CMIRPS Individual Practitioner Reporting

Canadian Medication Incident Reporting and Prevention System (CMIRPS)

A Collaborative Initiative of the Institute for Safe Medication Practices Canada, the Canadian Institute for Health Information and Health Canada

CMIRPS Core Data Set for Individual Practitioner Reporting

April 2006

ISMP CANADA

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ACKNOWLEDGEMENTS

The Institute for Safe Medication Practices Canada expresses sincere appreciation to the many health care professionals, hospital administrators, risk managers and other individuals working in the Canadian health care community for their initiative, efforts and demonstrated support for a culture of safety, by reporting medication incidents and related information to ISMP Canada and providing feedback for ongoing enhancements to a data standard for medication incidents.

The Canadian Medication Incident Reporting and Prevention System was initiated through the efforts of the members of the Canadian Coalition for Medication Incident Reporting and Prevention:

Canada's Research-Based Pharmaceutical Companies
Canadian Association of Chain Drug Stores
Canadian Healthcare Association
Canadian Institute for Health Information
Canadian Medical Association
Canadian Nurses Association
Canadian Pharmacists Association
Canadian Society of Hospital Pharmacists
College of Family Physicians of Canada
Consumers' Association of Canada
Federal/Provincial/Territorial Pharmaceutical Issues Committee (participating observer)
Health Canada, Marketed Health Products Directorate, Health Products and Foods Branch (secretariat)
Institute for Safe Medication Practices Canada
Royal College of Physicians and Surgeons of Canada

Development of the CMIRPS is a collaborative initiative, with an Operations Committee comprised of representatives from Health Canada, the Canadian Institute for Health Information, the Canadian Patient Safety Institute and ISMP Canada.

A CMIRPS Advisory Committee guides the development and implementation of the CMIRPS.

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A INTRODUCTION

1 ABOUT ISMP CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national non-profit agency committed to the advancement of medication safety in all health care settings

Vision: Collaborating nationally and internationally to advance safe medication use.

Purpose: ISMP Canada works collaboratively with the health care community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices.

Goals:

- To collect, review and analyze medication incident and near-miss reports according to a hazard identification model, identify contributing factors and causes and make recommendations for the prevention of harmful medication incidents.
- To promote safe medication use and system strategies for reduction of adverse drug events.
- To publish and disseminate information on safe medication practices for knowledge translation.
- To develop and provide tools and educational programs for building capacity to enhance patient safety.
- To provide expertise and consultation on medication systems in health service organizations and other patient care settings.
- To develop quality improvement programs for use by the health care community.
- To work with regulatory agencies, policy makers and manufacturers to promote enhancements to pharmaceutical product packaging and labelling.
- To facilitate patient safety research.
- To establish and maintain strong partnerships with the Institute for Safe Medication Practices (ISMP) in the US, and other key national and provincial organizations with an interest in patient safety.
- To achieve the outcomes envisioned by the Canadian Medication Incident Prevention and Reporting System (CMIRPS), a collaborative initiative of ISMP Canada, the Canadian Institute for Health Information (CIHI) and Health Canada (known as the collaborating parties for CMIRPS), in conjunction with the Canadian Patient Safety Institute (CPSI).

2 PRIVACY AND CONFIDENTIALITY

ISMP Canada has a data privacy and security program in place, designed in anticipation of implementation of Ontario's *Personal Health Information Protection Act, 2004* (PHIPA.) The program includes a privacy policy, a completed privacy impact assessment (2005), a privacy brochure and privacy "'Frequently Asked Questions" available on the ISMP Canada web-site.

Individual Practitioner Reporting will involve reporting of two types of information:

1) Non-identifiable information about a medication incident, such as a description of the incident, patient outcome, type of health care facility where the incident occurred, the names and dosages of the medications involved, description of how the incident was discovered, contributing factors and recommendations to prevent similar incidents in the future.

2) Additional information about a medication incident, such as information about the patient's medical condition, the types of health care practitioners involved in the incident, and reporters' contact information that they may provide voluntarily to ISMP Canada.

As is its past practice, ISMP Canada will request that practitioners remove all identifying information about patients *prior* to sharing information about medication incidents. Individual health care practitioners may choose to provide their contact information for the purpose of allowing ISMP Canada to carry out follow up investigations or to clarify information relating to a specific medication incident reported by the individual health care practitioner or institution, but ISMP Canada *never* needs to know the names or other identifiable information about individual patients involved in medication incidents.

In keeping with its privacy practices, if a practitioner inadvertently reports identifying patient information, ISMP Canada has mechanisms in place for prompt deletion/destruction of identifiable information. ISMP Canada does not use, store, or disclose identifiable patient information. Where practitioners voluntarily submit their contact information, this information is kept only as long as is necessary for the purpose of conducting follow up investigations or to clarify information relating to a specific medication incident.

3 BACKGROUND

Studies and reports within various jurisdictions have raised concerns regarding the number of adverse events experienced by patients within the health care system, and complications from drug therapy have been recognized to represent the most common non-operative category of adverse event. In the United States, the landmark Harvard Medical Practice study[1] and a similar study conducted in Colorado and Utah[2] found adverse drug events to represent 19.4% and 19.3% of all adverse events, respectively. Similarly, in the Canadian Adverse Event Study, drug and fluid related events were the second most common type of procedure or events to which adverse events were related (after surgical), at 23.6%. Clearly, efforts to improve medication safety will play a significant role in improving overall patient safety in Canadian health care.

In the fall of 2000, an invitational workshop was co-hosted by the Canadian Society of Hospital Pharmacists (CSHP) and Health Canada's Bureau of Licensed Product Assessment (BLPA) to address a number of key questions related to medication incident reporting and prevention. One outcome of the workshop was a recommendation to establish a coalition of stakeholders, the Canadian Coalition on Medication Incident Reporting and Prevention, to oversee the creation of a business plan for the development and implementation of a medication incident[3] reporting and prevention system. The business plan, published in March 2002[4], outlined a strategy for the development of the CMIRPS, the Canadian Medication Incident Reporting and Prevention System.

[1] Leape, LL Brennan, TA, Laird, N et al. The Nature of Adverse events in Hospitalized Patients, results of the Harvard Medical Practice Study II, *New Engl J Med* 1991, 324; 377-384.
[2] Thomas EJ Studdert DM et al. Incidence and Types of Adverse events and Negligent Care in Utah and Colorado, *Medical Care* 2000, 38(3) 261-71.
[3] The Canadian Patient Safety Dictionary recommends the term **incident** be defined as including events, processes, practices, or outcomes that are noteworthy by virtue of the hazards they create for, or the harms they cause, patients. Incident reporting systems are meant to capture any and all incidents that are worthy of reporting.
[4] Canadian Coalition on Medication Incident Reporting and Prevention, Sierra Systems. *A Medication Incident Reporting and Prevention System for Canada: Business Plan*. Ottawa, 2002.
http://www.hc-sc.gc.ca/dhp-mps/medeff/research-recherche/cmirps-scdpim_rep-rapp_e.html (accessed April 10,2006)

4 CMIRPS DESCRIPTION

The overall CMIRPS program is envisioned to be a medication incident reporting and prevention system for Canada. Ultimately, it will assist health professionals, health organizations, community-based pharmacies, governments and others to recognize potential problems before they actually occur, and to implement appropriate preventative strategies. The desired outcome of CMIRPS is a program that manages the risks inherent in medication use and moves toward a goal of risk prevention.

The purposes of the CMIRPS are to:

- coordinate the capture, analysis and dissemination of information on medication incidents;
- enhance the safety of the medication use system for Canadians; and
- support the effective use of resources through the reduction of potential or actual harm caused by preventable medication incidents.

The goals of the CMIRPS are to:

- collect and analyze data on medication incidents;
- facilitate the implementation of reporting of medication incidents;
- develop and disseminate timely and targeted information designed to reduce the risk of medication incidents and.
- develop and disseminate information on best practices in safe medication use systems.

According to its key principles and attributes, the CMIRPS should:

- be national in scope;
- be compatible with an overall patient safety system and other relevant patient safety initiatives;
- encourage extensive voluntary participation;
- support a non-punitive approach with respect to those who report;
- safeguard data integrity, privacy and confidentiality;
- encourage organizational and individual practitioner reporting;
- encourage the reporting of all medication incidents;
- allow for selected follow up to facilitate root cause analysis;
- allow for selected follow up to facilitate quality assurance of data and quality improvement;
- allow for organizations to access their own data for enhancing their patient safety efforts and
- be dynamic, to allow for the continued relevancy and utility of the system.

The CMIRPS has been developed and implemented through the collaborative efforts of three national organizations: Health Canada, the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Institute for Health Information (CIHI). Each organization leads in areas in which it has expertise and experience.

Health Canada:

- Provides funding, coordination and support for the CMIRPS program;
- Has defined its role in managing the post-market response for identified patient safety issues arising from medication incidents related to product naming, packaging and/or labelling; and
- Investigates avenues by which it can work together with the pharmaceutical industry, health care professionals and related organizations in responding to identified health product-related post-market safety issues arising from medication incidents, with the goal of preventing medication incidents, and improving patient safety.

ISMP Canada:

- Leads in collection and processing of data reported by individual practitioners;
- Leads in the development and maintenance of the core data set and transmission protocols for individual practitioner reporting;
- Performs root cause analysis for selected medication incidents submitted to CMIRPS through health service organization reporting, as well as through individual practitioner reporting;
- Develops and disseminates timely information bulletins (e.g. alert bulletins);
- Conducts analytical studies (e.g. aggregate root cause analysis based on data submitted to CMIRPS through standardized health service organization data, as well as data submitted through the individual practitioner reporting component); and
- Provides support for the development and implementation of preventative measures.

CIHI:

- Leads in collection and processing standardized data reported by health service organizations (HSOs), including managing issues related to data quality;
- Leads in the development and maintenance of the minimum data set and transmission protocols for HSO reporting;
- Developed a system capable of query and analysis for HSO data; and
- Conducts analytical studies and responds to ad hoc requests for HSO data.

The CMIRPS has both an individual practitioner reporting program (ISMP Canada's responsibility) and a health services organization (HSO) component (CIHI's responsibility) Information obtained through the CMIRPS reporting system components will be useful for identifying specific hazards related to medication use, as well as for tracking trends in medication incidents reported over time.

By sharing and analyzing information on incidents, contributing factors can be identified and information disseminated to avoid having the same errors occur repeatedly in different settings. Recent draft guidelines published by the World Health Organization note that "We know that health-care errors are provoked by weak systems and often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analyzed." [5] Critical incidents and potentially harmful incidents reported through both the individual practitioner reporting system component and the health service organization reporting system component will receive priority attention and potentially assistance with root cause analysis from ISMP Canada.

The three-party collaborative model for CMIRPS is unique in the world and will set a standard that will be of international interest. The two reporting system components within the CMIRPS program, (HSO reporting led by CIHI and individual practitioner reporting led by ISMP Canada) are designed to be complimentary for the benefit of Canadians.

[5] World Alliance for Patient Safety, WHO Draft Guidelines for Adverse Event Reporting and Learning Systems- from Information to Action. Geneva (Switzerland): World Health Organization; 2005. http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf (accessed April 10, 2006)

5 SCOPE

Reporting to CMIRPS by individual practitioners is an expansion of ISMP Canada's existing voluntary practitioner reporting program, which offers confidential (or anonymous, when preferred) reporting of an incident and does not collect information about individual patients.[6] The individual practitioner reporting component of CMIRPS allows individual practitioners in any patient care setting to directly report medication incidents they have been involved with, or incidents they have observed, with the option to submit information with complete/non-traceable anonymity.

The most important feature of the existing individual practitioner reporting component is that it permits narrative reporting of an incident through direct human review of incoming reports. As noted in recent draft guidelines published by the World Health Organization: "Narrative reports provide the opportunity to capture the rich context and storyline that allow the conditions that contributed to the error to be explored and understood. Indeed, some believe that only narrative reports are capable of providing information that provides meaningful insight into the nature of the underlying systems defects that caused the incident."[5] The mechanisms for reporting in the existing program component facilitate dialogue between the individual practitioner reporting an incident and the health professional receiving the report at ISMP Canada, and provide opportunity for hazard identification, as well as immediate feedback when requested. In addition, the qualitative nature of the reporting process (e.g. through direct phone communication) ensures that various levels of detail of an incident can be reported and explored with individuals close to the event (in time and operation), which is not always possible with pre-determined quantitative reporting formats or purely electronic reporting programs.

Additional features of the individual practitioner reporting component include: (i) ease of timely reporting; (ii) opportunity for facilitated discussion of medication incidents requiring timely attention; (iii) no requirement for registration by the reporter; and (iv) system capability for uploading product photographs or other documents pertinent to medication incident analysis.

Settings: The individual practitioners' voluntary reporting system component collects reports from practitioners within a wide variety of patient care settings, including but not limited to community pharmacies, hospitals, home care programs, residential care facilities, community health centres, emergency departments, ambulatory care facilities and clinics, physicians' offices, dentists' offices, coroners' offices and public health agencies. This reporting component is available to English and French speaking practitioners.

Reporters: The individual practitioners' reporting system component will receive reports from a variety of reporters, including but not limited to physicians, nurses, pharmacists, dentists, respiratory therapists, paramedics, risk managers and others.

[6] Hyland S, Hunt M. Medication safety alerts. Development of the Canadian Medication Incident Reporting and Prevention System (CMIRPS). *Can J Hosp Pharm.*2005;58(4):232-234.

Types of Incidents: The CMIRPS will collect reports on potential and actual incidents, both critical and noncritical, related to any medication and occurring at any stage of the medication use system — prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, monitoring, documentation, or use. The reporting of near misses and hazardous situations will be integral to the identification of latent conditions that may require adjustment to prevent harmful medication incidents.

Coordination of the HSO and Individual Practitioner Reporting Components:
A critical mechanism for coordinating the two CMIRPS reporting components is the use of selected common data elements so that information outputs can be aligned. The CMIRPS data elements and definitions of terms have been developed collaboratively by ISMP Canada and CIHI and will be refined as needed by both parties so that information outputs from CMIRPS data[7] can be coordinated to provide the most "complete picture" possible and optimal learning.

Enhancements to the existing ISMP Canada voluntary practitioner program component are being phased in over time and priority is given to aligning the data standard (ensuring consistency and coordination) to the extent possible with the HSO reporting component.

The HSO reporting component includes a mechanism to provide access to the de-identified data of a critical incident[8] or potentially critical incident to ISMP Canada in a timely fashion.

The HSO reporting component includes a mechanism to inform ISMP Canada when assistance with root cause analysis of an event is requested by users.

Branding of CMIRPS is planned with the transition of oversight to the Canadian Patient Safety Institute and this will facilitate coordinated communications by the CMIRPS collaborating parties.

[7] CMIRPS Data is defined as medication incident data collected through both the HSO reporting (CIHI lead) and the individual reporting (ISMP Canada lead) components of CMIRPS.
[8] The Canadian Patient Safety Dictionary recommends **critical incident** be defined as 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.

7 PURPOSE

The purpose of this document is to inform stakeholders of the CMIPRS Core Data Set and Minimum Data Set for collecting information about medication incidents from individual practitioners in order to:

- support hazard identification within the medication use system;
- support analysis of medication incidents, including determination/ assessment of actual and potential severity;
- support development and communication of preventative strategies and recommendations for medication system enhancements;
- support communication to pharmaceutical manufacturers when opportunities for product packaging and labelling improvements are identified;
- support development of quality improvement programs for medication use systems, and
- ultimately help to reduce the chance of harm from misuse of medications, thereby enhancing patient safety.

8 DISCLAIMER

ISMP Canada utilizes this Data Standard for the individual practitioner reporting component of CMIRPS.

This document does not constitute authorization to use copyright materials.

ISMP Canada encourages stakeholder feedback for ongoing development and enhancements. Any comments or concerns about existing data elements or suggestions that others be included should be submitted to ISMP Canada for consideration.

B CMIRPS DATA ELEMENTS FOR INDIVIDUAL PRACTITIONER REPORTING

1. DESCRIPTION

Data Elements included in the CMIRPS Core Data Set of information currently collected through the Individual Practitioner Reporting Program Component are indicated below.

The data elements which are **Mandatory** represent the data elements included in the **Minimum Data Set** of information currently collected through the Individual Practitioner Reporting Program Component.

In addition to the data elements of the Core Data Set, additional incident information may be collected through a qualitative data collection and hazard identification process (i.e. narrative process).

The shaded areas indicate data elements for which a similarly defined data element is listed in the draft minimum data set for HSO reporting, and therefore indicates potential alignment of the reporting components for coordination of information outputs.

CMIRPS Data Elements for Individual Practitioner Reporting		Mandatory / Optional Indicator
INCIDENT	Date	Optional
	Time	Optional
	Incident Description/ How discovered	Mandatory
	Type of Incident	Mandatory
	Stage(s) Involved	Mandatory
	Discovered By	Mandatory
	Patient Care Setting	Mandatory
OUTCOME	Severity/Outcome	Mandatory
	Intervention(s)	Optional
MEDICATION(S)	Medication Name	Mandatory
	Strength	Optional
	Route of Administration	Optional
	Manufacturer	Optional
	Lot Number	Optional

CMIRPS Data Elements for Individual Practitioner Reporting		Mandatory / Optional Indicator
FOLLOW UP	Actions	Optional
	Comments / Recommendations	Optional
	System Improvement Strategies Implemented	Optional
PATIENT	Non-patient Specific	Optional
	Age Category	Optional
	Gender	Optional
REPORTER	Name	Optional
	Practice Care Setting	Optional
	City	Optional
	Province	Optional
	Postal Code	Optional
	Email	Optional
	Permission to Contact Reporter	Optional
POSSIBLE CONTRIBUTING FACTORS	Critical Patient Information Missing	Optional
	Critical Drug Information Missing	Optional
	Miscommunication of Drug Order	Optional
	Drug name, label, packaging problem	Optional
	Drug storage or delivery problem	Optional
	Drug delivery device problem	Optional
	Environmental, staffing or workflow problem	Optional
	Staff education problem	Optional
	Patient education problem	Optional
	Lack of quality control or independent check systems	Optional

C CMIRPS CORE DATA SET FOR INDIVIDUAL PRACTITIONER REPORTING

The CMIRPS core data set for individual practitioner reporting is designed such that patient identifiers are not collected.

The data set is also designed to provide an option for anonymous/non-traceable reporting. The reporter may provide contact information or practice setting information for clarification or follow up purposes, or may choose to be anonymous. The reporter may also phone for direct dialogue with a medication safety expert for clarification of information and/or follow up purposes, without entry of reporter information, or practice setting, in the data base.

The CMIRPS core data set for individual practitioner reporting is adapted from the Analyze-ERR® software documentation (copyright 2001) program designed and developed by ISMP Canada for analyzing medication errors, determining underlying root causes of medication errors and identifying areas for medication system improvement.

ISMP Canada has received permission from the National Co-ordinating Council for Medication Error Reporting and Prevention (NCC MERP) to use their medication error taxonomy for Individual Practitioner Reporting.

The following information is provided with each data element:

Definition:	Explains the concept that is represented by the data element
Data Type:	Specifies what type of data (e.g. alphabetic, numeric) the data element stores
Representational Form:	Specifies how the data is stored (e.g. as a date, text, or code)
Field Size:	The maximum size of the information collected for the data element
Guide for Use:	Suggestions to consider as a starting point when providing information for this data element.

1 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 health care 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. (see Glossary of Terms – Definition for Medication Incident.)

1.1 DATE OF INCIDENT

DEFINITION:	Date (or estimated date) when the event occurred.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Date [YYYYMMDD]
MAXIMUM FIELD SIZE:	15
GUIDE FOR USE:	The date can be entered manually from a drop down calendar control. If day and/or month unknown, enter 00, rather than entering a default value (e.g. 01).

1.2 TIME OF INCIDENT

DEFINITION:	Time when the event occurred.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Time [0000h]
MAXIMUM FIELD SIZE:	15
GUIDE FOR USE:	User may type in the exact time or provide a time range. If the time of the event is not available, choose “Unknown”.

1.3 INCIDENT DESCRIPTION / HOW DISCOVERED

DEFINITION:	A description of the incident that can include how the incident was discovered.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 65535
GUIDE FOR USE:	Describe circumstances relating to the incident in an objective manner, including how the incident was discovered. How the incident was discovered often provides valuable information to guide action plans for improving safety. To support a non-blame environment, *avoid including staff, physician or patient names in this free text area*.

1.4 STAGE(S) INVOLVED

DEFINITION:	The medication use system has been classified into five stages with a sixth choice of 'not applicable'. The stages can be used to illustrate the progression of a medication incident until it was detected.
DATA TYPE:	Char
REPRESENTATIONAL FORM:	Boolean
MAXIMUM FIELD SIZE:	1 for each stage
GUIDE FOR USE:	More than one stage can be selected by clicking on the appropriate radio button. See Table 1 below for Stage(s) Involved Qualifier.

TABLE 1 – STAGE(S) INVOLVED QUALIFIER

CODE NAME	DESCRIPTION
Prescribing	All actions that occur during the process of the prescriber's order for a specific drug to a specific patient, including clinical decision making for the appropriate drug, dose and route to meet the patient needs and the processes used such as the hand-written paper order record, pre-printed order forms, telephone or verbal orders or computerized physician

CODE NAME	DESCRIPTION
	order entry system. Contributing factors in this stage may include illegible handwriting.
Order entry/ transcription	Includes all steps in the transcription or documentation process from the prescriber's order to dispensary records (e.g. pharmacy information system) and/or administration records (e.g. MAR and flow sheets), (paper and/or electronic).
Dispensing / delivery	Includes all the steps in compounding, dispensing and delivery of medications to patient care settings Note: "Dispensing" is a recognized act for Pharmacists and special delegation to named nurses only)
Administration	Includes all steps in the process to administer the drug to the patient, *and* the documentation.
Monitoring	Indicates where clinical decision-making is required for patient care related to medication use.
Not Applicable	Is reserved for incidents when unable to determine one or more of the above medication system phases.

1.5 TYPE OF INCIDENT

DEFINITION:	The selections are pre-defined and are adapted from the NCC MERP taxonomy of medication errors, with permission.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Code
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	This is entered from a drop down list. See Table 2 below for Type of Incident Qualifier.

TABLE 2 – TYPE OF INCIDENT QUALIFIER

CODE	DROP DOWN LIST OPTIONS:
1	**Dose omission**
2	**Incorrect dose**
2.3	**Extra dose**
3	**Incorrect strength/ concentration**
4	**Incorrect drug**
5	**Incorrect dosage form**
6	**Incorrect medication administration technique**
7 7.1 7.2 7.3 7.4 7.5 7.6	**Incorrect route of administration** o IV given, gastric intended o Intrathecal given, IV intended o IV given, oral intended o IV given, IM intended o IM given, IV intended o Other
8 8.1 8.2	**Incorrect rate** o Rate too fast o Rate too slow
9	**Incorrect duration**
10	**Incorrect time**
11	**Incorrect patient**
12 12.1 12.2 12.3 12.4 12.5	**Drug therapy monitoring problem** o Drug-drug interaction o Drug-food/ Nutrient interation o Documented allergy o Drug-disease interaction o Clinical
13	**Deteriorated drug**
13.1	**Outdated drug**
13.2	**Contaminated drug product**
14	**Other**

Source: National Coordinating Council for Medication Error Reporting and Prevention, © 2001, taxonomy of medication errors

1.6 DISCOVERED BY

DEFINITION:	Category of personnel that discovered the incident.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Code
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	This is entered from a drop down list. See Table 3 below for Discovered By Qualifier.

TABLE 3 – DISCOVERED BY QUALIFIER

CODE	DROP DOWN LIST OPTIONS
1.1	○ Physician
1.1.1	○ Physician – Intern
1.1.2	○ Physician – Resident
1.1.3	○ Physician – Practicing physician
1.1.4	○ Physician – Other
1.2	○ Pharmacist
1.3	○ Nurse
1.3.1	○ Nurse – Practitioner/advance practice
1.3.2	○ Nurse – Registered nurse
1.3.3	○ Nurse – Licensed practical nurse
1.3.4	○ Nurse – Other
1.4	○ Physician assistant
1.4.1	○ Paramedic
1.4.2	○ Midwife
1.4.3	○ Registered Respiratory Care Practitioner
1.5	○ Dentist
1.8	○ Support personnel
1.8.1	○ Support personnel – Pharmacy technician
1.8.2	○ Support personnel – Nurses aide
1.8.3	○ Support personnel – Medication aide
1.8.4	○ Support personnel – Clerical
1.9	○ Health professions student
1.9.1	○ Health professions student – Medicine
1.9.2	○ Health professions student – Pharmacy
1.9.3	○ Health professions student – Nursing
1.9.4	○ Health professions student – Other
1.10	○ Patient care giver
1.11	○ Other
1.12	○ Unknown
1.13	○ None
1.14	○ Patient

1.7 PATIENT CARE SETTING

DEFINITION:	Patient care setting type where the incident occurred.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	This is entered from a drop down list. See Table 4 below for Patient Care Setting Qualifier

TABLE 4 – PATIENT CARE SETTING QUALIFIER

CODE NAME
○ Community Pharmacy ○ Complex Continuing Care ○ Emergency Medical System (EMS) ○ Home ○ Hospital ○ Medical Office Practice ○ Nursing Home ○ Outpatient clinic ○ Rehabilitation Centre ○ Residential Care ○ Other

2 OUTCOME

2.1 SEVERITY/OUTCOME

DEFINITION:	A classification for medication incidents that helps determine (i) near miss incident or incident that reached the patient (ii) critical or non-critical incident. The selections are pre-defined and are adapted from the NCC MERP taxonomy of medication errors, with permission.
DATA TYPE:	Char
REPRESENTATIONAL FORM:	Code
MAXIMUM FIELD SIZE:	1
GUIDE FOR USE:	A drop down list consists of nine categories of severity from "no error" (a risky situation or a good catch) through levels of increasing seriousness of harm to the patient. The outcomes are adapted from the NCC MERP taxonomy of medication errors. See Table 5 below for Severity/Outcome Qualifier. Figure1 provides assistance for selecting the correct category.

TABLE 5 – SEVERITY/OUTCOME QUALIFIER

SEVERITY	DEFINITION
NO ERROR	Circumstances or events that have the capacity to cause harm. *(NCC MERP Category A) (Near miss)*
NO HARM	An incident occurred that did not reach the patient. (Does **not** include an error of omission.) *(NCC MERP Category B) (Near miss)*
NO HARM	An incident occurred that did reach the patient, but did not cause patient harm. *(NCC MERP Category C)*
NO HARM	An incident occurred that reached the patient and monitoring was required to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm. (NCC MERP Category D)
HARM	An incident occurred that may have contributed to or resulted in temporary harm to the patient and required intervention. *(NCC MERP Category E)*
HARM	An incident occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization. *(NCC MERP Category F)*

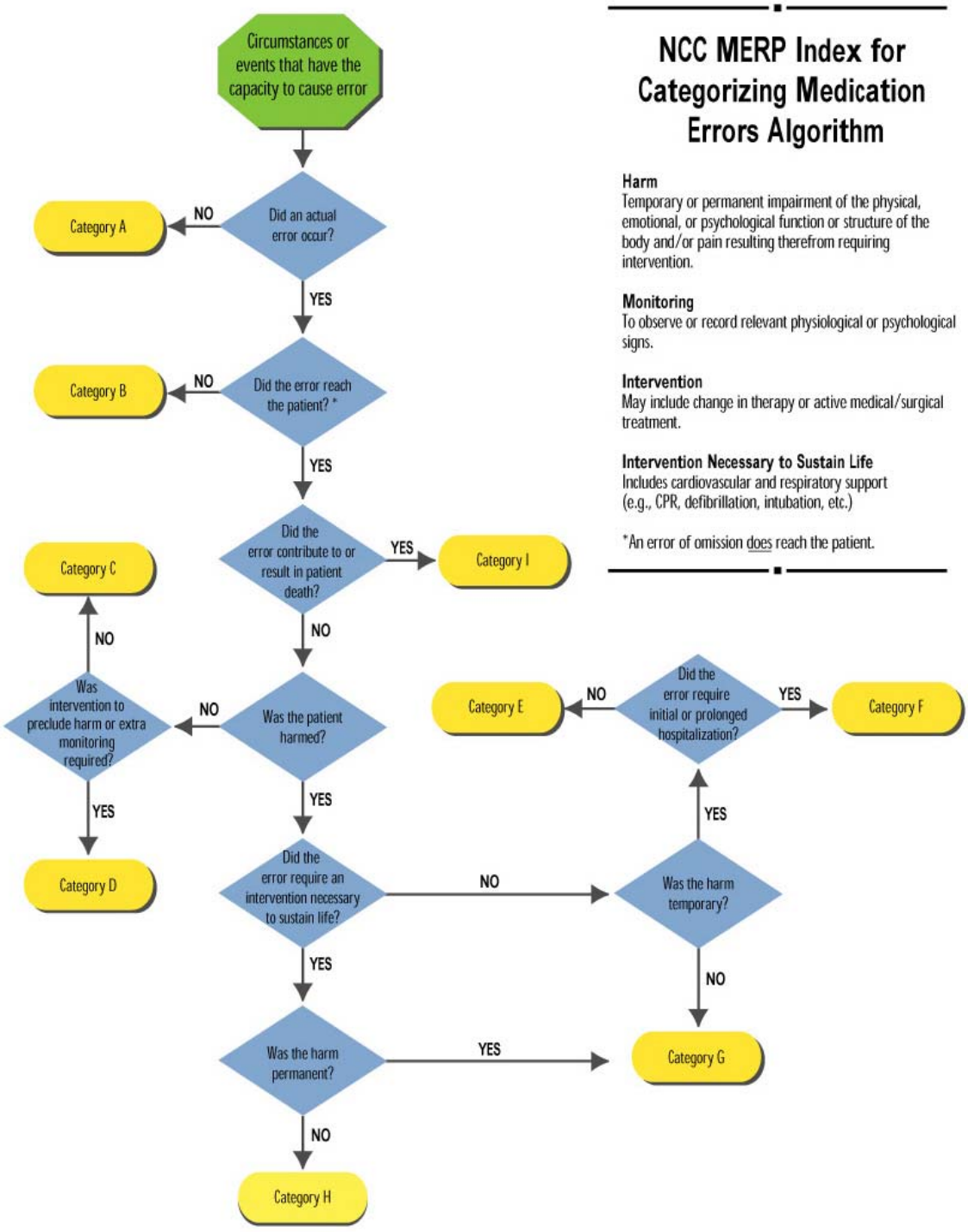
SEVERITY	DEFINITION
HARM	An incident occurred that may have contributed to or resulted in permanent patient harm. *(NCC MERP Category G)*
HARM	An incident occurred that required an intervention necessary to sustain life. *(NCC MERP Category H)*
DEATH	An incident occurred that may have contributed to or resulted in the patient's death. *(NCC MERP Category I)*

Source: National Coordinating Council for Medication Error Reporting and Prevention, © 2001, taxonomy of medication errors

2.2 INTERVENTION(S)

DEFINITION:	Immediate actions taken upon detection of the incident.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 65535
GUIDE FOR USE:	Define the specific actions taken upon identifying the incident. For example "medication stopped". Include actions taken to mitigate the harm of the incident.

FIGURE1: NCC MERP INDEX FOR CATEGORIZING MEDICATION ERRORS ALGORITHM (© 2001 NCC MERP)



3 MEDICATION(S)

3.1 MEDICATION NAME

DEFINITION:	The generic medication name or brand name of the product(s) involved in the incident.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	This is entered manually.

3.2 STRENGTH

DEFINITION:	The strength/concentration of the product(s).
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	Provides information about the strength/ concentration of the product(s).

3.4 ROUTE OF ADMINISTRATION

DEFINITION:	The route of administration intended for the product(s).
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	Provides information about the dosage form of the product(s).

3.2 MANUFACTURER

DEFINITION:	The manufacturer of the product(s).
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	This is an important data element if product labelling or packaging are considered a contributing factor in the incident.

3.3 LOT NUMBER

DEFINITION:	The lot number of the product(s), if relevant.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	This information is important when dealing with expired or incorrectly packaged medications.

4 FOLLOW UP

4.1 ACTION

DEFINITION:	Define the actions subsequent to the incident.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 65535
GUIDE FOR USE:	This element can provide suggested actions to impact patient safety.

4.2 COMMENTS / RECOMMENDATIONS

DEFINITION:	Further comments or recommendations relating to follow up can be entered here.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 65535
GUIDE FOR USE:	Free text field to add additional ideas and recommendations to reduce the likelihood of recurrence of the incident. *Action oriented statements* are the most helpful.

4.3 SYSTEM IMPROVEMENT STRATEGIES IMPLEMENTED

DEFINITION:	Describes actual system improvement strategies implemented.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 65535
GUIDE FOR USE:	Information shared informs others of potential system enhancements and considerations for system improvements as a result of learning from an incident.

5 PATIENT

5.1 Non-Patient Specific

DEFINITION:	When the event is not directly connected to a patient (e.g. medication found in wrong container), includes purchasing and storage problems.
DATA TYPE:	Char
REPRESENTATIONAL FORM:	Boolean
MAXIMUM FIELD SIZE:	1
GUIDE FOR USE:	Select to indicate an event or high risk situation that does not connect with a specific patient (includes purchasing and storage problems).

5.2 AGE CATEGORY

DEFINITION:	Choice of one of four age groups, or 'unknown'.
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	This is entered from a drop down List. Choice of one of four age groups, or unknown: o Neonatal 0-28 days inclusive o Paediatric 29 days – 17 years inclusive o Adult 18 years – 64 years inclusive o Geriatric 65 years and over o unknown

5.3 GENDER

DEFINITION:	Gender of patient.
DATA TYPE:	Char
REPRESENTATIONAL FORM:	Code
MAXIMUM FIELD SIZE:	1
GUIDE FOR USE:	This is entered from a drop down menu. Choice of: o Male o Female o Unknown

6 REPORTER

Reporters may provide contact information for clarification and follow up purposes.

6.1 NAME

DEFINITION:	Name of the reporter
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	Information is provided so ISMP Canada can follow up with additional information or provide assistance with further analysis.

6.2 PRACTICE SETTING

DEFINITION:	Practice setting
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	Information is provided so that ISMP Canada can follow up for additional information or provide assistance with further analysis.

6.3 CITY

DEFINITION:	City
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	

6.4 PROVINCE

DEFINITION:	Province
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Code
MAXIMUM FIELD SIZE:	2
GUIDE FOR USE:	This is entered from a drop down menu. Choice of: ○ British Columbia ○ Alberta ○ Saskatchewan ○ Manitoba ○ Ontario ○ Quebec ○ New Brunswick ○ Nova Scotia ○ Prince Edward Island ○ Newfoundland ○ Northwest Territories ○ Nunavut ○ Yukon Territory

6.5 POSTAL CODE

DEFINITION:	Postal Code
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text [xxx xxx]
MAXIMUM FIELD SIZE:	7
GUIDE FOR USE:	

6.6 EMAIL

DEFINITION:	Email Contact
DATA TYPE:	Text
REPRESENTATIONAL FORM:	Text
MAXIMUM FIELD SIZE:	Up to 255
GUIDE FOR USE:	Information is provided so ISMP Canada can follow up for additional information or provide assistance with further analysis.

6.7 I MAY BE CONTACTED BY ISMP CANADA ABOUT THIS MEDICATION INCIDENT FOR MORE INFORMATION / CLARIFICATION

DEFINITION:	Reporter confirms information above is provided for possible follow up or assistance with further analysis.
DATA TYPE:	Char
REPRESENTATIONAL FORM:	Boolean
MAXIMUM FIELD SIZE:	1
GUIDE FOR USE:	This is entered from a radio button group. Choice of: o Yes o No

7 POSSIBLE CONTRIBUTING FACTORS

DEFINITION:	The possible contributing factors are categorized by the 10 key elements of the medication use system used with permission from ISMP in the US.
DATA TYPE:	Char
REPRESENTATIONAL FORM:	Boolean
MAXIMUM FIELD SIZE:	1 for each possible contributing factor
GUIDE FOR USE:	The reporter can choose possible contributing factors from list boxes organized by the following Key Medication Use System Elements: ○ Critical patient information missing ○ Critical drug information missing ○ Miscommunication of drug order ○ Drug name, label, packaging problem ○ Drug storage or delivery problem ○ Drug delivery device problem ○ Environmental, staffing, or workflow problem ○ Staff education problem ○ Patient education problem ○ Lack of quality control or independent check systems See Table 6 below for Key Medication Use System Element Qualifier.

TABLE 6 – KEY MEDICATION USE SYSTEM ELEMENT QUALIFIER

KEY MEDICATION USE SYSTEM ELEMENT	POSSIBLE CONTRIBUTING FACTORS
Critical patient information missing	❑ Age ❑ Weight ❑ Allergies ❑ Vital signs ❑ Lab values ❑ Pregnancy ❑ Patient identity ❑ Location ❑ Renal/liver impairment ❑ Diagnosis ❑ Other
Critical drug information missing	❑ No medication history ❑ Inadequate medication reconciliation process ❑ Outdated/absent references ❑ Inadequate computer screening ❑ Inaccessible pharmacist ❑ Uncontrolled drug formulary ❑ Other
Miscommunication of drug order	❑ Illegible ❑ Ambiguous ❑ Incomplete ❑ Misheard orders ❑ Misunderstood orders ❑ Intimidation/faulty interaction ❑ Other
Drug name, label, packaging problem	❑ Look/sound-alike names ❑ Look-alike packaging ❑ Unclear/absent labelling ❑ Faulty drug identification ❑ Other
Drug storage or delivery problem	❑ Slow turn around time ❑ Inaccurate delivery ❑ Doses missing or expired ❑ Multiple concentrations ❑ Placed in wrong bin ❑ Other
Drug delivery device problem	❑ Poor device design ❑ Misprogramming ❑ Free-flow ❑ Mixed up lines ❑ IV administration of oral syringe contents ❑ Other

KEY MEDICATION USE SYSTEM ELEMENT	POSSIBLE CONTRIBUTING FACTORS
Environmental, staffing, or workflow problem	❑ Lighting ❑ Noise ❑ Clutter ❑ Emergency situation ❑ Interruptions ❑ Transition of care (e.g. change of shift) ❑ Staffing deficiencies ❑ Workload ❑ Inefficient workflow ❑ Employee safety ❑ Other
Staff education problem	❑ Competency validation ❑ New or unfamiliar drugs/devices ❑ Orientation process ❑ Feedback about errors/prevention ❑ Other
Patient education problem	❑ Lack of information ❑ Non-compliance ❑ Not encouraged to ask questions ❑ Lack of investigating patient inquires ❑ Other
Lack of quality control or independent check systems	❑ Equipment quality control checks ❑ Independent checks for high alert drugs/high risk patient population drugs ❑ Other

8 Reporting Medication Incidents to ISMP Canada

Any practitioner may report a medication incident through the ISMP Canada website at http://ismp-canada.org/cmirps.htm

Or by telephoning toll free 1-866-54-ISMPC; or 416-480-4099

E-mail: cmirps@ismp-canada.org

Mailing address:

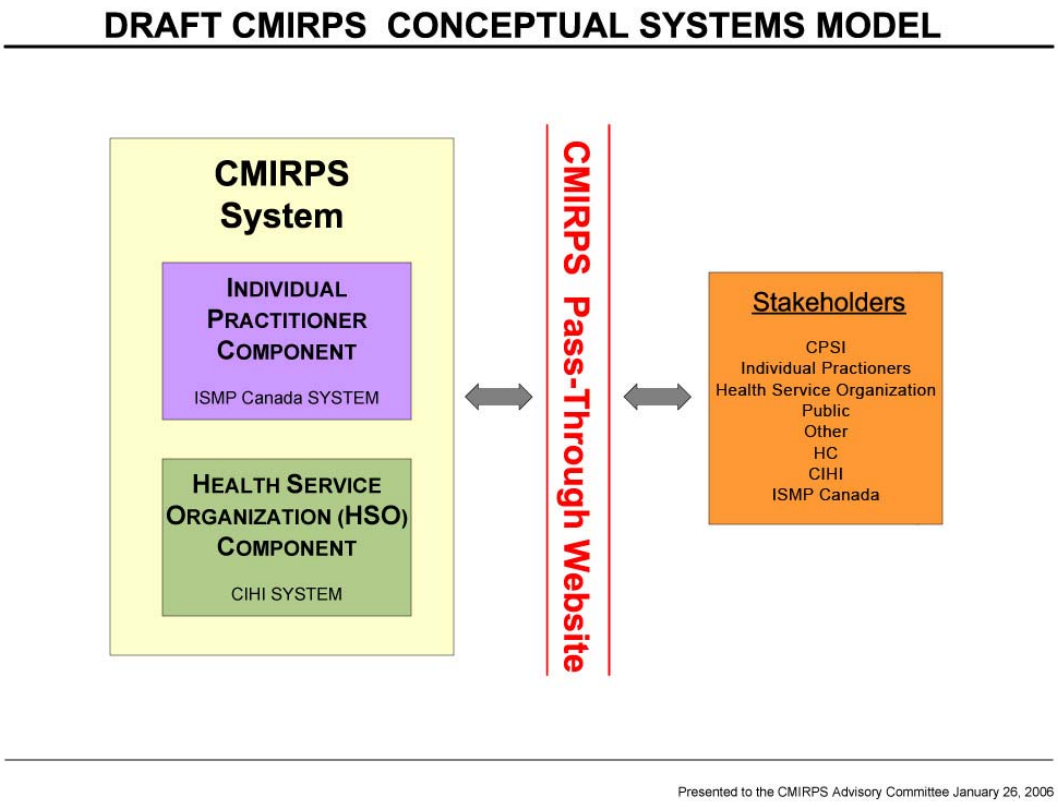
Institute for Safe Medication Practices Canada
2075 Bayview Avenue E226,
Toronto ON, M4N 3M5
Tel: (416) 480 4099 or toll free: 1-866-544-7672

The data submitted is safeguarded through a secure, encrypted transmission process. All data is treated with strict confidentiality.

No patient identifiers are collected during this process. The user needs to ensure no identifiers are included in free text fields. All files received by ISMP Canada are verified and cleansed in accordance with privacy policy and procedures to protect against inadvertent submission of identifying information.

Reporter information voluntarily submitted is deleted immediately after follow up or within 3 months from data entry.

APPENDIX 1: CMIRPS CONCEPTUAL MODEL



APPENDIX 2: CMIRPS GLOSSARY OF TERMS

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.

Similar Terms: sentinel event

J. Davies, P. Hebert and C. Hoffman, Canadian Patient Safety Dictionary (Ottawa: Royal College of Physicians and Surgeons of Canada, 2003).

HARM

Harm is defined as a temporary or permanent impairment in body functions or structures. Includes mental, physical, sensory functions and pain.

Definitions of terms. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2006. Available from: http://www.ismp-canada.org/definitions.htm. Developed by the Institute for Safe Medication Practices Canada, the Canadian Institute for Health Information, and Health Canada (collaborating parties for the development and implementation of the Canadian Medication Incident Reporting and Prevention System [CMIRPS]).

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 health care 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.

Similar Terms: medication error

Definitions of terms. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2006. Available from: http://www.ismp-canada.org/definitions.htm. Adapted from the National Coordination Council on Medication Error Reporting and Prevention, What Is Medication Error?, [online], cited March12, 2004 from <http://www.nccmerp.org/aboutMedErrors.html>. Developed by the Institute for Safe Medication Practices Canada, the Canadian Institute for Health Information, and Health Canada (collaborating parties for the development and implementation of the Canadian Medication Incident Reporting and Prevention System [CMIRPS]).

NEAR MISS OR CLOSE CALL

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.

Similar Terms: near hit, good catch

Definitions of terms. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2006. Available from: http://www.ismp-canada.org/definitions.htm. Developed by the Institute for Safe Medication Practices Canada, the Canadian Institute for Health Information, and Health Canada (collaborating parties for the development and implementation of the Canadian Medication Incident Reporting and Prevention System [CMIRPS]).

NO HARM EVENT

An incident occurs which reaches the patient, but results in no injury to the patient. Harm is avoided by chance or because of mitigating actions.

Definitions of terms. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2006. Available from: http://www.ismp-canada.org/definitions.htm. Developed by the Institute for Safe Medication Practices Canada, the Canadian Institute for Health Information, and Health Canada (collaborating parties for the development and implementation of the Canadian Medication Incident Reporting and Prevention System [CMIRPS]).

ROOT CAUSE ANALYSIS

An analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans.

C. Hoffman, P. Beard, J. Greenall, D. U and J. White. Canadian Root Cause Analysis Framework, Canadian Patient Safety Institute, Edmonton: March, 2006.

SYSTEM

A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

World Health Organization, World Alliance for Patient Safety – WHO Draft Guidelines for Adverse Event Reporting and Learning Systems (Geneva: 2005).