings of the Qualitative Analysis

The 79 incidents were independently reviewed and categorized into 2 major themes (Figure 1). These themes were divided into subthemes, with identification of contributing factors, where applicable.

Figure 1: Major Themes and Subthemes from the Qualitative Analysis



Characteristics of At-Risk Medications

Many of the medications that were most commonly involved in harmful dose omission incidents (as identified in Table 2) share certain characteristics.

- Medications used in acute clinical situations*
The medications listed in Table 2 include several that are used to treat acute clinical situations. For example, acetylsalicylic acid (ASA), metoprolol, and heparin are indicated for the acute management of myocardial infarction (MI),⁸⁻¹⁰ and insulin is used to treat diabetic ketoacidosis.¹¹ Dose omissions in these situations are likely to result in patient harm, because treatment of the acute underlying condition is suboptimal.
- High-alert medications with a narrow therapeutic range*
Medications such as heparin, warfarin, and insulin have a narrow therapeutic range (the difference between an effective dose and a toxic dose) and are also considered high-alert medications for which dose omission can lead to harm. For example, short-term omission of insulin can result in hyperglycemia accompanied by various symptoms (e.g., increased thirst, frequent urination) and may also increase the complexity of subsequent blood glucose management.
- Medications that may result in negative outcomes when omitted or delayed*
Evidence suggests that omissions or delays in

administering some of the medications listed in Table 2 can have negative effects on long-term outcomes. For example, delays in initiation of ASA during an acute MI are associated with an

increased risk of reinfarction,^{9,12} and omission of a prophylactic anticoagulation regimen for patients at high risk for deep vein thrombosis can lead to the occurrence of thrombosis.¹³

Table 3: System-Based Factors Contributing to Harmful Dose Omission Incidents at Different Stages of the Medication-Use Process

System-Based Contributing Factor	Stage of Medication-Use Process [§]	Description of Risk
Miscommunication during patient transfer	Order entry and transcription	New order not transcribed after transfer of patient from another location
	Dispensing and delivery	After transfer of patient to a new area, medications delivered to the previous patient care area
	Administration	Medications temporarily stopped before a procedure, but not restarted after the procedure
Misinterpretation of complex or unclear orders	Order entry and transcription	Misinterpretation of a dose change for an order listing multiple dosing times (i.e., unclear if dose change is applicable for all administration times or just one); lack of clarity about duration of therapy when a medication originally ordered for a defined duration is reordered (i.e., unclear whether new order is intended to have the same duration as the original order or if medication should be ongoing)
	Administration	Omission of medication when the medication order is dependent on laboratory results, because of misinterpretation of those results; misreading of a nomogram used to determine doses; lack of knowledge about when a nomogram should not be followed (e.g., if timing of blood tests is incorrect, results of test will be invalid and nomogram should not be used)
MAR miscommunication	Order entry and transcription	Order missed and/or not transcribed onto MAR; order not transcribed from one MAR to next MAR; order missed because of communication breakdown between shifts; transcription of regular standing order placed after the section for as-needed orders, leading to omission of regular medication
Incomplete or missing MAR	Administration	Misplacement of MAR, leading to omission of all of the patient's prescribed medications; incorrect ordering of MAR pages, leading to omission of all medications on the misplaced page; MAR not returned to proper place upon return to patient care area; incorrect documentation in MAR of doses administered or not administered

[§] Based on Canadian Medication Incident Reporting and Prevention System: CMIRPS core data set for individual practitioner reporting. Toronto (ON): Institute for Safe Medication Practices Canada; ©2001-2006 [cited 2013 Mar 25]. p.19-20. Available from: <http://www.ismp-canada.org/download/CMIRPS%20Core%20Data%20Set%20for%20Individual%20Practitioner%20Reporting%20April%202006%20ISMP%20Canada.pdf>

At-Risk Patient Care Processes

The qualitative analysis of incident narratives also identified 3 patient care processes that were associated with an increased risk for dose omissions. System-based potential contributing factors, where applicable, are highlighted:

- *Patient transfers*
Transfers between facilities, transfers within a facility, or temporary transfer to another patient care area (e.g., for a procedure) can contribute to dose omission errors. Communication breakdown related to patient transfer was identified as a key contributing factor in harmful dose omission incidents. These incidents occurred during various stages of the medication-use process, including transcription, dispensing, and administration.
- *Complex medication orders*
Complex orders, such as orders with conditions and orders with variable dosages dependent on monitoring parameters, as well as orders with unclear instructions, were associated with dose omission errors. Such orders are often misinterpreted, and the medication is administered in a way that was not intended, leading to omission of the intended dose. Furthermore, some medications are inadvertently discontinued and others are delayed or omitted because of the need for clarification.
- *Medication administration records*
Medication administration records (MARs) represent a key component to support the process of medication administration and related communications. Analysis of incident narratives identified 2 factors that potentially contributed to harmful dose omission incidents: use of an incomplete MAR (e.g., missing orders or pages) and miscommunication within the MAR (e.g., incorrect documentation of administration).

The aggregate analysis described here identified several system-based factors that contributed to dose omissions at various stages of the medication-use process (Table 3).

Conclusion

Dose omission is an important type of error because of its frequent occurrence and the associated potential for patient harm. This aggregate analysis identified the characteristics shared by medications commonly associated with harmful dose omission incidents, as reported by acute care facilities, as well as patient care processes that are more frequently involved with these types of errors.

As is typical of all voluntary reporting systems, it is not possible to conclude that the medications in Table 2 are the only ones with a high risk for dose omission errors associated with harm. However, this analysis identified medication characteristics that could be used to find other at-risk medications. For example, antibiotics, which are used in acute clinical situations, which often have a narrow therapeutic window, and which have been known to worsen patient outcomes when administration is delayed, did not appear on this list, but should be considered at-risk medications.¹

It is hoped that these preliminary findings will help organizations to focus attention on at-risk medications that are used in at-risk patient care processes during local quality improvement initiatives, with the goal of minimizing the number of dose omission errors and preventing those that could be harmful. Dose omissions can adversely affect patients along the continuum of care. As such, practitioners in all healthcare sectors are encouraged to review these findings and to take steps to effect improvements.

Disclaimer

Although the analyses described in this bulletin were based on data provided by the Canadian Institute for Health Information, the opinions expressed are those of ISMP Canada only.

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Health Canada Draft Revised Guidance Document for Industry: Review of Drug Names for Look-alike Sound-alike (LASA) Attributes

Health Canada is working to address issues regarding potentially confusable look-alike/sound-alike (LASA) medication names. As part of its effort to provide more detailed direction to product sponsors on the name-assessment process and the information required to be submitted, Health Canada recently released a revised guidance document on the review of proposed new drug names. The draft guidance document outlines the steps that sponsors (e.g., manufacturers) are to follow to determine the potential of a proposed drug name being confused with the name of another product already authorized for use in Canada. The aim is to reduce the potential for medication errors.

A copy of the draft guidance document is available from:

http://www.hc-sc.gc.ca/dhp-mps/consultation/medeff/_2013/lasa-pspcs/index-eng.php.

Feedback and comments from various stakeholders are an important part of the consultation process for the draft guidance document. Health Canada is seeking such input by April 19, 2013.

ISMP Canada encourages all stakeholders, including practitioners involved in medication-use processes, to review the draft document and send their comments to Health Canada: http://www.hc-sc.gc.ca/dhp-mps/consultation/medeff/_2013/lasa-pspcs/index-eng.php.

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ALERT: Using Clear Care Contact Lens Solution Without the Special Lens Case Supplied Can Cause Painful Eye Injuries

ISMP Canada's consumer reporting and learning program, SafeMedicationUse.ca (www.SafeMedicationUse.ca), has published 2 alerts warning consumers about the potential for harm with improper use of Clear Care contact lens cleaning solution.^{1,2} Since publication of the most recent alert, the program has received additional reports from consumers who experienced pain and burning in the eyes after confusing Clear Care with a regular contact lens solution. ISMP (US) also continues to receive reports of similar incidents, despite an added warning on the principal panel of the label of the US product.³

Unlike most other contact lens cleaning solutions, Clear Care contains 3% hydrogen peroxide, which can cause pain and burning if used directly in the eyes. For this reason, Clear Care must be used as directed, with the special lens case provided in the package. This ensures that the hydrogen peroxide is neutralized to a solution that is safe for the eyes. Unfortunately, consumers have reported experiencing pain and burning in the eyes after improperly selecting and using Clear Care, believing it to be a typical multipurpose contact lens cleaning and soaking solution. Some consumers soaked their contact lenses in Clear Care solution using a flat lens case. Another consumer reported using Clear Care to rinse lenses directly before placing them in the eyes.

ISMP Canada has contacted the manufacturer and Health Canada regarding the voluntary reports it has received. The manufacturer has indicated that labelling changes are planned for the Clear Care product distributed in Canada. ISMP Canada is urging healthcare practitioners—particularly eye care practitioners and community pharmacists—to share this information broadly. The SafeMedicationUse.ca Alert *Reminder: Take Care with Clear Care!*² can be shared to help educate consumers and patients. ISMP Canada encourages vendors of hydrogen peroxide-based contact lens cleaning solutions such as Clear Care to consider ways of separating them from multipurpose contact lens solutions. In pharmacies, this could include placing them behind the pharmacy counter to provide an opportunity for dialogue with the pharmacist about proper use prior to purchase.

References

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2. Reminder: take care with Clear Care! SafeMedicationUse Alert 2012 Oct 31 [cited 2013 Feb 22];3(5):1. Available from: http://www.safemedicationuse.ca/alerts/alerts_reminder_clear_care.html
3. Safety Brief: Should Clear Care be kept behind the pharmacy counter? ISMP Med Saf Alert 2013;18(3):1-2.



Figure 1: From left to right:
• Clear Care special lens case
• Clear Care outer box
• Clear Care product container

Dr. John Senders Retires from ISMP Canada Board of Directors

John W. Senders PhD has recently retired from the Board of Directors of ISMP Canada. It was Dr. Senders' ongoing research and promotion of failure mode and effects analysis (FMEA) and its applicability in various environments that led to its adoption as an important method for proactive risk assessment in healthcare. Dr. Senders has published numerous papers and taught extensively on the subjects of human factors engineering and psychology. In 1980, he organized a continuing series of conferences known as the Clambake Conferences on the Nature and Source of Human Error. As Principal Scientific Consultant for ISMP (US) and a founding member of ISMP Canada and its Board of Directors, he has helped to set the path we are following for the analysis of medication errors and associated prevention strategies. For more than 30 years, he has served as a scientific advisor and as an expert in investigations stemming from errors and accidents in hospitals and other environments. Dr. Senders is currently Professor Emeritus of Industrial Engineering at the University of Toronto.



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.



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.



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.

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