EVALUATION OF THE CANADIAN MEDICATION INCIDENT REPORTING AND PREVENTION SYSTEM SERVICES PROVIDED BY ISMP CANADA

Final Report

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Prepared for:

Institute for Safe Medication Practices Canada

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FORWARD

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The views and opinions expressed in this report are those of the authors and do not necessarily represent the views of Health Canada or the Institute for Safe Medication Practices Canada.

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EXECUTIVE SUMMARY

Introduction

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a national, collaborative effort led by Health Canada, the Institute for Safe Medication Practices Canada (ISMP Canada), the Canadian Institute for Health Information (CIHI), and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to strengthen Canada's ability to minimize and prevent harmful medication incidents, as well as to manage and share knowledge about voluntary reported medication incidents. This evaluation focuses on the impact of the products/services offered by ISMP Canada and their associated risk reduction and financial impact (i.e., value for money).

Program description

The main objective of CMIRPS is to reduce the possibility of harm caused by preventable medication incidents by identifying potential problems before they occur and implementing the appropriate preventative strategies. As CMIRPS is a collaborative effort, the roles and responsibilities specific to ISMP Canada that are covered in the evaluation are described in the table below.

ISMP Canada activities for CMIRPS	
Activities	**Brief description**
Collection of reports on medication incidents	As part of its Individual Practitioner Reporting System for Medication Incidents, ISMP Canada collects reports on medication incidents from practitioners. The Individual Practitioner Reporting System has been aligned with CIHI's reporting system for health service organizations—the National System for Incident Reporting (NSIR).
Processing and analyzing medication reports	ISMP Canada is responsible for reviewing and analyzing all data related to medication incidents found in both the Individual Practitioner Reporting System and the NSIR. This includes follow-up on specific incidents with the intent to conduct a Root Cause Analysis (RCA).
Safety bulletins and alerts	ISMP Canada assembles, summarizes, and disseminates information regarding medication incidents/issues and prevention strategies through bulletins and alerts.
Medication Safety Self-Assessment program	As the name implies, the Medication Safety Self-Assessment (MSSA) program is a self-assessment program designed to assist health care organizations in evaluating the safety of their medication systems by identifying areas requiring improvement, and developing strategies for systems enhancement. ISMP Canada offers MSSA modules for different health care settings.
Root Cause Analysis workshops and frameworks	Root Cause Analysis (RCA) refers to investigations of critical incidents to determine what factors led to the adverse outcome. The focus of RCAs is on how systems and processes contribute to the event, rather than individuals. ISMP Canada offers workshops on conducting RCAs.

ISMP Canada activities for CMIRPS	
Activities	**Brief description**
Failure Mode and Effects Analysis workshops and frameworks	Failure Mode and Effects Analysis (FMEA) is a prospective effort to identify potential system weaknesses and develop appropriate preventative strategies. ISMP Canada has developed an FMEA framework for health care processes, and conducts educational workshops on FMEA.
Consumer Reporting and Learning Strategy and Pilot	ISMP Canada developed and is piloting a consumer reporting and learning strategy, which includes a consumer website (www.SafeMedicationUse.ca). In addition to allowing consumers to report medication incidents, it also contains consumer-focused educational materials to encourage and support the proactive role of consumers in medication safety.
Medication safety conferences, workshops, and webinars	ISMP Canada offers one-day medication safety workshops specifically designed to suit individual organizations' needs, hosts safety conferences, and conducts webinars on specific medication safety issues.
Look-alike, sound-alike products	ISMP Canada is working with national and international experts to develop a framework for the assessment of look-alike, sound-alike drug product names.
Responding to queries on medication safety	ISMP Canada also serves as a resource to health care institutions and practitioners about medication safety issues and prevention strategies. Stakeholders can email or phone ISMP Canada and staff will assist them.

As part of the supplemental funding received from Health Canada in 2008, ISMP Canada committed to broadening the reach of CMIRPS. This includes efforts to increase the volume and participation in its MSSAs, RCA and FMEA workshops, and the medication safety conference series. It also included increasing its analyses of medication incidents from about 20 to 30 per month, developing and piloting a consumer reporting and learning strategy, and developing a framework for look-alike/sound-alike products.

Methodology

The methodology used to conduct this evaluation has four main components:

- a document review;
- case studies of six medication incidents/issues, which included interviews with key individuals involved in some aspect of the medication incident and/or response, and a review of relevant documents and literature;
- eight key informant interviews with a total of 14 individuals, including representatives of ISMP Canada, Health Canada, Accreditation Canada, and health care professionals in the fields of pharmacy (i.e., directors of pharmacy), medication safety and/or patient safety (i.e., director of quality, manager of medication safety, patient safety officer);
- a survey of stakeholders. A total of 611 stakeholders completed the survey and respondents included many types of health care professionals who worked in a variety of practice settings. All provinces and territories were represented among the respondents.

Conclusions

Awareness of ISMP Canada's activities for CMIRPS

The evaluation found the level of awareness of ISMP Canada's activities for CMIRPS to be high, particularly given the fact that ISMP Canada has focused on delivering the program and has not undertaken a promotional or communication strategy to build awareness. While awareness varies by type of activity, the majority of respondents reported they were at least somewhat aware (ranging from 99% for the safety bulletins and alerts to 55% for the recently launched Consumer Reporting and Learning Pilot Project). Based on interviews, awareness also varies by type of health care provider and institution. Physicians were singled out as a group that is less aware of CMIRPS. Survey results were not able to confirm this, given the small number of physicians who responded.

ISMP Canada has undertaken several activities to expand its network and target its message. Within less than two years, ISMP Canada has increased its distribution of safety bulletins threefold and has informal agreements with various professional organizations to fan out the bulletins to its membership. In addition, it has targeted its approach for specific medication issues to get the message to those health care professionals who are in the best position to reduce the risk for occurrence of a particular error.

One area of potential improvement in increasing awareness of CMIRPS and ensuring that the appropriate audience is reached is reviewing the distribution network to ensure it is achieving its desired coverage. Another suggestion made by some interviewees is for ISMP Canada to consider increasing its attention on health care sectors/organizations that might find implementing its recommendations more challenging. In particular, they mentioned sectors/organizations with less infrastructure for addressing medication safety than hospitals in urban areas (e.g., they might not have an in-house pharmacy that can take the lead and/or interdisciplinary committees or other committees expressly dedicated to medication safety).

Use of ISMP Canada's activities for CMIRPS

The evaluation found that CMIRPS safety bulletins and alerts are by far the activity that most individuals and organizations are engaged in, followed by attending medication safety conferences or webinars. For the safety bulletins, all lines of evidence showed that health care professionals and organizations are reviewing them, disseminating them, and using them to identify and implement changes in medication practices.

For other CMIRPS activities, the reported use reflects that they require training and, for some, the attendance at workshops, which cannot be expected to have the broad distribution of safety bulletins.

- ISMP Canada's MSSA module for hospitals has certainly received a high rate of adoption, with the 2008 Hospital Pharmacy in Canada Survey results showing that not only did the majority of hospitals conduct MSSAs within the previous two years, but almost all used the ISMP Canada tool. In addition, the reach of MSSAs are being

broadened—ISMP Canada now offers MSSA modules for long-term care, community pharmacies, and complex continuing care, and has increased its geographic coverage so that at least one type of module has been offered in nine provinces. Overall, supplemental funding has supported 488 modules being offered.

- About one-third of survey respondents reported that they have used/participated in RCA and FMEA frameworks and workshops, and just over 40% indicated their organizations have used them, although an almost equal percentage did not know if their organizations have. Although the reach of the workshops was to increase with the supplemental funding, between 2007 and 2009, the number of workshops and participation in them decreased. In the first quarter of 2010, this trend appears to be reversing itself.

- While reporting medication incidents directly to ISMP Canada was less common than participation in the other activities, based on survey responses alone, this does not reflect the provision of medication incidents to CMIRPS. Given that a large proportion of survey respondents work in the hospital sector, they are likely reporting to CIHI's NSIR or to provincial reporting programs. The Hospital Pharmacy in Canada Survey in 2007/08 found that all participating hospitals had a medication incident reporting system. This being said, the evaluation found that the system for medication reporting is becoming increasingly decentralized with provincial reporting systems, and how the information collected provincially will be shared with CMIRPS is not yet clear. A challenge for ISMP Canada and its partners (CIHI, Health Canada, and CPSI) will be to increase awareness of CMIRPS and the importance of a national database of medication incidents.

Beyond just using CMIRPS activities, the evaluation evidence demonstrates that the activities are being integrated into health care practice through either formal written policies or commonly understood expectations. In particular:

- Almost all respondents reported that their institution has formal policies or expectations that medication incidents be reported (although this does not have to be through the CMIRPS).

- Safety bulletins are being integrated into the fabric of health care organizations through formal policies or, at a minimum, expectations that they be disseminated, used to identify potential medication safety issues, and implement strategies to address them, including adopting the ISMP Canada recommendations that they contain. Approaches vary, but almost all interviewees described some method of dissemination to relevant staff and regular review of the bulletins and ISMP recommendations.

- Similarly, the majority of survey respondents reported that conducting local incident analyses using the RCA framework is either part of their organization's written policies or commonly understood expectations.

- The more preventative activities—conducting prospective risk assessment using the FMEA framework or conducting MSSAs—are less likely to be in written policies or to be expectations.

Impact of ISMP Canada's activities for CMIRPS

The evaluation evidence demonstrates that CMIRPS activities are having an impact on organizational policies and practices. In particular:

- Based on all lines of evidence, safety bulletins and the recommendations they contain have had the greatest effect on health care practices. In particular, case studies as well as survey results provided examples of changes in health care practices in response to specific medication issues and ISMP Canada recommendations. These included changes in storing, dispensing, and administering medications, such as removing certain products from patient care areas, using pre-mixed products, rearranging storage areas, and instituting safety procedures and labelling guidelines, to name a few.

- For all CMIRPS activities, almost all survey respondents who provided an opinion indicated that they have had at least a limited effect on their organizations' policies and practices.

In addition to changes in health care practices at the organizational level, ISMP Canada's CMIRPS activities also influence broader changes, such as Accreditation Canada Required Operation Procedures (ROPs). While many stakeholders are involved in developing ROPs, for those that concern medication issues, ISMP Canada is always consulted and in the case studies of medication incidents where an ROP was developed, its content corresponded to and was influenced by previously made ISMP Canada recommendations. ISMP Canada has also worked with manufacturers to remedy labelling, packaging, and naming issues identified as a contributing factor to medication incidents. In all, ISMP Canada has worked with manufacturers on 50 changes to medication labelling, packaging, and naming.

The survey results confirmed that of ISMP Canada's various CMIRPS activities, those perceived by stakeholders as having the greatest impact on Canadian health care practice are safety bulletins and alerts; changes to product labelling and packaging; and changes to processes (e.g., adoption of ISMP Canada recommendations into Accreditation Canada standards).

The evaluation cannot conduct a rigorous analysis to show that changes to medication practices based on ISMP recommendations have resulted in greater medication safety and improved outcomes for patients. Reliable data pre- and post-changes in practices would be necessary, which is not available given the underreporting of medication incidents.

Given this limitation, the evaluation relied on case studies and inferring effects from the medication incidents reported to CMIRPS pre- and post-ISMP Canada recommendations. Based on this, four case studies showed that medication incidents caused by the factors addressed in the recommendations either had not been reported or had occurred less often since the recommendations were made. Another demonstrated how the increased awareness did not prevent the occurrence but facilitated prompt and effective treatment of the affected patient. The sixth is a work in progress, but the intervention has a strong evidence base for its effectiveness in reducing premature death and costs of treatment. In addition, the perception of about three-quarters of the survey respondents is that ISMP Canada's CMIRPS activities have had an effect by increasing recognition of potential medication safety problems; improving identification of preventative strategies; and improved implementation of preventative strategies. A smaller

percentage of respondents (although still a majority) believe that CMIRPS has had an effect in reducing harmful medication incidents and improving outcomes for patients. This is due to a higher proportion of respondents not being able to provide an opinion, which is likely explained by the difficulty in demonstrating the connection due to the underreporting of medication incidents.

Capacity for change

Interviewees and survey respondents believe that these key stakeholder groups have the willingness and capacity to continue to make changes to medication safety practices based on ISMP Canada's work. Among survey respondents, there was increasing optimism for future willingness and capacity to make changes. The most common barriers cited included lack of human resources and time, followed by financial barriers.

Value for money

The available evidence supports the proposition that the benefits of ISMP Canada's activities for CMIRPS exceed its costs, i.e., it offers value for money. The analysis provides a conservative estimate, as it focuses on the value of averted loss of life and does not include the additional value of the reduction of non-lethal harm to patients. It is also based on only three case studies, as they provide the clearest evidence of lives saved by interventions from ISMP Canada recommendations. These case studies show a reduction in similar reported incidents that resulted in death after the ISMP recommendations were published.

Based on the Treasury Board estimates for the value of a life, we have taken the value of a statistical life to be $7 million in 2010 dollars. Based on the estimated 16.5 lives saved between 2004 and 2010 in the three case studies, the total benefit of lives saved is roughly $115.5 million for that time period, or $16.5 million per year. Attribution of the entire benefit to ISMP Canada's activities for CMIRPS is not possible. However, given the fact that ISMP Canada has published over 60 safety bulletins during that time period, with recommendations contained in almost all of these bulletins, the use of only three case studies to support the value for money analysis means that the resulting value of ISMP Canada's CMIRPS activities remains a conservative estimate. With a total estimated benefit based on three case studies of $115.5 million between 2004 and 2010 and a cost of ISMP Canada's activities for CMIRPS of $5.9 million for that same time period, the benefits far exceed the costs.

Value for money also goes beyond averting harm or death from medication incidents to include improving the efficiency and quality of the preventive strategies. According to the evaluation evidence, stakeholders believe that ISMP Canada's activities for CMIRPS provide value by increasing awareness of hazardous conditions, fashioning feasible responses that are backed by the credibility that ISMP Canada has with stakeholders, and reducing the inefficiency of each health care institution developing its own response, to name a few.

That being said, medication errors that result in premature death or substantial harm challenge the health care system and government to do better. CMIRPS provides value by enabling an evidence-based response that addresses the system issues involved in the medication incident.

Another measure of value is that ISMP Canada does not duplicate the work of other organizations. Most stakeholders could not list a similar organization that they would turn to if ISMP Canada could not perform its CMIRPS activities. The organizations most often mentioned were regulatory bodies/professional organizations and US organizations, such as ISMP US. With respect to ISMP US, interviewees noted that it was useful, but that ISMP Canada added value by relying on Canadian data and Canadian experiences with medication safety issues.

Broadening activities

These activities to broaden the scope of CMIRPS activities began in late 2008 at the earliest, so it is too early to assess their impact. That being said, interviewees believe that these initiatives, in particular the Consumer Reporting and Learning Strategy, have the potential to improve medication safety. The other initiatives to broaden the scope—the additional 10 analyses of medication incidents and the work on developing a standard operating procedure for look-alike, sound-alike products—were not areas that most key informants could comment on. However, based on documentation provided by ISMP Canada, the 10 additional analyses per month allow them to do more work on near-miss events or other events that did not result in patient harm, and include events from new sources (namely, the consumer reporting program and the community pharmacy program). It was noted that at the original level of approximately 20 analyses per month, not all reports of actual harm could be studied for some months. The look-alike, sound-alike initiative is on schedule: an expert advisory panel has been formed and has produced a "proof of concept" guidance document, which includes core concepts of drug name review and which has been tested through experiments with small cohorts of end-use practitioners.

Few suggestions were given for areas of expansion. They primarily included additional work to engage or educate health care professionals, broaden knowledge transfer activities, and market CMIRPS, which includes being more directly engaged in encouraging the reporting of medication incidents.

1.0 Introduction

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a national, collaborative effort led by Health Canada, the Institute for Safe Medication Practices Canada (ISMP Canada), the Canadian Institute for Health Information (CIHI), and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to strengthen Canada's ability to minimize and prevent harmful medication incidents, as well as to manage and share knowledge about voluntary reported medication incidents. The current evaluation focuses on the CMIRPS services provided by ISMP Canada.

ISMP Canada engaged PRA Inc. to conduct this evaluation of its CMIRPS services. The evaluation focuses on the impact of the products/services offered by ISMP Canada and their associated risk reduction and financial impact (i.e., value for money). This report presents the evaluation findings and offers conclusions.

1.1 Structure of the report

This report is divided into several sections. Section 2 provides a profile of ISMP Canada's activities for CMIRPS. Section 3 describes the methodology used to complete the evaluation. Section 4 presents the evaluation findings and section 5 concludes. The appendices are contained in a separate volume.

2.0 Profile of ISMP Canada's activities for CMIRPS

2.1 Context for the development of CMIRPS

ISMP Canada is an independent non-profit agency dedicated to gathering and analysis of information relating to medication incidents (including near-miss events) and the development of recommendations for the enhancement of patient safety. CMIRPS is a key program that ISMP Canada engages in to promote medication safety.[1]

Established in 1999, ISMP Canada's genesis coincided with increased interest in patient safety. Starting in the mid-1990s, several influential studies drew attention to the issue of patient safety, demonstrating that adverse events were common and often preventable.[2] Medication incidents were cited as the most common preventable cause of patient harm. Studies on adverse drug events in the United States estimated costs of these events to be substantial (about $2.8 million [US] annually for a 700-bed teaching hospital) (Sierra Systems, 2002, p. 1 & 4). Canada's first large-scale study of adverse events found that Canada was not immune to this issue: approximately 7.5% of patients admitted to acute care hospitals in Canada experienced one or more adverse events. Of these events, 37% were judged to have been highly preventable, which translates into about 70,000 preventable adverse events. The report also suggested that about one-quarter of preventable adverse events are related to medication errors (Baker & Norton et al., 2004).

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1 ISMP Canada is an active partner in the *Safer Healthcare Now!* (SHN) campaign conducted by the CPSI. In particular, ISMP Canada is involved in SHN's medication reconciliation intervention. In addition, ISMP Canada is also actively involved in various other projects, such as the Medication Safety Support Service (MSSS) (a joint venture with the Ontario Ministry of Health and Long-Term Care and the Ontario Hospital Association to promote medication safety); the Medication Management in Long-Term Care Project (as part of a joint task force that examines issues and impacts relating to medication management safety in long-term care homes in Ontario); the Ontario Antimicrobial Stewardship Project (a knowledge translation project, supported by the Ontario Agency for Health Protection and Promotion and the Ontario Ministry of Health and Long-Term Care); the Pharmaceutical Bar Coding Project (a joint initiative with CPSI in a collaborative effort to implement standardized bar codes at all levels of pharmaceutical labelling); Advancing Medication Safety in Paediatrics (a collaborative venture with the Canadian Association of Paediatric Health Centres, with support from CPSI, to enhance the safety of paediatric medication use). ISMP Canada also offers various customized consultant services ranging from mini-consults to focused reviews.

2 In 1995, the Quality in Australian Health Care Study revealed that one of six hospital admissions had suffered an adverse event, about half of which were considered highly preventable (Wilson et al., 1995). A few years later, a United States report—*To Err is Human: Building a Safer Health System*—estimated that medical errors cause between 44,000 and 98,000 deaths each year in hospitals, exceeding the number of deaths that were attributable to motor-vehicle accidents, breast cancer, and AIDS (Institute of Medicine, 2000). That same year, the National Health Service of Great Britain released its report *An Organisation with a Memory*, which identified adverse events causing harm as occurring in 10% of hospital admissions, costing the system about two billion pounds a year in additional hospital stay alone (Department of Health (UK), 2000).

Contemporaneously with many of these earlier studies, the Canadian Society of Hospital Pharmacists (CSHP) and Health Canada's Bureau of Licensed Product Assessment (BLPA) co-hosted an invitational workshop in the fall of 2000. The workshop addressed the key issue of the need for a national medication incident reporting system to enable Canada to identify common medication errors.[3]

A main outcome of the workshop was the establishment of the Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP). This coalition of stakeholders oversaw the creation of a business plan for the development and implementation of a medication incident reporting and prevention system. Under the guidance of this coalition, led by Health Canada with input from over 50 key stakeholders from across the country and international experts, the groundwork was laid for CMIRPS.

2.2 ISMP Canada's activities for CMIRPS

2.2.1 Objectives, roles, and responsibilities

The main objective of CMIRPS is to reduce the possibility of harm caused by preventable medication incidents by identifying potential problems before they occur and implementing the appropriate preventative strategies. Its key features include:

- An approach that encourages voluntary reporting and is non-punitive. It encourages reporting at all levels—organizational, individual practitioners, consumers or clients of the health care system, drug manufacturers, and others. It also encourages reporting of all types of medication incidents, including near misses and potential situations that may lead to an incident;
- Compatibility with other patient safety systems and integration of patient safety initiatives currently underway in Canada, with the intent to avoid duplication of effort and encourage coordinated access to information concerning patient safety;
- Policies and procedures that safeguard data integrity, privacy, and confidentiality; and
- A system that is national in scope (ISMP Canada, 2004, p. 11, 14–15, 18; ISMP Canada, 2005, p. 4).

[3] In 1999, the U.S. Food and Drug Administration (FDA) published a report on the importance of collecting data on medication incidents in managing the risks posed by medication errors (FDA, 1999).

CMIRPS is a collaborative effort of Health Canada, CIHI, and ISMP Canada. Each organization plays a defined role in the delivery and implementation of CMIRPS. The roles and responsibilities specific to ISMP Canada are:

- Lead the collection and processing of individual practitioner data (CIHI is responsible for the hospital-based reporting component of CMIRPS);
- Follow-up (with permission) on specific incidents, with the intent to conduct a root cause analysis (RCA) as part of the prevention mandate;
- Assemble, summarize, and disseminate information regarding medication incidents/issues and prevention strategies in a timely manner through bulletins and alerts;
- Conduct additional analytical studies (for example, an aggregate RCA based on CMIRPS data submitted through standardized health service organization data, as well as events from organizations such as coroners' offices, professional regulatory agencies, and health care insurers), and disseminate these results; and
- Provide support for the development and implementation of preventative measures (ISMP Canada, 2005, p. 5).

2.2.2 Resources

ISMP Canada conducts a number of activities to fulfill its role in CMIRPS. Wholly-funded through a contribution agreement with Health Canada, CMIRPS initially focused on the collection, analysis, and dissemination of information from medication incident reports (i.e., the reporting system, analyses of incidents, and safety bulletins and alerts). The initial term of the contribution agreement, December 11, 2003–March 31, 2008, was extended until March 31, 2010. In addition, in 2008, ISMP Canada received supplemental funding to expand its CMIRPS-related activities.[4] Resources for CMIRPS are provided in Table 1 (dollar figure and as a percentage of total ISMP Canada revenue).

Table 1: Resources for CMIRPS (in $)

	03/04	04/05	05/06	06/07	07/08	08/09	09/10	Total
Base program	427,574	693,778	799,665	799,468	799,993	800,000	800,000	5,120,478
Supplemental funding	0	0	0	0	0	400,000	400,000	800,000
Total CMIRPS resources	427,574	693,778	799,665	799,468	799,993	1,200,000	1,200,000	5,920,478
Total ISMP Canada revenue	993,030	1,350,643	1,974,037	2,030,687	2,496,980	3,019,107	3,373,291	15,238,045
CMIRPS as % of total revenue	43%	51%	41%	39%	32%	37%	38%	39%

[4] The supplemental funding was received for activities starting in September 2008 and covered 19 months until March 2010. ISMP Canada has received an extension until October 2010.

2.2.3 Activities

The core ISMP Canada activities for CMIRPS and the expansion activities under the supplemental agreement with Health Canada are described below.

Collection of reports on medication incidents. As part of its Individual Practitioner Reporting System for Medication Incidents, ISMP Canada had been collecting reports on medication incidents from practitioners prior to receiving funding by Health Canada. Between 2000 and 2004, ISMP Canada received more than 5,000 incident reports. The individual practitioners reporting component allows for the direct and voluntary reporting of medication incidents by any individual practitioner across various health settings. The practitioner may have been involved or may have observed the incident, and though confidentiality is safeguarded at all times the report may be submitted anonymously. Patient identifiers are not collected. Incidents reported are not restricted to actual critical medication incidents (which receive priority attention) but may be of potential events or near misses. Reports can be made via telephone, mail, email, web portal, or electronic transmission.

The Individual Practitioner Reporting System has been aligned with CIHI's reporting system for health service organizations—the National System for Incident Reporting (NSIR). This ensures consistency and coordination between the information being recorded in both systems, and facilitates analysis and comparability of the data on a national level. International standards have also been reviewed in defining the data elements of this system.

Processing and analyzing medication reports. ISMP Canada is responsible for reviewing and analyzing all data related to medication incidents found in both the Individual Practitioner Reporting System and the NSIR. Initially, ISMP Canada conducted approximately 20 analyses per month of medication incidents. The decision of what analyses to conduct is determined by the CMIRPS analysis framework and prioritization matrix (ISMP Canada, 2010, March). The matrix considers the actual and potential severity of the event and the likelihood of recurrence. With its expanded funding from Health Canada, ISMP Canada is conducting an additional 10 analyses per month (i.e., a total of 30 incidents per month), which enables more studies of near-miss events or other events that have the potential to, but did not result in patient harm, as well as cluster analyses of aggregate CMIRPS data.

Safety bulletins and alerts about medication incidents and prevention strategies. ISMP Canada produces about 10 safety bulletins per year for CMIRPS. These bulletins are part of its broader knowledge transfer strategy. The bulletins and alerts are intended to disseminate the knowledge gained through the analysis of medication incident reports, thereby raising awareness around specific medication incidents and strategies to prevent similar incidents. Bulletins generally provide recommendations developed by ISMP Canada in consultation with health care practitioners and other experts. The safety bulletins are posted on ISMP Canada's website. In addition, individuals can subscribe to receive CMIRPS-funded safety bulletins free of charge and the ISMP US medication safety alerts for a charge. ISMP Canada also has fan-out agreements with several organizations to further disseminate CMIRPS bulletins (ISMP Canada, 2010, p. 6).

Medication Safety Self-Assessment program. As the name implies, the Medication Safety Self-Assessment (MSSA) program is a self-assessment program designed to assist health care organizations in evaluating the safety of their medication systems by identifying areas requiring improvement, and developing strategies for systems enhancement. It provides the organization a baseline to compare progress in the area of medication safety. ISMP Canada has developed MSSA Programs for acute-care, long-term care, complex continuing care, and community/ambulatory pharmacy and operating room settings. Recently the interface for these programs was upgraded to allow users to compare data within health regions. Initially, provincial agreements with ISMP Canada for MSSAs were in Ontario, British Columbia, and Alberta. With expanded funding, it is being offered at reduced rates across Canada.

Root Cause Analysis workshops and frameworks. Root Cause Analysis (RCA) refers to investigations of critical incidents to determine what factors led to the adverse outcome. The focus of RCAs is on how systems and processes contribute to the event, rather than individuals. It includes identifying the root and contributing factors, appropriate risk reduction strategies, as well as developing an action plan and strategies to measure the effectiveness of the plan. The tool, though commonly used in acute care environments, is not limited to any particular health care setting and has been utilized in the areas of mental health and home care services. As part of CMIRPS, ISMP Canada conducts RCAs to follow-up on selected incidents that have been captured through the reporting system.[5] Results of the RCAs are disseminated through other CMIRPS activities (such as safety bulletins), with the appropriate permission.

ISMP Canada is also working to increase the capacity of health care organizations to conduct their own RCAs. To this end, the RCA framework was developed by ISMP Canada, with CPSI and Saskatchewan Health (Hoffman, Beard, Greenall, U, & White, 2006; with adaptation and French translation by *Groupe Vigilance pour la Sécurité des Soins*). Another capacity-building activity is ISMP Canada's one-day RCA workshops, which introduce participants to the process of RCAs, in part, through simulated activities. ISMP Canada has adapted and translated workshop materials into French and has conducted workshops in French. Under the supplemental funding, ISMP Canada is to increase the number of workshops and expand their reach to new target audiences.

In addition to the one-day RCA workshops, ISMP Canada, in collaboration with CPSI and Saskatchewan Health, developed a Train-the-Trainer educational program. These workshops lead to further dissemination of RCA teachings as participants take their knowledge back to their organizations.

Failure Mode and Effects Analysis workshops and frameworks. While an RCA is a method to find the cause of past incidents, Failure Mode and Effects Analysis (FMEA) is a prospective effort to identify potential system weaknesses and develop appropriate preventative strategies (ISMP Canada, 2006). ISMP Canada has developed an FMEA framework for health care processes, and conducts educational workshops on FMEA. Under the supplemental funding, ISMP Canada is to increase the number of FMEA workshops and expand their reach to new target audiences.

[5] ISMP Canada will also provide RCA consultations (for a fee) in response to requests from health care facilities. These RCAs are not part of ISMP Canada's activities for the CMIRPS.

Responding to queries on medication safety. ISMP Canada also serves as a resource to health care institutions and practitioners about medication safety issues and prevention strategies. Stakeholders can email or phone ISMP Canada and staff will assist them.

Consumer Reporting and Learning Strategy and Pilot. As part of its proposal to expand the reach of CMIRPS, ISMP Canada developed and is piloting a consumer reporting and learning strategy. The theory behind the expansion is that while consumers can provide valuable insight into issues regarding medication safety practices, their potential contribution is often ignored. By targeting consumers and encouraging them to report incidents, additional medication safety incidents that would not be reported through hospitals and/or practitioners will be collected, which will mean that more complete information will be gathered. The Individual Practitioner Reporting System has received reports from consumers; however, the volume has been low (ISMP Canada, 2009). On March 10, 2010, www.SafeMedicationUse.ca was launched. In addition to allowing consumers to report medication incidents, it also contains consumer-focused educational materials to encourage and support the proactive role of consumers in medication safety. Also, as part of CMIRPS consumer reporting and learning component, five additional safety bulletins have been produced specifically for consumers, and are available through the SafeMedicationUse and ISMP Canada websites.

Look-alike, sound-alike products. ISMP Canada is working with national and international experts to develop a draft standard operating procedure for the assessment of look-alike, sound-alike drug product names.

Medication safety conferences, workshops, and webinars. These are all knowledge transfer activities under the supplemental funding agreement. The one-day medication safety workshops are specifically designed to suit individual organization's needs. Four conferences per year were proposed. Within the span of twelve months (April 2009–March 2010), 45 workshops, conferences, and presentations were developed through CMIRPS (ISMP Canada, 2010).

3.0 Methodology

The evaluation comprised four lines of evidence and was guided by an evaluation matrix (see Appendix A). Data collection instruments (interview guides and survey questionnaire) used for the evaluation are in Appendix B. The methodological approach and the instruments were developed in consultation with representatives of ISMP Canada. Health Canada also provided feedback on the evaluation matrix and methodology. This section of the report describes each of the lines of evidence.

3.1 Document review

The purpose of this task was to provide background and contextual information for the evaluation and to respond directly to some of the questions identified in the evaluation matrix.

The document review included several types of documents:

- ISMP Canada's proposals and contribution agreement with Health Canada
- Documents created during the development of CMIRPS (e.g., the business plan, environmental scan, project charter)
- ISMP Canada's progress reports to Health Canada
- Previous evaluation of ISMP Canada
- ISMP Canada's website
- Relevant external literature

A bibliography of the documents reviewed is in Appendix C.

3.2 Case studies

The purpose of the case studies is to explore, in-depth, certain reported medication incidents/issues, ISMP Canada's response (through its activities for CMIRPS), and the effect of this work on health care practices and patient safety.

In total, six case studies were conducted. Each case study involved three interviews (some with small groups) with key individuals involved in some aspect of the medication incident and/or response. In total, 21 individuals were interviewed.[6] Of those, seven were ISMP Canada representatives and fourteen were other health care professionals (e.g., physicians, directors of pharmacies, clinical educators) or representatives of manufacturers. The interviews were conducted by telephone and each interview lasted approximately one hour. In addition to interviews, relevant documentation was reviewed (e.g., safety bulletins, RCA reports, academic literature).

The six case studies were chosen in consultation with ISMP Canada to highlight various ways in which ISMP Canada has been involved, through its activities for CMIRPS, in addressing medication incidents:

- Examples of the impacts of RCAs: the RCAs on hydromorphone and 5-fluorouracil
- Examples of the impacts of priority events where ISMP Canada analysts identify an issue and use the safety bulletin as an alert system to increase awareness of a medication issue: CMIRPS work on epinephrine
- Examples of the effect of evidence-based recommendations made in the CMIRPS safety bulletins: CMIRPS work on neuromuscular blocking agents (NMBA)
- An example of the synergies created by leveraging other projects with CMIRPS work: the work done on venous thromboembolism (VTE) prophylaxis and the concentrated potassium chloride work that led to a Required Organizational Practice or an accreditation standard

Summaries of each case study are in Appendix D.

[6] For ISMP Canada representatives, some individuals were interviewed for more than one case study. They are counted separately here for each case study they participated in.

3.3 Key informant interviews

PRA conducted 8 interviews with a total of 14 individuals. Key informants were chosen based on their detailed knowledge of some aspect of ISMP Canada's activities for CMIRPS. ISMP Canada identified appropriate key informants, including ISMP Canada staff (n=5); Health Canada representatives (n=2); members of Accreditation Canada (n=2); and individuals in the fields of pharmacy (i.e., directors of pharmacy), medication safety and/or patient safety (i.e., director of quality, manager of medication safety, patient safety officer) (n=5). Interviewees in the latter category represented health care institutions in Quebec, Ontario, Manitoba, Alberta, and British Columbia. The interviews were conducted by telephone and each interview lasted approximately one hour.

3.4 Survey of stakeholders

PRA conducted a web-based survey of ISMP Canada's CMIRPS clients. The survey supplements the case study and key informant analyses by providing a national picture of the use and effectiveness of ISMP Canada's CMIRPS activities.

ISMP Canada provided PRA with a list of potential survey respondents from their database of safety bulletin recipients and workshop participants.[7] The sample included each individual's name, position, organization, province, email address, and phone number, if available. PRA reviewed the sample and removed any records with duplicate email addresses or characteristics (such as same name and organization but separate email addresses) as well as individuals that did not have an associated email address. Employees of ISMP (whether in Canada or abroad) were also removed from the sample. This left 5,868 potential respondents.[8] The survey was made available in both English and French.

The survey was accessible from July 9, 2010 until July 27, 2010. To raise response rates, two reminder emails were sent out roughly one week apart to individuals who had not yet completed the survey. In total, 611 respondents completed the survey, which is a response rate of 10%. The response rate was likely affected by several factors. The distribution list for ISMP Canada has expanded substantially. Since March 2010 it doubled, which means that half of the potential respondents were among these more recent additions to the list and may have had less contact with ISMP Canada. In addition, due to project deadlines, the survey was online for only two and a half weeks, and it occurred during the summer. The survey also covered many topics in order

[7] ISMP Canada's initial sample list consisted of 6,748 individuals, including physicians, pharmacists, nurses, risk managers, and patient safety experts, among others. Consideration was given to distributing the survey using the distribution lists of health care associations (such as the Canadian Society of Hospital Pharmacists) in addition to ISMP Canada's list. However, because of the overlap between the ISMP Canada database and the distribution lists of health care associations and the need to target the survey to an audience that will be able to respond to the survey questions, it was determined that the ISMP database was the most appropriate method of distribution.

[8] It is important to note that this list would also contain individuals who had completed a key informant or case study interview for this evaluation.

to respond to the evaluation framework. It included 21 questions, many with multiple parts, and took on average 16.5 minutes to complete.[9]

Tabular results of the survey are in Appendix E.

3.4.1 Profile of client survey respondents

Survey respondents included a range of health care professionals.[10] However, three categories predominated: over one-third (39%) are nurses; about one-quarter (24%) are pharmacists; and just over one-sixth (17%) are hospital management/administration. Other health care professionals responding to the survey included risk managers (6%); patient safety officers and quality improvement personnel (each at 4%); physicians, academics, clinical educators, and government personnel (all under 4%).

Almost three-quarters (73%) of respondents work in urban centres. All provinces and territories are represented in the survey responses; however, the majority work in Ontario (56%); followed by British Columbia (12%); Alberta (8%); Manitoba (7%); Nova Scotia (7%); Saskatchewan (6%); and Quebec (5%). The remaining provinces and the territories each have either 1% or 2% of the respondents.

The top three practice settings reported by respondents are community hospitals (29%); nursing homes/long-term care (26%); and teaching hospitals (24%). Other settings in which respondents work include specialty hospitals, rehabilitation centres, complex community care, emergency medical services, community pharmacies, home care, and outpatient/ambulatory care (ranging between 3%–7%). Eight percent of respondents indicated they do not work in a health care setting.

9 This excludes respondents who took more than one hour to complete the survey. This is done to exclude situations where respondents leave their browser open but do not respond for lengthy periods of time or who close the survey and continue it on another day.

10 All of the questions discussed in this section allowed multiple responses.

4.0 Evaluation findings

This section of the report combines information from all lines of evidence. The presentation of the findings follows the main evaluation issues and responds to the questions identified in the evaluation matrix. In describing the interview findings, "interviewees" is used to refer to case study participants and key informants combined; otherwise, they are referred to separately.

4.1 Awareness of CMIRPS activities

The stakeholder survey asked participants about their level of awareness on ten ISMP Canada activities for CMIRPS. On average, participants indicated they were at least somewhat aware of eight of the ten activities, with the majority (73% to 89%) being at least somewhat aware, with the exception of awareness of safety bulletins and alerts (99%) and the Consumer Reporting and Learning Pilot Project (54%).[11] Complete results are in Table 2.

Table 2: Level of awareness of ISMP Canada's activities for CMIRPS (n=611)

What is your level of awareness of…?	Very aware	Somewhat aware	Not at all aware
Safety bulletins and alerts	85%	13%	1%
Medication safety workshops and webinars	50%	39%	11%
RCA workshops and framework	48%	33%	19%
Development and implementation of medication product improvements	45%	43%	12%
Development and/or facilitation of medication safety practice improvements	44%	44%	12%
MSSA Programs	44%	38%	18%
FMEA workshops and framework	43%	30%	27%
Individual Practitioner Reporting System	39%	48%	13%
Responding to queries on medication safety	29%	46%	26%
Consumer Reporting and Learning Pilot Project	11%	44%	46%

Source: Survey of stakeholders.

Interviewees found the level of awareness of ISMP Canada to be high, but noted that awareness of the fact that certain ISMP Canada activities are a component of CMIRPS is lower. ISMP Canada also reported that it has not undertaken a promotional or communications strategy to build awareness of CMIRPS. The concentration of its work has been on developing and delivering the program.

The evaluation evidence also indicates that awareness of ISMP Canada's activities for CMIRPS varies by the type of health care provider and institution. Interviewees believe that pharmacists are most aware of the program because of their pivotal role in medication safety (ordering, storing, dispensing). As medication safety initiatives in many health care organizations focus more on combined accountability, awareness of CMIRPS may also broaden. For example, in health care organizations where pharmacists are integrated into interdisciplinary teams to address patient safety issues, interviewees believe that other health care professionals, such as nurses and

[11] Combined percentages differ from Table 2due to rounding.

physicians, are more likely to be aware of CMIRPS. However, in general, it is believed that front line staff will know whether policies or procedures have changed, but are unlikely to know that ISMP Canada recommendations are the impetus or have influenced the changes.[12] Physicians were noted as a group with which CMIRPS has less of a profile. Interviewees made suggestions for how to gain the attention of physicians: create a medication safety bulletin that targets physicians specifically (similar to Nurse Advise-ERR); publish CMIRPS research results in peer-reviewed medical journals, such as the *Canadian Medical Association Journal*; have messages that appeal to the evidence-based approach to medicine that is predominant today (i.e., do not only warn of potential hazardous conditions but provide compilation of medication incidents that led to patient harm); contribute items to physicians professional organizations' newsletters; use more direct email contacts with physicians; and have information posted on the Canadian Medical Protective Association website and/or contained in its newsletter.

ISMP Canada has made efforts to expand its distribution network and reach more health care professionals. From 2008 to 2010, it increased its distribution of safety bulletins three-fold and has agreements with various professional associations to fan-out the bulletins to their membership (ISMP Canada, 2010, p. 3 & 6). That being said, ISMP Canada may want to review its distribution network to ensure it is achieving its desired coverage. For example, when considering only the Canadian entries (i.e., not international) in the distribution list, over 60% are from Ontario. Although the distribution list does not categorize the entries by type of health care professional, the survey respondents are mostly nurses, pharmacists, hospital administrators or management, and the majority work in a hospital setting.[13]

Case studies also demonstrate that ISMP Canada uses a combined approach of targeted and general distribution to alert the health care community to medication issues. Safety bulletins are always the primary method for general dissemination, but ISMP Canada has also incorporated some of the learning from medication incidents into RCA workshops. In addition, ISMP Canada targets relevant sectors of the health care community. For the inadvertent injection of topical epinephrine, ISMP Canada conducted additional dissemination efforts with groups whose members are most likely to have the greatest opportunities to reduce risk for occurrence of these particular errors (i.e., the Canadian Society of Otolaryngology, the Operating Room Nurses Association of Canada, the Canadian Society of Hospital Pharmacists, and the Canadian Anaesthesiologists' Society).

Interviewees generally believe that ISMP Canada has targeted those involved in the medication use cycle as is appropriate. Some did comment that ISMP Canada might consider a more concentrated effort on reaching health care sectors outside of hospitals, which tend to have an easier time implementing ISMP Canada recommendations because of the available infrastructure (e.g., medication safety committees with interdisciplinary teams). Sectors mentioned include community pharmacies, community clinics, long-term care facilities, and rural hospitals.

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12 Survey results support this view. Among the top three respondent groups (nurses, pharmacists, and hospital administrators/management), hospital administrators/management are more likely to be aware of CMIRPS activities and nurses are least likely to be aware.

13 It would be useful for ISMP Canada to review its distribution list on the demographic variables mentioned here. This would enable informed choices about the focus of any future promotional or communication strategy in terms of the type of health care providers/sectors and geographic areas it wants to target.

Additional suggestions were made to help increase awareness of ISMP Canada's activities for CMIRPS:

- Target communications to practitioners/organizations so that the particular message is relevant to their work
- Use its networks within each province/territory to further disseminate information
- Engage the provinces and negotiate a provincial agreement to supply bulletins and alerts to all hospitals, health authorities, etc., with the province being responsible for circulation of the material
- Increase efforts to educate particular stakeholder groups, such as community pharmacies, the geriatric community, and advocacy groups for the general public

4.2 Use of CMIRPS activities

Corresponding to the results on awareness of CMIRPS activities, the evaluation found that CMIRPS safety bulletins and alerts are by far the activity that most individuals and organizations are engaged in, followed by attending medication safety conferences or webinars. See Table 3. For many of the listed activities, one-third or more of respondents indicated they did not know whether their organization participated, hence the rate of participation among organizations may actually be greater.[14]

Table 3: Participation in ISMP Canada activities for CMIRPS (n=611)

Have you/your organization participated in the any of the following activities?	**You**			**Your organization**		
	Yes	**No**	**N/A**	**Yes**	**No**	**DK/NA**
Receiving bulletins and alerts	92%	5%	3%	82%	4%	14%
Attending medication safety conferences/webinars	61%	34%	5%	60%	11%	30%
Using MSSA modules	37%	48%	15%	41%	15%	44%
Using RCA framework	36%	54%	10%	42%	18%	40%
Using FMEA framework	36%	55%	10%	45%	15%	40%
Attending RCA workshops	35%	56%	9%	43%	18%	39%
Attending FMEA workshops	33%	59%	9%	39%	19%	42%
Asking ISMP Canada for medication safety-related information (phone or email queries)	31%	63%	7%	38%	17%	45%
Reporting or sharing information about medication incidents	28%	53%	19%	42%	20%	38%

Source: Survey of stakeholders.

[14] For the DK/NA category in Table 3, most respondents reported they did not know whether their organization engaged in these activities. Typically, less than 5% indicated these activities were not applicable to their organization. For complete results see Appendix E.

The evaluation had limited ability to determine differences in the use of CMIRPS activities among health care providers and institutions, as the interviewees and survey respondents mainly represented nurses, pharmacists, and hospital administration/management and worked in community hospitals, teaching hospitals, or long-term care facilities. Survey results show that pharmacists are more likely to be involved in reporting medication incidents and using MSSAs, and hospital administration/management are more likely to attend RCA and FMEA workshops and use the frameworks. All are equally likely to receive safety bulletins. Among institutions, the greatest differences involved attending and using RCA and FMEA workshops and frameworks as well as attending medication safety conferences/webinars, which community hospitals are most likely to engage in. Nursing homes/long-term care facilities are most likely to use MSSA modules, but less likely to report medication incidents. See Appendix E (Table 6) for these more detailed survey results.

The following discussion considers the use of key CMIRPS activities in more detail.

Reporting systems for medication incidents. As of March 31, 2010, ISMP Canada's complete database (which includes reports from individual practitioners, community pharmacy reporting, consumer reporting, and provincial initiatives that provide their information to ISMP Canada) had 53,452 reports of medication incidents (ISMP Canada, 2010, p. 3). Of those, 1,909 resulted in patient harm and 137 involved fatalities. Reporting medication incidents is voluntary, which is important to encourage reporting and is also consistent with a non-punitive approach. However, this means that even a national reporting system such as CMIRPS cannot provide an accurate count of the number of medication incidents.

The best available information on the use of medication incident reporting systems is the Hospital Pharmacy in Canada Survey. In 2007/08, all participating hospitals reported having a medication incident reporting system in place (Babich et al., 2008, p. 53).[15] This result demonstrates compliance with Accreditation Canada's ROP on Adverse Events Reporting, which requires that "the organization establishes a reporting system for sentinel events, adverse events, and near misses, including appropriate follow-up" (Accreditation Canada, 2010, p. 5).

The 2003/04 Hospital Pharmacy in Canada Survey report believed this widespread use of reporting systems would "facilitate future voluntary reporting to the national database" (McKerrow et al., 2004, p. 51). However, the 2007/08 survey results show that there are various routes for reporting medication incidents. Although all participating hospitals have a reporting system, just under half (47%) report to an external reporting program. Of these respondents, the avenues for reporting include health region reporting programs (54%), ISMP Canada (40%), and provincial reporting programs (34%) (Babich et al., 2008).[16] In the case of health region and provincial reporting programs, organizations direct their data on medication incidents to a provincial or regional office, which may or may not provide the information to CIHI's NSIR program. As the system for reporting medication incidents evolves, how the information will be shared with CMIRPS is unclear. A challenge for ISMP Canada and its partners (CIHI, Health

15 This is an increase from 96% in the 2005/06 survey (Babich et al., 2006, p. 58).

16 The hospitals reporting to ISMP Canada were likely using the Analyze-Err software program developed by ISMP Canada. As for provincial reporting systems, British Columbia, Alberta, Saskatchewan, and Quebec all have some form of provincial reporting.

Canada, and CPSI) will be to increase awareness of CMIRPS and the importance of a national database in addressing the challenges posed by medication incidents.

Safety bulletins and alerts. Corresponding to the survey results (see Table 3, above), virtually all interviewees indicated that their organizations received these bulletins and alerts, either through an individual or provincial subscription. Of survey respondents who have been receiving the bulletins and alerts, more than one-third (38%) have been receiving these bulletins for more than three years. Survey results show active use of the bulletins and alerts.[17]

- Almost nine-tenths (87%) of respondents read every or most bulletins.
- Just over 60% disseminate every or most bulletins within their organization.
- Two-thirds use every or most bulletins to identify potential medication safety issues within their organization (this rises to 94% if those who use "some" bulletins are included).
- Just under 50% use every or most bulletins to implement changes in their organization's policies/practices/processes/standards (this rises to 84% if those who use "some" bulletins are included).

[17] The bulleted results are based on respondents who have received safety bulletins and alerts. In addition, those respondents who indicated that the activity was not applicable to their role or position are excluded from the calculation of percentages.

As Figure 1 illustrates, awareness and interest in the CMIRPS safety bulletins has increased over the last couple of years, as the number of hits to ISMP Canada's CMIRPS safety bulletin website has increased. The total number of hits increased from 12,950 in 2008 to 16,300 in 2009, and the first half of 2010 is already registering 10,354 hits.

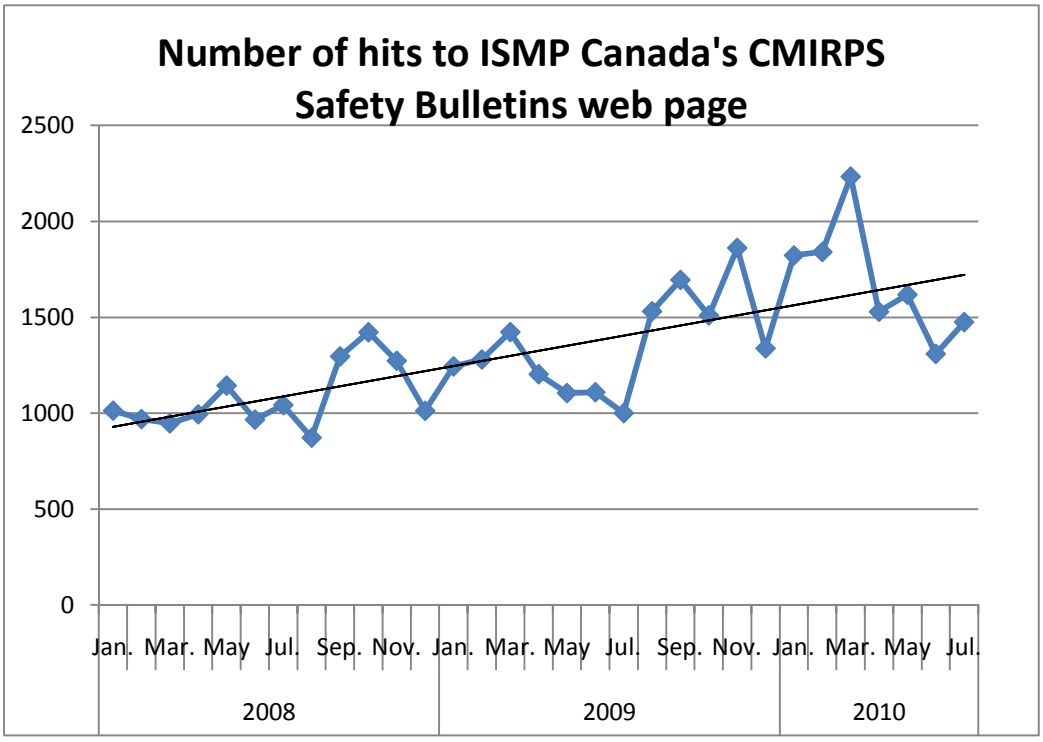

Figure 1[18]

According to interviewees, ISMP Canada bulletins and alerts are perceived as an excellent source of background/resource material that supplement the work being done within the organization, adding credibility to the organization's own work. Organizations with dedicated medication safety committees reported they systematically review safety bulletins to identify potentially hazardous situations in their facility that could result in a near miss or harmful error. Interviewees noted the value in having information on preventative strategies in the bulletin.

MSSA Programs. According to the 2008 Hospital Pharmacy in Canada Survey, almost two-thirds (63%) of participating hospitals conducted an MSSA within the previous two years. Of these, almost all (93%) used ISMP Canada's MSSA tool (Babich et al., 2008, p. 55). These survey results address the use of an MSSA module in hospitals with more than 50 acute care beds. In addition to the MSSA module for acute care, ISMP Canada offers modules for long-term care and nursing homes and community pharmacies (ISMP Canada, 2008), as well as complex continuing care. Confirming the Hospital Pharmacy in Canada Survey results, many key informants reported that their organizations conducted MSSAs systematically (e.g., every two or three years, a year prior to Accreditation Canada's assessment, across all hospitals in the

[18] The formula for the trend line is y=mx+b where y is the number of hits for the month, m is the slope of the line, x is the month number, and b is the y-intercept. Using this formula, the number of hits has increased on average by 26 hits per month.

province). Under the Managing Medications Standards, Accreditation Canada surveyors commonly ask whether the organization has conducted an MSSA, which key informants believe has increased the use of this tool.

Under the supplemental funding, ISMP Canada was to expand the program by offering the acute care and long-term care modules to provinces beyond Ontario, British Columbia, and Alberta. The community pharmacy MSSA launched in 2009/10. Table 4 provides the number of MSSA modules offered and shows that 488 modules took place between September 2008 and March 31, 2010 and, in addition to the original three provinces, expanded to another six provinces.

Table 4: MSSA modules offered with supplemental funding (September 2008–March 2010)

Type of MSSA module	Number and province
Community and ambulatory pharmacy	Nova Scotia (n=12) New Brunswick (n=18) Ontario (n=26) Alberta (n=17)
Complex continuing care and rehabilitation	Quebec (n=1) Ontario (n=7)
Hospitals	Prince Edward Island (n=1) Nova Scotia (n=1) Quebec (n=1) Ontario (n=11) Saskatchewan (n=7) British Columbia (n=1)
Long-term care	Prince Edward Island (n=1) Nova Scotia (n=2) Quebec (n=1) Ontario (n=323) Manitoba (n=8) British Columbia (n=8)
Operating room	New Brunswick (n=1) Ontario (n=28) Manitoba (n=1) British Columbia (n=12)

RCA and FMEA workshops and frameworks. Between 2007 and 2009, the number of RCA workshops had been decreasing, as was participation. The supplemental funding was intended to increase the reach of these workshops, and the first quarter of 2010 indicates an increase in both the number of workshops and participants. In addition, up to 2009, the majority of these workshops were held in Ontario. In 2010, ISMP Canada has spread its reach to organizations outside Ontario, although the number of workshops is too small to demonstrate a trend.

Table 5: RCA and FMEA workshop participation (by year)

	Number of workshops/participants (2006–2010)			
	RCA workshops	**RCA participants**	**FMEA workshops**	**FMEA participants**
January–March 2010	7	123	10	192
2009	5	96	18	374
2008*	9	187	16	688
2007	17	637	14	410
2006	12	405	22	695

* Some workshops were presented in combination (for example, an RCA and FMEA workshop, or a FMEA workshop wrapped into an Accreditation Canada workshop); hence, the number of actual participants may not be precise.

Key informants noted that uptake of these workshops may differ from one site to another. To take full advantage of these workshops and build capacity in different departments, organizations try to maximize participation through several measures. For example, presentations at patient safety conferences may incorporate an actual incident and the resulting RCA, and be presented by ISMP Canada and others that were actively involved in the analysis. As well, webcasting has allowed for greater knowledge about FMEA for individuals who could not attend a workshop in person, as well as providing a refresher to the workshop. Some organizations use the framework internally to train staff and use the Train-the-Trainer tool developed by ISMP Canada. The intention of these activities is to inform others on how to use these tools and to get them to use them.

Responding to queries on medication safety. ISMP Canada received 420 email inquiries and 65 telephone inquiries from April 2009 to March 2010—many sought information or requested assistance in applying medication safety practices (ISMP Canada, 2010, p. 32).

Those interviewed who have contacted ISMP Canada reported they value their relationship and found ISMP Canada very helpful and accommodating. They commented that those making queries are not limited to members of safe medication practice committees or other leadership groups, but included pharmacists and other front line staff. In the survey results in Table 3 (above), well over one-third (38%) of respondents report that their organization has used this CMIRPS service provided by ISMP Canada, which is a sizable proportion given the service is not well-publicized. Key informants reflect the survey results as some mentioned they were unaware of this service. On its website, ISMP Canada has a contact page, but it does not specify the types of assistance they provide (i.e., advice and information).

Integration of activities into health care practice. To understand the level of adoption of CMIRPS activities, the evaluation considered whether organizations have either formal written policies or informal but commonly understood expectations for their use. Survey results demonstrated substantial integration of CMIRPS activities into health care practice with a small minority of respondents (1%–14%) reporting their organizations do not have either expectations or policies. In particular, over 90% of respondents indicated their organizations have formal policies or expectations that medication incidents be reported (although this does not have to be through CMIRPS). Reporting medication incidents was the one area where the large majority have formal policies. For the other CMIRPS activities, organizations are more likely to have commonly understood expectations.

Survey results also demonstrate that safety bulletins have become well-integrated into the culture of health care organizations. While their use is more likely to be part of an organization's commonly understood expectations than written policies, over two-thirds of respondents' organizations have either expectations or policies about using safety bulletins. This includes disseminating them, using them to identify potential medication safety issues and/or to implement changes in practices or processes, and adopting the ISMP Canada recommendations they contain. A majority of respondents (60%) also reported that their organization has expectations or policies (almost equally split between the two) for conducting local analyses using the RCA framework. For the more preventative activities, conducting MSSAs or prospective risk assessment using the FMEA framework, half of respondents reported their organizations have policies or expectations for their use.

Table 6: Integration of CMIRPS activities into organizational polices or expectations (n=611)

Does your organization have either formal written policies or informal but commonly understood expectations for …	**Evidence of integration**			**Neither**	**DK/ NA**
	Expectations	**Formal policies**	**Total %**		
Reporting or providing information about medication incidents	9%	82%	**91%**	1%	8%
Using safety bulletins and alerts to identify potential medication safety issues	61%	10%	**71%**	11%	18%
Adopting ISMP Canada recommendations into policies, practices, processes, or standards	57%	13%	**70%**	9%	21%
Using safety bulletins and alerts to implement changes in policies, practices, processes, or standards	59%	11%	**70%**	12%	19%
Disseminating safety bulletins and alerts	59%	9%	**69%**	13%	18%
Conducting local incident analyses using the RCA framework	31%	29%	**60%**	10%	31%
Conducting prospective risk assessment using the FMEA framework	32%	18%	**50%**	14%	36%
Conducting MSSAs	36%	14%	**49%**	14%	37%

Source: Survey of stakeholders.
Note: Row percentages may not sum to 100% due to rounding. In addition, level of integration subparts may not sum to total level of integration percentage due to rounding.

4.3 Impact of CMIRPS activities

The evaluation evidence demonstrates that ISMP Canada activities have led to changes in organizational policies, practices, processes, and standards. The case studies provide detailed examples of organizational changes that resulted from ISMP Canada's work on six medication issues (see discussion in Table 9 below). Similarly, key informants provided examples of specific types of changes/impacts:

- In Alberta, MSSAs were conducted across the province and those results have been considered in establishing provincial priorities for medication safety.
- Within some health care organizations, gap analyses are conducted using ISMP Canada recommendations.
- Within one regional health authority, pharmacy labelling practices that used to vary by location are now standardized using ISMP Canada recommendations.
- After having an RCA conducted by ISMP Canada, which identified a different root cause for a medication event than had been determined from the local investigation, a regional health authority developed a new policy on incident management that recommends an RCA for a serious event.

The stakeholder survey provides a more pan-Canadian perspective of ISMP Canada's impact. Based on the stakeholder survey, ISMP Canada safety bulletins and alerts and ISMP recommendations have led to the greatest changes. About three-quarters of survey respondents reported some effect on their organizations' policies and practices as a result of using the bulletins and alerts to identify potential medication safety issues (76%) or to implement changes (73%). A similar proportion (72%) reported that adopting ISMP Canada recommendations has led to changes within their organizations.

Other ISMP Canada activities have also had an effect on organizational policies and practices. Over half of survey respondents said that reporting or sharing information about medication incidents to or with ISMP Canada has had some effect, while a similar proportion said that conducting local incident analyses using the RCA framework has had some effect (57% and 54% respectively). About half reported that their organizations' policies and practices have changed because of conducting Medication Safety Self-Assessments (50%) and conducting prospective risk assessment using the Failure Mode and Effects Analysis framework (48%).

It should be noted that respondents indicating no effect for ISMP Canada activities are in the single digits. The differences discussed above about the effects of the various activities are mainly a matter of degree (percentages reporting major, moderate, or limited effect) and/or are the result of the proportion of respondents who answered "don't know" or "not applicable."

Table 7: Perceived extent to which ISMP Canada CMIRPS activities led to changes in policies, practices, processes, or standards of stakeholder organizations (n=611)

To what extent have the following activities led to changes in your organization's policies, practices, processes, or standards?	No effect	Some effect				DK/ NA
		Limited effect	Moderate effect	Major effect	Total (some effect)	
Using ISMP Canada safety bulletins and alerts to identify potential medication safety issues within my organization	2%	20%	32%	24%	**76%**	22%
Using ISMP Canada safety bulletins and alerts to implement changes in my organization's policies, practices, processes, or standards	3%	19%	31%	23%	**73%**	25%
Adopting ISMP Canada recommendations into policies, practices, processes, or standards by my organization	2%	15%	31%	26%	**72%**	26%
Reporting or sharing information about medication incidents to/with ISMP Canada	4%	16%	22%	18%	**57%**	39%
Conducting local incident analyses using the RCA framework	5%	12%	25%	18%	**54%**	42%
Conducting Medication Safety Self-Assessments	3%	12%	23%	15%	**50%**	47%
Conducting prospective risk assessment using the FMEA framework	4%	12%	22%	14%	**48%**	48%

Source: Survey of stakeholders.
Note: Row percentages may not sum to 100% due to rounding. In addition, subparts of "some effect" may not sum to "total (some effect)" due to rounding.

Having published more than 90 safety bulletins over almost a decade, ISMP Canada has made hundreds of recommendations related to medication incidents. To gauge the impact of ISMP recommendations across the health care system, the evaluation chose to focus on six medication incidents through the case studies and seven through the survey (with overlap between the two). Because ISMP Canada recommendations specifically address the medication incident and the context in which it arises, the impact of the recommendations varies by the health care setting. Table 8 presents the results overall and by the three main practice settings represented by survey respondents. Key results are:

- The recommendations concerning dangerous abbreviations, symbols, or dose designations, which apply across health care settings, have had substantial impact —80% of survey respondents reported that their organizations have made changes based on these recommendations.

- Recommendations around narcotic/opioid products are relevant across many practice areas and almost two-thirds (63%) of survey respondents indicated that their organizations had made practice changes based on ISMP recommendations. That being said, adoption of ISMP Canada recommendations is higher in community hospitals (82%) and teaching hospitals (73%).

- Similarly, for heparin products, a majority (58%) of survey respondents reported changes in health care practices, which was also much higher for community hospitals (85%) and teaching hospitals (71%).

- Certain medications are used almost exclusively in the hospital setting, such as concentrated KCI, neuromuscular blocking agents (NMBA), concentrated epinephrine for topical use, and fluorouracil. For these medications, few respondents who practice in a hospital setting indicate that the ISMP recommendations are not applicable to their practice (for a break down of the DK/NA category, please see Appendix E).
  - For concentrated potassium chloride, 90% of community hospitals and 82% of teaching hospitals have made changes based on ISMP Canada recommendations.
  - For NMBAs and the inadvertent injection of concentrated epinephrine intended for topical use, a large proportion of respondents who practice in a hospital setting (over half) did not know whether changes in practice have occurred. This could be because these recommendations apply to incidents that occur in the operating room (and for epinephrine for specific types of surgeries). As a result, respondents who work outside of that area of the hospital would likely not be aware of any changes made. For both of these types of incidents, more respondents reported that changes had been made based on ISMP recommendations than those that indicated no changes in practice had occurred.
  - Similarly, fluorouracil is a drug used in chemotherapy. Only respondents who work in oncology would likely know if practice changes had occurred based on ISMP Canada recommendations. As a result, just over one-tenth of respondents who practice in community hospitals or teaching hospitals indicated that practice changes were made. However, an almost equal number reported no changes.

Table 8: Stakeholder organizations that made changes to health care policies, practices, or standards based on ISMP Canada recommendations				
Has your organization made any changes to its health care policies, practices, processes, or standards based on the following ISMP Canada recommendations or considerations?	**Overall (n=611)**	**Community hospital (n=175)**	**Teaching hospital (n=146)**	**Nursing home/ LTC (n=158)**
Concentrated potassium chloride				
Yes	57%	90%	82%	28%
No	6%	3%	1%	13%
NA/DK	37%	8%	18%	58%
Narcotic/opioid agents				
Yes	63%	82%	73%	68%
No	12%	4%	6%	20%
NA/DK	26%	15%	21%	11%
Heparin products				
Yes	58%	85%	71%	51%
No	11%	3%	8%	20%
NA/DK	31%	12%	21%	29%
Neuromuscular blocking agents				
Yes	23%	42%	32%	11%
No	15%	12%	12%	22%
NA/DK	62%	46%	56%	68%
Fluorouracil				
Yes	9%	11%	13%	4%
No	14%	13%	10%	18%
NA/DK	77%	77%	77%	78%
Concentrated epinephrine injection				
Yes	24%	39%	29%	15%
No	17%	14%	14%	23%
NA/DK	59%	47%	57%	62%
Dangerous abbreviations, symbols, or dose designations				
Yes	80%	89%	84%	83%
No	6%	4%	4%	9%
NA/DK	14%	7%	12%	7%

Source: Survey of stakeholders.
Note: The practice settings allowed for multiple responses. Overall results and the results for the three main practice settings of survey respondents are provided.

While ISMP Canada's recommendations produce changes in the policies and practices of individual health care organizations, they can also be linked to a number of broader changes and initiatives. For example, Accreditation Canada has developed Required Organizational Practices (ROPs) pertaining to venous thromboembolism prophylaxis, standards for managing medications (including removal of concentrated injectable electrolytes such as potassium chloride from client services areas), and several ROPs pertaining to narcotic/opioid products. In addition, a cancer strategy group is currently working with Accreditation Canada and the Canadian Association of Provincial Cancer Agencies in an attempt to make ISMP Canada's recommendations on fluorouracil become standard practice. While development of these ROPs cannot be solely linked to ISMP Canada's recommendations, they are consistent with those recommendations and ISMP Canada was consulted or influenced their development.

In addition to providing recommendations to address system and process issues within the health care setting, ISMP Canada has also worked with manufacturers to remedy labelling, packaging, and naming issues identified as a contributing factor to medication incidents. Three case studies reflect this work:

- *Concentrated potassium chloride:* This drug, which is highly fatal if injected in its concentrated form, has been mistakenly used due to similar packaging and labelling. ISMP Canada worked with manufacturers to make packaging and labelling more distinctive, and to identify the premixed potassium chloride IV solutions needed so that facilities could remove the concentrated potassium chloride.

- *NMBAs:* ISMP Canada hosted a meeting of Canadian manufacturers to identify "ideal features" for packaging and labelling that would reduce the errors in use caused by product mix-ups. As of May 2010, all manufacturers of these agents have now changed their products to have a warning on the caps (e.g., Caution: Paralyzing Agent). Other distinctive features include red caps and the use of a warning on the ferrule, label, and package.

- *Concentrated epinephrine for topical use:* ISMP Canada worked with a manufacturer on product changes so that concentrated epinephrine for topical use and other products that contain diluted epinephrine for injection are not confused. The manufacturer has agreed to change the packaging of the topical epinephrine so that there is a clear visual cue that the medication is for topical use only.

In all, ISMP Canada reports that fifty changes have been made by Canadian manufacturers to drug labelling, packaging, and naming based in whole or in part on ISMP Canada's work. In interviews, ISMP Canada was credited with product changes that will reduce medication errors. Manufacturers respond to ISMP Canada's concerns because it provides Canadian data on medication events and is knowledgeable about the needs of practitioners, particularly those in the hospital setting. The evaluation found that manufacturers seek the advice of ISMP Canada for new products or product changes in order to avoid inadvertently creating a potentially hazardous condition due to product packaging, labelling, and naming.

Data were not available to support a rigorous analysis of whether these changes in products have affected the number of medication incidents. In one case, topical epinephrine, the change has not yet occurred. For concentrated potassium chloride, no fatalities have been reported since 2003 that are attributable to its inadvertent injection. Although the interventions have included a number of changes in health care practice, the product changes played a contributing role. Finally, for NMBAs, the key intervention was the product packaging and labelling changes. Based on available evidence, the product changes appear to have had an effect. Interviewees reported that the changes in product appearance (caps and warnings on the ferrule, labels, and packaging) are an improvement. This is corroborated by a near-miss incident reported to ISMP Canada in 2007 in which the nurse involved credited the newly-introduced packaging and labelling features with preventing the inadvertent use of NMBAs (ISMP Canada, 2007). In addition, ISMP Canada reported that the 20 medication incidents involving inadvertent use of an NMBA occurred before 2008. Since 2008, no incidents have been reported.

Table 9 provides more detailed information on organizational and other changes stemming from ISMP Canada recommendations that were considered in the six case studies, and to the extent data are available, describes the impact of these changes to date.

Table 9: Changes linked to ISMP Canada recommendations

Recommendation	Organizational changes	Other changes	Impact on medication incidents to date
Hydromorphone-morphine mix ups	As reported above, 63% of respondents to the stakeholder survey reported that their organization has made changes in response to ISMP Canada's recommendations on narcotics/opioid agents. Based on the case studies, changes implemented by health care organizations include removal of concentrated narcotics from ward areas; reduction of the volume of infusion for both pharmaceuticals; reorganization of medication delivery areas and cabinets to reduce the potential for error; implementation of protocols for rescue efforts; and creation and distribution of educational material for patients and families. Changes have also been made or are in development to reduce errors involving narcotics more generally, such as the creation of a list of prohibited abbreviations; guidelines for the use of narcotics; pre-printed ordering specific to the area of care; and use of smart infusion pumps with a drug library that only allow for standardized concentrations. Results from the biennial Hospital Pharmacy in Canada Survey showed increases in the percentage of hospitals having a list of prohibited dangerous abbreviations and a list of high-alert medications, as well as increases in the percentage of hospitals that have removed concentrated narcotics from patient care units and that standardize infusion concentrations for narcotics such as hydromorphone.	The Health Quality Council of Alberta (HQCA) consulted with ISMP to produce a best practices review and recommendations on handling morphine and hydromorphone. Aspects of ISMP Canada's recommendations were incorporated into the HQCA report. In 2008, Accreditation Canada introduced an ROP that will assess health care organizations on whether they evaluate and limit the availability of narcotic products and remove high-dose, high-potency formats from patient care areas. Accreditation Canada also has guidelines and ROPs pertaining to patient education, prohibited abbreviations, and look-alike and sound-alike naming conventions, which were areas covered by ISMP Canada's recommendations. ISMP Canada provided input into the guidelines and ROPs.	Medication incidents reported to ISMP Canada since the incident that led to the ISMP Canada recommendations have been due to unrelated factors, providing some indication that information shared about hydromorphone-morphine mix ups and the ISMP Canada recommendations for prevention strategies may be having an effect.

Table 9: Changes linked to ISMP Canada recommendations

Recommendation	Organizational changes	Other changes	Impact on medication incidents to date
Concentrated potassium chloride (KCI)	As reported above, 90% of community hospitals and 82% of teaching hospitals have made changes in response to ISMP Canada's recommendations on concentrated KCI. Survey data from the Ontario Ministry of Health and Long-term Care show declines in the proportion of Ontario hospitals that store concentrated KCI in patient care areas, emergency departments, and intensive care units. Changes in methods of concentrated KCI distribution have also been implemented or were planned by the majority of hospitals responding to the survey. In addition, results from the 2007/08 Hospital Pharmacy in Canada Survey showed that 89% of respondents had a policy that describes the safety procedures for concentrated KCI and 96% of respondents had removed concentrated KCI from more than 90% of patient care units, compared to 72% in the 2003/04 survey and fewer than 40% in 2001/02 (the latter two surveys asked about concentrated electrolytes in general).	In 2005, Accreditation Canada released their Standards for Managing Medications, some of which were adopted from ISMP Canada's Medication Safety Self-Assessment. In addition, ISMP Canada's work as part of the Ontario strategy was used to support Accreditation Canada's decision to include in its ROP the removal of concentrated electrolytes from client service areas.	Since 2003 when ISMP Canada's work in Ontario began, ISMP Canada reports that it has not received any new reports of medication incidents involving the inadvertent injection of concentrated KCl in a patient care area that resulted in a patient death.
Concentrated epinephrine injection	Hospitals are reviewing their procedures on the handling and use of topical epinephrine. Examples of actions taken include using warning labels on topical epinephrine, placing topical epinephrine in a labelled open container, and infiltrating the surgical site with local anesthetic before gloving and gowning.	ISMP Canada met with the manufacturer of concentrated epinephrine in July 2010. The manufacturer agreed to make changes to the packaging that will serve as a clear visual clue that the medication is for topical use only, and will also write a letter to practitioners to explain the change in packaging. ISMP Canada's reports and recommendations regarding epinephrine have been referenced in material produced by ISMP US and the United States Food and Drug Administration.	Most reported incidents (n=7) occurred prior to the 2009 safety bulletin that set out recommendations. One reported incident has occurred since the safety bulletin and it demonstrates the issue with the product packaging and labelling. The changes to the product packaging and labelling are upcoming.

Table 9: Changes linked to ISMP Canada recommendations

Recommendation	Organizational changes	Other changes	Impact on medication incidents to date
NMBAs	Results from the 2007/08 Hospital Pharmacy in Canada Survey showed that 34% of respondents had a policy describing safety procedures for NMBAs. Similarly, in the evaluation survey, 42% of respondents working in community hospitals and 32% of respondents in teaching hospitals reported changes to practices in response to ISMP Canada recommendations.	Beginning in 2005/06, manufacturers began making changes to their products. As of May 2010, the manufacturers of all NMBA products distributed within Canada have made changes to their products that are consistent with ISMP Canada's recommendations on packaging and labelling, including, at a minimum, a warning on the cap. Manufacturers are waiting for further recommendations around the addition of a universal symbol for NMBAs.	In a near-miss incident reported to ISMP Canada in 2007, the nurse involved credited the newly-introduced packaging and labelling features with preventing the inadvertent use of NMBAs. In addition, ISMP Canada reports that all 20 reported medication incidents involving inadvertent use of NMBAs occurred before 2008. Since 2008, no incidents have been reported.
Fluorouracil	Alberta Health Services appointed a pharmacist solely responsible for implementing ISMP's recommendations. The hospital involved in the incident that prompted ISMP Canada's recommendations researched the safety of ambulatory pumps and switched to a safer elastomeric pump. Drugs that cannot be administered through an elastomeric pump have been handled with increased safety measures and Alberta Health Services eliminated pumps that required programming in millilitres per 24 hours. In addition, Cancer Care Ontario developed labelling guidelines in accordance with ISMP Canada recommendations, including reducing unnecessary information and eliminating use of millilitres per 24 hours.	A cancer strategy group is working with Accreditation Canada and the Canadian Association of Provincial Cancer Agencies in an attempt to make ISMP Canada recommendations standard protocol.	An incident of fluorouracil overdose occurred after ISMP Canada's recommendations were developed. In this incident, the physicians involved reviewed correct treatment procedures with the hospital that was originally the subject of ISMP Canada's RCA. Through increased awareness of this type of medication error and strategies to reduce harm, the patient was able to make a full recovery.

Table 9: Changes linked to ISMP Canada recommendations

Recommendation	Organizational changes	Other changes	Impact on medication incidents to date
Venous thromboembolism (VTE) prophylaxis	ISMP Canada considers its work on VTE prophylaxis to be a work in progress, so extensive dissemination and knowledge transfer activities have not yet been undertaken. Furthermore, its work in this area is in collaboration with other organizations. It is currently working with Sunnybrook Health Sciences Centre to develop a self-assessment tool for hospitals to use and promote the inclusion of VTE prophylaxis in the activities of other organizations like Accreditation Canada and CPSI.	ISMP Canada suggested VTE prophylaxis be named as an intervention for *Safer Healthcare Now!* (SHN), an initiative of CPSI. ISMP Canada was involved in the discussions between the Sunnybrook Health Sciences researchers and CPSI; VTE prophylaxis is now one of ten SHN interventions. Accreditation Canada has developed a new ROP on VTE prophylaxis for 2011. The ROP corresponds with ISMP Canada recommendations by having—as tests for compliance—an organization-wide VTE prophylaxis policy, identification of at-risk patients with appropriate evidence-based prophylaxis used, and performance of audits to show implementation of the policy.	None reported to date. This work is still underway

As shown above, the evaluation found strong evidence of ISMP Canada's impact on health care organization's policies, practices, processes, or standards. Of course, the desire is not just to affect change, but for this change to have the desired effects (i.e., increase recognition of potential medication safety problems, reduce harmful medication incidents, and improve patient outcomes). Based on the survey results, stakeholders believe their organization's involvement in ISMP Canada's activities for CMIRPS has had this type of positive effect on medication safety. Three-quarters of respondents reported increased recognition of potential medication safety problems (77%), as well as improved identification of preventative strategies, improved development of preventative strategies, and improved implementation of preventative strategies (all 73%). Just over half reported a reduction in harmful medication incidents (57%) and improved outcomes for patients (54%). Respondents reporting no effect on any one of these dimensions were in the single digits (i.e., 2%–4%). Differences in effects reported by respondents are mainly a matter of degree (percentages reporting major, moderate, or limited effect) and/or are the result of the proportion of respondents who answered "don't know" or "not applicable."

Table 10: Perceived effect of organizations' involvement in ISMP Canada's CMIRPS activities on medication safety (n=611)

Has your organization's involvement in ISMP Canada's activities for CMIRPS had any of the following effects?	**No effect**	**Some effect**				**DK/ NA**
		Limited effect	**Moderate effect**	**Major effect**	**Total (some effect)**	
Increased recognition of potential medication safety problems	2%	10%	34%	32%	**77%**	21%
Improved identification of preventative strategies	3%	11%	37%	25%	**73%**	24%
Improved development of preventative strategies	3%	14%	35%	24%	**73%**	24%
Improved implementation of preventative strategies	3%	16%	34%	23%	**73%**	25%
Reduction in harmful medication incidents	3%	15%	29%	13%	**57%**	40%
Improvement in outcomes for patients	4%	14%	28%	12%	**54%**	42%

Source: Survey of stakeholders.
Note: Row percentages may not sum to 100% due to rounding. In addition, subparts of "some effect" may not sum to "total (some effect)" due to rounding.

The above discussion of impact has focused primarily on the influence ISMP Canada has had on changing individual organization's health care practices. To close the discussion on impact, the evaluation sought information on whether ISMP Canada was perceived as having a national impact on Canadian health care practice, and which of its CMIRPS activities were considered to have had the most impact. Key informants almost unanimously believe that ISMP Canada has had an impact on Canadian health care practice. In particular, they commented on the importance of having a national source of information on medication safety that relied on data coming from Canadian sources.

Of ISMP Canada's various CMIRPS activities, those perceived by stakeholders as having the greatest impact on Canadian health care practice are safety bulletins and alerts; changes to product labelling and packaging; and changes to processes (e.g., adoption of ISMP Canada recommendations into Accreditation Canada standards). Around 80% of survey respondents believe these activities are having an impact, including nearly half who believe the impact of changes to processes and changes to product labelling and packaging is substantial, and over 40% who believe safety bulletins and alerts are having a substantial effect.

Other ISMP Canada activities, including the Individual Practitioner Reporting System for Medication Incidents; the Medication Safety Self-Assessment program; the RCA analysis workshops and frameworks; the FMEA workshops and frameworks; and acting as a medication safety resource, are perceived as having an impact on Canadian health care practice by between 53% and 58% of survey respondents. However, about 40% of respondents reported they did not know if these activities are having an impact.

Table 11: Perceived magnitude of impact of ISMP Canada's CMIRPS activities on Canadian health care practice (n=611)

How great is the impact of the following ISMP Canada activities for CMIRPS on Canadian health care practice?	No effect	Some effect				DK
		Limited effect	Moderate effect	Major effect	Total (some effect)	
Safety bulletins and alerts by ISMP Canada about medication incidents and prevention strategies	2%	8%	36%	41%	**85%**	13%
Changes to product labelling and packaging	3%	5%	29%	48%	**82%**	16%
Changes to processes (e.g., adoption of ISMP Canada recommendations into Accreditation Canada standards)	3%	4%	26%	49%	**79%**	18%
Individual Practitioner Reporting System for Medication Incidents	5%	11%	28%	19%	**58%**	37%
Medication Safety Self-Assessment program	4%	10%	29%	20%	**58%**	38%
RCA workshops and frameworks	4%	13%	26%	19%	**58%**	38%
FMEA workshops and frameworks	5%	12%	26%	17%	**55%**	40%
Medication safety resource (e.g., responding to email or telephone queries)	5%	9%	26%	18%	**53%**	43%

Source: Survey of stakeholders.
Note: Row percentages may not sum to 100% due to rounding. In addition, subparts of "some effect" may not sum to "total (some effect)" due to rounding.

4.4 Capacity for change

Any organization attempting to change processes and procedures in other institutions will not be successful without sufficient buy-in among the stakeholders who must undertake the change. For ISMP Canada, this includes a variety of stakeholders (e.g., front line staff, health system decision-makers [e.g., CEOs], and policy makers). Most interviewees thought there was present and future capacity and willingness to use ISMP Canada's products and services. Health professionals recognize the importance of addressing patient safety issues (and medication safety in particular), and ISMP Canada's recommendations were generally considered to be feasible, practical, and not costly to implement.

Evidence of this buy-in is also found in the survey results. When asked to assess the current willingness of front line managers, practitioners and patient care staff, and health system risk managers to use ISMP Canada's products and services, about three-quarters of respondents believe they are very or somewhat willing. For future willingness the proportion increased to over four-fifths (80%). About two-thirds of respondents believe that professional standard-setting organizations/regulatory authorities, health system decision-makers (e.g., CEOs), and policymakers are very or somewhat willing (the lower proportion is due to the fact that about one-quarter of respondents did not feel they could provide an assessment). About three-quarters of respondents believe these groups are very or somewhat willing to use ISMP Canada products

in the future. Interestingly, those providing direct patient care (practitioners and patient care staff and front line managers) were considered least likely to be very willing to use ISMP Canada's products and resources when compared to health system risk managers and health system decision-makers. Respondents are likely referring to their colleagues, and this result could be demonstrating the difficulties inherent in getting people to change practices; interviewees noted that most front line staff would not be aware of changes in their practices being the result of ISMP Canada recommendations.

Although generally positive about capacity for making changes, survey respondents did note some barriers to incorporating practice changes based on ISMP guidelines and recommendations. Just over one-third (36%) pointed to a lack of human resources and time, about one-fifth (19%) mentioned financial barriers, followed by resistance to change (16%) and the need to create awareness/educate staff (13%), and lack of consistency or agreement among various types of health care professionals with the proposed approach (10%). All other barriers were cited by less than one-tenth of survey respondents and can be found in Appendix E.

A few interviewees provided suggestions for how to build willingness to make the necessary changes to improve medication safety. In particular, they commented that ISMP Canada could help hospital administrators justify any additional costs and human resource commitments by demonstrating the costs of leaving potentially hazardous conditions or practices in place.

4.5 Value for money

The Treasury Board of Canada defines "value for money" as the extent to which a program demonstrates relevance and performance (Treasury Board of Canada, 2009). A *relevant* program meets a need, is appropriate for the federal government, and responds to the needs of Canadians. *Performance* means the program is economical, efficient, and effective. The terms of reference for this study do not include a detailed examination of all aspects of relevance and performance.

The terms of reference do point to a specific value for money question:

> *How do ISMP Canada's CMIRPS activities provide value for money to other organizations? (Evaluation question 7)*

This question deals with the performance of ISMP Canada with respect to offering benefits that exceed the costs of the program.

The calculation of benefit-cost ratios is usually a complex undertaking that requires a range of outcomes be converted to financial equivalents and then compared to the costs of producing those outcomes. Any program where benefits exceed costs (benefit-cost ratio exceeds 1), offers value for money. Information demands for benefit-cost analysis are usually extensive, especially in complex systems such as health care interventions.

Based on the interviews, the case studies and survey responses, it is possible to offer a preliminary conclusion on each point. This section assesses whether ISMP Canada offers benefits in excess of the program's costs.

4.5.1 Value for money—benefits in relation to costs

The logic of value for money, or benefit-cost analysis in any health care intervention starts with a consideration of cost. Health care costs are the sum of direct costs of the intervention, indirect costs such as undesired side effects, and patient time/discomfort spent in treatment. Measures to avoid or reduce these costs are defined as benefits.

In health care, the benefits of any intervention divide into three elements:[19]

- *Reductions in the costs of treatment*, which refers to the costs to provider in the first instance and the funder (tax payer) in the second instance. Medication incidents often involve increased health care costs as patients may require initial or additional hospitalization or treatment therapies to respond to the adverse health effects caused by the medication error.

- *Preservation/extension of life*, which in most cases refers to the preservation of working life. The courts have validated this approach to valuing life in countless injury and wrongful death suits—individual work is the sum of the discounted value of future earnings.

- *Increased quality of life* arises when health care intervention preserves/extends the psychological benefits to the patient (ability to enjoy life, free of pain, and with full scope of activities). The financial equivalents of these benefits are hard to estimate and are typically only cited in general terms.

4.5.2 Benefits and costs of ISMP Canada recommendations—concepts

The goal or benefit of ISMP Canada activities is to realize a reduction in the number and/or severity of the consequences of medication error incidents. In the six case studies, the medication errors resulted in consequences such as discomfort/pain, alarm over an adverse event, actual injury, the medical costs of dealing with adverse event, and, in a few cases, death. Valuing the avoidance of these consequences are the benefits in the benefit-cost calculation that underlies value for money of ISMP Canada activities.

The costs of the intervention, the other half, include:

- Expenditures involved in the detection of the incidence
- Local incident analysis, such as RCA
- Developing measures of risk in each setting
- Creating and testing mitigation strategies
- Notification and outreach to communicate the nature of the risk
- Supporting the implementation of the mitigation strategies across the health care system

[19] Another benefit often cited is the reduction in risk of litigation. This issue is more relevant in the US health care setting.

4.5.3 The value of life

The cost-benefit literature has spent considerable effort estimating the value of a life, termed the statistical value of life. Two methods exist for this estimation. First, one can estimate the future stream of income and then discount this stream to the present using a suitable interest value in a process termed the "discount present value of future benefits."[20] Second, one can look at what people are willing to pay to insure their lives or the increase in wages needed to enter hazardous occupations. In the latter case, an income earner in a household may rationalize the purchase of insurance on the grounds that the family will need a source of replacement income in the event of death.

Insurance awards and court decisions on compensation for premature death often start with some measure of the discounted present value of lifetime earnings. If one assumes a death occurs at the age of 40, when an individual is earning $40,000, annual increases amount to 2%, the interest rate is 5%, and one can expect to work uninterrupted to the age of 65, the present value of that income stream is $687,366. For someone age 25, the present value of these lifetime earnings increases to $1.5 million.

Earnings-based estimates of the value of life have long ceased in favour of methods that use more direct valuation such as willingness to pay for life insurance or the extra pay needed to accept occupations with high risks from loss of life (Viscusi, 2008). Estimates of the value of life based on these methods range between $0 and $30 million (US); the typical ranges for recent studies in the United States appear to be between $3.7 and $5.1 million and use a range of techniques based on the two principles above (Boardman et al., 2006, pp. 407–410). The Treasury Board of Canada set a 2004 value of $6.11 million (based on a survey of the literature), which translates to about $7 million in 2011 dollars.[21] Recent work has clarified how this measure varies with age. The simplistic earnings-based formulation would suggest that the value of statistical life peaks at birth and then declines uniformly until death. Recent work by Becker, Murphy and Philipson (2007) and Viscusi (2008) shows that seniors are willing to pay substantially to avoid the risk of death and produce estimates of around 75% of the average valuation across all ages.

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20 The present value of $100 received in a year is given by the formula $100/(1+i), where i is the interest rate. The present value of that $100 received in two years is $100/$(1+i)^2$ and in "n" years $100/$(1+i)^n$.

21 The Treasury Board of Canada (2007) recommends this value be used in all regulatory evaluations of federal programs.

4.5.4 Valuing health interventions—quantitative requirements

Measuring the net value of health care interventions across a population requires the following data and analytical steps:

- The incidence of the underlying condition must be recorded. In the case of medication errors, the incidence of the condition being treated, the incidence of the medication used, and the number of medication errors (number of incidents) must be documented over time.

- A counterfactual or baseline is needed against which to compare events with and without the medication errors. The value that exists in this counterfactual state must also be known and consist of profiles of social an economic attributes of affected parties. To take a simple dimension of the situation, the incomes of those undergoing treatment must be known, so that a loss can be computed if the income is interrupted. The difference between this counterfactual income and the income that exists after the error is the avoided loss from mitigation or the benefit (value of mitigation).

- The costs of the errors (consequences) comprise the direct and indirect costs noted above (Section 4.5.1).

- Finally, the cost of mitigation as enumerated above (Section 4.5.2) must be known.

In some cases, it is possible to assess all these elements. In cancer treatments, incidence and patient profiles are often numerous and detailed, the costs of treatment well known, and it is possible to identify the results of any change. Therefore, it is possible to estimate the net extension of life, quality of life, and costs of treatment to assess the value of a specific intervention. The challenge in measuring the impact of interventions to address medication errors is that the incidence of the type of medication incident may not be high, or it may not be documented, and the incidence of adverse outcomes is likely low, in which case developing a counterfactual is not feasible. Case study participants could not offer with any certainty the number of errors, let alone the number that had produced adverse outcomes. Several of the most experienced health practitioners interviewed for the evaluation readily admitted that no one has an accurate measure of the true incidence of errors in hospitals, community pharmacies, or other settings. Most believe that errors are underreported.

Attribution is another issue. It is important to unambiguously connect the intervention and the outcome. For example, in many domains, such as cancer screening, it is reasonably certain that a certain test leads to early diagnosis and the patient enters a pathway for treatment, defined treatment/costs, and experiences an extension of life. An unambiguous connection exists between the intervention and outcome. It is possible to also study the intervention locally, such as with a few cases in a single hospital, and then extend the results to a wider domain. For interventions to respond to specific medication errors, the situation is much more challenging. First, the number of reported errors is small. Second, the intervention is likely identified, developed, disseminated, and implemented by a number of different organizations. For example, ISMP Canada often works in partnership with other organizations, is involved as part of a provincial initiative, or is one stakeholder consulted in the development of new standards.

Attributing changes in health care practice to just one player when consultation, collaboration, and partnership are involved would be inaccurate and misleading. Finally, mitigation also involves several steps that need to be executed—many players need to make changes. The diffusion of new practice takes time and defining the point at which changed practice becomes dominant is quite hard.

The other challenge for measuring value is that a common cancer, such as colorectal cancer, has enough cases to provide a baseline against which small changes can be measured and assessed to identify any change that is statistically "unusual." In the case of medication errors, the officially reported incidence is low, which can make it hard to place reported incidents into a quantitative context.

The "bottom line" is that with the six cases studied in this report, there is minimal quantitative foundation for measuring value for money of the intervention. Rather, the case studies present varying opportunities to understand the general value for money for the interventions offered by ISMP in regard to reducing this risk of Canadians experiencing a medication error.

4.5.5 The value of reporting and mitigating medication errors

This section reviews each case study for value for money arising from ISMP Canada activity in relation to a medication error.

- *Inadvertent Injection of Topical Epinephrine Case Study*: Of the eight cases reported to ISMP Canada, two resulted in death, four led to patient harm (with three needing to be transferred to intensive care/critical care), and two were recorded as causing no harm to the patient. Since this pharmaceutical is associated with otolaryngology (ear, nose, and throat) surgical procedures, these patients tend to be from across the age spectrum. Using the values citied in Section 4.5.3, the loss of these two lives is $14 million. The avoided loss of the intensive/critical care costs for the three patients amounts to anywhere from $5,000 to $12,000 per day.

  The case study revealed that surveys among members of the American Academy of Otolaryngology Head and Neck Surgery have shown that this form of error is quite common, with about 30% of respondents having either had direct experience or heard of this type of error. Across Canada, the numbers of averted deaths and patient harm resulting from adoption of all suggested ISMP Canada recommendations could be substantial. Unfortunately, the number of annual surgeries that use epinephrine is not known, and so it is not possible to estimate the number of averted deaths or cases of harm. The cost of the investigation and preparation of the mitigation response is also not known.

- *Fluorouracil Overdose Case Study*: This is a case where the evidence of actual incidents in Canada is small. However, a review of national and international medication and device reporting programs, medical literature, and the Internet conducted by ISMP Canada for the RCA report found seven similar overdose cases resulting in death. The case study suggests that at least one death has been averted following the publication of the RCA report. Due to increased awareness of this potential medication issue, a hospital where an overdose occurred learned the correct treatment procedures from the hospital involved with the RCA report.

- *Hydromorphone-Morphine Mix up Case Study:* Hydromorphone and morphine, two drugs administered for pain but with very different strengths, have been confused because the names and concentrations are similar. In a worst case scenario, patients who mistakenly receive hydromorphone, which is six to eight times more potent than morphine, can stop breathing, suffer cardiac arrest and die. ISMP Canada conducted a full RCA of one such case in a Canadian hospital. However, patient harm depends on the patient's tolerance to narcotics and can range from death to effects that are reversible in a few hours. Based on incidents reported to CMIRPS involving hydromorphone and the administration of the incorrect drug, 20 adverse events resulting in premature death (n=4) or harm (n=16) have occurred between 2001 and 2006.

  When these drugs are kept in patient care areas, the mix up can affect any patient who may have been prescribed morphine as a painkiller. Morphine is typically not a drug prescribed for younger people, but it could be prescribed to otherwise healthy individuals who have had a serious accident or surgery and need strong, but temporary pain relief.

  The potential of averting almost one death a year is a substantial value to society. Because the age and other relevant characteristics of the patients at risk for the inadvertent administration of hydromorphone, a precise figure cannot be attached. That being said, the avoided loss could be in the range of $1 million a year.

- *Concentrated potassium chloride (KCl):* This compound is used intravenously to increase the potassium levels of patients. Calculating the dosage and infusion concentration is very important, and errors involving the direct injection of the concentrated product without dilution have had fatal outcomes. This safety issue first emerged through Ontario. After two fatal incidents, the Ontario Ministry of Health and Long-Term Care started work with ISMP Canada to bring the issue to wider attention. Since 2003, when ISMP Canada's work in Ontario began, ISMP Canada reports that it has not received any new reports of medication incidents involving the inadvertent injection of concentrated KCl in a patient care area that resulted in a patient death. The role of ISMP Canada in this example was to develop the recommendations and to "push" the message into the system.

- *Neuromuscular Blocking Agents Case Study*: Neuromuscular blocking agents (NMBAs) are respiratory paralyzing agents used in settings where patients are intubated and mechanically ventilated (for example, operating rooms, emergency departments, and critical care areas). These drugs have significant potential for harm; however, most incidents in Canada can be described as "near misses." The value offered by ISMP Canada in this case is through the work with manufacturers to change packaging and labelling to minimize the inadvertent mix up of these drugs with other injectable medications.

- *Venous Thromboembolism Prophylaxis Case Study:* Patients on extended hospital stays (more than a couple of days) are at risk from venous thromboembolism (VTE) *(blood clots)* and the use of prophylaxis is indicated to avert this problem. In this case, ISMP Canada became involved because of a failure to administer the appropriate course of medication. ISMP Canada is working with a broad range of health care organizations to raise awareness on this issue and remains a work in progress. There are no Canadian studies of the number of deaths due to pulmonary embolism (a type of VTE); however, based on studies in other countries, it can be estimated that the use of VTE prophylaxis could prevent 2,000 premature deaths a year. Other benefits to the system include reducing the cost of treatment of non-fatal cases, such as the cost of hospitalization, therapeutic drugs, and patient monitoring, as well as reducing the risk of patients developing post-thrombotic syndrome. Based on studies in the UK, the costs arising from preventable VTE are substantial (£204.7 to £222.8 million in 1993). Based on these estimates, VTE prophylaxis offers value both by reducing the number of premature deaths caused by VTE and saving the expenses otherwise incurred by the health care system from treating preventable VTE.

Table 12 presents a synopsis of the benefits (value for averted loss of life) distilled from three of the cases studied (hydromorphone, epinephrine, and concentrated KCI). It is important to emphasize that this analysis only tracks the averted costs of premature death. Excluded from the analysis, because they are small relative to the value of life are other avoided costs such as elimination of intensive care visits, the time lost by those affected, and other costs associated with mitigating the effects of the error are quite small relative to the value of lives preserved. Their inclusion does not affect the analysis substantively. The analysis assumes that the ISMP Canada recommendations, if implemented, would have averted these premature deaths. This assumption is supported by the absence of fatalities due to these medication incidents since the ISMP recommendations were made.

Based on the rationale above, the analysis uses a value of $7 million for each premature death averted. The use of the $7 million figure is justified, as the medication incidents used to estimate the value of lives preserved (hydromorphone, epinephrine, and potassium chloride) cannot be assumed to typically involve patients over 65 years of age. As an example, for epinephrine, most patients would be considerably younger, given the type of surgery involved. The annual number of deaths estimated in Table 12 is based on the lives saved between 2004 and 2010 from the case studies.

Table 12: Summary of the value of lives preserved (2004–2010)

	Annual deaths (est.) Averted	Lives saved 2004–2010	Total benefit	Comment
Hydromorphone	0.6	4	$28 million	Between 2001 and 2006 hydromorphone-morphine medication mix ups accounted for appromiately four deaths over 2004–2010
Epinephrine	0.3	2	$14 million	Two deaths occurred between 2004–2009 due to the inadvertent injection of topical epinephrine. The assumption is that these deaths will be averted in the future as a result of the ISMP action that ocurred in 2009.
Concentrated KCl	1.5	10.5	$73.5 million	Direct injection of concentrated KCl is almost always fatal and prior to ISMP involvement, the errors resulted in approximately 1.5 premature deaths annually or 10.5 deaths over 2004–2010.
Total	2.4	16.5	$115.5 million	

The cost of CMIRPS over the 2004 to 2010 period ($5.9 million) plus the costs of making the changes to the system (e.g., activities involved in diagnosing causes of the error, developing information bulletins, associated outreach, and changing practices) are certainly much less than the estimated value of averting premature deaths over this period ($115.5 million). Further, the estimated benefits in Table 12 understate the true benefit for three reasons:

- Only three case studies appear in the table since insufficient information exists to estimate the benefits from mitigating medication errors in the other cases.
- Medication errors occur for other pharmaceuticals.
- The three cases presented in Table 12 do not include the value of reducing the other costs of mitigating errors (intensive care and other hospital procedures, lost time at work, and effects on quality of life).

Two other aspects of value are more subtle. First, the occurrence and migration of errors for one medication has probable demonstrated value for other domains. Health care providers that respond to changed practices that arise from medication errors may adopt other practices that confer benefits to patients. Second, health care professionals involved in medication error can be traumatized, and some may need to withdraw from practice. Avoiding these traumas in the first place and preserving the careers of highly trained professionals is a benefit to the health care system, as well as to the profession.

Interviewees also provided a qualitative assessment of the value for money provided by ISMP Canada. In particular, ISMP Canada's activities for CMIRPS were seen as important to raising awareness of medication incidents. Because not every health care institution would have experienced each incident, gaining knowledge about hazardous conditions enables the organizations to respond proactively to prevent adverse events from occurring. Interviewees also

pointed to the credibility that ISMP Canada has in the health care community, which means its recommendations receive attention and a level of buy-in that might not be achieved were changes to processes and procedures developed internally by health care organizations. Each individual health care organization developing its own response to medication incidents was also considered inefficient. Having a national body with awareness of trends and an expertise in fashioning recommendations to respond to medication incidents was credited with saving organizations' time and money. For smaller institutions that might not be able to draw on interdisciplinary teams internally to study an incident and form a response, ISMP Canada was seen as offering even greater value. Finally, most interviewees believe ISMP Canada's recommendations are generally feasible with minimal cost (although there are some exceptions) as they primarily involve process and procedural changes.

Another measure of value is that ISMP Canada does not duplicate the work of other organizations. When asked what other organizations they would turn to for medication safety products and services, such as those provided by ISMP Canada's activities for CMIRPS, almost 60% of survey respondents said that no similar organization exists. The organizations most mentioned were regulatory bodies/professional associations and US organizations (6% each). Similarly, interviewees typically said there was not a similar organization. Those who did list one most often mentioned ISMP US.

Considerable value exists in government maintaining the capacity to respond to issues as they arise, and increasingly to prevent these situations in the first place. From the federal perspective, this function provides a pan-Canadian service that reduces the need for provincial and territorial governments to maintain such a system, which is an undoubted benefit to smaller jurisdictions.

4.6 Broadening CMIRPS activities

As described in Section 2.0, ISMP Canada received supplemental funding to enable it to expand several of its existing activities and offer some new products. The evaluation considered three areas of expansion to assess whether they have improved or have the potential to improve patient safety. Because the supplemental funding began in 2008, there is insufficient time to demonstrate that these areas of expansion have improved patient safety. However, there is some evidence to indicate that they have the potential to do so.

Consumer Reporting and Learning Strategy. From September 2008 until March 2010, ISMP Canada was developing its strategy for a consumer reporting and learning program, a web-based consumer reporting tool, and educational materials for its consumer website. The site (www.SafeMedicationUse.ca) went live March 10, 2010. As of early July, there were 20 incidents reported. Internationally, there is interest in expanding reporting systems to include consumer reports. In September 2008, the US Agency for Healthcare Research and Quality (AHRQ) announced a project to develop a possible consumer reporting system to be completed in September 2010 (AHRQ, May 2009). Studies provide evidence that consumers are aware of incidents that would likely be missed by reporting systems that rely exclusively on health care professionals. In a 2005 study on the differences between harmful events documented through medical records, and those events documented through patient interviews, only 55% of events identified by patients were also listed in the medical record (Weingart et al., 2008). Furthermore, none of these events were found in the hospitals' incident reporting system.

Most interviewees who offered to comment saw a value in offering consumers an opportunity to report medication incidents. However, because the strategy is so new, few could provide an opinion. Some concern was expressed about whether consumers would have the ability to identify medication errors as opposed to issues created by other factors (e.g., failure to provide complete information on medications they are taking).

Additional analyses. As explained in Section 2.1.3, with the supplemental funding, ISMP Canada is conducting an additional 10 analyses per month for a total of 30. Several aggregate analyses are also being conducted concurrently. The additional analyses began in April 2009. The additional resources for analyses is intended to enable ISMP Canada to conduct more studies of near-miss events or other events that have the potential to, but did not result in patient harm, as well as cluster analyses of aggregate CMIRPS data.

Based on the number of incidents submitted to ISMP Canada, 30 analyses means that approximately 3% of reported incidents are analyzed.[22] ISMP Canada representatives noted that there is no literature available to assist in determining the optimal number of incidents to analyze. Based on program experience, ISMP Canada and Health Canada agreed to the additional 10 analyses. All analyses are chosen using the Analysis Prioritization Matrix, which considers the event's actual and potential severity as well as the likelihood of recurrence. ISMP Canada reports that the additional analyses enable it to analyze more no harm or near-miss reports as well as reports from its various sources (the individual practitioner reporting program, NSIR, the community pharmacy program, and the consumer reporting program). At the level of 20 analyses a month, ISMP Canada could not analyze all reports of actual harm as they exceeded 20 reports in some months. Additionally, it was reported that the number of incidents appropriate for analysis under the Analysis Prioritization Matrix can exceed 30 incidents. This indicates that the incremental increase is not unreasonable in light of the nature and severity of incidents reported.

Although ISMP Canada staff cannot definitely state which analyses and subsequent reviews would not have occurred if the number of analyses per month was limited to 20, they have identified examples of analyses that, based on their experience, were unlikely to have occurred. A brief description of these medication incidents is in Appendix F and provides evidence of the additional analyses leading to recommendations published in safety bulletins, and work with manufactures on improving product naming and labelling. It also contains some descriptions of work in progress for eventual publication in safety bulletins.

ISMP Canada staff reported that the additional resources have enabled them to respond to several Health Canada requests for specific analyses (e.g., Rivastigmine, confusing oncology drug names, Lasix/Losec confusion, Tamiflu suspension errors, epipen). Staff also indicated that the resources have enabled them to provide more timely responses to near-miss reports.

[22] ISMP Canada received 2,685 medication incident reports and CIHI's NSIR program received 316 between April 1, 2010 and June 30, 2010. This average of about 1,000 medication incident reports per month was used to determine that 3% of reported incidents are analyzed.

Look-alike, sound-alike products. In its 2008 proposal for supplemental funding, ISMP Canada committed to developing, in consultation with other national and international experts, a "draft standard operating procedure for the assessment of look alike, sound alike drug product names which could be used during a drug name review" (ISMP Canada, 2008, p. 6). The intended outcome for this project is a procedure that is evidence-based and will reduce the harm to patients caused by product confusion due to look-alike, sound-alike names. ISMP Canada projected developing the procedure in 2008/09 and having it ready for testing in 2009/10.

While it is too early to evaluate whether this project has achieved its intended outcomes, the project appears to be on schedule.[23] An expert advisory panel has been formed with representatives of the U.S. Food and Drug Administration, psycholinguistic experts, Health Canada product reviewers, Health Canada post-market reviewers, and ISMP Canada staff. The expert advisory panel has produced a "proof of concept" guiding document, which includes the core concepts of drug name review to prevent errors due to look-alike, sound-alike products. To test the validity and feasibility of these core concepts, four drug confusion experiments were conducted with a small cohort of end-use practitioners. The experiment findings are being analyzed and will be submitted as a report. Future activities include an FMEA exercise and a stakeholder consultation.

Suggested areas of future expansion. Interviewees and survey respondents generally did not have suggestions for areas of future expansion of ISMP Canada's activities for CMIRPS. Many directed their comments more toward areas for improvement, rather than expanded activities. For example, the most common survey responses included suggestions that more be done to engage or educate health professionals (n=25, or 4%) and broaden knowledge transfer activities around information on medication incidents/recommendation (n=19, or 3%). Interviewee comments provide context for the survey responses. For example, many believe that ISMP Canada should focus any expansion on knowledge transfer activities:

- Provide webinars free of charge
- Develop presentations on medication safety that could be used for orientation of staff
- Assist with developing safety patient officer training
- More consumer education
- Offer RCAs at lower cost

Other suggestions included:

- Do more to market ISMP Canada services
- Maintain and strengthen its links with standard-setting organizations like Accreditation Canada, regulatory bodies, and professional organizations that engage in regulation/standard-setting (e.g., the Ontario College of Pharmacists is currently moving toward regulating technicians)
- Be more directly engaged in encouraging reporting of medication incidents

[23] Information on the look-alike, sound-alike project is taken from a summary of achievements provided by ISMP Canada on August 12, 2010.

5.0 Conclusions

This final section of the report presents conclusions and lessons learned based on the findings presented in the previous sections. The information is structured along the evaluation issues and questions that are included in Appendix A.

5.1 Awareness of ISMP Canada's activities for CMIRPS

1. What are the most appropriate audiences for ISMP Canada's CMIRPS activities? Are those audiences being reached?

The evaluation found the level of awareness of ISMP Canada's activities for CMIRPS to be high, particularly given the fact that ISMP Canada has focused on delivering the program and has not undertaken a promotional or communication strategy to build awareness. While awareness varies by type of activity, the majority of respondents reported they were at least somewhat aware (ranging from 99% for the safety bulletins and alerts to 55% for the recently launched Consumer Reporting and Learning Pilot Project). Based on interviews, awareness also varies by type of health care provider and institution. Physicians were singled out as a group that is less aware of CMIRPS. Survey results were not able to confirm this, given the small number of physicians who responded.

ISMP Canada has undertaken several activities to expand its network and target its message. Within less than two years, ISMP Canada has increased its distribution of safety bulletins threefold and has informal agreements with various professional organizations to fan out the bulletins to its membership. In addition, it has targeted its approach for specific medication issues to get the message to those health care professionals who are in the best position to reduce the risk for occurrence of a particular error.

One area of potential improvement in increasing awareness of CMIRPS and ensuring that the appropriate audience is reached is reviewing the distribution network to ensure it is achieving its desired coverage. Another suggestion made by some interviewees is for ISMP Canada to consider increasing its attention on health care sectors/organizations that might find implementing its recommendations more challenging. In particular, they mentioned sectors/organizations with less infrastructure for addressing medication safety than hospitals in urban areas (e.g., they might not have an in-house pharmacy that can take the lead and/or interdisciplinary committees or other committees expressly dedicated to medication safety).

5.2 Use of ISMP Canada's activities for CMIRPS

2. What is the level of participation in ISMP Canada's CMIRPS activities among health care providers and institutions?

The evaluation found that CMIRPS safety bulletins and alerts are by far the activity that most individuals and organizations are engaged in, followed by attending medication safety conferences or webinars. For the safety bulletins, all lines of evidence showed that health care professionals and organizations are reviewing them, disseminating them, and using them to identify and implement changes in medication practices.

For other CMIRPS activities, the reported use reflects that they require training and, for some, the attendance at workshops, which cannot be expected to have the broad distribution of safety bulletins.

- ISMP Canada's MSSA module for hospitals has certainly received a high rate of adoption, with the 2008 Hospital Pharmacy in Canada Survey results showing that not only did the majority of hospitals conduct MSSAs within the previous two years, but almost all used the ISMP Canada tool. In addition, the reach of MSSAs are being broadened—ISMP Canada now offers MSSA modules for long-term care, community pharmacies, and complex continuing care, and has increased its geographic coverage so that at least one type of module has been offered in nine provinces. Overall, supplemental funding has supported 488 modules being offered.

- About one-third of survey respondents reported that they have used/participated in RCA and FMEA frameworks and workshops, and just over 40% indicated their organizations have used them, although an almost equal percentage did not know if their organizations have. Although the reach of the workshops was to increase with the supplemental funding, between 2007 and 2009, the number of workshops and participation in them decreased. In the first quarter of 2010, this trend appears to be reversing itself.

- While reporting medication incidents directly to ISMP Canada was less common than participation in the other activities, based on survey responses alone, this does not reflect the provision of medication incidents to CMIRPS. Given that a large proportion of survey respondents work in the hospital sector, they are likely reporting to CIHI's NSIR or to provincial reporting programs. The Hospital Pharmacy in Canada Survey in 2007/08 found that all participating hospitals had a medication incident reporting system. This being said, the evaluation found that the system for medication reporting is becoming increasingly decentralized with provincial reporting systems, and how the information collected provincially will be shared with CMIRPS is not yet clear. A challenge for ISMP Canada and its partners (CIHI, Health Canada, and CPSI) will be to increase awareness of CMIRPS and the importance of a national database of medication incidents.

3. Are ISMP Canada's CMIRPS activities being integrated into health care practice?

The evaluation evidence demonstrates that CMIRPS activities are being integrated into health care practice through either formal written policies or commonly understood expectations. In particular:

- Almost all respondents reported that their institution has formal policies or expectations that medication incidents be reported (although this does not have to be through the CMIRPS).
- Safety bulletins are being integrated into the fabric of health care organizations through formal policies or, at a minimum, expectations that they be disseminated, used to identify potential medication safety issues, and implement strategies to address them, including adopting the ISMP Canada recommendations that they contain. Approaches vary, but almost all interviewees described some method of dissemination to relevant staff and regular review of the bulletins and ISMP recommendations.
- Similarly, the majority of survey respondents reported that conducting local incident analyses using the RCA framework is either part of their organization's written policies or commonly understood expectations.
- The more preventative activities—conducting prospective risk assessment using the FMEA framework or conducting MSSAs—are less likely to be in written policies or to be expectations.

5.3 Impact of ISMP Canada's activities for CMIRPS

4. How and to what extent are ISMP Canada's CMIRPS activities directly or indirectly influencing changes in health care practice?

5. Which of ISMP Canada's CMIRPS activities are having the most impact on health care practice?

The evaluation evidence demonstrates that CMIRPS activities are having an impact on organizational policies and practices. In particular:

- Based on all lines of evidence, safety bulletins and the recommendations they contain have had the greatest effect on health care practices. In particular, case studies as well as survey results provided examples of changes in health care practices in response to specific medication issues and ISMP Canada recommendations. These included changes in storing, dispensing, and administering medications, such as removing certain products from patient care areas, using pre-mixed products, rearranging storage areas, and instituting safety procedures and labelling guidelines, to name a few.

- For all CMIRPS activities, almost all survey respondents who provided an opinion indicated that they have had at least a limited effect on their organizations' policies and practices.

In addition to changes in health care practices at the organizational level, ISMP Canada's CMIRPS activities also influence broader changes, such as Accreditation Canada ROPs. While many stakeholders are involved in developing ROPs, for those that concern medication issues, ISMP Canada is always consulted and in the case studies of medication incidents where an ROP was developed, its content corresponded to and was influenced by previously made ISMP Canada recommendations. ISMP Canada has also worked with manufacturers to remedy labelling, packaging, and naming issues identified as a contributing factor to medication incidents. In all, ISMP Canada has worked with manufacturers on 50 changes to medication labelling, packaging, and naming.

The survey results confirmed that of ISMP Canada's various CMIRPS activities, those perceived by stakeholders as having the greatest impact on Canadian health care practice are safety bulletins and alerts; changes to product labelling and packaging; and changes to processes (e.g., adoption of ISMP Canada recommendations into Accreditation Canada standards).

6. Have these changes in health care practice resulted in greater medication safety?

The evaluation cannot conduct a rigorous analysis to show that changes to medication practices based on ISMP recommendations have resulted in greater medication safety and improved outcomes for patients. Reliable data pre- and post-changes in practices would be necessary, which is not available given the underreporting of medication incidents.

Given this limitation, the evaluation relied on case studies and inferring effects from the medication incidents reported to CMIRPS pre- and post-ISMP Canada recommendations. Based on this, four case studies showed that medication incidents caused by the factors addressed in the recommendations either had not been reported or had occurred less often since the recommendations were made. Another demonstrated how the increased awareness did not prevent the occurrence but facilitated prompt and effective treatment of the affected patient. The sixth is a work in progress, but the intervention has a strong evidence base for its effectiveness in reducing premature death and costs of treatment. In addition, the perception of about three-quarters of the survey respondents is that ISMP Canada's CMIRPS activities have had an effect by increasing recognition of potential medication safety problems; improving identification of preventative strategies; and improved implementation of preventative strategies. A smaller percentage of respondents (although still a majority) believe that CMIRPS has had an effect in reducing harmful medication incidents and improving outcomes for patients. This is due to a higher proportion of respondents not being able to provide an opinion, which is likely explained by the difficulty in demonstrating the connection due to the underreporting of medication incidents.

5.4 Capacity for change

7. Is there evidence that health system managers, policy-makers, and decision-makers can and will continue to incorporate change to improve medication safety as a result of ISMP Canada's work? What are the barriers?

Interviewees and survey respondents believe that these key stakeholder groups have the willingness and capacity to continue to make changes to medication safety practices based on ISMP Canada's work. Among survey respondents, there was increasing optimism for future willingness and capacity to make changes. The most common barriers cited included lack of human resources and time, followed by financial barriers.

5.5 Value for money

8. How do ISMP Canada's CMIRPS activities provide value for money to other organizations?

The available evidence supports the proposition that the benefits of ISMP Canada's activities for CMIRPS exceed its costs, i.e., it offers value for money. The analysis provides a conservative estimate, as it focuses on the value of averted loss of life and does not include the additional value of the reduction of non-lethal harm to patients. It is also based on only three case studies, as they provide the clearest evidence of lives saved by interventions from ISMP Canada recommendations. These case studies show a reduction in similar reported incidents that resulted in death after the ISMP recommendations were published.

Based on the Treasury Board estimates for the value of a life, we have taken the value of a statistical life to be $7 million in 2010 dollars. Based on the estimated 16.5 lives saved between 2004 and 2010 in the three case studies, the total benefit of lives saved is roughly $115.5 million for that time period, or $16.5 million per year. Attribution of the entire benefit to ISMP Canada's activities for CMIRPS is not possible. However, given the fact that ISMP Canada has published over 60 safety bulletins during that time period, with recommendations contained in almost all of these bulletins, the use of only three case studies to support the value for money analysis means that the resulting value of ISMP Canada's CMIRPS activities remains a conservative estimate. With a total estimated benefit based on three case studies of $115.5 million between 2004 and 2010 and a cost of ISMP Canada's activities for CMIRPS of $5.9 million for that same time period, the benefits far exceed the costs.

Value for money also goes beyond averting harm or death from medication incidents to include improving the efficiency and quality of the preventive strategies. According to the evaluation evidence, stakeholders believe that ISMP Canada's activities for CMIRPS provide value by increasing awareness of hazardous conditions, fashioning feasible responses that are backed by the credibility that ISMP Canada has with stakeholders, and reducing the inefficiency of each health care institution developing its own response, to name a few.

That being said, medication errors that result in premature death or substantial harm challenge the health care system and government to do better. CMIRPS provides value by enabling an evidence-based response that addresses the system issues involved in the medication incident.

9. Who would other organizations turn to if ISMP Canada could not perform all of its proposed activities?

Most stakeholders could not list a similar organization that they would turn to if ISMP Canada could not perform its CMIRPS activities. The organizations most often mentioned were regulatory bodies/professional organizations and US organizations, such as ISMP US. With respect to ISMP US, interviewees noted that it was useful, but that ISMP Canada added value by relying on Canadian data and Canadian experiences with medication safety issues.

5.6 Broadening activities

10. Have ISMP Canada's initiatives to broaden the scope of CMIRPS activities either improved or do they have the potential to improve medication safety?

11. If ISMP Canada could further expand its CMIRPS-related work, in what areas should it concentrate its expansion to have the greatest impact?

These activities to broaden the scope of CMIRPS activities began in late 2008 at the earliest, so it is too early to assess their impact. That being said, interviewees believe that these initiatives, in particular the Consumer Reporting and Learning Strategy, have the potential to improve medication safety. The other initiatives to broaden the scope—the additional 10 analyses of medication incidents and the work on developing a standard operating procedure for look-alike, sound-alike products—were not areas that most key informants could comment on. However, based on documentation provided by ISMP Canada, the 10 additional analyses per month allow them to do more work on near-miss events or other events that did not result in patient harm, and include events from new sources (namely, the consumer reporting program and the community pharmacy program). It was noted that at the original level of approximately 20 analyses per month, not all reports of actual harm could be studied for some months. The look-alike, sound-alike initiative is on schedule: an expert advisory panel has been formed and has produced a "proof of concept" guidance document, which includes core concepts of drug name review and which has been tested through experiments with small cohorts of end-use practitioners.

Few suggestions were given for areas of expansion. They primarily included additional work to engage or educate health care professionals, broaden knowledge transfer activities, and market CMIRPS, which includes being more directly engaged in encouraging the reporting of medication incidents.