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Medication Incidents: Guidelines on Reporting and Prevention

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Medication Incidents: Guidelines on Reporting and Prevention

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Introduction

This is the 2012 version of Medication Incidents: Guidelines on Reporting and Prevention co-developed by the Canadian Society of Hospital Pharmacists (CSHP) and the Institute for Safe Medication Practices Canada (ISMP Canada). These consensus-based guidelines, approved by the CSHP Council and ISMP Canada in 2012, replace the 1999 version of Medication Incidents: Guidelines on Reporting and Prevention.

ISMP Canada and CSHP acknowledge the contributions of a group of CSHP members in the development of these guidelines.

Regardless of the setting, activities involving the use of medications do not always go according to plan. Although not all medication incidents result in harm, some can lead to serious harm or even death.

Worldwide, leaders of healthcare organizations are called upon, through their fiduciary responsibility, to create safe, reliable, high-performing medication-use systems, with the goal of preventing harm. Through their knowledge and expertise, pharmacy personnel are well positioned to contribute to the development of such systems. They have a central role as advocates for the implementation of patient safety measures that recognize individuals' capacity for error and address system limitations.

An effective incident reporting system is a key element in the establishment of a safe medication-use system; but it is not sufficient on its own to improve safety: an effective response to what is reported is also required.[1]

1 Scope

These guidelines provide practical, best-practice information for healthcare organizations that are establishing programs to report and help prevent medication incidents. As such, the guidelines are intended to support enhancements in the quality of patient care through improvements in medication-use systems in a variety of settings, such as hospitals, long-term care facilities, ambulatory care programs, and home care programs. These guidelines will augment but not replace each healthcare organization's specific policies and procedures regarding medication incident reporting and prevention.

The guidelines address methods of reporting and analyzing medication incidents, the role of the patient and family, the sharing of learning about medication incidents, and general processes for developing strategies to prevent medication incidents. The guidelines also provide background information on broad topics related to leadership and the nurturing of a culture of medication safety within a healthcare organization, including processes to disclose information about medication incidents.

The guidelines do not address the legal requirements related to risk management programs or the disclosure of information pertaining to medication incidents. It is assumed that any such activities undertaken by a healthcare organization will comply with the legislation and practice framework relevant to the organization's particular area of practice and geographic location. It is recommended that a healthcare organization's legal counsel review the medication incident reporting and prevention program to ensure compatibility with current legal opinion regarding such programs. Furthermore, the guidelines do not provide specific system or practice recommendations to prevent incidents; rather, they address general processes to identify preventive strategies. Knowledge in the area of medication incident prevention is constantly growing. Additional resources that will aid healthcare organizations in the development of strategies to advance medication safety are provided in the Additional Resources at the end of the guidelines.

2 Glossary

The following definitions apply to terms used in these guidelines. They may have different meanings in other contexts.

Critical incident	"An incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence."[2]
Culture of safety	At the organizational level, "the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management. Organisations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures."[3]
Error	"Failure to complete a planned action as it was intended or when an incorrect plan is used in an attempt to achieve a given aim."[2]
Failure mode and effects analysis (FMEA)	"A systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change."[4]
Healthcare organization	An organization that provides healthcare services such as, but not limited to, acute care, long-term care, ambulatory care, community pharmacies, and home care.
High-alert medications	"Drugs that bear a heightened risk of causing significant patient harm when they are used in error."[5]
Medication incident	"[Any] preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use."[6]
Medication safety	"Freedom from preventable harm with medication use."[5]
Medication-use process	A continuous, complex closed-loop process that consists of the following interconnected stages: procurement, prescribing, order transcription, order processing, preparation, dispensing, administration, and monitoring.[7]
Near miss	"An event that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention the event did not reach the patient."[5]
Shall	Denotes an expectation, or a practice that is widely accepted as being required.
Should	A recommendation, something that is advised but not mandatory.
Systems-based	Having a focus on systems, processes, or products, not individuals.

3 Administration and Governance

Establishing an effective program for monitoring and reporting medication incidents is a responsibility of the healthcare organization's management.

The development, implementation, and ongoing review of a program for reporting medication incidents should be delegated to a multidisciplinary committee. Depending on the size and management structure of the healthcare organization, the committee should be chaired by a quality improvement, risk management, or patient safety representative, or by a representative of any discipline involved in the prevention of medication incidents.

The committee members should represent a diverse group of care providers, such as healthcare staff from nursing, pharmacy, and medicine, as well as patient safety representatives, other healthcare providers, and patient or family advocates.

3.1 Roles and Responsibilities

The multidisciplinary committee should be responsible for the following activities:

a) establishing timely, comprehensive, and consistent processes to review medication incidents, with the goal of assisting the patient safety coordinator, risk manager, and/or hospital administrators in tracking incidents and determining any trends;
b) making recommendations on changes to systems, processes, policies, and procedures that will improve the safety and consistency of patient care; and
c) establishing accountabilities for managing, reporting, and investigating medication incidents, and for disseminating key findings.

All healthcare staff are responsible for reporting incidents and adhering to the practice and principles of quality care, risk management, and patient safety.

Patients and family members can also play a role in processes designed to ensure the safety of care. They should be made aware of and given opportunities to participate in such processes, including incident reporting systems.

4 Culture of Patient Safety

The healthcare organization shall foster a culture of safety that is just and that embraces learning to help improve the safety of patient care.

An organization with such a culture in place should exhibit the following characteristics:

a) Leaders give safety a high priority.[8-10]
b) Accountability is promoted[11] and workers accept responsibility for safety.[9] An accountability model distinguishes between incidents occurring as a result of human error (unintentional behaviour) and incidents occurring as a result of intentional behaviour[10] (e.g., noncompliance with standard practice and procedures, or intention to harm), with recognition that punishing an individual staff member for an error does not prevent others from making the same error.
c) Teamwork[11] and collaboration are fostered[8-10] and patients are recognized "as partners in their [own] care".[8]
d) Patients are encouraged to become involved in processes to improve patient safety[10,11] (e.g., by providing information about their concerns[8]).
e) Openness is supported[8,11] and the reporting of information vital to improving patient safety, including hazardous situations, close calls, and adverse events, is encouraged and rewarded.[8-10] Staff members know in advance the probable organizational response should errors occur, and report errors without fearing retribution.[7]
f) Disclosure of incidents to patients is supported and expected.[12]
g) Learning from the organizational incident reporting system is embraced and the actions required to translate the knowledge gained into

improvements in patient safety are supported.[8,10]

5 Patient Involvement

Patients and family members may be aware of incidents and underlying contributing factors that are unknown to healthcare providers and/or that have not been reported by healthcare providers. Therefore, including patients and their family members in the process of reporting and analyzing medication incidents enhances the identification of incidents and their underlying causes and the development of potential safety solutions.

5.1 Developing a Policy on Disclosure of Medication Incidents

A policy defining the healthcare organization's position on disclosure of medication incidents to patients and families shall be in place. At a minimum, medication incidents that result in harm to the patient, or for which a risk of future harm exists, shall be disclosed.[12]

Note: refer to "Canadian Disclosure Guidelines: Being Open with Patients and Families"[12] for more information on how to disclose.

5.2 Reporting by Patient or Patient's Family Member

Medication incident reporting systems should incorporate a patient-friendly mechanism to support reporting of an incident by a patient who has experienced an incident during care or by a member of the patient's family. This mechanism should include a component to support reporting of near misses or unsafe conditions observed during the course of care.

Patients and family members should routinely be given information about how to report incidents, including near misses and hazardous conditions. Patients should also be given ready access to support from individuals who can assist with the reporting process (e.g., patient representatives or advocates).

5.3 Incorporating Input from Patients during Investigations of Incidents

Mechanisms should be in place to incorporate input from patients and their families during the investigation of incidents, including in-depth analysis of critical, serious, or potentially serious incidents, as appropriate.

6 Medication Incident Reporting System

The size and complexity of the healthcare organization will determine how medication incidents are reported, investigated, and followed up.

All medication incident reporting systems should have the capability to capture comprehensive information about medication incidents, including near misses, so that this information may be used as a source of learning and a basis for preventive action in the future.[1,13]

An incident report should be initiated and completed as soon as possible after the incident is discovered.

A user-friendly reporting form shall be readily available in all patient care areas. A mechanism for anonymous reporting of incidents should be available. Once an incident has been documented, an investigation should be initiated by a manager or supervisor for the clinical area, service, or program involved in the incident.

A mechanism should be in place to acknowledge the receipt of reports and provide feedback to reporters, as appropriate.

Numerous incident reporting systems are in use, and such systems may be electronic or paper-based. An electronic version may improve the healthcare organization's ability to analyze the data from reported incidents, which will facilitate tracking and

identification of trends. A review of trends can, in turn, facilitate the development of recommendations on how to adapt and update processes or practices that may affect patient safety.[13]

6.1 Information to be Collected about Incidents

Incident reporting systems should have the capacity to document relevant information for each medication incident, including near misses. Recognized data standards for medication incident reporting (such as those developed by the Canadian Institute for Health Information or the Institute for Safe Medication Practices Canada) should be considered in determining the information to be collected.

The information included in the medication incident report shall be appropriate to support follow-up of individual incidents and analysis of incident-related trends. Details of incidents, including near misses and hazardous conditions, should be documented in a manner that facilitates review and analysis of the incidents and the generation of system-based recommendations.

The following list suggests elements for consideration:[14]

a) patient characteristics (if relevant);
b) reporter information (e.g., name, contact information);
c) incident details (e.g., date and time of incident, care area, description of incident, type of incident, stages of medication-use system involved);
d) medication information (e.g., name of medication, manufacturer, strength, dosage form);
e) outcome of incident (degree of harm suffered);
f) investigation and findings (e.g., contributing factors); and
g) follow-up required (e.g., recommendations, system improvements implemented).

Additional details or information may be collected at the discretion of the healthcare facility or institution.

6.2 Notification about Medication Incidents

a) When the occurrence of a medication incident has been confirmed, the appropriate personnel or departments shall be notified as soon as possible to ensure that the following actions are taken:
b) the patient receives any treatment necessary to mitigate harm;
c) hazardous conditions requiring immediate action are addressed; and
d) appropriate follow-up and analysis are conducted.

The persons and departments to be notified may include the following, depending on the organization's policy:

a) the manager or designate in charge of the care area (e.g., supervisor, charge nurse, team lead);
b) the attending physician;
c) the pharmacy department; the patient and/or family; and
d) other disciplines as appropriate.

6.3 Review and Investigation of Medication Incidents

All reports of suspected and confirmed medication incidents, including near misses and hazardous conditions, shall be reviewed and investigated as appropriate. The severity of an incident shall determine the extent of the detail required in the review, the timeline for review, and the need to involve higher levels of management. Additional information obtained from the review shall be documented.

Note: A reasonable amount of discretion may be applied in determining whether a medication

incident has occurred (e.g., a patient's legitimate absence from the nursing unit contributing to a minor delay in administering a drug would usually not be considered a medication incident).

6.4 Reporting to External Organizations

The volume of incident reports within a single healthcare organization may not allow for identification of broader trends. Confidential submission of de-identified reports about medication incidents to external reporting systems can facilitate early identification of hazards, allow broader sharing of learning throughout the [regional/national] healthcare system, and may help prevent harmful incidents in the future. Healthcare organizations should consider submitting medication incident data to provincial and national organizations with links to the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

7 Analysis of Incident Reports

Appropriate analysis of incident reports is necessary to obtain useful information for preventing similar events in the future. All medication incident reports should be analyzed promptly, using a systems-based approach, to identify contributing factors and potential solutions. An appropriate classification system (taxonomy) will support the aggregate analysis of incident data.[13,15,16]

Practitioners should receive regular and timely feedback from the healthcare organization about the results of incident analyses and recommended system enhancements. Recommendations should focus on changes to systems, processes, or products, and should be broadly disseminated to the appropriate individuals, teams, and departments.

7.1 Analysis of Reports of Individual Medication Incidents

Each medication incident report should be screened by a designated individual, who will conduct a preliminary follow-up, confirm that the incident report contains all required information, ensure that the incident has been appropriately categorized on the basis of a predetermined classification system, initiate additional investigation if necessary, and ensure that any immediate hazards are addressed.

Predetermined criteria shall be applied to categorize each incident according to the level of harm or potential harm.

A multidisciplinary team with expertise and training in the analysis of incidents (e.g., pharmacists, nurses, physicians, patient safety officers) shall be responsible for ensuring that reports of medication incidents are analyzed. A comprehensive and systematic investigation and analysis, designed to study the circumstances surrounding the incident and to identify its underlying causes, shall be conducted for any critical incident, serious incident, or potentially serious incident. Near misses and hazardous situations with the potential to cause patient harm should be given the same high priority for analysis as incidents that actually cause patient harm.[16,17]

A detailed report of the analysis of any critical incident, serious incident, or potentially serious incident should be prepared as soon as possible and should contain the following information:

a) an overview of the incident;
b) a description of contributing factors and system issues identified;
c) specific recommendations to address the issues identified; and
d) specific action plans for each recommendation, with responsibilities, measures of success, and timelines defined.

The healthcare organization should establish clear procedures for final disposition of completed incident report forms (manual or electronic) and summary reports.

Learning and recommendations from analyses should be disseminated to appropriate internal and

external stakeholders, including patients and families where applicable.

Note: Refer to the Canadian Framework for Managing Patient Safety Incidents[18] for additional information about the analysis of incidents.

7.2 Analysis of Aggregate Data from Medication Incident Reports

When information about medication incidents is aggregated, trends may become apparent, and common underlying causes may be identified.[13]

The organization should critically analyze aggregate information collected through its medication incident reporting system.

Although rates of reported medication incidents should not be used as a measure of quality or safety,[19] the monitoring of trends and patterns may identify new or evolving hazards and provide insight into potential system failures. With an appropriate classification system, analysis of aggregate information can provide insight into the occurrence of incidents involving specific drugs, stages of the medication-use process, underlying factors, and correlations.

The focus should be on learning from reported incidents and preventing future incidents through a systems-based review. Statistical analysis of data should be used to identify trends and to classify events and contributing factors. The following are among the potential benefits of such analyses:[13,15,16]

a) provision of early warnings about hazards;
b) identification of system-related causes of medication incidents, including near misses;
c) identification of priorities for development of proactive prevention strategies;
d) creation of opportunities to share learning and to implement proactive prevention strategies in other areas, sites, and facilities; and
e) identification of directions for change to practices, policies, and standards.

8 Effecting Change

As the World Alliance for Patient Safety has noted, "It is important to note that reporting or for that matter any system for detecting problems - does not in itself improve safety. It is the response adopted that leads to change."[1] Therefore, the organization should use analyses of medication incidents that have been reported as learning opportunities and should implement changes accordingly to improve patient safety.

8.1 Learning from Medication Incidents

In addition to learning from critical review and analysis of incidents that have occurred within the organization, healthcare organizations should review reports and recommendations generated by the analysis of incidents that have occurred in other organizations or jurisdictions.

8.2 Integrating Knowledge into Practice

Changes in practices and processes should be implemented in a timely manner to reduce the likelihood of the medication incident recurring. The conclusions drawn from the analysis of medication incidents reported by the healthcare organization, and by other organizations, should help to inform these changes in practice.

Action plans should be developed for implementing changes in practice to address a specific problem. Building on the knowledge garnered from the analysis of medication incident reports, the organization should consider the following activities:[20]

a) adapting knowledge to suit the local context by determining how the information applies to the practice setting;
b) assessing barriers to knowledge use;
c) selecting, tailoring, and implementing interventions to address barriers to knowledge use, on the basis of feedback from end-users

and specific to the context or working environment;

d) establishing "change leaders" or "champions" in individual care areas to facilitate dissemination of education and to encourage buy-in from front-line staff;

e) monitoring knowledge use by providing a format for positive and constructive feedback, conducting random audits, reviewing incident reporting, and determining if the initiative has resulted in a sustained change in practice or behaviour;

f) developing mechanisms to sustain knowledge use, such as conducting routine audits, organizing education days, using communication tools (e.g., publishing newsletters, establishing discussion boards, soliciting feedback and questions, disseminating written or electronic messages), and offering refresher workshops for practices and skills; and

g) evaluating outcomes, gauging if the knowledge or change in practice has had a positive effect on the ultimate goal of improving patient safety, keeping track of trends in medication incident reporting, and celebrating successes.

8.3 Disseminating What Is Learned

Knowledge acquired during the investigation and analysis should be communicated effectively and in a timely manner to help prevent similar medication incidents from occurring in the future.

For effective communication, messages should be tailored with consideration of the following requirements:

a) The content of the message shall be based on the perspectives and needs of the audience.

b) The message shall be delivered clearly, concisely, consistently, continuously, and in a compelling manner.21

c) The message should respect the audience's level of health literacy.

To encourage the uptake of information, it may be helpful to enlist people who are respected by staff members (e.g., peers, members of similar professions) to provide the information in a suitable format (such as slide presentations, bulletins, newsletters, or hands-on or interactive workshops).

8.3.1 Communicating within the Healthcare Organization

Dissemination to healthcare professionals of information collected by the medication incident reporting program should be succinct and clear.

A quality improvement committee, or other patient safety group, should develop various strategies to deliver information about recommendations arising from analysis of medication incidents that have occurred both within and outside the organization. The recommendations may be published on posters and wall charts, in newsletters or memos, or by alerts on hospital intranet sites. More direct approaches may include grand rounds, interdisciplinary rounds, staff meetings, interactive workshops, and other forums.[19]

8.3.2 Communicating with other Healthcare Organizations

To assist other organizations in improving the safety of their patient care, the healthcare organization should share its findings, including recommendations for change, with other healthcare organizations by reporting to an external system with links to CMIRPS. (See also section 8.1.)

9 Risk Reduction Strategies

Medication incidents can be prevented through collaborative systems-related controls, which may include processes established and analyzed by multidisciplinary healthcare teams and administrators, and which may involve patients and their families. To help prioritize the development of risk reduction strategies, the organization should

focus on preventing incidents that could result in harm.

9.1 Systems-Related Controls

System controls should be established for all aspects of the medication-use process, with a view to preventing errors. Suggested approaches include the following:

a) implementing a quality management system;
b) establishing processes to review the safety of the medication-use system on an ongoing basis;
c) conducting a systems-focused review to identify opportunities for improvements;
d) developing appropriate system safeguards, for example, procedures for handling high-alert medications; and
e) creating effective interdisciplinary communication.

9.2 Prospective Analysis

A healthcare organization should carry out prospective analyses (e.g., failure mode and effects analysis, medication safety self-assessments) of processes related to medications and should use the information gained from such analyses to make system improvements. Such analyses should focus on areas of the medication-use system that could be associated with substantial risk to patients.[22]

Prospective analysis is useful whenever a new medication-use system is implemented or a new component is introduced into the medication-use system.[4]

10 Quality improvement program

An ongoing quality improvement program shall be in place to assess and improve the organization's medication incident monitoring and reporting program.

The multidisciplinary committee (see section 3) should determine which measures (or end points) it should monitor to effectively assess the structure, process, and outcomes of the program. Methods should be established to regularly collect and analyze the data for these measures (or end points). A plan should be developed to effect change, with the goal of improving the medication incident monitoring and reporting program.

At least once a year, a report highlighting the accomplishments of the program over the past year should be compiled. The report should describe plans to continually improve the performance of the medication incident monitoring and reporting program, according to the analysis of outcome measures. This report should be submitted to the hospital administration, along with a recommendation about further communication of the report (e.g., to staff).

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Additional Resources

Canadian Medication Incident Reporting and Prevention System. (http://www.cmirps-scdpim.ca/) The website provides information on the Canadian Medication Incident Reporting and Prevention System, a description of the roles of the participating organizations, and links to the websites of participating organizations, including links for healthcare facilities, healthcare professionals, patients and consumers to report medication incidents.

Canadian Patient Safety Institute. (http://www.patientsafetyinstitute.ca). The website provides educational resources, research opportunities, and other tools and resources.

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Institute for Safe Medication Practices Canada. (http://www.ismp-canada.org). The website offers publications, tools, and resources to support medication-use practices, as well as medication incident reporting tools for healthcare professionals and consumers.

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