



Working with Consumers to Prevent Medication Incidents

A Consumer Reporting and Learning Strategy for the Canadian Medication Incident Reporting and Prevention System

DRAFT for Review and Consultation

June 2, 2009

Institute for Safe Medication Practices Canada
Institut pour l'utilisation sécuritaire des médicaments
du Canada

info@ismp-canada.org
www.ismp-canada.org

4711 Yonge Street, Suite 501
Toronto, ON M2N 6K8

telephone: 416-733-3131
toll free: 1-866-54-ISMPC
(1-866-544-7672)
fax: 416-733-1146

*A Key Partner in the Canadian Medication Incident Reporting and Prevention System
Un partenaire clé du Système canadien de déclaration et de prévention des incidents médicamenteux*

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency committed to the advancement of medication safety in all health care settings. 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.

ISMP Canada's mandate includes collection, review and analysis of medication incident and near-miss reports, identifying contributing factors and causes and making recommendations for the prevention of harmful medication incidents. Information on safe medication practices for knowledge translation is published and disseminated.

Additional information about ISMP Canada, and its products and services, is available on the website: www.ismp-canada.org

This strategy is being developed in consultation with Patients for Patient Safety Canada, and Health Canada. The Canadian Institute for Health Information and the Canadian Patient Safety Institute have provided input and feedback and the strategy is also being reviewed by provincial, national and international stakeholder organizations as part of the consultation process.

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Executive Summary

Canadian health professionals and consumers are increasingly seeking ways to reduce the health risks associated with complications from drug therapy. The Canadian Adverse Events Study found that the administration of drugs and fluids is frequently associated with adverse events in Canadian hospitals¹ and harmful medication incidents have received extensive coverage in the lay press. The term “adverse drug event” is used to describe any event where the use of a drug results in harm. Adverse drug events include *adverse drug reactions*, which are generally considered non-preventable, and *medication incidents* (also referred to as “medication errors”²) which are preventable. Medication incidents do not always result in harm, but even non-harmful incidents can provide valuable insight into underlying system problems. When information about medication incidents is collected and analyzed, the knowledge gained can be used to improve the safety of systems and to prevent harmful events.

Canada has recently made great strides in learning about medication incidents and potential strategies for prevention through the development of the Canadian Medication Incident Reporting and Prevention System (CMIRPS). The aim of CMIRPS is to reduce and prevent harm from medication incidents, by managing and sharing learning from voluntarily-reported information about medication incidents. Incident reporting systems that analyze reports of errors and near misses are particularly effective when reports are collected from multiple sources and when the learning and recommended prevention strategies are shared broadly.

Consumers (*defined as patients, family members, caregivers or any other individuals who may be acting for, or in support of, a patient or client receiving health care*³) who have experienced medication incidents often have a strong desire to convey information that may prevent others from being harmed. Recognizing the interest of consumers in sharing information about medication incidents and the associated potential to enhance medication safety learning, the CMIRPS vision included consumer reporting. The individual practitioner reporting component of CMIRPS has already accepted reports from consumers, but the program has not been promoted to consumers and the volume of reports has

¹ 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

² Definition of terms [Internet]. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2008 [cited 2008 Nov 3]. Available from: <http://www.ismp-canada.org/definitions.htm>

³ Adapted from definition provided in Consumer Adverse Event Reporting AHIC Extension Gap US Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Dec 31, 2008 Page 20 [cited 2009 Jan 15]. Available from <http://www.hhs.gov/healthit/usecases/documents/CAERFinalExtGap.pdf>

been low. CMIRPS is now ready to move forward with a strengthened and coordinated approach to consumer reporting and learning.

The expansion of the consumer's role in CMIRPS offers many advantages. A consumer reporting and learning program will serve to both **inform** and **empower** consumers. To be proactive about medication safety, consumers need information on the consequences of medication incidents, the steps they can take to reduce their chances of experiencing adverse events from medication incidents and information on what to do if a medication incident occurs. There is a need for targeted information on safe medication use and practical tools that consumers can use to enhance medication safety. As consumers increasingly turn to the internet for health information, the establishment of a reliable website with high-quality consumer-oriented information about medication safety can be expected to have a positive impact on patient knowledge. This knowledge will equip consumers to join health professionals in the reporting, analysis and prevention of medication incidents and will ultimately improve health outcomes.

Experience with adverse event reporting programs in Canada and other jurisdictions suggests that consumer involvement can generate a significant volume of reports and provide useful information for detection of system issues. Consumers may be less limited by the time constraints that can discourage health professionals from reporting, may be aware of errors that have not been identified or reported by caregivers, and can play an active role in identifying underlying factors that contribute to errors. Consumer reports to ISMP Canada's individual practitioner reporting system have already formed the basis of two previous ISMP Canada Safety Bulletins.^{4,5} By promoting the program and providing a consumer-friendly reporting process, it is anticipated that consumer reporting will become a key component of CMIRPS activity.

ISMP Canada will develop a consumer-focused medication safety website (www.safemedicationuse.ca; www.medicamentssecuritaires.ca) that will have a significant educational element. The website will be accessible directly or through links from key websites. To avoid duplication of effort, information on the site will be adapted from ISMP Canada's existing forms and publications. In addition to an electronic medication incident reporting tool, the site will provide general information on medication safety, consumer-oriented publications pertaining to safe medication use, consumer-focused medication safety bulletins and alerts, links to Health Canada alerts and industry alerts, and practical tools such as downloadable forms.

A unique consumer-oriented online reporting form will be developed, by modifying ISMP Canada's existing online medication incident reporting system to incorporate consumer-friendly terminology. To allow data comparisons and learning across datasets, key fields will be mapped to those used in other CMIRPS components. A reporter may report about an incident that he/she

⁴ Codeine Syrup-Dangerous "Near Miss" in the Community. ISMP Canada Safety Bulletin, Volume 2 Issue 3, March 2002

⁵ Patient Report of Insulin Mix-up Shared. ISMP Canada Safety Bulletin, Volume 7 Issue 6 Dec 8, 2007

experienced, or about the experience of a family member or some other person. Although it is anticipated that the majority of reports will be received through the web-based system, an option for telephone reporting will also be available for consumers who are unable to submit a report to the website.

Because medication error information stems from an event that has been experienced by an individual, sharing of incident information may raise concerns about privacy and confidentiality. Although medication incident reports need only consist of facts about the incident that are non-identifying, it is recognized that consumer reports may be submitted directly by patients who have experienced errors and as such, the reporter contact information may reveal the identity of the involved patient. For this reason, and in light of the best-practices related to limiting collection of identifying information, the consumer reporting and learning program may begin by collecting only anonymous reports during the pilot stage. (The implications of anonymous reporting and the feasibility of collecting reporter contact information at a later stage would be explored during the pilot.)

It is anticipated that consumers will eventually be offered the choice of either reporting anonymously or of providing contact information for the purposes of follow-up. Collection of contact information will only happen with the documentation of informed and voluntary consent of the consumer. ISMP Canada will put processes in place to ensure that, where the reporter chooses to provide contact information, this contact information will be retained only for an appropriate follow-up period, after which it will be destroyed.

The processes and practices used to collect, analyze and communicate medication incident reports from consumers will be consistent with ISMP Canada's Privacy Policy, available on the ISMP Canada website. The consumer reporting and learning website will provide a summary of relevant points from the privacy policy in consumer-appropriate language, as well as access to a downloadable copy of the full privacy policy. During the reporting processes, consumers will be provided with clearly visible online reminders that personal identifying information should not be included within the report and that sensitive personal information such as a social insurance number or date of birth should not be provided. Additionally, as for reports submitted to the individual practitioner reporting program, all consumer reports received by ISMP Canada will be reviewed and cleansed in accordance with the privacy policy and procedures and to protect against inadvertent submission of identifying information.

Each report will be screened by an ISMP Canada expert analyst and assigned an analysis priority based on the severity (or potential severity) of the event and the likelihood of recurrence. High-priority reports will be analyzed to identify the nature of the incident and possible contributing factors. When reports are submitted anonymously, consumer involvement would end with the submission of the report. In cases where a report is incomplete or contains information that ISMP Canada believes may be inaccurate or about which ISMP Canada has

unanswered questions, the information will not be analyzed or included in any safety bulletins, reports or other publications.

The collection of contact information would allow for an expanded consumer role in a small number of selected cases. If a report is identified as high priority and the reporter has consented to follow-up, an ISMP Canada staff member may contact the reporter to verify facts and to obtain additional information to facilitate the analysis of the report. In some cases, an ISMP Canada staff member may also discuss with the consumer the benefits of inviting the health professional(s) involved to contact ISMP Canada to participate in the follow-up and analysis of the incident.

Many Canadian consumers are already familiar with Health Canada's MedEffect™ site, which provides safety information about marketed health products and about the Canada Vigilance Program. The Canada Vigilance Program has the capability to collect and analyze reports of medication incidents, but is chiefly intended to capture information on adverse drug reactions— non-preventable adverse events that occur when marketed drugs are used as intended. It is important to note that the Canada Vigilance Program collects information only on events where *actual* harm has occurred, while CMIRPS captures information on near misses and hazardous situations. It will be necessary to develop mechanisms to address potential consumer confusion and overlap between the Canada Vigilance Program and the CMIRPS consumer reporting and learning component. Mechanisms could include conducting information campaigns for consumers and health professionals, inclusion of screening questions in reporting forms and collaboration and sharing of information between the programs. ISMP Canada will work with Health Canada to develop mechanisms to avoid duplication of effort and to maximize learning.

ISMP Canada will respond to issues identified through consumer reporting by working with consumers, health professionals and medication safety experts to identify or develop strategies to prevent errors and to mitigate harm. These strategies may take the form of recommendations to health care professionals regarding system changes, recommendations to manufacturers on packaging and labelling, or advice to consumers on strategies to reduce the likelihood of experiencing an adverse event. The knowledge generated will form the basis of consumer-focused medication safety bulletins and will also contribute to bulletins and alerts designed for health professional audiences.

With an established track record and expertise in incident reporting and analysis, ISMP Canada is ideally positioned to develop the consumer reporting and learning component of CMIRPS. By providing consumers with a reliable and accessible source of medication safety information and an effective process to report medication incidents, Canada's capacity to learn from medication incidents will be strengthened and consumers will become participants in efforts to improve the safety of medication systems.

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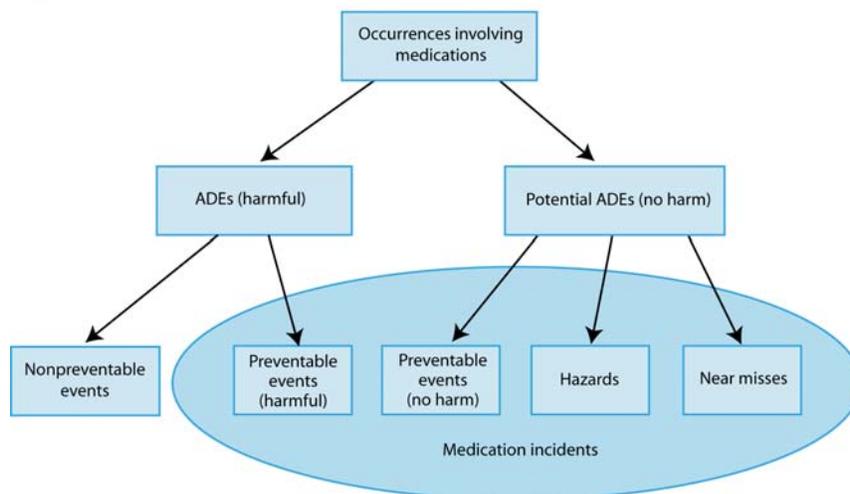
A Consumer Reporting and Learning Strategy for the Canadian Medication Incident Reporting and Prevention System

1. Introduction

Canadian consumers are increasingly becoming aware of the health risks associated with complications from drug therapy. The Canadian Adverse Events Study found that the administration of drugs and fluids is frequently associated with adverse events in Canadian hospitals,⁶ and harmful medication incidents have received extensive coverage in the lay press. In a recent survey of adults with health problems, nearly one in ten Canadians reported receiving the wrong medication or the wrong dose when filling a prescription at a pharmacy or when hospitalized within the previous two years.⁷ While not all medication incidents lead to a harmful adverse event, medication incidents are clearly an important health safety issue in Canada.

The term “adverse drug event” is used to describe any drug-related event that causes harm. Adverse drug events include *adverse drug reactions*, which are generally considered non-preventable, and *medication incidents* (also referred to as “medication errors”⁸) which are preventable (see Figure 1⁹).

Figure 1 Schematic representation of medication incidents and adverse drug events (ADEs)



⁶ 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

⁷ Commonwealth Fund 2008 International Health Policy Survey of Sicker Adults, [cited 2009 May 24]. Available from http://www.commonwealthfund.org/~media/Files/Surveys/2008/The%202008%20Commonwealth%20Fund%20International%20Health%20Policy%20Survey%20of%20Sicker%20Adults/IHP2008_CMWF_DSQ_for_web%20pdf.pdf

⁸ Definition of terms [Internet]. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2008 [cited 2008 Nov 3]. Available from: <http://www.ismp-canada.org/definitions.htm>

⁹ From Safe and Effective, The Eight Essential Elements of an Optimal Drug Use System, Canadian Pharmacists Association 2007.

Often, medication incidents are caused by inherent system problems that can be identified and corrected if the incidents are reported and analyzed. Incident reporting systems are particularly effective when reports are collected from multiple sources and shared broadly.

Canada has recently made great strides in medication incident prevention through the development of the Canadian Medication Incident Reporting and Prevention System (CMIRPS). CMIRPS has been developed through the collaborative efforts of Health Canada, the Institute for Safe Medication Practices Canada (ISMP Canada), and the Canadian Institute for Health Information (CIHI), with input from stakeholders across Canada and ongoing collaboration with the Canadian Patient Safety Institute (CPSI). The aim of CMIRPS is to reduce and prevent harm from medication incidents, by managing and sharing learning from voluntarily-reported information about medication incidents. A recent ISMP Canada bulletin with information on CMIRPS is attached as Appendix I.

CMIRPS collects and analyzes reports on potential and actual medication incidents. The reporting of near misses and hazardous situations is considered as important as collecting information on actual adverse events, since this allows latent conditions to be corrected and actual errors to be prevented. Currently, the CMIRPS program includes hospital-based reporting (in which hospitals collect reports and then submit the reports to CMIRPS through CIHI's National System for Incident Reporting) and individual practitioner reporting (in which individual practitioners from any health care setting can submit a report directly to CMIRPS through ISMP Canada).

Consumers who have experienced medication incidents often have a strong desire to convey information that may prevent others from being harmed. Recognizing the interest of consumers in sharing information about medication incidents and the associated potential to enhance medication safety learning, the original CMIRPS vision incorporated the inclusion of consumer reporting. The individual practitioner reporting component of CMIRPS has already accepted reports from consumers and consumer reports have formed the basis of two previous ISMP Canada Safety Bulletins^{10, 11}. The program has not been promoted to consumers, however, and the volume of reports submitted by consumers has been low. CMIRPS is now ready to move forward with a strengthened and coordinated approach to consumer reporting and learning.

ISMP Canada is ideally positioned to develop the consumer reporting and learning program for CMIRPS. ISMP Canada offers:

- Credibility and recognized leadership in medication safety, nationally and internationally. (ISMP Canada publications have been referenced in publications of the World Health Organization, the National Patient

¹⁰ Codeine Syrup-Dangerous "Near Miss" in the Community. ISMP Canada Safety Bulletin, Volume 2 Issue 3, Mar 2002.

¹¹ Patient Report of Insulin Mix-up Shared. ISMP Canada Safety Bulletin, Volume 7 Issue 6 Dec 8, 2007.

Safety Agency of the NHS in the UK, as well as the Australian Council for Safety and Quality in Healthcare.);

- An established online medication incident reporting system that can serve as the foundation for a consumer reporting program;
- A process and infrastructure that facilitates rapid review and timely response to reports;
- An extensive collection of medication safety information and tools that, with appropriate modifications, can be readily shared with consumers;
- An interdisciplinary staff of medication safety experts, with extensive experience in collecting medication incident reports, analyzing causes and developing strategies to prevent errors and mitigate harm from errors;
- An established network of health professionals, willing to provide advice and expertise to ISMP Canada's medication safety endeavours;
- Experience in handling confidential and sensitive information. All ISMP Canada staff, consultants and service providers must sign confidentiality agreements and must adhere to ISMP Canada policies and procedures which, at a minimum, meet the provincial and national privacy legislation requirements and standards;
- Positive working relationships and established, effective communication mechanisms with CMIRPS partners and other patient safety organizations (within Canada and globally);
- A strong working relationship with ISMP US, which will allow the CMIRPS consumer reporting and learning component to benefit from groundwork, experience and knowledge gained from the ISMP US consumer reporting and learning program.

ISMP Canada's responsibility for the CMIRPS consumer reporting and learning program is consistent with its role in the analysis and dissemination of information collected through the health service and individual practitioner reporting component of CMIRPS.

2. Rationale for a Consumer Reporting and Learning Strategy

A recent US Institute of Medicine report, "Preventing Medication Errors", argues that optimizing medication safety requires a fundamental shift away from the traditional top-down (i.e. provider to patient) approach to care, in favour of a patient-centered model characterized by true "consumer-provider partnerships".¹² The report notes that "*The most powerful strategy for improving safety may be motivating providers and organizations to support the full engagement of patients and surrogates in improving the safety of medication use*".¹³ The report describes a new vision for a patient-centered, integrated medication-use system. A

¹² Committee on Identifying and Preventing Medication Errors, P Aspden, J Wolcott, JL Bootman, LR Cronenwett, eds. *Preventing Medication Errors: Quality Chasm Series*. National Academies Press, 2006. Page 153. [cited 2009 Feb 19]. Available from http://books.nap.edu/openbook.php?record_id=11623&page=153

¹³ *ibid* Page x, [cited 2009 Jan 13]. Available from http://books.nap.edu/openbook.php?record_id=11623&page=R10

prominent feature of the vision is that *“reporting systems with multiple options capture reports of medication errors from patients and families”*.¹⁴

In recognition of the need for an expanded role for consumers in patient safety initiatives, the World Health Organization’s (WHO’s) World Alliance for Patient Safety has established a “Patients for Patient Safety” initiative. The WHO’s website notes that this initiative is *“designed to ensure that the perspective of patients and families, consumers and citizens – whichever term resonates best -- in both developed and developing countries is a central reference point in shaping the important work of the Alliance.”* Information on the site points out that *“Patients and their lay caregivers see things that busy healthcare workers often do not. It follows that safety will be improved if patients are included as full partners in reform initiatives, and learning can be used to inform systemic quality and safety improvements.”*¹⁵ The Canadian arm of this initiative, Patients for Patient Safety Canada (PFPS Canada), is now being supported by CPSI and is actively collaborating with healthcare providers to improve patient safety. A recent publication authored by a PFPS Canada leader highlights the need to move away from the paternalistic attitudes that have excluded patients from meaningful involvement in the past, and to recognize patients as true partners who share a deep interest in improving the system¹⁶. Representatives from PFPS Canada provided valuable advice to ISMP Canada on the development of this consumer reporting and learning strategy.

Involving consumers in reporting incidents and sharing learning related to medication incidents can help to build trust between consumers and healthcare providers. The Patients for Patient Safety (World Alliance) site recognizes that consumers may be perceived as potential antagonists when an error occurs, and this may have previously impeded the meaningful involvement of consumers in identifying contributing factors and potential system improvements. *“At the healthcare service delivery level, consumers who wish to contribute knowledge gained or lessons learned have often found few effective pathways for doing so...When consumers register concerns their actions are often perceived as adversarial threats or unscientific anecdotes rather than potential knowledge contributors.”*⁹ Educating consumers on the systems aspect of medication incidents will encourage a focus on collaborative initiatives to enhance safety.

Interest in consumer reporting of adverse events continues to grow. In the US, the Agency for Healthcare Research and Quality (AHRQ) recently awarded a large contract to the organization “Consumers Advancing Patient Safety” (CAPS) and two partners for the development of recommendations for a possible patient safety event reporting system for consumers. The project will identify types of information to be collected from consumers and determine the best mechanisms for information capture.¹⁷

¹⁴ ibid page 146, [cited 2009 Feb 19]. Available from http://books.nap.edu/openbook.php?record_id=11623&page=146

¹⁵ [cited 2009 Jan 13]. Available from http://www.who.int/patientsafety/patients_for_patient/statement/en/index.html

¹⁶ Kovacs Burns, Katharina, Canadian Patient Safety Champions:Collaborating on Improving Patient Safety Healthcare Quarterly Vol 11 (Special Issue, Patient Safety Papers) 2008; p.95-100.

¹⁷ CAPS Partnering with RTI and Baruch College to Design Consumer Reporting Systems for Patient Safety Events [cited 2009 Feb 11]. Available from http://www.patientsafety.org/index.v3page?ct=cdisplay&nt=true&cd_eid=66008

2.1 Enhancing the Medication Safety Knowledge of Consumers

Consumers have a significant vested interest in improving healthcare system safety. In spite of a growing consensus on the importance of including patients in efforts to improve the safety of their care, the healthcare community continues to struggle with establishing meaningful roles and methods for consumer engagement. Clearly, in order to have an impact on the safety of their care, health consumers must be both **informed** and **empowered**. The Institute for Healthcare Improvement (IHI) notes that *“Patient-centred care puts responsibility for important aspects of self-care and monitoring in patients’ hands — along with the tools and support they need to carry out that responsibility.”*¹⁸ A recently published text entitled “Engaging Patients as Safety Partners” also notes the importance of “sharing information that empowers patients to prevent errors”¹⁹. Armed with appropriate and reliable information on their medications and medication safety issues, consumers will be more likely to engage in dialogue and activities that will lead to true patient-centred care and ultimately to enhanced patient safety.

Although Health Canada, CPSI and provincial patient safety organizations have taken some steps to educate consumers on health safety issues, including the development of a variety of brochures outlining the role of consumers in preventing errors, there is clearly an opportunity to enhance Canadian consumers’ access to accurate and unbiased information specifically focused on medication safety. To be proactive about their own medication safety, consumers require information on why medication incidents occur, the consequences of medication incidents, the steps that a consumer can take to reduce the chances that he or she will experience an adverse event from a medication incident and information on what to do and expect if a medication incident occurs. There is a need for targeted information on safe medication use and practical tools that consumers can use to enhance medication safety.

2.2 Enhancing the Quantity and Quality of Reports Collected by CMIRPS

It is generally accepted that incident reporting systems capture only a small percentage of events and near misses that occur. Studies conducted in the hospital setting have demonstrated adverse event rates far in excess of those typically documented by in-house reporting systems¹ and the results of a survey conducted in the UK in 2004 suggested that pharmacists and support staff in community pharmacies are unlikely to report adverse events.²⁰ Consumers are an untapped resource that can be expected to increase the volume of reports received by CMIRPS.

¹⁸ [cited 2009 Feb 18]. Available from <http://www.ihl.org/IHI/Topics/PatientCenteredCare/PatientCenteredCareGeneral/PatientCenteredCareGeneralHome.htm>

¹⁹ Spath PL, Safety from the Patient’s Point of View, In: Spath PL Ed. Engaging Patients as Safety Partners, A Guide for Reducing Errors and Improving Satisfaction. Chicago, (IL) AHA Press 2008. p 27.

²⁰ Ashcroft DM, Morecroft C, Parker D, Noyce PR, Likelihood of reporting Adverse Events in Community Pharmacy: An Experimental Study. Qual Saf Health Care 2006;15: 48-54.

- Consumers who have experienced incidents often have a strong desire to share information that may prevent others from being harmed, but may be frustrated by the lack of opportunities to do so.
- Consumers may be aware of incidents that have not been identified or reported by care givers. In a 2005 study that contrasted adverse events identified through medical record review with adverse events identified through patient interviews (during hospitalization and by telephone 10 days post-discharge), only 11 (55%) of 20 adverse events and 4 (31%) of 13 near misses identified by patients had been documented in the medical record; none were found in the hospital's incident reporting system.²¹ In a more recent study where patients were interviewed post-discharge regarding adverse events that occurred during their care, 23% had at least one adverse events detected in the interview, while only 11% of these patient had an error detected through medical record review.²²
- Consumers may be willing to take the time to report incidents that were not reported by health professionals due to time constraints.

Canadian consumers' interest in medication-related safety issues and willingness to report problems is reflected by information provided in a recent report of Canada's Standing Committee on Health, which notes that the percentage of the adverse drug reaction reports submitted by consumers to Health Canada's Canada Vigilance Program increased from 7.1% to 24.2% between 1998 and 2006.²³ The percentage of reports submitted by consumers continues to rise; in 2007 consumers/patients submitted 29.2% of all adverse reaction reports received by the program, making this the second largest group reporting adverse drug reactions, after physicians.²⁴ Health Canada has provided a number of tools to promote and support consumer reporting of adverse drug reactions, including online presentations and guidebooks.²⁵

Consumers can clearly play an active role in identifying underlying factors that contribute to errors. It is anticipated that this will enhance the quality of incident analyses, since:

- Consumers will bring a new perspective to the analysis of medication incidents. Patients and families may have observed the full sequence of events leading to an incident, while individual health professionals may only have witnessed one aspect.
- Consumers can provide insight into factors that may not be immediately evident to health professionals (e.g. utility of directions, labelling and packaging in the home setting). A UK study that interviewed patients who

²¹ Weissman JS, Pagovich O., Sands DZ, Li JM, et.al., What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents. *J. Gen Intern Med* 2005 Sept 20 (9) 830-6.

²² Weissman JS, Schneider EC, Weingart, SN, Epstein, AM et.al, Comparing patient-reported hospital events with medical record review-do patients know something that hospitals do not? *Ann Intern Med* 2008 Jul 15; 149 (2): 100-8.

²³ House of Commons Canada Report of the Standing Committee on Health, Post marketing Surveillance of Pharmaceuticals, June 2008 page 6 [cited 2009 Jan 13]. Available from <http://www2.parl.gc.ca/content/hoc/Committee/392/HESA/Reports/RP3598191/hesarp07/hesarp07-e.pdf>

²⁴ Adverse Reaction Reporting 2007, Canadian Adverse Reaction Newsletter 18(2) April 2008 [cited 2009 Jan 16].

Available from http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei_v18n2-eng.php#table2b

²⁵[cited 2009 Jan 16]. Available from <http://www.hc-sc.gc.ca/dhp-mps/medeff/centre-learn-appren/index-eng.php#1>

had used infusion pumps demonstrated benefit in seeking patients' views, since this "raised new and important issues for consideration."²⁶

2.3 Access to Consumer Reporting Programs for Medication Incidents

The national and collaborative CMIRPS program vision was designed to avoid duplication of efforts. Unlike other countries where multiple programs collect medication incident reports from consumers and health professionals, Canadian efforts have focused on the development of a single collaborative program, through which key partners share responsibility for the collection and analysis of incident reports and dissemination of learning. A brief overview of Canadian programs with related, but different, mandates follows.

Licensing bodies (e.g. provincial Colleges of Physicians and Surgeons, Nurses, and Pharmacists) typically have "complaints" processes through which consumers can report events. These processes have tended to focus on the actions of individual practitioners rather than underlying system issues.

The Canadian Patient Safety Institute (CPSI) has a broad patient safety mandate, but does not accept incident reports from health professionals or from consumers. A recently-published consultation paper on a proposed Canadian Adverse Event Reporting and Learning System (CAERLS) recognizes a potential role for consumers in reporting patient safety events and includes a key recommendation that "*The Canadian Medication Incident Reporting and Prevention System (CMIRPS) will form the basis for the medication portion of a pan-Canadian adverse event reporting and learning system,*"²⁷ therefore the inclusion of a consumer reporting and learning program in CMIRPS is consistent with the approach recommended in the CAERLS consultation paper.

Various provincial patient safety programs exist, but the collection of incident reports from consumers is currently not a focus. Saskatchewan, Manitoba and Quebec have mandated the reporting of serious adverse events by healthcare organizations, but consumer reporting programs have not been established. The web-based reporting tool of British Columbia's Patient Safety and Learning System is accessible only to healthcare providers. The Health Quality Council of Alberta (HQCA) does not collect reports of specific individual incidents, although, consistent with its mission of "listening and responding to patients" direct surveys of Alberta consumers are conducted. (Medication errors were the second most common type of medical error described by respondents to a 2004 HQCA survey).²⁸ The Manitoba Institute for Patient Safety (MIPS) has made a commitment to communicate about patient safety matters with patients, families and citizens in general, but its mandate is much broader than that of medication

²⁶ Richardson A, Infusion Pumps: The Views of Patients In: Spath PL Ed. Engaging Patients as Safety Partners, A Guide for Reducing Errors and Improving Satisfaction. Chicago, (Il) AHA Press 2008. p 31-40.

²⁷ Building a Safer System- The Canadian Adverse Event Reporting and Learning System Consultation Paper, Canadian Patient Safety Institute, July 2008, Page 4, [cited 2009 Jan 12]. Available from http://www.patientsafetyinstitute.ca/uploadedFile/Resources/CAERLS_Consultation_Paper.pdf

²⁸ Health Quality Council of Alberta- Playing it Safe, You and Your Medication in Health Report to Albertans, Jan 2007, [cited 2009 Jan 15]. Available from <http://www.hqca.ca/assets/pdf/HQCA%20Health%20Report%202007.pdf>

safety and direct reports of incidents are not accepted. Neither the Ontario Health Quality Council nor the Ontario Hospital Association's Patient Safety Support Service collect reports of incidents. The CMIRPS program's consumer reporting and learning component will generate additional information that can be disseminated by patient safety organizations at the provincial level.

Health Canada has recently developed the "MedEffect™" website, which provides centralized access to safety information about marketed health products. The website is also intended to raise awareness about Health Canada's adverse drug reaction reporting program, the Canada Vigilance Program. Consumers/patients are specifically recognized as potential reporters to the Canada Vigilance Program, in addition to health professionals, manufacturers and distributors.²⁹ The Canada Vigilance Program has the capability to collect and analyze reports of medication incidents, but is chiefly intended to collect information on adverse drug reactions— non-preventable adverse events that occur when marketed drugs are used as intended. In keeping with the Program's mandate, the primary focus for analyses of data and communication with practitioners is the risks inherent in the properties of the drug itself. The clinical skills required for the analysis of adverse drug reactions differ considerably from those required for medication incident analysis. It is also important to note that the Canada Vigilance Program collects information only on events where *actual* harm has occurred, while CMIRPS captures information on near misses and hazardous situations.

2.4 Successful Consumer Reporting and Learning Programs in Other Countries

The US Food and Drug Administration's (FDA's) MedWatch program, which collects safety information and adverse event reports, accepts reports from consumers. The MedWatch program has a dedicated webpage for consumers, which provides information on the program, links to product safety information, a sign-up option for MedWatch safety alerts and information on toll-free lines that can be used to obtain information on medical products. Consumers who believe that an adverse reaction has occurred are encouraged to take the reporting form to a physician for completion, but the consumer may also opt to complete an online form if they do not wish to have the form filled out by the health care provider. Although the focus of the MedWatch program is adverse drug reactions, reports of medication incidents are also accepted. There have been criticisms that the terminology on the MedWatch program's forms and telephone services will present problems to the average consumer and that the instructions to fill out the forms in cooperation with a doctor will discourage patients from completing the forms themselves.³⁰

²⁹[cited 2009 Jan 14]. Available from <http://www.hc-sc.gc.ca/dhp-mpps/medeff/faq/index-eng.php#1>

³⁰Committee on Identifying and Preventing Medication Errors, P Aspden, J Wolcott, JL Bootman, LR Cronenwett, eds. *Preventing Medication Errors: Quality Chasm Series*. National Academies Press, 2006. Page 28, [cited 2009 Jan 17]. Available from http://books.nap.edu/openbook.php?record_id=11897&page=28

Reports submitted to MedWatch are tracked by the FDA's Adverse Event Reporting System (AERS), which also includes mandatory and non-mandatory reports submitted by manufacturers. Information on AERS reporting by health providers and consumers between 1999 and 2008 indicates that the percentage of reports submitted by consumers is significant. Between 1999 and 2005, the percentage of reports submitted by consumers ranged from 21.1%-38% and for 2006, 2007 and the first three quarters of 2008 the percentage of reports submitted by consumers was 40.8%, 46.2% and 44.9% respectively.³¹ Additionally, in reporting on the new "QuarterWatch" pilot program, which analyzes and classifies excerpts of adverse drug events reported to the FDA, ISMP US noted a 40% increase in the average number of cases reported between April and June of 2008 compared to the average of reported cases in 2007, and also noted that the increase came about equally in reported cases submitted by consumers and health professionals.³²

The Institute for Safe Medication Practices (US) has recently launched a website for consumer reporting and learning related to medication incidents, www.consumermedsafety.org. In addition to providing access to an online medication incident reporting form, the site provides consumers with safety articles and drug alerts. Consumers can register to receive customized safety alerts based on medications being taken by them or by their family members. The educational focus of the ISMP US website can be expected to generate considerable traffic which in turn could be anticipated to generate additional reporting. Information on the number of medication incident reports submitted to the ISMP US website is not currently available, but the learning aspect of the site has clearly been well-received, with over 40,000 unique visitors to the site during its first month of operation (December 2008). Nearly 10,000 individuals signed up to receive safety alerts, of which 6,970 could be confirmed by return email from their addresses.³³

In the United Kingdom (UK), the National Patient Safety Agency (NPSA) National Reporting and Learning System (NRLS) collects reports of patient safety incidents, including medication incidents, in National Health Service (NHS) organizations in England and Wales. Although the majority of reports are collected through the risk management services of NHS organizations, patients and the public are able to report incidents using a dedicated online reporting form which was made available in April 2006.

The UK Medicines and Healthcare Products Regulatory Agency (MHRA) collects information on adverse drug reactions through the "Yellow Card Scheme". This program began collecting reports from health professionals over forty years ago but began accepting reports from consumers only in 2005, initially on a pilot

³¹ Calculated from statistics available from

http://www.fda.gov/cder/aers/statistics/aers_hcp_consumer.htm [cited 2009 Jan 17].

³² ISMP QuarterWatch (2nd quarter 2008)- Questions arise regarding manufacturing practices, recall effectiveness and premarket testing for psychiatric side effects. ISMP Medication Safety Alert, Acute Care edition 14(1) Jan 15, 2009.

³³ Email communication to ISMP Canada from ISMP US, Jan 5, 2009.

basis.³⁴ The consumer program uses a specially-designed reporting form; reports can be made over the internet or can be submitted on a hard copy of the form which can be downloaded from the internet or obtained from pharmacies. Reports can also be submitted by phoning a toll-free number. The MHRA website notes that “*The pilot demonstrated that patient reporting provides valuable information and was established as a permanent part of the Scheme in February 2008 with new paper and online reporting forms.*”³⁵ A recent MHRA newsletter asks health professionals to encourage patients to submit reports to the Yellow Card Scheme.³⁶

The potential overlap between the NRLS and the Yellow Card Scheme is addressed by reminders in the NRLS reporting form, which direct reporters to complete a Yellow Card form if an adverse drug reaction has occurred.

In Australia, consumers can submit reports on both adverse drug reactions and medication errors to an “Adverse Medicines Events Line.” The line, launched in 2003, is manned by clinical pharmacists, who are available on weekdays to respond to queries, provide medication safety information to consumers and collect reports. The involvement of the pharmacists in the process helps to ensure that specified reporting criteria are met.³⁷ A recent report of the Australian Commission on Safety and Quality in Health Care notes that “*the service is proving successful in contributing to identifying previously unrecognised reactions, as evidenced by consumer reports of adverse events associated with hypnotics*”.³⁸ An Adverse Medicine Events Line website also provides separate reporting forms for medication errors and adverse drug reactions that allow consumers, relatives, doctors or others to submit reports online.

³⁴ MHRA press release 25 Oct 2005 [cited 2009 Jan 17]. Available from

<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Medicines/Reportingsuspectedadversedrugreactions/Patientreporting/index.htm>

³⁵ From “Questions and Answers on Yellow Card data, MHRA website [cited 2009 Jan 19]. Available from

<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Medicines/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/Druganalysisprints/QuestionsandanswersonYellowCarddata/index.htm>

³⁶ MHRA Drug Safety Update 2 (7) Feb 2009 [cited 2009 Mar 07]. Available from

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON038625>

³⁷ Australian Prescriber, 27(2) April 2004 Page 38, [cited 2009 Jan 19]. Available from

<http://www.australianprescriber.com/upload/pdf/articles/502.pdf>

³⁸ Australian Commission on Safety and Quality in Health Care (October 2008), Windows into Safety and Quality in Health Care 2008, ACSQHC, Sydney (Chapter 4 Medication Safety)

3. Proposed Consumer Reporting and Learning Program for CMIRPS-Overview

Based on an identified need and the experience with medication-related consumer reporting programs in other countries, it is clear that the establishment of a strengthened and coordinated approach to consumer reporting and learning should be a priority for CMIRPS.

Consumer reports are currently collected by ISMP Canada, but there is a need for a unique CMIRPS consumer reporting and learning component that is specifically designed to provide consumer-oriented medication safety information and collect reports from members of the public. For the purpose of establishing the target audience for the program, “consumers” will be defined as *patients, family members, caregivers or any other individual who may be acting for, or in support of, a patient or client receiving health care.*³⁹

As consumers increasingly turn to the internet for health information, the establishment of a reliable website with high-quality consumer-oriented information about medication safety can be expected to have a positive impact on patient knowledge and improve health outcomes. This knowledge will also equip consumers to join health professionals in the reporting and analysis of medication incidents, which will improve the safety of medication systems in Canada.

3.1 Goal

To strengthen Canada’s capacity to enhance medication safety by increasing the involvement of consumers in the Canadian Medication Incident Reporting and Prevention System.

3.2 Objectives

- To provide an improved mechanism for the collection of medication incident reports from consumers,
- To increase overall medication safety learning through the increased volume of reports and information contributed by consumers.
- To increase consumers’ knowledge and awareness related to medication incidents and safe use of medications.

³⁹ Adapted from definition provided in Consumer Adverse Event Reporting AHIC Extension Gap US Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Dec 31, 2008 Page 20 [cited 2009 Jan 15]. Available from <http://www.hhs.gov/healthit/usecases/documents/CAERFinalExtGap.pdf>

3.3 System Attributes:

- **Confidential and Secure:** A consumer may provide information on his or her identity for “follow-up” purposes, but that information will be protected and kept confidential.
- **Easy to use:** The system will be user-friendly and readily accessible for Canadian consumers. All information, reporting forms and processes will be tailored to meet the needs of consumers.
- **Focused on learning:** Information collected by the system will be used for learning about *why* errors occur and the corrective and preventative steps that can be taken. Information will not be used to blame health care practitioners. Information gained will be used to inform changes in the way a medication is used, including how it is prescribed, dispensed or administered.
- **Complementary:** The consumers reporting and learning component will complement other components of the CMIRPS program. The CMIRPS program complements the existing reporting system for adverse drug reactions (Canada Vigilance System).
- **Collaborative:** The system will enable consumers and healthcare providers to work together to improve reporting and improve patient safety. The system will also provide mechanisms for collaboration among provincial, national and international safety organizations.

4. CMIRPS Consumer Reporting and Learning Website

A unique CMIRPS consumer reporting and learning website will be established. To avoid duplication of effort, information for the CMIRPS consumer reporting and learning website will be adapted from ISMP Canada’s existing forms and publications. The English language version of the website will use the domain name of www.safemedicationuse.ca and the French language version will be found at www.medicamentssecuritaires.ca. The website will be accessible through links from key websites, which could include, for example:

- The ISMP Canada main website
- Health Canada’s Med Effect™ website
- Health Canada’s Consumer Product Safety website
- CIHI’s CMIRPS webpage
- Patients for Patient Safety Canada website
- Consumer association and consumer advocacy websites
- The websites of caregiver associations
- CPSI’s website
- Provincial Ministry of Health websites
- Professional licensing body websites
- The websites of provincial patient safety organizations (e.g. MPSI, HQCA)
- The websites of major Canadian pharmacy chains
- The websites of hospitals and health districts

It is proposed that, in addition to incident reporting functions, the site will have a significant educational element. Although discussion with stakeholder groups and consumers will be necessary to determine the specific content, examples of information that could be provided include:

- Information on how to report a medication incident;
- General information on medication incidents and incident reporting programs, for example:
 - A definition of a medication incident,
 - The importance of reporting medication incidents so that future incidents can be prevented,
 - The rationale for a non-blame, non-punitive approach
- General consumer-oriented publications pertaining to safe medication use, e.g. how can consumers reduce their chances of experiencing a medication incident;
- Medication safety bulletins and alerts, with content specially designed for consumers (based on reports submitted by consumers as well as reports submitted to the CMIRPS program through other components such as the individual practitioner reporting program and the hospital-based reporting program);
- Practical tools for enhancing medication safety- e.g. downloadable forms for consumers to record medication use lists;
- Notifications of, and links to, Health Canada advisories;
- Information on the difference between adverse drug reactions and medication incidents, with a link to the Canada Vigilance Program reporting form;
- A “Frequently Asked Questions” section.

Information on both the English and French language sites will be provided in a format and literacy level that will be readily understood by consumers.

5. Collection of Medication Incident Reports

An important focus of the CMIRPS consumer website will be the collection of medication incident reports from consumers. A consumer-oriented online reporting form will be developed, by modifying ISMP Canada’s existing online medication incident reporting system to incorporate consumer-friendly terminology. To allow shared learning across CMIRPS datasets, key data fields in the online consumer reporting form will be mapped to those used in other CMIRPS components.

Although it is anticipated that the majority of reports will be collected through the web-based system, the option of telephone reporting in either official language will be available for consumers who are unable to submit a report through the website.

ISMP Canada will work with the CMIRPS partners to align the consumer reporting and learning program with other medication incident reporting components of CMIRPS. ISMP Canada will be responsible for ensuring effective performance with respect to

- Data standards development and maintenance;
- Secure data collection, transmission protocols, processing and data quality;
- Analysis and reporting;
- Systems to safeguard privacy and
- Promotion and communication services

The consumer reporting and learning program will initially be offered on a pilot basis to a limited audience.

6. Privacy and Confidentiality

Because medication error information stems from an event that has been experienced by an individual patient or consumer, sharing of incident information may raise concerns about privacy and confidentiality. As reflected in the Canadian Standards Association (CSA) Model Code and in privacy legislation nationally, fair information practices require that collection of information be limited to what is required for the purposes of an activity.

This is significant in light of the characteristics of incident information. It is important to remember that, unlike some other types of information related to errors or incidents, medication incident reports need only consist of facts about the incident that are non-identifying — information that is about the incident itself, and not about the person who was the subject of the information.⁴⁰ Nonetheless, privacy is of great importance. It is recognized that consumer reports may be submitted directly by patients who have experienced errors and as such, the reporter contact information may reveal the identity of the involved patient. For this reason, and in light of the best-practices related to limiting collection of identifying information, the consumer reporting and learning program may begin by collecting only anonymous reports during the pilot stage. The implications of anonymous reporting and the feasibility of collecting reporter contact information at a later stage would be explored during the pilot.

It is anticipated that consumers will eventually be offered the option of providing contact information when an incident is reported, for the purposes of follow-up. The option of anonymous reporting will continue to be offered and collection of contact information will only happen with the informed and voluntary consent of the consumer. ISMP Canada will put processes in place to ensure that, where the reporter chooses to provide contact information, this contact information will be retained only for an appropriate follow-up period, after which it will be destroyed.

⁴⁰ Weisbaum, K, Hyland S. Morton, E. Striking a Balance: Facilitating Access to Patient Safety Data While Protecting Privacy Through Creation of a National Harmonized Standard, March 2008, [cited 2009 Mar 08]. Available from [http://www.patientsafetyinstitute.ca/uploadedFiles/Research/Final%20Report\(7\).pdf](http://www.patientsafetyinstitute.ca/uploadedFiles/Research/Final%20Report(7).pdf)

ISMP Canada is committed to protecting the privacy, confidentiality and security of all information with which it is entrusted in order to carry out its mandate. All processes and practices used to collect, analyze and communicate medication incident reports from consumers will be consistent with ISMP Canada's Privacy Policy, available at

<https://www.ismp-canada.org/download/ISMPCanadaPrivacyPolicy.pdf>

The consumer reporting and learning website will provide information on ISMP Canada's Privacy Policy. Consumers will have access to a downloadable copy of the full privacy policy and will also be provided with a summary of relevant points from the privacy policy in consumer-appropriate language. This summary will address potential concerns that the consumers might have with respect to protection of their personal privacy and processes to be followed to protect the identity of health professionals involved in the incident. During the reporting process, consumers will be provided with clearly visible online reminders that personal identifying information should not be included within the report and that sensitive personal information such as a social insurance number or date of birth should not be provided. Additionally, as for reports submitted to the individual practitioner reporting program, all consumer reports received by ISMP Canada will be reviewed and cleansed in accordance with the privacy policy and procedures and to protect against inadvertent submission of identifying information.

7. Analysis and Follow-up of Reports

Analysis of medication incident reports submitted by consumers will be in accordance with the CMIRPS Medication Incident Analysis and Learning Framework[®]. Each report will be screened by an ISMP Canada's expert analyst to determine its analysis priority. Medication incident reports of high severity and frequent occurrence will be given priority for analysis. An Analysis Prioritization Matrix (APM) will be used to determine whether a particular report will be

- immediately analyzed
- assigned to a predetermined category for aggregate analysis if a threshold number of reports for the category is reached, or
- flagged in the ISMP Canada database for possible use in monitoring trends

ISMP Canada's APM takes into consideration the actual severity of the event, the potential severity of the event and the likelihood of recurrence of the event. This ensures that near misses with the potential for severe harm will be prioritized appropriately.

Where reports are submitted anonymously, consumer involvement would end with the submission of the report. It is recognized that, without the opportunity to conduct follow-up or invite involvement of a health professional, it may not always be possible to fully determine the information necessary (environmental

factors...etc.) to conduct a systems-based analysis of the incident. In cases where a report is incomplete or contains information that ISMP Canada believes may be inaccurate or about which ISMP Canada has unanswered questions, the information will not be analyzed or included in any safety bulletins, reports or other publications.

The implications of anonymous reporting for completeness and accuracy of reporting and overall effectiveness of the program will be assessed during the pilot phase. In the event that reporter follow up is deemed to be integral to the success of the program, the feasibility of developing a mechanism to allow reporters the option of submitting contact information will be explored. Such a mechanism would allow for an expanded consumer role in selected cases. If a report is identified as high priority and the reporter has consented to follow-up, an ISMP Canada staff member may contact the reporter to verify facts and to obtain additional information to facilitate the analysis of the report. Additional information may be requested from the reporter such as:

- Product packaging and labelling samples, if available, or photographs of the item(s)
- Additional information to support event analysis information

Unlike the Canada Vigilance Program's MedEffect™ site¹⁴, the CMIRPS consumer reporting website will not express a preference that consumers submit reports in conjunction with a health professional. Although the inclusion of health professionals provides a mechanism to ensure that relevant health information is included in reports, it may discourage some consumers from reporting incidents in cases involving an error on the part of a health professional. In some cases, however, an ISMP Canada staff member may discuss with the consumer the benefits of inviting the health professional(s) involved to contact ISMP Canada to participate in the follow-up and analysis of the incident.

Situations may also arise where the consumer who reported the incident is not the individual who experienced the incident. For example, a medication incident could be reported by a patient's family member or caregiver. In cases where direct contact with the individual who experienced the error may add accuracy and clarity to the collection of facts, an ISMP Canada staff member may discuss with the surrogate reporter the benefits of including the individual who experienced the medication incident. If determined to be beneficial to the analysis, the ISMP Canada staff member may request that the surrogate reporter invite the individual who experienced the medication incident to contact ISMP Canada.

After information gathering is completed, high priority reports are analyzed by ISMP Canada's expert analysts to identify the nature of the error and possible contributing factors. For a serious incident, ISMP Canada may work with the consumer and relevant health professionals to conduct a full root cause analysis, if this possibility is acceptable to all parties.

It is anticipated that ISMP Canada will conduct a separate analysis for reports submitted by consumers. Information from analysis of consumer reports will add to and complement information received through the individual practitioner and hospital-based components of CMIRPS. Mechanisms will be established to allow learning across the different datasets. The three components of CMIRPS will facilitate detection and identification of hazards in the medication use system.

8. Solutions Development and Information Sharing

ISMP Canada will work with CMIRPS users (including consumers), health professionals and medication safety experts to identify or develop strategies to prevent errors and to mitigate harm in response to issues identified through the analysis of consumer reports. These strategies may take the form of:

- Recommendations to health care professionals regarding system changes,
- Recommendations to manufacturers on packaging and labelling,
- Advice to consumers on strategies to reduce the likelihood of experiencing an adverse event. This may include general strategies or specific strategies that have been designed to address concerns related to a particular medication or class of medication.

Reports from consumers will contribute to the development of safety bulletins designed for health professional audiences as well as safety bulletins designed specifically for consumers.

9. Feedback to Reporters

Prompt feedback to reporters has been credited as a cornerstone without which ongoing participation in incident reporting systems cannot be assured. The consumer reporting and learning system can only achieve its full potential if consumers have an opportunity to see that the efforts they make to submit reports lead to changes and safer services. Feedback to reporters establishes trust in the system, acknowledges the value of reporting efforts, encourages reporters to continue to report and makes reporters more likely to encourage others to report.

Mechanisms that ISMP Canada will use to provide feedback to participating consumers include:

- Provision of an automated online message on completion of a report, to thank the reporter and to provide basic information on the steps in the incident review process and how the information is used. (The current ISMP Canada Individual Practitioner Reporting system provides the following message: *“Thank you for taking the time to share this information with us. Information from medication incident reports is used to identify areas of risk in the medication use system, identify contributing factors*

and causes and make recommendations for the prevention of harmful medication incidents. If you have consented to being contacted and have provided contact information, an ISMP Canada staff member may contact you in the near future to obtain additional information.”),

- Provision of ongoing information on program activities on the CMIRPS consumer website, including
 - safety bulletins/alerts,
 - tailored feedback reports that address issues identified by consumers or describe case histories of how consumer reports have influenced change,
 - Other reports on program activities.

The establishment of a mechanism to collect reporter contact information would allow additional feedback mechanisms to be established, including:

- Direct contact with reporters of selected high priority incidents (where contact information has been provided) to seek additional information as necessary and to provide information to the reporter on next steps,
- For a small number of selected incidents, provision of opportunities to participate in the identification of hazards, contributing factors and potential solutions.

10. Links to Other Programs

Many Canadian consumers are already familiar with Health Canada’s MedEffect™ site, which provides safety information about marketed health products and about the Canada Vigilance Program. Links to and collaboration with the Canada Vigilance Program will be of key importance to the CMIRPS consumer reporting and learning program. Cooperation and collaboration between CMIRPS and the Canada Vigilance Program is necessary for all categories of reporters, but particularly for consumers, who may not be immediately aware of the differences in the mandates of the two programs.

Health Canada, through participation in CMIRPS, works collaboratively with ISMP Canada when adverse events reported to the Canada Vigilance site are associated with a medication incident. Additionally, when ISMP Canada receives incident reports that describe adverse drug reactions, information is forwarded to Health Canada (and the reporter is notified when reporter information is available). ISMP Canada will work with Health Canada to establish additional processes to direct the consumer to the appropriate program and to ensure that report information is shared as appropriate. Other measures that will be considered to improve the flow of information between the programs include:

- Inclusion of prompts in the medication incident reporting form to remind the reporter to consider whether an adverse drug reaction has occurred and to direct the reporter to the Canada Vigilance Program if appropriate.
- Establishment of a formal mechanism for ongoing collaboration between the programs to ensure optimal learning from reports submitted to the respective programs.

ISMP Canada will work with Health Canada to develop mechanisms to avoid duplication of effort and to maximize learning.

11. Stakeholder Consultation

A preliminary strategy document has been forwarded to PFPS Canada, the CMIRPS collaborating parties (Health Canada and CIHI) and CPSI for initial comment. Feedback received has been incorporated into this revised draft, which will then be circulated to additional stakeholders. Organizations approached for input in this second phase of consultation include:

- Consumers' Association of Canada,
- Consumers' Council of Canada,
- Institute for Optimizing Health Outcomes,
- Canadian Association of Retired Persons,
- Provincial patient safety councils/organizations,
- Professional bodies (Canadian Medical Association, Canadian Nurses Association, Canadian Pharmacists Association, Canadian Society of Hospital Pharmacists, Canadian Healthcare Association, Royal College of Physicians and Surgeons, College of Family Physicians Canada),
- Provincial licensing bodies for pharmacy,
- Pharmaceutical manufacturer's associations (Canada's Research-Based Pharmaceutical Companies, Canadian Generic Pharmaceutical Association),
- Accreditation Canada,
- Health Council of Canada,
- Health Canada's Expert Advisory Committee on the Pharmacovigilance of Health Products,
- Other consumer associations, advocacy groups and additional stakeholders as determined by the consultation framework.

All stakeholders are invited to suggest additional organizations for consultation as appropriate.

12. Promotion of the Program

The program will initially be offered on a pilot basis, working with key consumer-based and healthcare organizations. A "newsletter" for initial communication about the program (draft included as Appendix II) has been developed, using consumer-friendly terms and language. This newsletter will be circulated to the appropriate healthcare and consumer organizations for distribution to consumers. ISMP Canada will also approach Health Canada, provincial ministries of health and other organizations to request that information and links be included on key websites.

In preparation for the broader launch of the consumer reporting and learning program, a strategy for marketing and communication will be developed as a component of an overall marketing and communication strategy for CMIRPS.

13. Program Funding

Workload and financial implications of the program will be assessed during the pilot project. Following consultation on the strategy and evaluation of the pilot, ISMP Canada will create a financial plan for the consumer reporting and learning program.

14. Summary

Establishment of a strengthened and coordinated approach to consumer reporting and learning within CMIRPS offers opportunities to increase the involvement of consumers in medication safety activities, educate consumers about medication safety issues and improve the overall safety of medication use systems. With an established incident reporting and analysis infrastructure, access to internal and external expertise, demonstrated leadership in the development of medication safety strategies and established communication mechanisms with other patient safety organizations, ISMP Canada is ideally positioned to develop this program. By providing consumers with a reliable and accessible source of medication safety information and an effective process to report medication incidents, Canada's capacity to learn from medication incidents will be strengthened and consumers will become full participants in efforts to improve the safety of medication systems.

Appendix I

ISMP Canada Safety Bulletin December 22, 2008

Canadian Medication Incident Reporting and Prevention System

Canadian Medication Incident Reporting and Prevention System

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) has been developed through the collaborative efforts of Health Canada, the Institute for Safe Medication Practices Canada (ISMP Canada), and the Canadian Institute for Health Information (CIHI), with input from stakeholders across Canada. Discussions continue with the Canadian Patient Safety Institute to help ensure that CMIRPS is coordinated with other patient safety initiatives.

The aim of CMIRPS is to strengthen Canada's capacity to reduce and prevent harmful medication incidents and to manage and share information about voluntarily reported medication incidents. The term "medication incident" is widely used to refer to the preventable subset of potential and actual adverse drug events. It is also recognized as an alternative term for "medication error".¹ This bulletin provides a brief update on CMIRPS.

Scope and Features of CMIRPS

CMIRPS collects and analyzes reports on potential and actual incidents, both critical and noncritical, related to any medication and occurring at any stage of the medication use system, including prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, and monitoring. The reporting of near misses and hazardous situations is considered as important as collecting information on actual adverse events, since this allows latent conditions to be corrected in a proactive manner.

The features of CMIRPS include the capacity for both *hospital-based* and *individual practitioner* reporting. These two reporting features are complementary and have been developed to enhance the reporting of medication incidents by healthcare practitioners across the continuum of care. Recognizing the interest of consumers in sharing information about medication incidents, a strategy to enhance reporting capability and the associated medication safety learning from consumers is currently under development.

Hospital-Based Reporting

The expertise of CIHI has been instrumental to the development of the hospital-based reporting system. This component includes an analytical tool that will allow participating institutions to conduct individualized analyses using their own data as well as de-identified aggregate data from across Canada. A 4-month national pilot test of a

secure web-based reporting system was launched in November 2008, and there are plans for wider release of the system in 2009.

In addition to the ongoing management and support of the hospital-based reporting feature, CIHI will conduct analytical studies, respond to ad hoc requests for information, and provide stakeholders with comprehensive reports on the data.

Individual Practitioner Reporting

Individual practitioners can report medication incidents to CMIRPS through ISMP Canada. Individual practitioner reporting complements hospital-based reporting and allows for the timely collection and processing of medication incident reports submitted by individuals working in any healthcare setting. Any healthcare practitioner may submit a report, including physicians, nurses, pharmacists, pharmacy technicians, dentists, respiratory therapists, paramedics, and risk managers. Consumers may also submit incident reports directly to ISMP Canada through this component of CMIRPS.

A variety of reporting mechanisms are available to individual practitioners and consumers, including telephone or web portal (electronic) submission. Reports may be submitted anonymously if desired. Processes for reporting are available in both official languages.

Learning, Analysis, and Prevention

Learning, analysis, and prevention are integral to the success of any reporting program. Working collaboratively with a variety of stakeholders, ISMP Canada has a key role in analyzing and disseminating the information collected through CMIRPS. Activities include conducting follow-up of incident reports, providing support for the development and implementation of preventive measures, developing and disseminating information bulletins and alerts, and conducting analytical studies.

Since the inception of CMIRPS, more than 40 issues of the *ISMP Canada Safety Bulletin* have been published reporting the findings of incident analyses to CMIRPS stakeholders. These bulletins, developed in collaboration with practitioners and other stakeholders, are available at the ISMP Canada website (<http://www.ismp-canada.org/ISMPCSafetyBulletins.htm>). The majority of the ISMP Canada Safety Bulletins include recommendations for

preventive measures that can be used to guide system-based improvements.

The Marketed Health Products Directorate within the Health Products and Food Branch has led Health Canada's contribution to the development of CMIRPS. As the regulator, Health Canada has both shared and primary responsibilities related to the management of medication-related risks. Although professional practice issues arising from medication incidents often fall under provincial and territorial jurisdiction, issues relating to the naming, packaging, and labelling of health products fall under

federal jurisdiction. Health Canada and ISMP Canada have been working with stakeholders and the pharmaceutical industry to address issues in these areas when reports and incident analyses indicate that such efforts are warranted.

This bulletin provides an opportunity to express sincere appreciation to the many healthcare professionals, administrators, risk managers, and other individuals in the Canadian healthcare community for their initiative, efforts, and demonstrated support for a culture of safety, exemplified by their sharing of information about medication incidents and related findings.

Reference

1. Definition of terms [Internet]. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2008 [cited 2008 Nov 3]. Available from: <http://www.ismp-canada.org/definitions.htm>

Canadian Failure Mode and Effects Analysis Framework Proactively Assessing Risk in Healthcare

ISMP Canada has developed the *Canadian Failure Mode and Effects Analysis Framework — Proactively Assessing Risk in Healthcare* with support from Health Canada, through the Canadian Medication Incident Reporting and Prevention System, and with assistance from healthcare and human factors engineering consultants.

Failure Mode and Effects Analysis (FMEA) is a proactive safety technique that helps to identify process and product problems before they occur. It is one of several methods of proactive risk assessment that can be used in the healthcare setting, and it is also widely used as an integral aspect of improving quality and safety in a variety of other industries, e.g., automotive, aviation, and nuclear power.

Workshops on FMEA are provided by ISMP Canada; attendees participate in a simulated FMEA, which can be customized to meet the needs of the participants or of individual organizations. According to the feedback we have received from our workshops, the 8 steps for conducting an FMEA described in the Framework constitute a straightforward and understandable technique that users can readily apply to their own practice settings.

ISMP Canada also offers facilitation of site-specific FMEA projects.

For more information, contact ISMP Canada at fmea@ismp-canada.org or 1-866-54-ISMPC (1-866-544-7672).

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ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

Medication Incidents (including near misses) can be reported to ISMP Canada:

(i) through the website: http://www.ismp-canada.org/err_report.htm or (ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.

ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System

Appendix II

Sample Document

Working with Consumers to Prevent Medication Incidents

Medication incidents (also known as medication errors) are an important safety issue for Canadians. Medication errors can happen whenever and wherever medicine is prescribed - in hospitals, nursing homes, clinics, pharmacies, even at home. Most medication incidents don't cause harm, but some have serious consequences. Fortunately, many harmful incidents can be prevented, because medication incidents are often caused by underlying system problems. By collecting and studying reports of medication errors and near misses, problems can be identified and corrected.

This makes the system safer and reduces the chance of incidents happening again.

In the works...

ISMP Canada will develop and maintain a Canadian consumer reporting and learning website, where consumers will be able to report medication incidents. Consumers will also have the option to report incidents by phone. Pharmacists, doctors and nurses will use information provided by consumers to develop ways to reduce the occurrence of harmful medication incidents.

The website will also aim to increase public understanding about medication incidents, and suggest ways to help avoid these incidents.

The website will be confidential, easy to use, will focus on learning and collaboration and will work with existing Canadian systems to improve medication safety.

What will I report?

You will be able to report any medication incident.

Medication incidents are broadly defined as 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.

This includes obvious things such as receiving the wrong medication or dose, but might also include problems such as confusing labeling of a product that **could** lead to someone receiving the wrong medication.

Aren't medication incidents reported now?

There is a reporting system, called the Canadian Medication Incident Reporting and Prevention System (CMIRPS). This system collects medication incident reports, but most reports are submitted by health care workers. CMIRPS needs information that consumers can provide, but there hasn't been a convenient location where consumers can report medication incidents.

With the planned website and telephone number there will be a simple way to report experiences with medication incidents.

The Strategy

Key to making medications safer is a way for consumers to report when they have, or could have been harmed. By collecting and studying these reports, problems can be identified and fixed. This makes prescribing, delivering and taking medication safer for all Canadians. This strategy sets out five key features of a new “reporting and learning” system, that will allow consumers to report medication incidents when someone has been, or could have been harmed.

Confidential and Secure: A consumer may provide information on their identity for “follow-up” purposes, but information will be protected and kept confidential.

Easy to use: The system will be easy for consumers to access and use.

Focused on learning: The system will focus on learning from incidents. Information will not be used to blame health practitioners, nor will a patient be blamed for reporting an incident. By learning *why* errors occur, corrective and preventative steps can be taken.

The information gained from the reports will be used to make changes in the way medication is prescribed or delivered, the way medication information is communicated or the products themselves.

Complementary

This system will complement Canadian systems that are already in place to capture safety information about medications.

Collaborative: Patients, families and healthcare providers can work together to improve reporting and to improve patient safety.

Medication Incidents

Consumers have a large stake in improving medication safety.

- In 2008, nearly one in ten Canadians with health problems reported receiving a wrong medication or dose from a health care provider within the last two years.
- David U, president and CEO of ISMP Canada, says that Canada does not yet have accurate data on the extent of medication incidents, but extrapolation from the US data suggests that about 2% of hospitalized patients experience a preventable adverse drug event and that an estimated 700 deaths per year result from medication incidents.

Further information about ISMP, and the planned Canadian medication consumer reporting and learning system, can be obtained at www.ismp-canada.org

A consumer report of a medication incident

After administering his prescribed dose of insulin one morning, a man was found perspiring and nearly unconscious. Fortunately, the person who found him recognized his symptoms as hypoglycemia, and gave him sugar followed by additional food.

The man had picked up several boxes of his insulin at a community pharmacy at one time. Most of the boxes he had picked up were the correct insulin product, but one box was an ultrashort-acting brand of insulin.

The patient shared the incident with ISMP Canada, in the hope of preventing similar incidents in the future.

What did we learn?

- Both of the medications that the man received had very similar names (they both started with the same four letters),
- Both of the medications looked alike (similar packaging and labeling),
- Both were a form of insulin that require refrigeration, so were likely to be stored close to each other in the pharmacy 'fridge,
- Although a barcode system was used to check medications at the pharmacy, only the first box (which contained the correct product) was scanned.

An incident like this one could have easily happened in other pharmacies.

How can we use what we learned from the consumer report to avoid this type of incident in the future?

The community pharmacy alerted its staff to the incident as a reminder of the standard procedure to check and scan every package during the dispensing process.

ISMP Canada alerted the manufacturer of the insulin to the incident and the look-alike concern. ISMP Canada also offered the following recommendations to pharmacies:

- Pharmacies can segregate insulin products in the fridge, and store them according to their onset of action (e.g. rapid-acting, short-acting, intermediate-acting, long-acting).
- When a patient picks up his or her prescription, pharmacists can do a review of the medications (e.g., packages, labels, the medication itself) with the patient. This is an opportunity for an additional check.
- Pharmacists can actively involve patients (and their family members) in the medication-use process, and alert them to ask questions if they notice any unexplained changes in either the packaging of a medication or in the drug itself at any time.

As a consumer, you can help avoid this type of incident, too. Do you check your prescription medication with your pharmacist? Ask yourself, "Is this my prescribed medication?"

ISMP Canada

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national nonprofit agency established for the collection and analysis of medication incident reports and the development of recommendations for the enhancement of patient safety.