The Development of a Canadian Medication Incident Reporting and Prevention System (CMIRPS) for Canada

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

ISMP Canada Project Charter Executive Summary

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Background

Recent reports have raised concerns regarding the number of adverse events experienced by patients within the healthcare system. In the United States, the 1999 Institute of Medicine Report *To Err is Human- Building a Safer Health System* galvanized the health care community, the press, the public and politicians with an extrapolation that 44,000 to 98,000 deaths related to medical errors occur annually within the United States.[1] The report, which provided an extensive review of adverse event studies, identified the importance of system issues in the occurrence of error and called for a national reporting system for the collection of information on adverse events. In Canada, the 2002 report of the National Steering Committee on Patient Safety- *Building a Safer System- a National Integrated Strategy for Improving Patient Safety in Canadian Healthcare* [2] provided 19 recommendations for the improvement of patient safety, including the adoption of non-punitive reporting policies and investment in infrastructures that support the standardized identification, reporting and tracking of patient safety data.

The recent Canadian Adverse Events Study [3] also provides evidence that adverse events occur commonly in Canadian healthcare, and sometimes result in serious harm or even death. This study found an overall adverse event rate of 7.5/100 hospital admissions, with 36.9% of the adverse events preventable. The authors of this study note that "Efforts to make patient care safer will require leadership to encourage the reporting of AE's, continued monitoring of the incidence of these events, the judicious application of new technologies, and improved communication and coordination among caregivers".

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[4] and a similar study conducted in Colorado and Utah[5] 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

[1] Kohn, LT, Corrigan, JM, Donaldson MS, Editors. *To Err is Human, Building a safer Health System* Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington D.C. 1999.
[2] Building a Safer system- a National Integrated Strategy for Improving Patient Safety in Canadian Health Care, http://rcpsc.medical.org
[3] Baker, G.R. Norton. P.G. The Canadian Adverse Events Study: the incidence of adverse events among hospitalized patients in Canada *CMAJ* 2004;170 (11):1678-86.
[4] 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.
[5] 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.

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second most common type of procedure or events to which adverse events were related (after surgical), at 23.6%.

While additional work is required to achieve a consensus in terminology related to adverse drug events, medication incidents are generally accepted to be a preventable subset of the broad category of adverse drug events (including potential adverse drug events). The prevalence, seriousness and preventability of adverse drug events has been clearly documented. One study, conducted at two prestigious U.S. teaching hospitals, found a rate of 6.5 adverse drug events and 5.5 potential adverse events per 100 non-obstetric hospital admissions.[6] One percent of the adverse drug events were fatal, 12% were judged to be life-threatening and 30% serious. Twenty eight percent of all adverse drug events and 42% of the life threatening or serious adverse drug events were judged to be preventable.

In addition to patient safety concerns, medication incidents increase the cost of health care delivery. In a continuation of the study noted above, Bates and colleagues reported that, for the admissions where a preventable adverse drug event was identified, the average length of stay increased by 4.6 days. After adjusting for sampling strategy, the authors estimated the post-event cost of a preventable adverse drug event to be $4,685 US amounting to approximately $2.8 million U.S. annually (based on 1993 costs) for a 700-bed teaching hospital.[7] Yet another U.S. study found that for every dollar spent on drugs in skilled nursing facilities, $1.33 is consumed in the treatment of drug-related morbidity and mortality.[8]

Clearly, efforts to improve medication safety will play a significant role in improving overall patient safety in Canadian healthcare. Better information on the number, types, sources, causes and outcomes of medication incidents is needed in Canada to assist in:

- identifying areas requiring change;
- identifying potential preventative strategies;
- implementing strategies that have been shown to reduce the risk of incidents; and
- evaluating implementation outcomes.

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 of the outcomes of the workshop was the recommendation to establish a coalition of stakeholders, the Canadian Coalition on Medication Incident Reporting and Prevention (or CCMIRP), to oversee the creation of a business plan for the development and implementation of a medication incident reporting and prevention system. The business plan outlined a strategy for the development of the CMIRPS, the Canadian Medication Incident Reporting and Prevention System.

[6] Bates, D.W. et.al, The incidence of Adverse Drug Events and Potential Adverse Drug events, implications for Prevention *JAMA* 1995; 274; 29-34.
[7] Bates, D.W. et.al, the Costs of Adverse Drug Events in Hospitalized Patients, *JAMA* 1997;277:307-11.
[8] Bootman, J.L. Harrison, LTC, Donald L and.Cox, E. The health care cost of drug related morbidity and mortality in nursing facilities. *Arch Intern Med*. 1997; 157 (18):2089-2096.

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Canadian Medication Incident[9] Reporting and Prevention System (CMIRPS) Brief 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 proposed 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; and
- develop and disseminate timely and targeted information designed to reduce the risk of medication incidents.
- 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 for enhancing their patient safety efforts and
- be dynamic, to allow for the continued relevancy and utility of the system.

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

[9] 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.

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access to the CMIRPS data to fulfill their respective mandate and responsibilities under CMIRPS. Data-sharing agreements will be designed to facilitate sharing of information.

- Health Canada will:
    - Provide secretariat support for the CMIRPS Operations Committee and CMIRPS Advisory Committee;
    - Define 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
    - Investigate 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 will:
    - Take the lead in collecting and processing individual practitioner data;
    - Conduct root cause analysis for selected medication incidents; and
    - Develop and disseminate timely information bulletins (e.g. alert bulletins); and
    - Conduct analytical studies (e.g. aggregate root cause analysis based on data submitted to CMIRPS through standardized health service organization data, as well as events from coroner offices, professional regulatory agencies and healthcare insurers)
    - Provide support for the development and implementation of preventative measures.
- CIHI will:
    - Take the lead in collecting and processing standardized health service organization data;
    - Develop a system capable of query and analysis; and
    - Conduct analytical studies and ad hoc requests.

The CMIRPS will allow for the following types of reporting:

- **Individual practitioner** [10]— The individual practitioner reporting program component will be designed for timely reporting of medication incidents by individuals working in any health care setting.
- **Health service organization**—A standardized information system will track data related to medication incidents within Canadian health service organizations. This information will be useful in tracking overall trends in reported medication incidents over time. At the present time, the health service organization data collection will be limited to hospitals. Other health service organizations such as community pharmacies and long term care

[10] An individual practitioner for the purposes of the ISMP Canada medication incident reporting program includes physicians, nurses, pharmacists, technicians, risk managers, regulatory colleges, coroner offices, insurance providers and others involved in the identity, or review of an incident.

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facilities may report information on specific incidents through the individual practitioner reporting program component.

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.

Sentinel events (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 a root cause analysis.

ISMP Canada Project Scope for CMIRPS

Introduction:

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 are designed to be complimentary for the benefit of Canadians. The individual practitioner reporting component will provide a confidential mechanism to allow individual practitioners in any health care setting to directly report medication incidents they have been involved with, or incidents they have observed, with the option to submit information anonymously. The individual practitioner system component will not collect information on the identities of patients.

Enhancements to the existing ISMP Canada voluntary practitioner program will be phased in over time and priority will be given to aligning the data standard (ensuring consistency and coordination) to the extent possible with the CIHI system component such that the use of CMIRPS data[11] can be optimized for the Canadian environment, and ultimately the international environment. With the increased understanding about system failures that can lead to medication incidents, there is increasing awareness of the value of reporting programs for the purposes of warning others. Encouraging the sharing of incident information is core to improvements in patient safety in both relation to analysis of root causes and engendering a culture of openness. Identification of low-frequency events with serious harm or potential serious harm can permit early identification of unsuspected hazards. Aggregate root cause analysis can identify common contributing factors. Under the terms and conditions of the ISMP Canada /Health Canada Contribution Agreement (2003–2004 to 2007–2008), ISMP Canada will be responsible for the following CMIRPS programs and activities:

[11] CMIRPS Data is defined as medication incident data collected through both the CIHI information system and the ISMP Canada information system.

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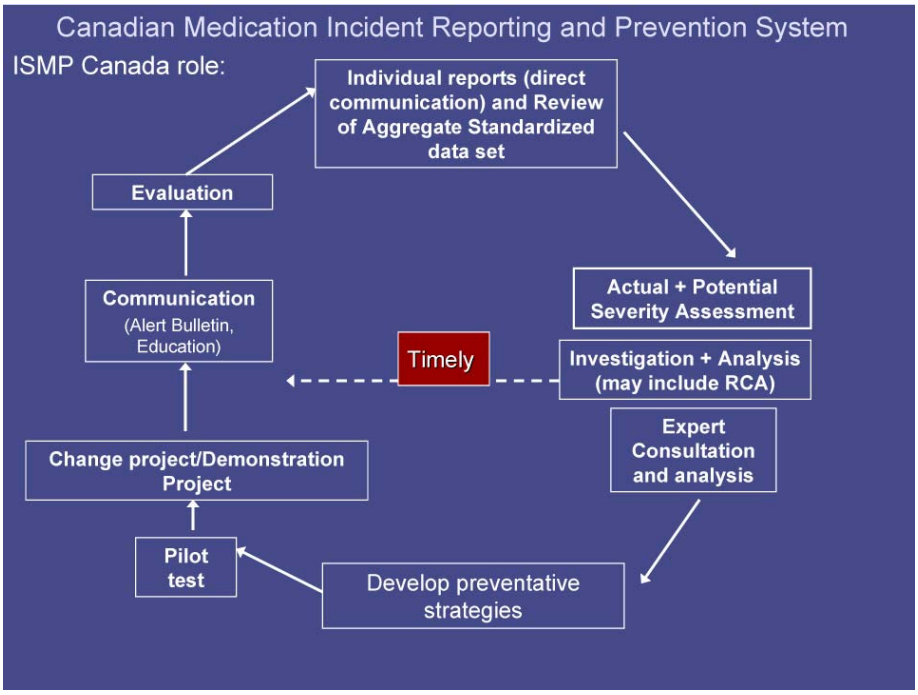

1. Individual Practitioner Reporting Program (Critical[12] Incident, Potentially Harmful Incident or Hazardous Situation Reporting):

ISMP Canada will be responsible for enhancing an existing reporting program designed for the collection and processing of critical and potentially harmful medication incident (or hazardous situation) reports submitted by practitioners (not restricted to physicians, nurses, pharmacists and technicians), risk managers, regulatory colleges, coroner offices, insurance providers and others involved in the identity, or review of an incident requiring timely attention, and possibly a root cause analysis and/or dissemination of information to healthcare providers and/or follow-up to identify preventative actions.

To facilitate reporting, various communication channels may be used to collect reports, including telephone, mail, email, web portal or electronic transmission.

It is envisaged that the CMIRPS will include a mechanism to provide the de-identified data of a critical incident or potentially critical incident to ISMP Canada in a timely fashion.

Data and Information requirements: The data set is designed such that patient identifiers are not collected. The data set is also designed to provide an option for anonymous reporting. Existing national and international standards to facilitate comparability have been considered in defining data elements. A priority for the data set will be to optimize

[12] 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.

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coordination with the CIHI system component. ISMP Canada will work with CIHI to establish optimal consistency between the individual practitioners' voluntary reporting and the health service organization-based data collection, to ensure effective performance of CMIRPS with respect to coordinating information. Enhancements will be made to optimize:

- Data standards and maintenance;
- Data collection, transmission protocols, encryption, processing and data quality;
- Analysis and reporting;
- Systems to safeguard privacy;
- Promotion and communication services; and
- Client support services.

Settings: The individual practitioners' voluntary reporting system component will collect reports from practitioners within a wide variety of health care settings, including but not limited to community pharmacists, 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.

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

Types of incidents: The individual practitioners' voluntary reporting program will collect reports on potential and actual critical medication incidents related to prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, monitoring, documentation and use. The reporting of potential medication incidents (that is, near misses) and hazardous situations will be integral to facilitating the identification of latent conditions that may require adjustment in order to prevent actual incidents and serious adverse events.

Types of Medications: The program will collect reports on all types of medications.

2. Analysis of CMIRPS data[13]: Data collected through both the CIHI information system component and the ISMP Canada information system component will be analyzed by ISMP Canada to fulfill ISMP Canada's mandate under CMIRPS.

[13] Analysis of CMIRPS data is an area of key importance for ISMP Canada. Expert analysis of information, combined with timely and effective communication, is critical to the success of CMIRPS in improving patient safety. With appropriate analysis of the ISMP Canada collected data and the CIHI collected data, new hazards and trends can be identified, alerts can be generated and information regarding new incident prevention methods and leading practices can be communicated. The importance of this role is highlighted in a recent Health Policy Report in the New England Journal of Medicine by Leape[13], who notes that one of the characteristics of a successful reporting system is that "reports are evaluated by experts who understand the clinical circumstances and who are trained to recognize underlying systems causes."

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ISMP Canada will be responsible for conducting root cause analyses[14] of selected incidents reported to CMIRPS. Such analyses are generally done in collaboration with the reporter or reporting organization and will be of key importance for sentinel events and critical incidents involving serious harm to patients, or incidents that have the potential for serious harm to occur. The existing voluntary practitioner reporting program receives critical incident data information from organizations such as coroner's offices, professional regulatory agencies and insurance providers. The process of root cause analysis may identify issues of urgent concern where immediate communication, education or other actions are required (e.g. communication with Health Canada regarding product-related issues).

It is envisaged that the CMIRPS will include a mechanism to inform ISMP Canada when root cause analysis of an event is requested by users.

ISMP Canada will perform routine and special analysis of the CMIRPS data, identify specific areas of concern and recommend approaches to prevention. This will include broad analysis of CMIRPS data to perform aggregate root cause analysis.

The training of ISMP Canada staff will continue to focus on the recognition of underlying causes, human factors engineering principles for system re-designs and understanding of the clinical environment.

3. Information Bulletins:

ISMP Canada will be responsible for the timely development and dissemination of bulletins designed to share information on medication incidents and educate health care providers about strategies to prevent medication incident-related harm to patients. Alerts about unrecognized hazards can be generated from even a few incident reports. Information about the experience of individual hospitals in using new methods to prevent incidents can be disseminated in an anonymous fashion through ISMP Canada's information bulletins. The bulletins will provide information and education designed to guide organizations and practitioners in the implementation of preventative strategies. Such information can ultimately lead to testing and implementing 'best practices'. Bulletins will be developed in response to critical information identified through the CIHI information system component or the ISMP Canada information system component.

4. Analytical Reports:

ISMP Canada will produce analytical reports based on the priorities and information needs of users. These will include reports from root cause analyses and special studies

[14] The Canadian Patient Safety Dictionary[14] defines root cause analysis as "a systematic process of investigating a critical incident or an adverse outcome to determine the multiple, underlying contributing factors. The analysis focuses on identifying the latent conditions that underlie variation in performance and, if applicable, developing recommendations for improvements to decrease the likelihood of a similar incident in the future."

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on specific topics or critical issues. Studies could address specific needs of users, and could be collaborative initiatives involving several organizations.

5. Preventative Measures:
ISMP Canada will work with CMIRPS users and medication safety experts to identify or develop and test preventative measures in response to issues identified through the analysis of reports.

6. Research:
ISMP Canada will continue to collaborate with researchers and research initiatives in patient safety-related projects.

7. Collaboration:
The CMIRPS will be developed and implemented through the collaborative efforts of the three national organizations: Health Canada, ISMP Canada, and CIHI. ISMP Canada will work with CIHI and Health Canada according to the terms of a memorandum of understanding. ISMP Canada will participate in the development and implementation of the CMIRPS communication plan.

ISMP Canada will continue the collaborative review of medication incidents reported by professional regulatory agencies, provincial coroners' offices, emergency medical services, healthcare insurance organizations, and other organizations with similar mandates.

ISMP Canada is collaborating with the Canadian Patient Safety Institute (CPSI),the Canadian Council on Health Services Accreditation (CCHSA), on a number of important patient safety initiatives related to CMIRPS deliverables.

Links will be established between the CMIRPS and other patient safety initiatives to encourage coordinated access to patient safety information (e.g. currently links have been established with provincial governments and professional associations).

8. Other: ISMP Canada will assist with developing standard terminology (French and English) related to medication incidents and incident reporting for CMIRPS.

Project Phases and Major Deliverables

The development of the CMIRPS is comprised of the following phases, major deliverables and timelines:

Project Phase	Timelines
Project initiation, infrastructure enhancement and training	December 2003 to March 2005
Collaboration with CIHI to identify overall system requirements. Privacy impact assessment. Provision of services to French-speaking practitioners.	March 2004 to May 2005

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System component design enhancements, communications to practitioners, additional collaborations	June 2005 to June 2006
Ongoing Evaluation and enhancements with stakeholder input	April 2006 to March 2008

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