Working with Consumers to Prevent Medication Incidents

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

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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 healthcare settings. ISMP Canada works collaboratively with the healthcare 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 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

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This strategy is being developed in consultation with Patients for Patient Safety Canada, and Health Canada. The strategy is also being reviewed by provincial, national and international stakeholder organizations as part of the consultation process. As of December 2009, comments on the strategy have also been received from the following organizations:

- Accreditation Canada
- Best Medicines Coalition
- Canadian Institute for Health Information
- Canadian Patient Safety Institute
- Canadian Society of Hospital Pharmacists
- Creating Synergy Health Coalition
- Health Canada's Expert Advisory Committee on the Vigilance of Health Products
- Health Council of Canada
- Institute for Optimizing Health Outcomes
- Manitoba Institute for Patient Safety
- National Association of Pharmacy Regulatory Authorities
- Patients for Patient Safety Canada

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Executive Summary

Canadian consumers and health professionals are 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 frequently causes harm to patients in Canadian hospitals,[1] and harmful medication incidents have received extensive media coverage. In a recent survey, nearly one in ten adult Canadians with health problems reported receiving the wrong medication or the wrong dose when filling a prescription at a pharmacy or when hospitalized within the previous two years.[2] Even though not all medication incidents cause harm, this is clearly an important health safety issue.

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* (also known as side effects), which are generally considered **non-preventable**, and *medication incidents* (also referred to as "medication errors"[3]) which are **preventable**. Health Canada has collected reports of suspected adverse drug reactions since 1965, but efforts to collect and study information about medication incidents on a national level are relatively recent.

Canada has 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. Even reports of non-harmful incidents can provide valuable insight into the underlying system problems that cause errors.

Consumers who have experienced medication incidents often have a strong desire to convey information that may prevent others from being harmed.

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[1] Baker GR, Norton PG, Flintoff V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospitalized patients in Canada CMAJ 2004;170 (11):1678-86

[2] Commonwealth Fund 2008 International Health Policy Survey of Sicker Adults. 2008 [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

[3] Definition of terms [Internet]. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2008 [cited 2008 Nov 3]. Developed by the collaborating parties of the Canadian Medication Incident Reporting and Prevention System, 2001. Available from: http://www.ismp-canada.org/definitions.htm

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. CMIRPS has already accepted reports from consumers, but the program has not been promoted to consumers and the volume of consumer reports has been low. CMIRPS is now ready to move forward with a strengthened and coordinated approach to consumer reporting and learning. The defined audience of consumers will include patients, family members and caregivers.

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 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 component of CMIRPS have already formed the basis of two previous ISMP Canada Safety Bulletins. 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 an educational element. The website will be accessible directly or through links from key websites. In addition to an electronic medication incident reporting tool, the site will provide targeted, consumer-friendly materials designed to support a proactive consumer role in medication safety. Examples of information to be provided include: general information on medication safety, consumer-focused medication safety bulletins and alerts, links to Health Canada alerts and industry alerts, and practical tools that consumers can use to reduce their chances of experiencing harm from medication incidents. 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.

The online reporting form will be developed by adapting 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 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 incident 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, consumers will 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 when the consumer provides informed and voluntary consent. 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 online 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.

Reports will be screened by an ISMP Canada analyst. 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. If a report is identified as high priority and the reporter has consented to follow-up and submitted contact information, an ISMP Canada staff member may contact the reporter to ensure understanding of the 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. It is important to note the key distinctions between the Canada Vigilance Program and the CMIRPS program. The Canada Vigilance program is primarily intended to collect information on adverse drug reactions (also known as "side effects") while the CMIRPS program collects information about medication incidents—mistakes with medications, or unsafe conditions that could lead to mistakes being made. Adverse drug

reactions are generally not preventable, but medication incidents are preventable. And while all events reported to the Canada Vigilance Program involve some degree of harm to patients, CMIRPS also captures information on non-harmful incidents, 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 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 healthcare professionals regarding changes to systems, practices and processes, 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 for health professional audiences.

The consumer reporting and learning program will initially be offered on a pilot basis. A test version of the consumer reporting and learning website will provide consumers with access to the online medication incident reporting form and a limited selection of educational materials. An evaluation tool, currently in development, will collect consumer input on key features of the site, including utility of the online reporting system and educational content of the site.

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 join health professionals in collaborative efforts to improve the safety of medication systems.

Working with Consumers to Prevent Medication Incidents
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1. Introduction

Canadian consumers and health professionals are 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 hospitals,[1] and harmful medication incidents have received extensive media coverage. 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.[2] 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 (also referred to as "side effects")*, which are generally considered non-preventable, and *medication incidents* (also referred to as "medication errors"[3]) which are preventable (see Figure 1[4]).

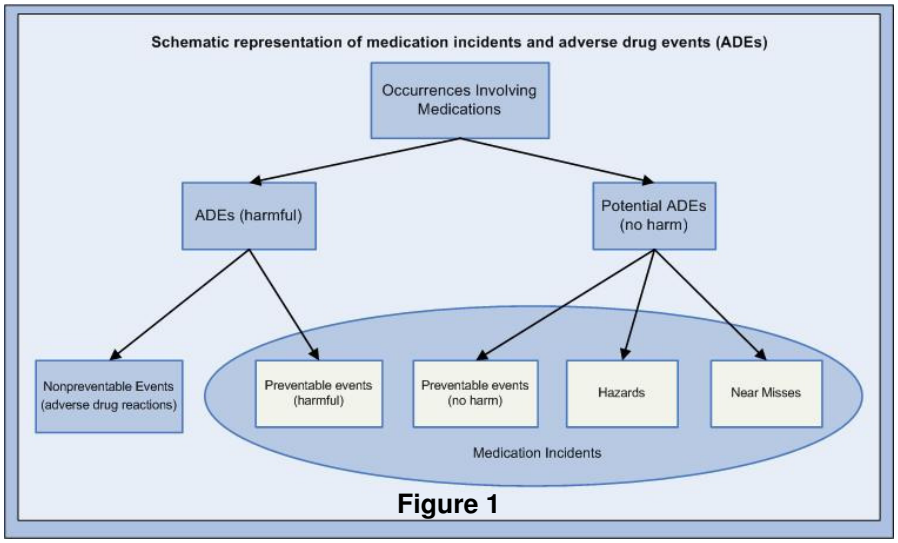

Figure 1

[1] Baker GR, Norton PG, Flintoff V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospitalized patients in Canada, CMAJ 2004;170 (11):1678-86.
[2] Commonwealth Fund 2008 International Health Policy Survey of Sicker Adults. 2008 [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
[3] Definition of terms [Internet]. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2008 [cited 2008 Nov 3]. Developed by the collaborating parties of the Canadian Medication Incident Reporting and Prevention System, 2001. Available from: http://www.ismp-canada.org/definitions.htm
[4] Adapted with permission From Safe and Effective, The Eight Essential Elements of an Optimal Drug Use System, Canadian Pharmacists Association 2007.

Health Canada has collected reports of suspected adverse drug reactions since 1965, but efforts to collect and study information about medication incidents on a national level are relatively recent.

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 available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2008-09CMIRPS.pdf

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 healthcare 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 [5,6]. The program has not been promoted to consumers, however, and the volume of reports submitted by consumers has

[5] Codeine syrup: dangerous "near miss" in the community. ISMP Can Saf Bull. 2002 [cited 2009 Nov 3];2(3):1. Available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2002-03Codeine.pdf
[6] Patient report of insulin mix-up shared. ISMP Can Saf Bull. 2007 [cited 2009 Nov 3];(6):1-2. Available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2007-06InsulinMixUp.pdf

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 including those of the World Health Organization, the National Patient Safety Agency of the National Health Service in the United Kingdom, the Australian Council for Safety and Quality in Healthcare, the US Food and Drug Administration, and the Joint Commission International);
- 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 input and expertise to ISMP Canada's medication safety endeavours;
- Experience in handling confidential and sensitive information. Additionally, 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); and
- 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 National System for Incident Reporting and Individual Practitioner Reporting components 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".[7] 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.*"[8] The report describes a new vision for a patient-centered, integrated medication-use system. A prominent feature of the vision is that "*reporting systems with multiple options capture reports of medication errors from patients and families*".[9]

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 health-care 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*."[10] 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 system.[11] 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

[7] Committee on Identifying and Preventing Medication Errors. P Aspden, J Wolcott, JL Bootman, LR Cronenwett, eds. Preventing Medication Errors: Quality Chasm Series. Washington (DC):The National Academies Press. 2006 [cited 2009 Feb 19]:p.153. Available from http://books.nap.edu/openbook.php?record_id=11623&page=153
[8] Ibid [cited 2009 Jan 13]: preface, p. x. Available from http://books.nap.edu/openbook.php?record_id=11623&page=R10
[9] Ibid [cited 2009 Feb 19]: p.146. Available from http://books.nap.edu/openbook.php?record_id=11623&page=146
[10] Patients for patient safety: statement of case [Internet]. Geneva (Switzerland): World Health Organization; 2009 [cited 2009 Jan 13]. Available from: http://www.who.int/patientsafety/patients_for_patient/statement/en/index.html
[11] Kovacs Burns, K. Canadian patient safety champions: collaborating on improving patient safety. Healthcare Quarterly. 2008 11(Spec Issue):95-100.

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.[12] AHRQ notes that "consumers can be an important source of information about patient safety, and systems that include patients' reports of patient safety events will complement information that is collected from healthcare providers through other reporting mechanisms".[13]

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*."[14] A recently published text entitled "Engaging Patients as Safety Partners" also notes the importance of "sharing information that empowers patients to prevent errors"[15]. Provided 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

[12] 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
[13] Agency for Healthcare Research and Quality. Designing consumer reporting systems for patient safety events. AHRQ pub. No. 09-MO23. 2009 May [cited 2009 Dec 8]. p. 1. Available from: http://www.ahrq.gov/qual/consrepflyer.pdf
[14] Patient-centered care [internet]. Cambridge (MA): Institute for Healthcare Improvement. [cited 2009 Feb 18]. Available from: http://www.ihi.org/IHI/Topics/PatientCenteredCare/PatientCenteredCareGeneral/PatientCenteredCareGeneralHome.htm
[15] 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.

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 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 harm 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 systems 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.[16] Consumers are an untapped resource that can be expected to increase the volume of reports received by CMIRPS and enhance medication safety learning.

- Consumers who have experienced incidents and have a strong desire to share information that may prevent others from being harmed 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.[17] 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[18];
- Consumers may be willing to take the time to report incidents that were not reported by health professionals due to time constraints; and
- Consumers are not constrained by the fear of discipline and liability that may discourage health professionals from reporting.

[16] 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.
[17] 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.
[18] 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;149 (2): 100-8.

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.[19] 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.[20] Health Canada has provided a number of tools to promote and support consumer reporting of adverse drug reactions, including online presentations and guidebooks.[21]

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. For example, patients and families may have observed the full sequence of events along the care continuum leading to an incident, while individual health professionals may only have witnessed one aspect; and
- 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 had used infusion pumps demonstrated benefit in seeking patients' views, since this "raised new and important issues for consideration"[22].

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

[19] House of Commons Canada Report of the Standing Committee on Health. Post marketing Surveillance of Pharmaceuticals. 2008 June [cited 2009 Jan 13]: p.6. Available from: http://www2.parl.gc.ca/content/hoc/Committee/392/HESA/Reports/RP3598191/hesarp07/hesarp07-e.pdf
[20] Adverse reaction reporting: 2007; Table 2 [internet]. Canadian Adverse Reaction Newsletter. 2008 April [cited 2009 Jan 16];18. Available from: http://www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/carn-bcei_v18n2-eng.php#table2b
[21] Educational tools for consumers and patients [internet]. Health Canada [cited 2009 Jan 16]. Available from: http://www.hc-sc.gc.ca/dhp-mps/medeff/centre-learn-appren/index-eng.php#1
[22] 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.

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 collect 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. The consultation paper also 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,*"[23] 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.[24]) 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 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 collects reports of incidents. The CMIRPS 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

[23] Building a safer system: the Canadian Adverse Event Reporting and Learning System. Consultation Paper [internet]. Edmonton (AB): Canadian Patient Safety Institute. 2008 July [cited 2009 Jan 12]: p.4. Available from: http://www.patientsafetyinstitute.ca/English/toolsResources/ReportingAndLearning/CanadianAdverseEventsReportingAndLearningSystem/Documents/CAERLS%20Consultation%20Paper.pdf

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

to the Canada Vigilance Program, in addition to health professionals, manufacturers and distributors.[25]

It is important to note the key distinctions between the Canada Vigilance Program and the CMIRPS program. The Canada Vigilance Program is chiefly intended to collect information on adverse drug reactions ("side effects")—non-preventable adverse events that occur when marketed drugs are used as intended. The CMIRPS program focuses on medication incidents—mistakes with medications, or unsafe conditions that could lead to mistakes being made. Adverse drug reactions are generally not preventable, but medication incidents are preventable. And while the events reported to the Canada Vigilance Program have caused some degree of harm to patients, CMIRPS also captures information on non-harmful incidents, near misses and hazardous situations. For the Canada Vigilance Program, the primary focus for analyses of data and communication with practitioners is identifying risks inherent in the properties of the drug itself, while the CMIRPS program focuses on identifying practice and system changes that can prevent errors. Consequently, the skills required for medication incident analysis differ considerably from those required for the analysis of adverse drug reactions. The differences between the Canada Vigilance Program and the CMIRPS Program are summarized in Table 1.

Table 1- Distinctions between the Canada Vigilance Program and the CMIRPS Program

Canada Vigilance Program	CMIRPS Program
Chiefly collects adverse drug reaction reports	Established to collect medication incident reports
Harmful events are captured	Harmful and non-harmful events are captured
Generally non-preventable events	Preventable events
Actual events	Actual events, near misses and hazardous situations
Recommendations generally address risks inherent in the properties of the medication itself	Recommendations address risks inherent in the medication system

2.4 Successful Consumer Reporting and Learning Programs in Other Countries

The US FDA's MedWatch program, which collects safety information and adverse event reports, accepts reports from consumers. The MedWatch program

[25]Frequently asked questions (FAQs) [internet]. Ottawa (ON): Health Canada. 2009 Nov 3 [cited 2009 Dec 14]. Available from: http://www.hc-sc.gc.ca/dhp-mps/medeff/faq-eng.php#a1

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 concerns 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.[26]

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.[27] 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.[28]

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

[26] Committee on Identifying and Preventing Medication Errors, P Aspden, J Wolcott, JL Bootman, LR Cronenwett, eds. Preventing Medication Errors: Quality Chasm Series. Washington (DC): The National Acadmies Press. 2006 [cited 2009 Jan 17]: p.28. Available from: http://books.nap.edu/openbook.php?record_id=11897&page=28

[27] AERS reporting by healthcare providers and consumers by year [internet; cited 2009 Jan 17]. Calculated from statistics available from: http://www.fda.gov/cder/aers/statistics/aers_hcp_consumer.htm

[28] ISMP QuarterWatch (2nd quarter 2008): questions arise regarding manufacturing practices, recall effectiveness and premarket testing for psychiatric side effects. ISMP Med Saf Alert, Acute Care edition. 2009 Jan 15 [cited 2009 Dec 14];14(1):1-3. Available from: http://www.ismp.org/Newsletters/acutecare/articles/20090115.asp

up to receive safety alerts, of which 6,970 could be confirmed by return email from their addresses.[29]

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 NPSA gives the following example of how consumer reports have contributed: "patients have helped us find ways of reducing the risk of taking too much methotrexate." The NPSA notes that this has led to: "published patient information to tell people about the risks, and [the agency is] also working with the drug manufacturers to redesign the packaging."[30]

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 basis.[31] 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.*"[32] A recent MHRA newsletter asks health professionals to encourage patients to submit reports to the Yellow Card Scheme.[33] 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

[29] Email communication to ISMP Canada from ISMP (US). 2009, Jan 5.
[30] National Patient Safety Agency. Frequently asked questions: how does sharing my experience help make the NHS safer for others [internet]? London, England: NPSA. c2008 [cited 2009 Dec 9]. Available from: http://www.npsa.nhs.uk/pleaseask/experience/faqs/
[31] Press release: yellow card scheme [internet]. MHRA. 2005 Oct 25 [cited 2009 Jan 17]. Available from: http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON2020275
[32] Questions and answers on Yellow Card data [internet]. MHRA. 2008, April 27 [cited 2009 Jan 19]. Available from: http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Medicines/Reportingsuspectedadversedrugreactions/Healthcareprofessionalreporting/Druganalysisprints/QuestionsandanswersonYellowCarddata/index.htm
[33] Drug safety update: latest advice for all medicines users. 2009 Feb [cited 2009 Mar 07];2(7):5-6. Available from: http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON038626&RevisionSelectionMethod=LatestReleased

collect reports. The involvement of the pharmacists in the process helps to ensure that specified reporting criteria are met.[34] 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*".[35] 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.

3. Proposed Consumer Reporting and Learning Program for CMIRPS: An 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 collect reports from members of the public and provide consumer-oriented medication safety information.

ISMP Canada will develop a consumer-focused medication safety website (www.safemedicationuse.ca; www.medicamentssecuritaires.ca) that will be accessible directly or through links from key websites. In addition to an electronic medication incident reporting tool, the site will provide targeted, consumer-friendly materials designed to support a proactive consumer role in 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 safe medication use 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

The goal is to strengthen Canada's capacity to enhance medication safety by increasing the involvement of consumers in the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

[34] Introducing the Adverse Medicines Events Line. Australian Prescriber. 2004 April [cited 2009 Jan 19];27(2):38. Available from: http://www.australianprescriber.com/upload/pdf/articles/502.pdf
[35] Australian Commission on Safety and Quality in Health Care. Windows into Safety and Quality in Health Care. Medication Safety, Chapter 4. 2008 October. Sydney (Australia):ACSQHC.

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, and
- To increase consumers' knowledge and awareness related to medication incidents and safe use of medications.

3.3 Definition of Consumers

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 healthcare.***[36]

3.4 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 or reprimand healthcare 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.

[36] Consumer adverse event reporting AHIC Extension/Gap. Washington (DC): US Department of Health and Human Services, Office of National Coordinator for Health Information Technology; 2008 Dec 31 [cited 2009 Jan 15]. p. 20. Available from: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848115_0_0_18/CAERFinalExtGap.pdf

4. CMIRPS Consumer Reporting and Learning Website

A unique CMIRPS consumer reporting and learning website will be established. 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. In addition to an electronic medication incident reporting tool, the site will provide targeted, consumer-friendly materials designed to support a proactive consumer role in medication safety. 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 website
- CPSI's website
- Patients for Patient Safety Canada webpage
- The Accreditation Canada website
- Consumer association and consumer/patient advocacy websites
- The websites of caregiver associations
- The websites of provincial patient safety organizations (e.g. MPSI, HQCA)
- Provincial Ministry of Health websites
- Professional licensing body websites
- Professional association websites
- The websites of major Canadian pharmacy chains
- The websites of hospitals and health districts

4.1 Collection of 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. Although the format for the online consumer reporting form will be simplified considerably, key data fields in the form will be mapped to those used in other CMIRPS components to allow shared learning across the datasets.

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.

The system will collect reports from consumers on medication incidents, defined by CMIRPS 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. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.*"[37] Incidents to be reported may involve use of prescription and non-prescription products.

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.

4.2 Educational Content

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

- General Information on medication incidents and on the consumer reporting and learning program, including:
    - A definition of a medication incident
    - The goal and objectives of the program
    - The importance of reporting medication incidents so that future incidents can be prevented
    - How to report an incident
    - The rationale for a non-blame, non-punitive approach
    - What ISMP Canada **will** and **will not** do when an incident is reported
    - Systems to safeguard privacy
    - Feedback to consumers

[37] Definition of terms [Internet]. Toronto (ON): Institute for Safe Medication Practices Canada; c2000-2009 [cited 2009 Dec 3]. Developed by the collaborating parties of the Canadian Medication Incident Reporting and Prevention System, 2001. Available from: http://www.ismp-canada.org/definitions.htm

- Consumer-oriented tools and resources designed to enhance medication safety, e.g. information on how consumers can reduce their chances of experiencing a medication incident; downloadable forms for consumers to record medication use lists,
- 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 National System for Incident Reporting program),
- 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, and
- 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. 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.

5. 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.[38] 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, consumers will be offered the choice of reporting anonymously or of providing contact information when an incident is reported, for the purposes of follow-up. ISMP Canada will establish a mechanism to obtain

[38] 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. 2008 March [cited 2009 May 8]. Available from: http://www.patientsafetyinstitute.ca/English/research/cpsiResearchCompetitions/2005/Documents/Weisbaum/Reports/Full%20Report.pdf

and document the informed and voluntary consent of the consumer prior to the collection of contact information. ISMP Canada will also 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.

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 in CMIRPS. 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.

6. Involvement of Health Professionals in Consumer Reporting

The CMIRPS consumer reporting website will not express a preference that consumers submit reports in conjunction with a health professional. ISMP Canada believes it is important to offer consumers a simple route to independently report a medication incident for the purposes of improving the safety of the healthcare system. The consumer reporting and learning website will however encourage consumers to advise their health professional that an incident has occurred and to seek medical advice in cases where an error has reached a patient.

Consumers will be advised, through website instructions (or, in the case of telephoned reports, by the staff member receiving the incident report) that information that identifies the individual health professionals or organizations involved in the incident should not be included in the report. Consumers will also be advised that ISMP Canada will not intervene on a consumer's behalf with healthcare providers of regulatory bodies and will not provide advice to the

consumer regarding requests for compensation or potential litigation related to harm caused by medication incidents.

It is recognized that systems-based analysis of incidents is best conducted collaboratively, and that participation of the involved health professional(s) may be optimal to identify contributing factors and potential solutions. Where appropriate, an ISMP Canada staff member may discuss with the consumer the benefits of inviting the health professional(s) to contact ISMP Canada to participate in the follow-up and analysis of the incident.

ISMP Canada will also strive to reinforce with health professionals the value of consumer involvement in reporting systems, by preparing communications describing the goals and objectives of the consumer reporting and learning program.

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® and will focus on opportunities to improve the safety of the healthcare system. Each report will be screened by an ISMP Canada 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.

In many cases, for example where the reported incident does not require in-depth analysis or where reports are submitted anonymously, consumer involvement would end with the submission of the report. In a small number of selected cases, the consumer role may be expanded. 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 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), and
- Additional information to support event analysis information.

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. ISMP Canada will not accept information on the identity of the patient from other individuals who report an incident. In cases where direct contact with the individual who experienced the incident 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 in the analysis. Where appropriate, the ISMP Canada staff member may request that the surrogate reporter invite the individual who experienced the medication incident to contact ISMP Canada.

As noted above, recognizing the value of including involved health professionals in the analysis of individual incidents, 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.

It is recognized that offering consumers the option to report anonymously may limit ISMP Canada's ability to conduct analysis. In cases where a report is incomplete or contains information about which ISMP Canada has unanswered questions, the information will not be analyzed or included in any safety bulletins, reports or other publications.

After information gathering is completed, high priority reports are analyzed by ISMP Canada 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 healthcare professionals regarding system changes to facilitate changes to practices and processes,
- Recommendations to manufacturers on packaging and labelling, and
- 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. Ultimately, it is intended that the knowledge gained through the analysis of incidents reported by consumers will be translated into action by healthcare providers, consumers, manufacturers and policy makers to improve the safety of healthcare.

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 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, and
- for a small number of selected incidents, provision of opportunities to participate in the identification of hazards, contributing factors and potential solutions.

There is a concern that patients may expect feedback on their issue and the specific actions that were taken to prevent future incidents. Although this may occur for high-priority critical incidents, it will not be possible to routinely provide this level of feedback. To address this, the website will include information on what ISMP Canada **will** and **will not** do when an incident is reported.

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 on the consumer reporting and learning website 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, and
- 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 was developed and circulated to PFPS Canada, the CMIRPS collaborating parties (Health Canada and CIHI) and CPSI for input. Feedback received was incorporated into a revised draft, which was circulated to additional stakeholders. During the second phase of consultation, the draft strategy was forwarded to a broad selection of consumer, healthcare and patient safety organizations. All stakeholders were invited to suggest additional organizations for consultation as appropriate, and the strategy document has been posted in the CMIRPS section of the ISMP Canada website.

ISMP Canada expresses sincere appreciation to all of the organizations and individuals who have provided input to this strategy document. As of December 2009, comments on the strategy have been received from the following organizations:

- Health Canada
- Health Canada's Expert Advisory Committee on the Vigilance of Health Products
- Canadian Institute for Health Information
- Canadian Patient Safety Institute
- Patients for Patient Safety Canada
- Best Medicines Coalition
- Creating Synergy Health Coalition
- Institute for Optimizing Health Outcomes
- Manitoba Institute for Patient Safety
- Canadian Society of Hospital Pharmacists
- Accreditation Canada

- Health Council of Canada
- National Association of Pharmacy Regulatory Authorities

Overall, input on the concept of a consumer reporting and learning program was highly positive. Some details of the strategy document have been changed to reflect input received from stakeholders. Feedback on the revised document and on the site itself will continue to be accepted throughout the pilot project and will be considered in the ongoing development of approaches and tools for the program.

12. Program Evaluation and Consumer Input

The consumer reporting and learning program will initially be offered on a pilot basis. A test version of the consumer reporting and learning website will provide consumers with access to the online medication incident reporting form and a limited selection of educational materials. An online survey will collect feedback from consumers on the utility and educational content of the site. The evaluation tool, currently in development, will seek consumer input on key features of the site, which may include:

- whether consumers see a need for the system,
- the name and branding of the site,
- accessibility of the online reporting form,
- user-friendliness of the online reporting form and suggestions for change,
- use of consumer-appropriate terminology,
- reading level of site materials,
- value of educational content,
- whether information on the site affected the consumers approach to handling medication,
- suggestions for additional educational content and tools, and
- privacy concerns.

ISMP Canada will develop mechanisms to allow ongoing consumer input into site design and content, for example through online feedback mechanisms and/or consumer advisory groups.

13. Promotion of the Program

ISMP Canada is currently developing a plan for communication and marketing of the pilot project. The support of key stakeholder organizations, including consumer/patient groups, will be sought in engaging consumer participation in the pilot. A newsletter announcing the pilot site launch will be circulated to the appropriate healthcare and consumer organizations for distribution to consumers.

ISMP Canada will also approach Health Canada, key consumer and patient organizations and healthcare 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.

14. Program Funding

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

15. 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 join health professionals in collaborative efforts to improve the safety of medication systems.