A Medication Incident Reporting And Prevention System For Canada

Business Plan

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Canadian Coalition on Medication Incident Reporting and Prevention

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Canadian Coalition on Medication Incident Reporting and Prevention
Consensus Response
to
A Medication Incident Reporting and Prevention System for Canada

Introduction

The mandate of the Canadian Coalition on Medication Incident Reporting and Prevention is:

To develop options, in the form of a business plan, for a comprehensive, viable, sustainable, and affordable medication incident reporting and prevention system for Canadians.

The desired outcome is a program that manages the risks inherent in medication use, and moves toward a goal of risk prevention. In September 2001 Sierra Systems Inc. began a contract to develop this business plan. The Report, *A Medication Incident Reporting and Prevention System for Canada* (CMIRPS), represents the outcome of investigations, consultations, and analysis conducted by Sierra Systems. Feedback with regard to the quality and completeness of the Report, and the manner in which this challenging task was conducted, has been very positive.

The Report clearly identifies the urgent need for action, noting that medication incidents are the most common single preventable cause of patient injury. Chapter 1 details the significant human and financial costs; quoting U.S. estimates of 44,000 to 98,000 deaths per year associated with medical error, and financial costs from preventable adverse drug events in the range of $2.8 million per year in a 700 bed teaching hospital.

The Report identifies a partnered approach to deliver a system consistent with key principles and attributes. The proposed partnership builds on the strengths, core competencies and missions of relevant organizations in Canada. A partnership which includes government, an independent pan-Canadian not-for-profit organization with links to federal / provincial / territorial Ministries of Health, and an independent not-for-profit agency is unique.

Principles, Goals and Attributes of a Proposed CMIRPS

Coalition members strongly support the key principles, goals, and attributes expressed in this Report. These principles are detailed in Chapter 4, and are complemented by *factors critical for success* in Chapter 8. While readers are encouraged to review the full report, the importance of the key principles warrant added emphasis:

The purpose of the proposed CMIRPS is to:

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

The goals of the CMIRPS are to:

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

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) should:

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

The factors identified as critical to the success of the proposed CMIRPS include:

- buy-in and support from key stakeholders;
- relevancy, utility, and credibility of information;
- communication and education;
- non punitive use of the information;
- integrated approach;
- assurance of confidentiality of data; and
- national leadership and effective coordination of activities.

Key Considerations

The next phase of this initiative will build on the work to-date. The Report identifies in Chapter 9, *Future Consideration*, issues to be addressed to ensure successful development and implementation of a system. By clearly identifying issues for future consideration, the Report serves to inform ongoing work of the Coalition. The Coalition stresses that work should proceed to address these outstanding questions, with the desired outcome being implementation of a system that reduces the harm caused by preventable medication incidents. The Coalition recommends particular focus on the following:

- A legal review and opinion regarding the proposed partnership; as well as an open, fair, and transparent process for selection and funding of partners.
- Emphasis on the active role of the consumer, including participation in governance of the system, as well as an important role as a reporter of medication incidents.
- Emphasis on the need for evaluation throughout development and testing of the program. Ongoing evaluation is equally important to ensure the program provides the primary goal of reducing harm caused by preventable medication incidents.

- The need to develop clearly defined linkages and collaboration with other patient safety initiatives, such as the National Steering Committee on Patient Safety, and other surveillance programs such as those for blood products.
- The need for a complete privacy impact assessment (building on the assessment presented in the Report) and need to obtain appropriate legal advice.
- The need to review and further define funding options for CMIRPS.

Summary

Coalition members strongly support the principles, goals and attributes detailed in this Report. As noted in the business plan: *"the development and implementation of a Canadian Medication Incident Reporting and Prevention System is a formidable challenge, and a long-term project that will require participation and collaboration from a number of stakeholders across the country".*

A key aspect of the Coalition's mandate is *"to ensure the Plan is championed, marketed, and implemented".* This Report represents a significant milestone in the evolution of a proposed system. The Coalition recognizes that more work remains to be done to ensure successful development and implementation of the system. By clearly identifying additional issues that must be addressed before this can occur, the Report serves to inform ongoing work of the Coalition, expediting the goal of moving this important patient safety initiative forward.

Readers are strongly encouraged to review the full Report to provide a complete picture of the background, rationale and important elements that comprise the proposed Canadian Medication Incident Reporting and Prevention System.

Presented on behalf of the members of the
Canadian Coalition on Medication Incident Reporting and Prevention

Support-in-Principle provided from:

Marketed Health Products Directorate, Health Products and Foods Branch, Health Canada
Canadian Association of Chain Drug Stores
Canadian Healthcare Association
Canadian Institute for Health Information
Canadian Medical Association
Canadian Nurses Association
Canadian Pharmacists Association
Canada's Research Based Pharmaceutical Companies
Canadian Society of Hospital Pharmacists
Consumers Association of Canada
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Acknowledgement

The Canadian Coalition on Medication Incident Reporting and Prevention (CCMIRP) wishes to acknowledge and thank the many individuals from across Canada and in other countries that provided their ideas, advice, and opinions during the consultations leading to the development of this report. We are grateful for the generous contribution of their time and assistance in helping us to shape this report. All of these individuals are identified by name in Appendix A.

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Executive Summary

Recent reports have raised safety concerns regarding the number of adverse events experienced by patients, including those events that relate to medication incidents. Medication incidents have not only proven to occasionally result in significant patient harm but also to increase the costs of health care delivery. Clearly, better information on the number, types, sources, causes, and outcomes of medication incidents is needed in Canada to assist in:

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

Most of the data on the socio-economic impact of medication incidents has been generated in the United States. Extrapolations from medical incident studies conducted there result in estimates ranging from approximately 44,000 to 98,000 deaths annually – medication incidents constitute the single largest category of these incidents. Medication incidents are the most common single preventable cause of patient injury. A recent study conducted at two prestigious U.S. teaching hospitals found that almost 2% of hospital admissions experienced a preventable adverse drug event, resulting in an average increased length of stay of 4.6 days, with an average increased hospital cost of nearly $4,700 per admission. This amounts to approximately $2.8 million U.S. annually for a 700-bed teaching hospital. Another U.S. study estimates medication incidents account for one out of 131 outpatient deaths. Yet another U.S. study found that for every dollar spent on drugs in nursing homes, $1.33 is consumed in the treatment of drug-related morbidity and mortality.

In the fall of 2000, an invitational workshop was co-hosted by the Canadian Society of Hospital Pharmacists (CSHP) and Health Canada's Bureau of Licensed Product Assessment (BLPA) to address a number of key questions related to medication incident reporting and prevention. One of the outcomes of the workshop was the recommendation to establish a coalition of stakeholders - *Canadian Coalition on Medication Incident Reporting and Prevention – CCMIRP* - to oversee the creation of a business plan for the development and implementation of a medication incident reporting and prevention system. Members of the Coalition include representatives from consumers, medicine, nursing, pharmacy, healthcare associations, information management, federal and provincial governments, and the pharmaceutical industry.

The purpose of this report is to present a business plan for a *viable, sustainable, and affordable* medication incident reporting and prevention system for Canadians. An extensive consultation process provided the opportunity to gain from experiences of safety programs in other jurisdictions, determined key concerns and needs of professions, governments and health care organizations and identified the significant components of a viable program. Close to fifty key stakeholders from across the country and selected international experts were contacted.

The key components of this business plan include:

- establishment of a partnership between the Institute for Safe Medication Practices Canada (ISMP Canada), Health Canada and the Canadian Institute for Health Information (CIHI);
- a secure, anonymous system that allows input from all health care delivery sites including hospitals, the consumer's home, nursing homes, clinician offices and pharmacies;
- creation of a timely intervention and prevention program; and
- enhancement and augmentation of existing resources.

The development and implementation of the proposed Canadian Medication Incident Reporting and Prevention System will serve to further strengthen our health care system and benefit Canadians by enhancing the safety of the medication use system and the effective use of scarce resources.

Development and implementation of such a system is a formidable challenge that will require participation and collaboration from a number of stakeholders at the federal, provincial and territorial levels. This report represents a significant milestone in the evolution of a proposed system, however much work remains to be done. It will also be important to coordinate this work with relevant patient safety initiatives currently underway in Canada.

Introduction

As a result of concerns relating to medication incidents and the need for better information, a number of meetings and discussions were held between Health Canada and a number of key stakeholders over the last few years. In the fall of 2000, an invitational workshop was co-hosted by the Canadian Society of Hospital Pharmacists (CSHP) and Health Canada's Bureau of Licensed Product Assessment (BLPA) to address a number of key questions related to medication incident reporting and prevention. One of the outcomes of the workshop was the recommendation to establish a coalition of stakeholders – the *Canadian Coalition on Medication Incident Reporting and Prevention – CCMIRP* (see Appendix A for membership) to guide the development of a business plan for the development and implementation of a national medication incident reporting and prevention system.

The development of the business plan would be led by Health Canada and would be a collaborative effort of the Coalition.

About This Report

The purpose of this report is to present a business plan for a *viable, sustainable, and affordable* medication incident reporting and prevention system for Canadians.

This report builds on the experience achieved to date – in Canada and abroad. Much of what is presented in this report is based on the outcome of consultations held with over fifty key stakeholders from across the country and selected experts from Spain, the United Kingdom and the United States.

The development and implementation of a Canadian Medication Incident Reporting and Prevention System is a formidable challenge and a long-term project that will require participation and collaboration from a number of stakeholders across the country. The completion of this report represents a significant milestone in the evolution the proposed system. It is recognized however, that much more work remains to be done to ensure the successful development and implementation of the system. In this regard, recommendations regarding future areas of additional investigation and discussion are also presented in the report.

Chapter 1: Why Bother?

> *The motivation for those with governance responsibility for our health systems to improve those systems so as to reduce patient harm, rather than simply improve efficiency with resource consumption, needs to be fuelled by measurement of the problem.*[1]

Medication incidents – wrong drug, wrong dose, wrong route of administration, wrong patient, or wrong time – are the most common single preventable cause of patient injury.[1] Recent reports have raised safety concerns regarding the number of adverse events experienced by patients, including those events that are related to medication incidents.[2, 3] While there is little data to draw from on the Canadian experience, recent data from the United States show that medical incidents result in approximately 44,000 to 98,000 deaths annually - medication incidents constitute the single largest category of these incidents.[2] While there are various estimates of the number of medication incidents, a recent evaluation of a United States' national clinical pharmacy database published in 2001 found that each hospital in the database experienced a medication incident for every 19.7 hospital admissions and had a medication incident that adversely affected patient care outcomes every 401 admissions.[4]

Although there is less information regarding medication incidents in primary or ambulatory care, some data does exist. For example, one study in the United States has estimated that medication incidents account for one out of 131 outpatient deaths.[5] Another study conducted by the state of Massachusetts in the United States, estimated that 2.4 million prescriptions are filled improperly in ambulatory care settings each year.[2]

Although medication-related incidents occur frequently, most do not result in actual harm to the patient or consumer, but those that do are costly. One recent study conducted at two prestigious teaching hospitals in the United States found that almost two percent of admissions experienced a preventable adverse drug event (ADE) resulting in an average increased length of stay of 4.6 days and an average increased hospital cost of nearly $4,700 per admission. This amounts to approximately $2.8 million (U.S.) annually for a 700-bed teaching hospital. Of all ADEs, 1% were fatal (none preventable), 12% life-threatening, 30% serious, and 57% significant. Twenty-eight percent of all ADEs were judged to be preventable. Of the life-threatening and serious ADEs, 42% were preventable, compared with 18% of significant ADEs.[6, 7]

While little information is available on the cost impact of medication incidents in other types of health care settings, one study in the United States found that for every dollar spent on drugs in nursing facilities, $1.33 is consumed in the treatment of drug-related morbidity and mortality.[8]

So why do we need a national medication incident reporting and prevention system? Don't we know what incidents there are currently? Don't we know the solutions already?

First, despite the emergence of new technologies, the number of deaths related to medications continues to increase. One study in the United States found a 257% increase over a 5 year span.[9] This can be ascribed, in part, to the increased opportunity for incidents with the introduction of new medications with their individual attendant problems (e.g. labelling, correct prescribing, confusion regarding nomenclature).

Second, there are no comprehensive, national sources of data for measuring the services provided by health professionals and no method of measuring how the provision of these services relates to patient outcomes.[10] A national medication incident reporting and prevention system can be used to assist in measuring the performance of the health care system.

Third, most data on medication incident rates comes from institutional-based practice. Little is known of the nature and volume of medication incidents that occur in the community.[11] Since approximately 85% of prescriptions are written in community or ambulatory care settings[12], the information we do have likely only represents a fraction of what actually occurs. A national medication incident reporting and prevention system would not only assist in documenting the extent of the problem but would provide opportunities to develop and implement preventative strategies designed to reduce the risk of patient and consumer harm, as well as reduce the unnecessary use of health care resources.

Finally, a national medication incident reporting and prevention system can assist health professionals, health organizations, community-based pharmacies, governments and others to recognize potential problems before they actually occur, and implement appropriate preventative strategies.[13]

Strategies to decrease medical incidents are generally based in systems analysis as many causes are thought to be systemic.[14] Medication incidents can arise from many factors including, miscommunication, understaffing, processes related to drug preparation, distribution, transcription, human fatigue, as well as contributing factors such as poor lighting, frequent interruptions, inadequate training, and deficient organizational policies and procedures.

Baker and Norton from the University of Toronto and University of Calgary, respectively, identified three essential strategies to reduce the number of medical incidents:[15]

- the development of better information about the numbers and types of incidents that occur in order to help pinpoint change efforts;
- a set of strategies focussing on the development of more effective systems, and
- the creation of more effective cultures oriented by healthcare organizations toward preventing incidents and effectively addressing incidents that inevitably occur.

This is consistent with recommendations in the seminal report by the Unites States' Institute of Medicine - *To Err is Human: Building a Safer Health System*.[2] The report recommends that certain key areas of health care be targeted for national voluntary reporting systems. Medication incidents are the most frequent type of medical incidents and, as has been shown in numerous studies, can lead to disastrous consequences. The report recommends that the framework for such a system should be:

- ✓ national in scope;
- ✓ voluntary in nature;
- ✓ confidential;
- ✓ non-punitive with respect to those who report;
- ✓ independent of regulatory or accrediting bodies;
- ✓ objective with findings and recommendations;
- ✓ embraced and supported by the full health care community;
- ✓ effective and credible in analyzing and using the information;
- ✓ timely and widespread with communications about incidents and their prevention;
- ✓ encourage unrestricted practitioner reporting;
- ✓ receive reports of serious and fatal events caused by incidents, "near misses," and hazardous situations that could lead to incidents;
- ✓ provide incentives for reporting;
- ✓ encourage universal acknowledgment, adoption, and implementation of proven safety practices; and
- ✓ offer a level of evidentiary protection for the incident information reported to it.

A 1999 report titled, *Managing the Risks from Medical Product Use: Creating a Risk Management Framework* published by the United States' Food and Drug Administration, stated that data is integral to a systematic approach to risk management and the use of data is essential to effectively plan and evaluate the success of risk interventions.[16] In order to better understand incidents, the contributing and causal factors need to be understood to facilitate the introduction of preventative strategies. The first step in the development of the science of 'medical incidents' is a monitoring and descriptive one that is based on common definitions, descriptors, and data sets.[17]

Clearly, better information on the number, types, sources, causes, and outcomes of medication incidents is needed in Canada to assist in:

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

In order to ensure that Canadians continue to have access to new, appropriate and cost-effective drugs, the First Ministers at their September 2000 meeting agreed to work together and mandate their Health Ministers to develop strategies for assessing the cost-effectiveness of prescription drugs. These strategies would be informed by an examination of current best practices. These strategies would complement ongoing work to ensure the optimal use of pharmaceuticals in health care, thereby contributing to continued improvements in the quality and efficiency of health care services.[18] A national medication incident reporting and prevention system would provide much needed information to assist in improving and strengthening Canada's health care system by enhancing the cost-effective use of resources by preventing medication incidents and reducing the unnecessary use of scarce resources.

This report provides recommendations for the establishment of a Medication Incident Reporting and Prevention System for Canadians. The report addresses the purpose, attributes, scope, feedback mechanisms, costs, and implementation strategies. The proposed

Canadian Medication Incident Reporting and Prevention System calls for the involvement of all levels of health care delivery in order to improve patient safety and the effective use of health care resources.

Chapter 2: Methodology

The development of the business plan was carried out by a team of consultants from Sierra Systems under the leadership of Health Canada and guidance from the CCMIRP. The business plan was developed between September 2001 and February 2002 and involved the phases described below.

Phase 1 – Project Initiation

The initial phase of the project consisted of confirming the project expectations, completing the project terms of reference and work plan, and establishing a consultation plan. The consultation plan was reviewed with Health Canada and included proposed approach and contacts for consultations.

Phase 2 – Environmental Scan and Expert Consultations

Phase 2 involved completing the following steps:

(a) review of the literature: A Medline literature search and web-search were conducted to identify relevant information on the types of medication incidents, cost of incidents to the health care system and types of established medication incident reporting and prevention programs; and

(b) consultations with selected experts from across Canada and other countries.

A two-staged approach was used for consultations. The first stage involved consulting with organizations/agencies that already have a system in place (e.g. United States Pharmacopoeia, United States' Veterans Health Administration, ISMP Canada/United States) or have a relevant project currently underway (e.g. Canadian Institute for Health Information, Canadian Institutes for Health Research, Health Canada, Canadian Coordinating Office of Health Technology Assessment) to determine strengths and weaknesses of various systems and how they may apply to the Canadian environment. The intent during the first stage was to gather relevant information in order to begin defining the proposed CMIRPS. A template of questions was disseminated to agencies/organizations with systems in place to ensure that information was systematically gathered on each system.

The second stage of consultations involved consulting with selected key experts and stakeholders from across Canada to solicit opinions and suggestions regarding the proposed system. These experts and stakeholders were identified in the first phase and through consultation with Coalition stakeholders and Health Canada. A consultation document was prepared to facilitate discussions. The objectives of this second set of consultations were to:

- solicit feedback regarding proposed system definition (e.g. purpose, scope, functions, data set, products);

- solicit feedback regarding potential options for the proposed system;
- identify potential users of proposed system;
- identify other stakeholders of proposed system and define their roles;
- identify critical success factors, implementation issues and concerns regarding proposed system including potential solutions; and
- discuss potential models for the governance and management of proposed system.

All of the individuals who were consulted for this project are identified by name in Appendix A.

Phase 3 – Analysis of Issues and Potential Options

This phase consisted of analyzing all of the information gathered from the environmental scan and the outcome of the consultations. Common themes were summarized, and strategy options identified for key issues and concerns identified during the consultations. The analysis included an assessment of potential options – for the system solution, and governance and management models.

Elements of the proposed system were enhanced based on the information gathered.

Phase 4 – Technical and Resource Requirement Definition

The fourth phase involved translating the preferred system solution into technical requirements and identifying the necessary resources. Resources were estimated for the start-up costs as well as ongoing maintenance. Potential funding approaches were also identified.

Phase 5 – Development of Strategy and Business Plan

The final phase of the project consisted of completing the final report. This involved a number of additional discussions with Health Canada, CIHI, and ISMP Canada to reach agreement regarding potential roles and responsibilities, should such a model be pursued, and to finalize the estimated costs of the proposed system. Members of the Coalition were provided with an opportunity to comment on two drafts of the business plan. Comments and suggestions received were reviewed and the report containing the business plan finalized.

Chapter 3: State Of The Art

Over the last decade many different healthcare providers have identified the need for the development of a patient safety organization and, more specifically, the development of medication incident databases and preventative programs. Various rationales have been put forward for the implementation of these programs. In the United States and Australia, two important reports[2, 3] led to the development of new programs and the enhancement of existing ones. In other situations, individuals or professional organizations realized the importance of developing a program to decrease the incidence and impact of medication incidents and ultimately reduce the risk of patient harm.

In preparing this report, a number of organizations were contacted in order to determine the types of programs available, the structure and process, issues in implementation and outcomes, if any. Many were in the early phases of their programs and so no outcome data was available. As well, several different tools were identified that were used in the various programs.

Below is a summary of the information found. Literature references and/or websites are provided for further information.

Canada

No national medication incident reporting and prevention program is in place at the present time. While Health Canada is currently responsible for maintaining the Canadian Adverse Drug Reaction Monitoring Program (CADRMP), this program only includes data pertaining to medication incidents that resulted in adverse drug reactions.

Hospitals have some type of internal program for identifying patient incidents. Some hospitals have purchased commercial programs that have a medication component in their patient safety data collection system. Others have instituted paper systems in nursing and/or pharmacy departments where medication incidents are documented on forms and sent to a central authority. Some ambulatory pharmacies have instituted a documentation process for identifying incidents.

Part of the motivation to implement such a system within institutions, is to satisfy requirements of the Canadian Council on Health Services Accreditation, as well as a mandatory component of a risk management program. As indicated, some institutions purchase programs as part of an overall patient safety program. While these programs are of some benefit as they help to identify some common issues, large databases are required to identify rare but recurrent events.[5]

A Canadian hospital has piloted the USP's MedMARx system (see description of program below under United States). A recent innovation has been the development of the Analyze-ERR® by ISMP Canada.[19] The purpose of this voluntary system is to report and record medication incidents and near misses as well as, to provide a mechanism for users to perform root causes analysis for the purpose of identifying weaknesses in the medication use

system. Analyze-ERR® has been piloted in four Ontario institutions and is slated for further distribution. The intent is to provide for not only institutions but also individual practitioner reporting. ISMP Canada provides medication alert bulletins aimed at risk managers, pharmacy directors and administrators of hospitals across Canada. Regular medication alert and newsletters are distributed to subscribers of ISMP Medication Safety Alert! Newsletters.

The Analyze-ERR® utilizes a web page format where individuals can electronically transmit to ISMP Canada's database. The individual reporting the event is encouraged to provide some contact information to allow ISMP Canada to conduct more detailed follow-up and provide the opportunity for supporting the completion of root cause analysis. ISMP Canada plans to enhance its database to enable query capabilities for analytical purposes using aggregate data. The taxonomy used by ISMP Canada is based on the taxonomy of the National Coordinating Council for Medication Incident Reporting and Prevention, which is also used by the USP MERP and MedMARx programs.

Major Canadian Relevant Initiatives

Clearly, it will be important to coordinate the development and implementation of a CMIRPS with relevant patient safety initiatives currently underway across the country. The major Canadian relevant initiatives identified are summarized below.

- For the first time in Canada, the extent of medical errors in hospitals will be investigated in a peer-reviewed research study being commissioned by the Canadian Institutes for Health Research (CIHR) and the Canadian Institute for Health Information (CIHI). The study will determine, through a systematic review of Canadian hospital charts: i) the extent of health system error in Canadian hospitals; and ii) the availability of routinely collected data that could serve to monitor and reduce the occurrence of health system incident. The research is to be completed at the earliest by the fall 2003.

- The Royal College of Physicians and Surgeons of Canada recently established a Steering Committee on Patient Safety during a meeting on patient safety held at the Royal College's annual conference in September 2001. The meeting, entitled *Roundtable on Patient Safety and Error in Medicine: Toward a Canadian National Strategy,* brought together 55 leaders from government, health-care professions and non-governmental organizations who reached a national consensus on the need to develop a framework and strategy, and released a statement calling for an immediate effort to promote better health care through improved patient safety.

  Members of the Steering Committee are drawn from family medicine, information management, medical administration, nursing, pharmacy, the public, regulatory agencies, research, and specialty medicine. The National Steering Committee, a self-standing group that will report to participating organizations, appointed the following five Working Groups, and charged each with addressing key aspects of the patient safety issue:

  1. Measurement/Evaluation
  2. System Issues

3. Regulatory/Legal Issues
4. Education/Professional Development
5. Information/Communication

The members have set a strict, 12-month timeframe to consider the issue of patient safety from a broadly based and multi-disciplinary perspective, and to develop a formal proposal for a framework and national strategy on patient safety. The National Steering Committee and Working Groups will work collaboratively and consult widely to develop a clear set of goals and objectives, a detailed action plan, and a realistic projection of the time, money and human resources required to implement the proposed national strategy. This effort will focus on systemic incidents, and build on the growing acceptance that disclosure is required and can lead to a direct positive impact on patients and the quality of care they receive.

- Drs. Ross Baker from the University of Toronto and Peter Norton, from the University of Calgary are currently completing a study commissioned by Health Canada on patient safety and healthcare incident in the Canadian healthcare system. The project has three components: i) a literature review; ii) telephone and mail surveys; and iii) a gap analysis of current relevant activities across Canada and in other countries.

- The Alberta College of Physicians and Surgeons is leading an initiative to develop a patient safety program that shifts the focus from blame to one of reporting medical incidents as a means of preventing future incidents. The College hosted a two-day Conference on Medical Safety in March 2001 in Edmonton that was partially funded by Alberta Health and Wellness. As a result of a recommendation by Conference participants, a Steering Committee was established to develop a model for patient safety, funded by Alberta Health and Wellness. This model was presented in November 2001 at a conference on patient safety in Edmonton. Possible next steps could include the creation of an arms length, independent body/institute to champion and oversee patient safety issues in Alberta. A *white paper* on the medical incident situation in Alberta is currently being developed.

- In April 2000, Québec Health Minister Pauline Marois announced the creation of a committee to study *avoidable medical accidents* in the Québec healthcare system. The committee's mandate was to i) report on the current state of the problem in Québec; ii) assess existing approaches (mostly from other jurisdictions) for addressing the issue; iii) and propose mechanisms to prevent the occurrence of such accidents. The committee's report, *Les accidents évitables dans la prestation des soins de santé - La gestion des risques, une priorité pour le réseau*, was released on March 1, 2001. The report noted a significant lack of data on medical incidents in the province. Among its recommendations, it called for a study to be undertaken to determine the incidence rates of avoidable accidents and their consequences, their probable causes, as well as the costs associated with these accidents. An Action Plan is being prepared by the Ministry to work toward the implementation of the Report's main recommendations.

- In January 2002, the Quebec College of Physicians and Surgeons announced that it has moved to change its code of conduct to require doctors to reveal incidents to patients as

soon as possible or face disciplinary action. Quebec's National Assembly is expected to ratify the amendments to the code by September.

- In January 2002, the Quebec Ministry of Health announced a plan to reduce medical accidents of all kinds in health organizations. Hospitals will now be required to inform patients when medical accidents occur and to explain the steps being taken to prevent similar incidents in the future.

Australia

The 1995 publication, *Quality in Australian Health Care Study*[3], sparked a government-appointed Taskforce that established strategic directions for Australia. This led to the formation of the Australian Council on the Safety and Quality of Health Care, with financial support on a population basis from the state, territory and federal governments to a level of $50 million, to implement an action plan to improve healthcare safety. An existing organization (Australian Patient Safety Foundation (APSF), a non-profit, independent organisation) was engaged to look at options for reducing risk in South Australian health care units. They developed an incident monitoring system known as AIMS (Australian Incident Monitoring System) [5] to identify and analyse incidents occurring in healthcare. The system has its roots in a program implemented in anaesthesia units in the late 1980's. The system has recently been implemented in a New Zealand site.

AIMS, introduced in 1996, provides a mechanism for an incident or accident (real or potential) in healthcare to be reported using a single standardized form. A specific classification system for coding and reporting of incidents is based on the seminal 1995 Australian report cited above and the Harvard Medical Practice Study (United States). The incidents recorded are both medication and non-medication related events.

Incident information is collected on paper and then entered and coded using the APSF software. The software elicits the key features of the incident, places the event in context and records the contributing factors for both system and human-based incidents. Some of the contributing factors that are recorded are:

- management decision;
- infrastructure, working conditions;
- communications, records;
- staff quantity and quality;
- supervision and tasking;
- equipment availability and/or suitability; and
- policies, protocols and pathways.

APSF collects data, de-identifies it and then conducts aggregate analysis. The database allows all health units to receive comparative information linking their performance with other 'like' organisations.

United States

Three national programs are in place in the United States. The oldest, Medwatch, is sponsored by the Food and Drug Administration (FDA). Ostensibly, it was put into place as a component of their post-marketing surveillance program. Medication incidents primarily involve reports of incidents related to the product, in particular the labelling of the product.

The second program, the Medication Error Reporting (MER) Program, is a co-operative effort of the United States Pharmacopoeia (USP) and the Institute for Safe Medication Practices (ISMP). ISMP was initiated as a voluntary reporting system in 1975 and was incorporated in 1994 – the same year it entered in a partnership with USP to establish the USP-MER Program. Health care practitioners submit incidents individually on a voluntary basis. An opportunity exists to follow-up individual reports to conduct root cause analysis and to aggregate data to determine areas of improvement.

Although the MER program is useful, many issues related to the medication use process (i.e. prescribing, documenting, dispensing, administering, and monitoring) contribute to medication incidents. This spawned the formation of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The primary outcome of this council was the development of a nomenclature and classification system for medication incidents. From this a new program called MedMARx was developed. The purpose was to allow hospitals to report, track, and share medication incident data in a standardized format. A beta-test of the program in 27 hospitals was completed in July 1998 and became available for general use one month later.

MedMARx provides hospitals with an internal performance improvement tool to help reduce medication incidents by providing a mechanism for root cause analysis. As well the program provides opportunities to detect trends, identify unusual incidents and perform comparative analysis. An annual fee is paid by participating hospitals. Because many hospitals had existing performance improvement systems collection of medication incident information may vary, including:

- use of an internal incident reporting program for risk management purposes;
- use of a paper-based internal medication incident reporting form;
- use of the paper-based MedMARx data collection form; or
- direct internet entry of reports into MedMARx from patient care units.

The system relies on internal 'gatekeepers' responsible for creating and assigning rights for multiple users within their own facility. Individual facilities have up to 60 days to review the information before it is permanently captured by the database system. A demo of MedMARx is available on USP's web-site.[20] Their first report, summarizing data captured in 1999, was recently published.[21]

One other significant program in the United States has been instituted nation-wide. All of the Veterans Administration (VA) hospitals participate in a patient safety program coordinated by the VA National Centre for Patient Safety.[22] They have developed an overall patient safety program that focuses on 4 categories: medication incidents, patient falls, para-

suicides and patient elopements (patient missing or left). They have developed their own taxonomy and severity coding system. A tool called the Safety Assessment Code Matrix combines severity and probability to produce a score of 1 (lowest risk) to 3 (highest risk). These ranks, or *Safety Assessment Codes (SAC)*, can then be used for comparative analysis. Although the program has been in place for a few years many components are still being developed. Only within the last year have they standardized the definition of a medication incident. The program focuses on sentinel events and those events receiving the highest safety assessment codes. A detailed set of guidelines for each institution as well as policies for individuals involved in the program have been developed. A cornerstone of the program is root cause analysis. All staff are trained in this skill to better enable determination of underlying causes in order to improve the system.

Spain

A Spanish version of ISMP was begun in 1999. The program was initially implemented in a few sites in January 2000, and primarily focussed on institutional practice. They are working on expanding to pharmacies, individual practitioners, etc. They are now coordinating with the Spanish hospital pharmacy association in developing a system equivalent to MERP using the NCC MERP taxonomy.

Incidents are reported to the Spanish ISMP via email, Internet or by paper form. Currently it is a voluntary organization that employs 3 people. They receive grants from the pharmaceutical industry, hospital pharmacies and from the health districts where the program is currently implemented. The plans are to expand to the rest of Spain.

. Similar to the Canadian and US ISMP programs, reporters of the incidents are contacted to request further information useful in root cause analysis. Reporters have the option to send in individual reports or a batch of individual reports. Hospitals themselves do not participate as institutions; the program is currently geared towards individuals or programs of departments (primarily hospital pharmacies at this time) reporting. To date, they have received approximately 500 individual reports. The program currently does not have the capability to analyze individual processes within institutions.

Great Britain

No specific national program has yet been developed for medication incident reporting and prevention. However, with the publication of some high-profile incidents a National Patient Safety Agency has been established. One of the key areas they will focus on is medication incident. However, no formal programs, other than regional/institutional programs, are in place.

Of interest is a program developed by Boots Pharmacies for all of their stores. The program is client focussed with any complaints/concerns/incidents expressed by patients documented and followed. There are two stated purposes for the program:

- to alert central management when incidents happen; and
- to ensure learning is spread through the organisation and incorporated into processes and systems.

The program is mandatory for all staff with disciplinary action taken if staff do not report incidents. The frequency of incidents is reported monthly with analytical studies undertaken when required to modify systems and processes. A special form and software program has been developed to streamline the program. The intent, for the most part, is to improve systems on a local level. However, some trending is done system-wide. Future plans include linking to the expected nation-wide medication incident reporting system emanating out of the work of the National Patient Safety Agency.

Other

There are a number of commercially available systems available in North America. Medication incidents are generally contained within a whole program geared towards a risk management program dealing with patient safety issues. Some focus on documentation, follow-up and then risk reduction strategies. Others identify common incidents, develop a tool to aid the institution to 'discover' their rate and prescribe how the institution might change their policies and procedures in order to avoid future events.

An example of a commercially available program is the Safety Optimizer™ program from Zynx Health Inc., a subsidiary of Cedars-Sinai Health System.[23] The Safety Optimizer™ is a web-based incident-reduction tool featuring guidelines for improving safety within the acute care setting and for tracking progress in achieving improvements. The program is designed for use by the multidisciplinary clinical team, including nurses, pharmacists, and physicians, as well as for experts in quality-improvement and risk-management.

There are several limitations with commercial products, including:

- they are limited in their ability to pick out infrequent but important incidents;
- they lack the sophistication necessary for complete root cause analysis; and
- with the system using common known incidents, many other types of incidents go undetected.

Comparison of Existing Systems

This brief overview provides a glimpse into the types of programs available both within Canada and internationally. On the whole, most programs work anonymously although some encourage the identification of the reporter in order to solicit further information. A number of different types of health care settings have implemented these programs. The most comprehensive and well-developed programs have been instituted in the United States. The use of web-based services has allowed simple access for many and ensured a more standardized and secure approach to data transmission and reporting.

The following table presents a summary comparison of the major existing systems identified from the environmental scan.

Table 1. Comparison Of Existing Medication Incident Reporting and Prevention Systems

Criteria	System					
	MedMARx	**ISMP (MERP)**	**U.S.VA**	**MedWatch**	**Boots**	**AIMS**
Country	United States	United States Canada	United States	United States	United Kingdom	Australia
Scope	Hospitals	Individual Practitioners Hospitals	Veterans Hospitals	Individual Practitioners	Individual Practitioners and Stores	Hospitals
Voluntary/ Mandatory Reporting	Voluntary	Voluntary	Sentinel events mandatory, rest voluntary	Voluntary (Individual practitioners)	Mandatory	Voluntary
Non-Punitive/ Punitive	Non-Punitive	Non-Punitive	Non-Punitive	Non-Punitive	Punitive (If incident is not reported)	Non-Punitive
Types Of Medication Incidents	All – both actual and near misses	All – both actual and near misses	All; focus on sentinel events	Actual Incidents - Related to product	Actual and near misses -related to distribution	All – both actual and near misses
Types Of Output Reports	Newsletters Standard Web-based User defined	Newsletters Standard	Newsletters Standard User defined	Newsletters Standard	Newsletters Standard User defined	Newsletters Standard User defined
Allows For Follow-Up	No	Yes	Yes	Yes	Yes	No
Users Can Access Their Own Data For Risk Management	Yes	No	Yes	No	Yes	Yes

Chapter 4: Canadian Medication Incident Reporting and Prevention System

The definition of the proposed Canadian Medication Incident Reporting and Prevention System (CMIRPS) that follows is based on the advice, ideas, and opinions provided during the consultations with stakeholders from across the country and results of the research conducted by the project team.

Purpose And Attributes Of Proposed System

Purpose

The purpose of the proposed CMIRPS is:

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

The goals of the system are to:

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

Attributes

The Canadian Medication Incident Reporting and Prevention System (CMIRPS) should:

1. be national in scope;
2. be compatible with an overall patient safety system;
3. encourage extensive voluntary participation;
4. be non-punitive with respect to those who report;
5. safeguard data integrity, privacy and confidentiality;
6. encourage organizational and individual practitioner reporting
7. encourage the reporting of all medication incidents;
8. allow for selected follow-up to facilitate root cause analysis and quality assurance of data;
9. allow organizations to access their own data for risk management purposes; and
10. be dynamic to allow for the continued relevancy and utility of the system.

A brief description of each of these attributes follows.

1. National In Scope

The CMIRPS should include data from across the country and address the information needs of users in both of Canada's official languages.

2. Compatible With An Overall Patient Safety System

Given that many existing organizational reporting systems include the reporting of all types of patient safety-related incidents, the CMIRPS should integrate or be compatible with an overall patient safety system. This will minimize the burden of additional data collection efforts. In addition, links should be established between the CMIRPS and other patient safety initiatives currently under way across the country to avoid any duplication of effort and encourage coordinated access to patient safety information. The CMIRPS should feed into, and be an integral component of, an overall national patient safety program should one ever be established.

3. Encourage Extensive Voluntary Participation

The CMIRPS should encourage extensive voluntary participation from individual health care practitioners as well as from organizations. In terms of a mandatory versus a voluntary reporting system, most experts argue that the system should be voluntary. The primary arguments against a mandatory system include: [24]

- that it tends to assign blame rather than facilitating the identification and correction of the system-based causes of medication incidents. Mandatory systems often do not include information that is crucial and necessary for the identification of system-based causes of medication incidents;
- there is a tendency to minimize the organization's exposure to liability and public distrust; and
- finally, there is no evidence available that shows that mandatory reporting results in higher levels of participation from organizations and individual health service providers.

4. Non-Punitive With Respect To Those Who Report

The CMIRPS must use a non-punitive approach if it is to be successful. Assigning blame tends to discourage reporting and is a powerful barrier to collaborative problem solving. Further, a non-punitive approach assists in focussing on processes thereby identifying the root causes for the problems and improves the chances that future events will be reduced.

5. Safeguard Data Integrity, Privacy And Confidentiality

The CMIRPS will operate within a secure environment with strict polices and procedures in order to safeguard the integrity of the data, as well as its privacy and confidentiality. Organizations and individual health service providers that report data on medication incidents will be assured that the security, privacy and confidentiality of their data is safeguarded. Any information produced will be anonymous and will not identify individual patients/consumers, health service providers, or health service organizations/community-based pharmacies.

6. Encourage Organizational And Individual Practitioner Reporting

To encourage the extensive reporting of medication incidents, the CMIRPS should allow for the reporting of data by health organizations across the continuum of health service delivery, as well as from individual practitioners, patients/consumers, drug manufacturers, and others. During the initial roll-out of the system, it is recommended that implementation be phased-in starting with the reporting by health organizations and individual health service providers to ensure that implementation support efforts are targeted as much as possible. In parallel with these efforts, other potential reporters such as consumers, drug manufacturers and others should be consulted regarding how best they can participate in the CMIRPS to ensure that their support is not lost during the early roll-out phase.

7. Encourage The Reporting Of All Medication Incidents

The CMIRPS should encourage the reporting of all type of medication incidents – including those that result in patient harm or death, as well as near misses and situations that could lead to medication incidents. Through the reporting of all types of incidents, potential problems can be averted before they occur, and strategies for preventing medication incidents can be more effectively identified and disseminated to the health care community.

8. Allow For Selected Follow-Up To Facilitate Root Cause Analysis And Quality Assurance Of Data

The CMIRPS should provide the ability to actively perform root cause analysis. Through root cause analysis, the CMIRPS may identify issues of urgent concern where immediate communication/education is warranted. This will require that the reporter consents to their identification and that the CMIRPS will have to, through policies and procedures, ensure that the identifying information be held separately from the central database for a defined period of time, for follow-up purposes only. The CMIRPS must ensure the anonymity of the data so that there is no impediment to reporting.

9. Allow Organizations To Access Their Own Data For Risk Management Purposes

The CMIRPS should provide some flexibility in the services it provides to allow for both documentation and analysis of data including key or sentinel incidents for risk management purposes. Detailed process analysis, if required by the program for individual institutions and/or health regions, will be in place allowing comparative time analysis as well as root cause analysis capabilities.

10. Allow For The Continued Relevancy And Utility Of The System.

If the CMIRPS is to remain relevant and useful to users, it must be dynamic and allow for enhancements and changes over time.

Scope Of The System

The scope of the proposed CMIRPS is defined below by major subject area.
(a) Health Care Settings

The CMIRPS should include medication incident data from a variety of settings across the continuum of health service delivery. This includes, but is not limited to hospitals, home, community-based pharmacies, long-term care facilities, home care, and physician offices.

(b) Types Of Reporters Of Data

The CMIRPS should allow for the reporting of medication incidents by individual health care practitioners, health service organizations, community-based pharmacies, consumers, drug manufacturers, governments, and others.

(c) Types Of Medication Incidents

The CMIRPS should include potential and actual medication incidents related to prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, monitoring, documentation and use. The reporting of potential medication incidents will be integral to facilitating the identification of processes that may require adjustments in order to prevent potentially hazardous and serious adverse outcomes.

(d) Types Of Medications

The CMIRPS should include the reporting of incidents related to all types of medications including any substance or mixture of substances used in i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms; and ii) restoring, correcting or modifying organic functions.[25] This includes but is not limited to, biological products such as bacterial and viral vaccines, blood, plasma and their derivatives, interferons and erythropoietin. Recognition of special needs of some types of services and/or products will require further consultation to ensure that the CMIRPS effectively addresses the complete scope of possible situations and products (e.g. blood products and radio pharmaceuticals).

(e) Data Set

The data set should be based on the taxonomy developed by the United States National Coordinating Council for Medication Error Reporting and Prevention to allow for international sharing of experiences between countries (see http://www.nccmerp.org/ for taxonomy). The data set should be:

- a *minimum data set* to minimize the burden and costs of data collection;
- based on the information needs of users;
- flexible to allow for the collection of more detailed data (optional fields) based on specific local and regional information needs.

Major Functions

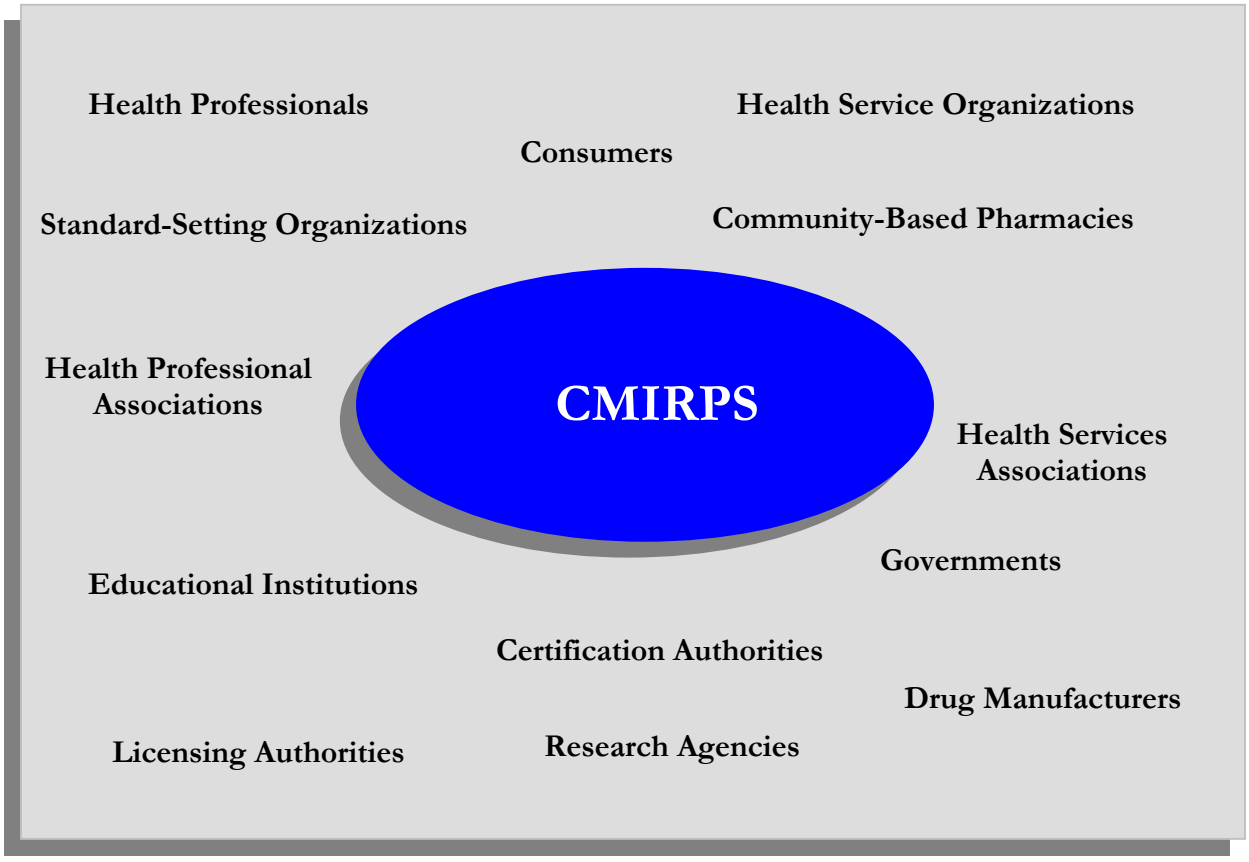
The major functions of the CMIRPS include:

- data standards development and maintenance;
- data collection, processing and data quality;
- analysis and reporting;
- identification and dissemination of preventative strategies;
- marketing and communication services; and
- client support services.

Users Of The System

The users of the CMIRPS are those individuals and organizations that can use the information to enhance the safety of the medication use system for Canadians by effecting or influencing change. Potential users are presented in the table below.

Table 2. Potential Users of CMIRPS



To ensure that the proposed system is 'user-friendly' and responsive to their information needs, consumers, as potential users should be provided with an opportunity to contribute to the development, implementation, and use of the CMIRPS.

Information Products and Services

In order to meet the information needs of users, the CMIRPS will provide a number of products and services that are described below. The implementation of these products and services will be phased-in and will be heavily dependant on the degree of participation and needs of reporters (individual practitioners, health organizations, community-based pharmacies, and others). It is also important to emphasize that since participation in the proposed system is voluntary, analysis of the information will be limited by both the sampling frame of the database (i.e. total and types of reporters), as well as the need to maintain anonymity.

(a) Analytical Reports:

The CMIRPS will produce a number of analytical reports based on the priorities, and information needs of users. The types of analytical reports will include:

- reports from root cause analyses;
- retrospective descriptive analysis of the morbidity and mortality related to medication incidents; and
- special studies on specific topics or critical issues. Special studies could be collaborative initiatives involving several organizations and/or address specific issues related to the needs of users.

(b) Web-Based Standardized Reports:

The CMIRPS will use state-of-the art technology that incorporates query-based functionality to disseminate standardized reports to authorized users via the Web. Registered users will be able to define their own queries (using selected fields) and customize their own reports based on their information needs. Examples of queries could include:

- what is the reported number of medication incidents with a specific drug product?
- what are the variances in medication incident types by type of pharmacy distribution systems?
- what are the variances in medication incident types by category of health profession in drug preparation and/or administration?
- what is the reported number of medication incidents, by type of incident, by type of hospital (e.g. teaching, community);
- are there any early trends of medication incidents with the introduction of new drug products?
- which type of medication incident is the most frequently associated with patient harm?
- are there seasonal, time of day, day of week variances in the number of reported medication incidents?
- what is the impact of policy change on the incidence of medication incidents?
- what is the reported number of medication incidents by route of drug product administration (e.g. IV vs. oral)?

(c) Bulletins:

The CMIRPS will develop and disseminate information bulletins to users highlighting early trends of medication incidents and preventative strategies based on the analysis of the national database. These bulletins will be developed as critical information is identified from the database, and disseminated on a timely basis to enable corrective measures or strategies to be implemented by appropriate organizations and professionals in the field.

(d) Ad Hoc Requests For Information:

The CMIRPS will meet the information needs of users not met through standardized reports through the completion of ad hoc requests for information. Custom tabulations will be performed upon request ensuring that the privacy and confidentiality of the data is safeguarded.

(e) Ongoing Implementation Support Services:

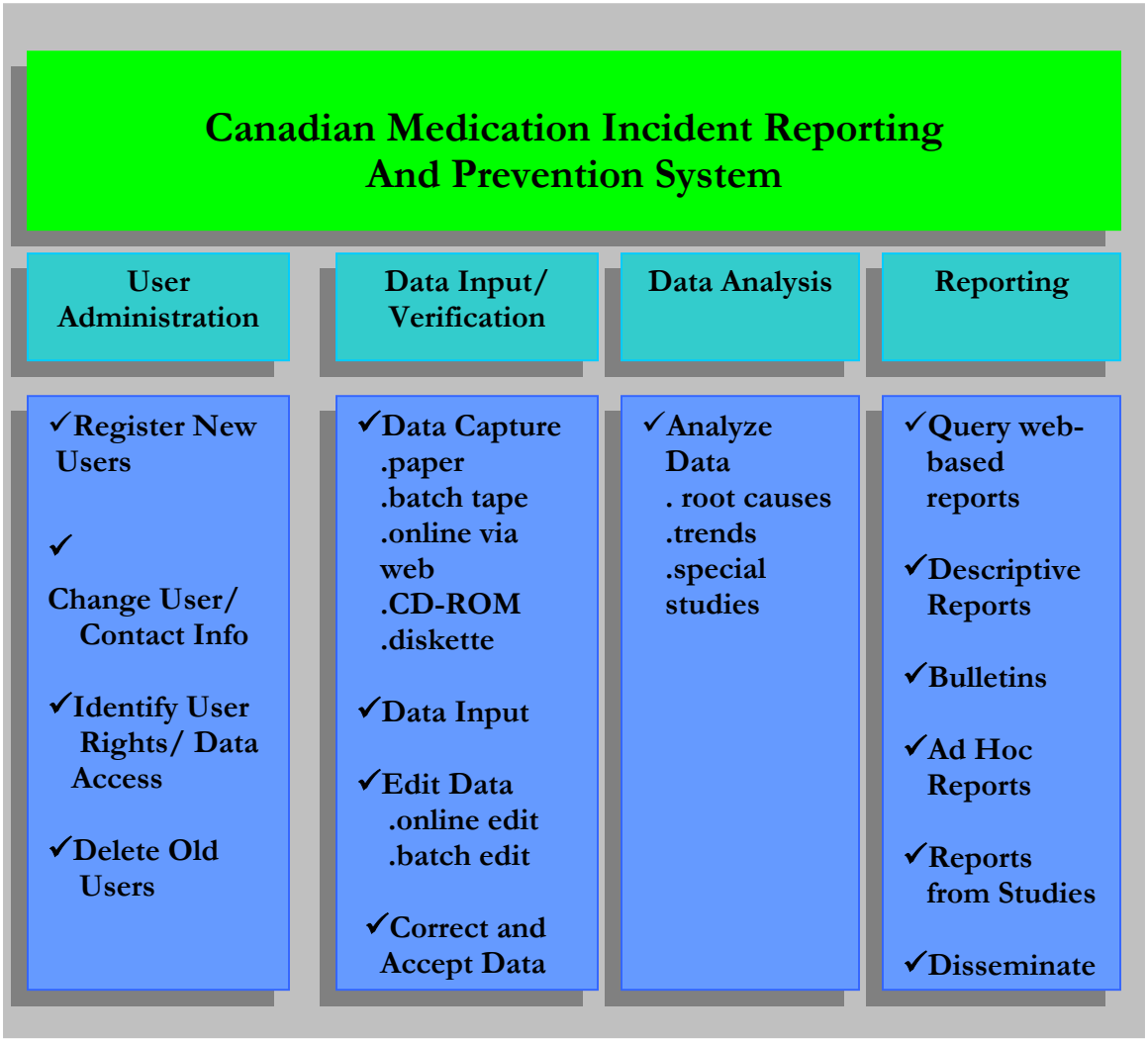
To ensure the effective interpretation of information, as well as implementation of the system across the country, the CMIRPS will provide ongoing client support services. These services will include:

- educational/training services/workshops related to the system;
- technical support services related to the transmission of electronic data or provision of reports; and
- ongoing interpretative services related to data standards and reports.

Chapter 5: Preferred Solution for Canada

Based on the input of the members of the Coalition and a review of existing systems, the following conceptual model depicts the major functions and features that have been defined for the information system for the Canadian Medication Incident Reporting and Prevention Program. A description of the technical requirements of the system is also presented below. Note that in this context users are defined as reporters of data to the CMIRPS.

Major Technical Functions and Features



Data Input

Medication incident reports will come from a broad range of potential users including institutions such as hospitals, nursing homes and community-based pharmacies through to individuals such as independent practitioners and the general public. In order to ensure maximum reporting levels, it is important that the burden of reporting be reduced to a minimum for each category of user. The system will therefore provide a variety of easy-to-use vehicles for data capture. These include:

- a paper-based form that can be mailed or Faxed to the Custodian who would data enter the information;
- an Internet-based form that could be accessed using any browser and which would support the entry of individual incidents;
- an Internet-based file transfer process that would allow a user to download a batch file of incident records; and
- a data media transfer process that would permit batches of records to be sent on media such as a diskette or CD.

In the case of the first two vehicles, the system and process ensure that a standard taxonomy for the incident is enforced. In the case of the last two vehicles, the reporting user would be required to ensure that their data is presented in accordance with a prescribed format and taxonomy.

For large institutional users having an existing reporting system, the creation of a file with standard format and taxonomy may prove sufficiently difficult that it prevents them from reporting. In these special cases, the custodian may work with the user and develop a program to convert the data for use in the CMIRP System.

The web front end of the system is envisioned as a portal which will provide features to input data; to access data/statistics; and to share important information.

Data Processing Functionality

The system will support the following functions:

1. User Administration:
   The users reporting to the system will have the choice of being completely anonymous or becoming a registered user. Both types of users are important and will be treated with due respect for confidentiality. The former group will be able to enter information on paper or via the web and will have access to any general information published from time to time on the web site.

The second group will have access to greater services and more data. These users will, for example, be able to review their own data and compare that data with institutions or practices having a similar profile. Registered users are particularly important since they may be contacted for follow-up during root cause analysis.

The system will accommodate the addition of new registered users; changes to their basic contact information; deletion of users, etc. The user information will not be available to any organization or individual outside the custodian. The information will not be attached to the detail incident record.

2. Data Input/Verification:
   The data input to the system must be verified in order to ensure that all mandatory information is captured, that the information is in the standard taxonomy and meets basic logic and data definition standards. The feedback will be instantaneous for the web-based form, but will be in batch response for the registered users who submit data using one of the batch input processes.

   The data verification process must accommodate the identification of duplicate reports. In addition, to further ensure data integrity, non-validated data pertaining to anonymous reports will be segregated from the overall database.

3. Data Analysis:
   The data captured by the system, once verified, will be made available for analysis. This is perceived as a two-part process.
   a) Preliminary Follow-up
      As individual reports are entered, they will be scrutinized for follow-up. Sentinel incidents (i.e. where significant patient morbidity or death occurs as a result of the incident) and incidents where root cause analysis is important will be identified and reporters that consented to providing identifying information, will be contacted.

   b) Routine Analysis:
      Most incidents, however, will be simply directed to the database where analysis by the custodian can occur. The analysis performed will address trends, sentinel events, etc with respect to the incidents themselves. However, the analysis will also address the utilization of the system – assessing whether use is increasing, diminishing, or remaining stable. The analysis will provide comparators to determine the level of participation across the country and in specific geographic areas.

      The analysis will be augmented with supportive database tools that permit sorting, grouping, counting, et cetera.

4. Data Reporting:
   Data reporting could take many forms, including:
   a) standard reports will be available on the web site for the general public. These reports will typically consist of counts of incidents by various groupings.

b) standard reports will be available on the web site to registered users. These reports will include those available to the general public, but will also include reports that allow the reporter to define their own queries.
c) ad Hoc reports will be available upon documented request through the custodian's data analysis team. These will be forwarded in hard or electronic copy to the requestor.
d) sanitized data (data that contains no identifying information) will be available to researchers in soft copy – either on media such as CD or diskette or as a file transferred via the Internet.

Privacy, Confidentiality and Security of Data

Confidentiality of the information is a paramount concern to all reporting users. Therefore, a variety of steps will be taken to ensure that confidentiality is not breached:

- no data which could be used to identify a patient, practitioner, or organization will be captured or retained on the central database;
- reporters who choose to remain anonymous will be able to report data without leaving any identifying information;
- registered reporters will be protected through the separation of contact detail from the incident data itself; and
- logic will be built in to the data analysis and reporting components of the system to ensure that aggregate data made public (including to registered users) contains no data that can, by deduction, identify an individual reporting user.

In addition, the technical infrastructure of the system will provide a number of layers of security, including:

- a secure user identification process (account codes and passwords);
- a firewall to protect the system from unauthorised access by hackers;
- virus-checking software to prevent destruction of the system files; and
- encryption of all data sent over the Internet.

Preliminary information regarding the proposed CMIRPS that can be used to support the completion of a privacy impact assessment is found in Appendix B.

Chapter 6: Governance and Management

The governance and management models were formulated based on a review of oversight models of other existing systems, a review of missions of relevant organizations in Canada, and consultations with key stakeholders across the country. While the consultations did not recommend preferred or specific models for the governance and management of the proposed CMIRPS, they did identify key criteria or underlying principles for guiding the establishment of the models.

Recommendations relating to governance and management were formulated in the absence of a national patient safety or citizen's council on health care quality and confirmed funding sources. The intent is to allow for flexibility for making changes to adapt to emerging issues/needs.

Governance

A Steering Committee should be established to oversee and guide the strategic directions of the CMIRPS. Key attributes of the Steering Committee that were identified during the consultations include:

- objective and at arms-length from government;
- include experts in the field of patient safety, specifically medication incidents;
- include individuals that are representative of organizations or groups that are likely to be affected by information from the CMIRPS;
- be manageable in terms of numbers of members;
- include individuals that can effect change designed to improve the Canadian medication use system; and
- individual members should be able and willing to contribute to the vision and strategic direction of the program.

The Steering Committee would be accountable for determining the strategic directions of the overall system. Its responsibilities would be to:

- make recommendations regarding analytical priorities and preventative strategies;
- provide advice to the data custodian regarding system policies relating to access, dissemination, privacy and confidentiality;
- ensure appropriate liaison and input with key stakeholders; and
- review and approve annual goals and strategic plans.

In order to effectively deliver its mandate, the Steering Committee should be composed of no more than 12-15 members and include the following representation:

- regional;
- relevant health professions with subject-matter expertise;

- relevant national organizations representing organizational reporters (e.g. community-based pharmacies, health service organizations);
- drug manufacturers;
- consumers;
- academic/research expertise;
- provincial/territorial governments (e.g. representative from federal/provincial/territorial Steering Committee on Health Services);
- Health Canada (non-voting status);
- ISMP – Canada (non-voting status);
- CIHI (non-voting status).

It is recommended that the following 3 sub-committees be established:
(a) a small *operations sub-committee* charged with developing a formal administrative agreement, including a dispute resolution mechanism, outlining the roles, responsibilities and deliverables relating to the CMIRPS. This committee would be composed of Health Canada, CIHI and ISMP Canada and would be accountable for the outcomes set out in annual goals and CMIRPS strategic plan, to the Steering Committee. The Committee would meet on a regular basis to resolve administrative and operational issues related to the CMIRPS.

(b) an *implementation sub-committee* composed of representative reporters. This committee would be responsible for providing advice regarding the initial rollout of the CMIRPS. This committee would also be accountable to the Steering Committee and would provide advice regarding implementation strategies and would assist in the identification of issues regarding implementation.

(c) a *research and development sub-committee* composed of research and subject matter experts. This committee would be accountable to the Steering Committee and would provide advice regarding analytical studies, methods and the ongoing development of the data.

Mechanism For Consultations/Communications With Stakeholders of CMIRPS

It is recommended that a **National Coordinating Council** be established to provide a mechanism for consultations and communications with the various stakeholder groups that would likely have an interest in the system. The purpose of the Council would be to:

- promote participation in the CMIRPS;
- promote an awareness of medication incidents and prevention strategies to their constituent communities;
- facilitate the dissemination of information related to the CMIRPS;
- implement preventative strategies related to medication incidents such as education;
- provide input and feedback related to data standards, analytical priorities, information products and modifications related to CMIRPS; and
- provide input to and recommend preventative strategies related to medication incidents.

Members of the National Coordinating Council would include organizations that have an interest or stake in the CMIRPS. Examples include but are not limited to:

- accreditation and standard-setting organizations;

- national health professions licensing authorities;
- consumer agencies;
- relevant research agencies;
- relevant academic institutions;
- health professions certification organizations;
- national organizations for relevant health professionals; and
- national organizations for health service organizations.

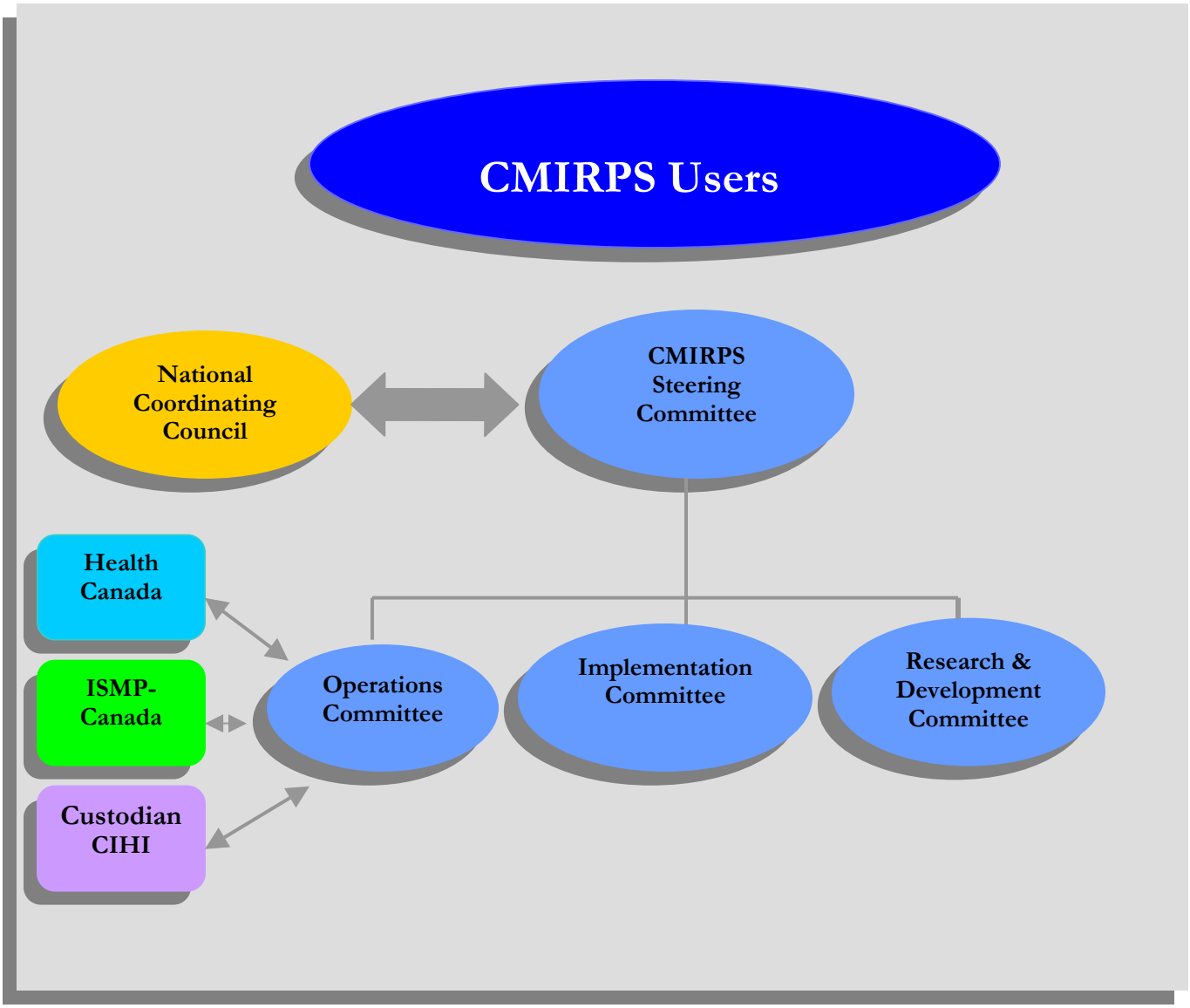
The National Coordinating Council would have at least one face-to-face meeting per year.

CMIRPS Secretariat

A Secretariat housed at Health Canada should be established to support the work of the Steering Committee, as well as the Operations, Implementation and Research and Development Committees. The Secretariat would also ensure effective coordination of communications with the National Coordinating Council.

The secretariat would be responsible and accountable for any contractual arrangements related to the CMIRPS. The role, responsibilities and accountability relationship of the CMIRPS secretariat should be further defined as a next step to this report.

A conceptual model of the governance and management of CMIRPS follows.



Management of CMIRPS

Key to the success of the proposed CMIRPS is the identification and selection of an organization to manage the operations of the system. The environmental scan and the consultations with key stakeholders identified a number of potential options for the management of the CMIRPS. Consultations also recommended that an existing organization should manage the CMIRPS and that a new corporate entity should not be established.

The options identified included:

A. Health Canada (HC);
B. Canadian Institute for Health Information (CIHI);
C. Institute for Safe Medication Practices (ISMP) – Canada;
D. Outsourcing the management of the CMIRPS to the United States Pharmacopoeia (USP).
E. Partnership arrangement among HC, CIHI and ISMP Canada.

These options were assessed against the proposed major functions (see Chapter 5) of the CMIRPS using the evaluation criteria presented in table 3. Evaluation criteria were identified from the consultations and from discussions at the project team level.

Table 3. Evaluation Criteria

EVALUATION CRITERIA
1. Objective and Arms Length From Government **2. CMIRPS relevant to Current Mandate** **3. Knowledge of Subject Matter and Analytical Capacity** ▪ knowledge of patient safety concepts, medication incidents, root cause analysis and prevention programs/data; ▪ availability of appropriate skill sets; ▪ experience in producing relevant analytical reports; ▪ experience in relevant data linkage studies/availability of other data sets; ▪ established relationships with relevant research organizations. **4. Knowledge of Privacy, Confidentiality, and Security Issues** ▪ policies and procedures currently in place; ▪ established relationship with privacy personnel in government; ▪ availability of in-house expertise on matters relating to privacy/confidentiality; ▪ capacity to operate CMIRPS in a secure environment. **5. Experience with Information Systems** ▪ developing/maintaining relevant technical and content standards; ▪ developing/maintaining data submission protocols; ▪ developing/maintaining sophisticated information system platforms; ▪ developing/maintaining web-based reporting applications; ▪ availability of appropriate skill sets; and ▪ availability of robust technical infrastructure.

Summary of Assessment Results

The summary of the assessment results is presented as follows.

A. Health Canada:

With the exception of the first criterion, Health Canada fared well on the majority of assessment criteria. The CMIRPS is relevant to the mandate of Health Canada; Health Canada has personnel with knowledge of the subject matter and analytical expertise; Health Canada has extensive knowledge of privacy, confidentiality and security issues; and finally, Health Canada has experience in developing and maintaining health surveillance systems, databases, and registries.

Health Canada is currently responsible for maintaining the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) and has regulatory authority over some matters pertaining to therapeutic drug products.

While the assessment of Health Canada yielded positive results overall, this option is problematic for two reasons:

- the majority of consultations recommended that the CMIRPS be at arms-length from government to allow objective reporting of information;
- consultations recommended that the CMIRPS be managed outside of government.

For these reasons, Health Canada was not considered an appropriate option that would encourage extensive participation in the system. Nonetheless, it is recognized that Health Canada has a vital and important role to play in the system, especially in terms of post-marketing surveillance of drug products and liasing with the drug and device manufacturers. If problems related to drug product labelling and packaging or to related devices are identified through the system, Health Canada can play an important role in liaising with the manufacturers to resolve any issues. Further, Health Canada currently manages the CADRMP. There is a relationship between the CMIRPS and the CADRMP in that data pertaining to medication incidents that result in adverse drug reactions would need to be forwarded to the CADRMP housed at Health Canada. Finally, Health Canada has regulatory powers that can ensure certain standards are maintained and enforced (e.g. drug labelling).

B. Canadian Institute for Health Information (CIHI)

CIHI is an incorporated, not-for-profit organization with a mandate to coordinate the development of Canada's health information system. CIHI's Board is composed of both government and non-government representatives from senior levels within the health system. CIHI operates at arms length from government. It meets on a regular basis with the Federal/Provincial/Territorial Deputy Ministers of Health to ensure that health information development efforts are consistent with strategic directions in terms of health policy.

The CMIRPS is within the scope of CIHI's mandate. CIHI has significantly developed its analytical capacity in recent years. Given that CIHI manages a number of data holdings, it has extensive experience in developing and maintaining sophisticated information systems, including the development of web-based reporting systems. The organization has a robust technical infrastructure, secure operating environment and a variety of informatics and analytical skill sets.

CIHI has strict privacy, confidentiality and security practices based on principles and policies approved by its Board of Directors. These principles and policies are based on the national standards in Schedule 1 of the Federal Personal Information Protection and Electronic Documents Act, with modifications reflecting CIHI's role and mandate. CIHI abides with agreements established with provincial/territorial ministries of health and expects to be subject to Ontario's planned Privacy of Personal Information Act. CIHI has a privacy secretariat reporting directly to its President and CEO that is dedicated to matters pertaining to privacy, confidentiality and security of personal health information. In addition, CIHI has a Chief Privacy Advisor who reviews and comments on its privacy practices.

CIHI currently has two Pharmacists on staff with experience in hospital medication incident reporting and prevention. CIHI is co-sponsoring a research grant with the Canadian Institutes for Health Research on medical errors. While CIHI has significant strengths related to information management and analysis, it currently is not involved in the identification or recommendation of preventative strategies related to medication incidents.

C. Institute for Safe Medication Practices (ISMP) - Canada

ISMP Canada's mandate is consistent with the proposed CMIRPS. It is based on a proven model in the United States that was originally established in 1975. It has recently initiated a pilot medication incident reporting and prevention system to healthcare providers and practitioners in Ontario. It is also engaged in a number of patient safety projects with other professional and research organizations. Presently, reports are received by ISMP Canada through a web-based form (form to be revised), email, letters, fax and phone calls. Reports have come from pharmacists, nurses, physicians and patients (or their families) in both hospital and ambulatory settings. ISMP Canada has experience in root cause analysis and dissemination of prevention strategies related to medication incidents.

A lack of a properly funded infrastructure, inadequate resources and limited national input has restricted its abilities to be a comprehensive program. As a result, ISMP Canada has little infrastructure and resources to build from. ISMP Canada's Business Plan has called for a self-sustaining operation in the long run.

D. Outsourcing to United States Pharmacopeia (USP)

USP's mandate is to promote public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and other health care technologies by health professionals, patients, and consumers. In the last few years, USP has developed and implemented a web-based medication incident reporting and prevention system designed to meet the information needs of hospitals. Registered hospitals have access to the system at an annual fee.

USP's system does not currently meet the proposed requirements of CMIRPS as it is currently focussed on meeting the needs of hospitals only. The USP system does not accommodate data from individual practitioners, community-based pharmacies and other health organizations outside of hospitals. USP are open to enhancing their system to include a module designed to meet the information needs of Canada.

A second key consideration for outsourcing to USP is its ability to meet CMIRPS's requirements related to safeguarding the privacy and confidentiality of the data. Health information is protected by statute in most provinces and territories. The exception is Ontario where legislation is pending. Canadian data reporters may be reluctant to send their data to an agency in another country where the reach of Canadian legislation does not extend.
A third consideration relates to the ability of a foreign agency to meet the product and service needs of Canadian users in a timely fashion. Canadian users will have different information needs, priorities and issues. It is difficult to assess USP's ability to effectively meet Canadian needs.

Preferred Model: Partnership arrangement among HC, CIHI and ISMP Canada.

Based on the assessment of the potential options for the management of the CMIRPS, the preferred model is one that builds on the strengths and core competencies of Health Canada, ISMP Canada, and CIHI. It is recommended that Health Canada, ISMP Canada and CIHI work collaboratively with the CMIRPS Steering Committee to ensure that the purpose and goals of the system are effectively delivered. It is recommended that a formal administrative agreement be developed that defines the roles and responsibilities of the three parties. Health Canada, ISMP Canada, and CIHI would be members of the Operations Committee and non-voting members of the CMIRPS Steering Committee. Operational issues regarding the CMIRPS would be discussed and resolved at the Operations Committee.

While the above model is presented as the preferred option, there are a number of questions that need to be addressed in the next phase of this initiative before this option should be selected . These include, but may not be limited to:

- A legal opinion on the proposed partnership arrangement including review of the formal administrative agreement and dispute resolution mechanisms;
- Clarification of contracting requirements (including request for proposals) related to (government) funding of such a partnership.

Roles and Responsibilities

The proposed roles and responsibilities of the three organizations are presented below and summarized in table 4.

Health Canada

Health Canada would be responsible for:
- providing secretariat support to the Steering Committee and its sub-committees;
- conducting post-marketing analytical studies;
- completing analytical studies on adverse drug reactions that occurred because of medication incidents; and
- liaising with drug manufacturers, and manufacturers of medication-related devices to address any issues relating to medication incidents.

ISMP- Canada

ISMP Canada would be responsible for:
- completing any follow-up with reporters to conduct root cause analysis for selected medication incidents;
- developing and disseminating information bulletins regarding preventative strategies;
- conducting analytical studies regarding preventative strategies;
- the development and disseminating of special analytical studies; and
- providing support for the development and implementation of preventative measures.

ISMP Canada will continue to receive individual practitioner reports. These will be entered in the CMIRPS system. ISMP Canada will perform routine and specialized analysis of the CMIRPS data. It will identify specific areas of concern and will recommended approaches to prevention. In order to perform this role, ISMP Canada will have the authorization to follow-up specific incidents (where the reporter has agreed to permit such review and follow-up). The intent would be to perform root cause analysis as part of the prevention program.

CIHI

The recommended model would establish CIHI as the custodian of the central data repository. CIHI would design, implement and operate the computer system. It would register users; capture batch data; perform routine and ad hoc data analysis; market and promote the system to its intended users; and disseminate relevant information. CIHI would be responsible for:
- the development and maintenance of data standards, and transmission protocols;
- where required, assistance to reporters with the development of conversion tables;
- data collection, processing and data quality;
- the development and maintenance of a web-based query system;
- the development and dissemination of analytical reports;
- the completion of ad hoc requests for information; and
- the development and dissemination of special analytical studies.

CIHI and ISMP Canada would share responsibility and/or partner with appropriate health-related organization (e.g. professional association) for developing and delivering education programs designed to address specific needs in the field where the need exists and no other health-related organization takes responsibility. For example, CIHI may develop and implement education workshops designed to facilitate the effective implementation of the CMIRPS data set; ISMP Canada may develop and implement education workshops focused on preventative strategies and root cause analysis.

Table 5. Distribution Of Responsibilities

Note: ✓Indicates lead role

Responsibility	ISMP - Canada	Health Canada	CIHI	Steering Committee	National Coordinating Council
Information Needs Identification	Input Provided	Input Provided	✓	Input Provided	Input Provided
Development And Maintenance Of Data Standards and Transmission Protocols	Input Provided	Input Provided	✓	Input Provided	Input Provided
Data Collection (via single portal entry to CMIRPS)	✓Individual Practitioners		✓Organizations		
Follow-up with root cause analysis for selected medication incidents	✓				
Processing, Data Quality (May Include Follow-Up For Data Corrections)	Input Provided	Input Provided	✓		
Development/Maintenance Of Web-Based Query System	Input Provided	Input Provided	✓	Input Provided	Input Provided
Development/Dissemination Of Information Bulletins Re. Preventative Strategies	✓	Input Provided		Input Provided	Input Provided
Development/Dissemination Of Analytical Reports	Input Provided	Input Provided	✓	Input Provided	Input Provided
Completion Of Ongoing Ad Hoc Requests For Information On Medication Incidents			✓		
Analysis - Post Market Medication Surveillance	Input Provided	✓	Input Provided		
Analysis – Medication Incidents That Result In Adverse Drug Reactions	Input Provided	✓			
Analysis, Identification, And Dissemination Of Preventative Strategies	✓	Input Provided		✓	Input Provided
Development/Dissemination Special Analytical Studies	✓	✓	✓	✓	Input Provided
Facilitation Of Implementation Of Preventative Strategies	Input Provided	Input Provided		Input Provided	✓

CMIRPS Conceptual Systems Model

The information system that would support CMIRPS is shown as a conceptual model in Figure 1. This model is presented at a very high level and is not intended to be the basis for system design. Rather it is intended to represent a concept of how the system may operate. CMIRPS is envisioned as primarily a Web based system. The information system and associated repository database will be housed at the Canadian Institute of Health Information (CIHI). A conceptual architecture of the system is shown in Figure 1.
The CMIRPS system will consist of the following main elements:

1. A Web Portal that is accessible by any computer connected to the Internet and having a current release of a web browser. The Portal will be identified as a CMIRPS site. While the relationship and support of ISMP Canada and CIHI will be highlighted on the Portal, the site will have a CMIRPS branding. The Portal will feature information on the CMIRPS program; links to the ISMP and CIHI web sites; link to the Health Canada ADR (adverse drug reaction) site for reporting and related information; narrative and informational reports; bulletins; functions supporting registration, incident reporting, data access, and much more. Registered users of the system can login through the Portal, thereby identifying them to the application.

2. A firewall that is a key component of the security that will surround the computer system and the data. The intention is to screen the system from unauthorized access to restricted elements of the technical architecture.

3. A Security Rights Manager that will define the functions and data that each user of the system can access. For example, an unregistered user might be permitted to enter an incident, and access general information such as pre-defined aggregate reports. A registered user may be permitted to enter incidents; hold incident reports temporarily for updates; access all the incidents they have reported; compare their own incidents and trends against similar users; etc. The controls provided by the Security Rights Manager will apply to all users of the system. Both ISMP Canada and CIHI will have equal access to the database (with inherent protective limitations such as not being able to make changes or alter the data etc.). A contractual agreement will be drawn to outline the security access for these two organizations and the parameters will be built into the control of the Security Rights Manager to provide access to these two organizations.

4. A Request Processor that will process transactions that have been authorized by the Security Rights Manager.

5. A database of medication incidents that are placed on hold for follow-up. Registered users reporting incidents can place specific incidents on hold until all information is available to complete the report. This database will provide registered users with an opportunity to provide a complete incident report without fear of losing the initial data.

6. A database of completed incident reports with all reporters' identifying information removed. This database will be the information source for the statistical reports used to

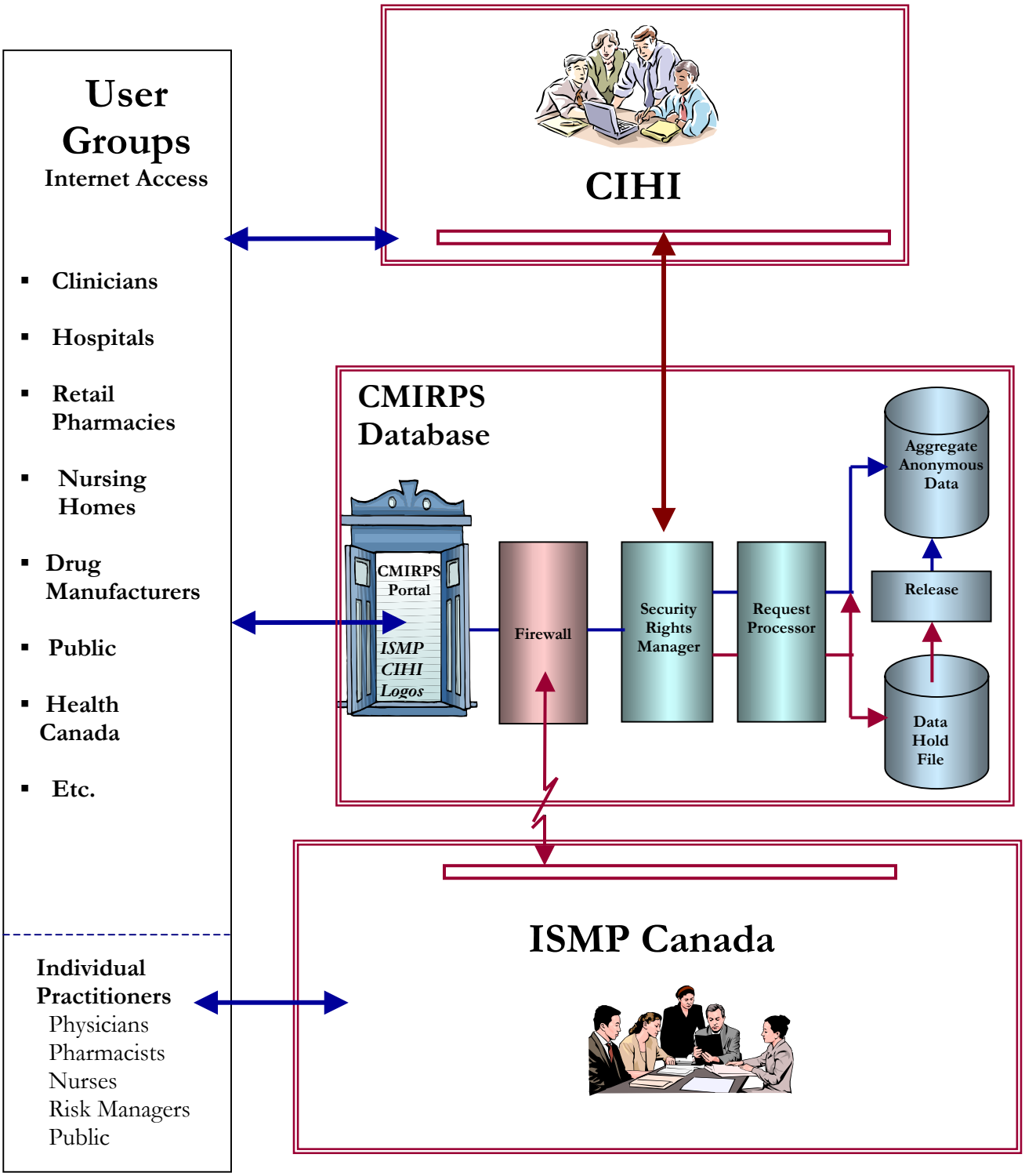
identify trends in medication incidents and the impact of prevention efforts. It will also be the source of data for approved on-line queries.

There are two key players in the management of the CMIRPS system: CIHI and ISMP Canada will share responsibility for, and will have equal access to, the CMIRPS Data Centre, as outlined in a contractual agreement.

a) CIHI will design and implement and operate the computer system. CIHI will vet and register qualified users; capture batch data; perform routine and ad hoc data analysis; market the system to its intended users; and disseminate relevant information.

b) ISMP Canada will continue to receive individual practitioner reports that are not submitted via the CMIRPS portal. These will be entered in the CMIRPS system. ISMP Canada will perform routine and specialized analysis of the CMIRPS data. It will identify specific areas of concern and will recommend approaches to prevention. In order to perform this role, ISMP will have the authorization to follow-up specific incidents (where the user has agreed to permit such review and follow up). The intent would be to perform root cause analysis as part of the prevention program.

Figure 1
CMIRPS Conceptual Systems Model



Chapter 7 – Resource Requirements

Assumptions

In estimating the anticipated costs of the proposed CMIRPS the following assumptions were made:

1. the costs of maintaining and supporting ISMP Canada's Analyse-ERR® software are excluded from the estimated costs. It is recommended that the Steering Committee further examine this software program as a feeder system to the CMIRPS database
2. name brand equipment/technology will be used;
3. indirect expenses were estimated at 20% of direct operating expenses;
4. all costs are estimates based on the limited information available at the time the report was produced;
5. there will be one-time costs incurred related to the initial investment to establish and promote and the business of CMIRPS as well as to build the application system;
6. depreciation of capital expenses such as computer hardware is not included in these estimates;
7. the compensation costs for ISMP, Health Canada, and CIHI are based on the estimated resources required to perform the functions noted in Chapter 6; and
8. the computer hardware and software costs are based on the configuration of an information system as described in Chapter 5 and the assumptions related to data and transaction volumes described below.

Medication incidents - volumes and capacity estimates: The system will accommodate up to 1M medication incidents per year; 40 gigabytes of storage required.

Data elements: There would be approximately 50 data elements included in the database structure. The average medication incident record data length is 500 bytes.

Data sources: The data sources are assumed to be primarily health organizations, community-based pharmacies, individual health practitioners, and other individual reporters such as the public, drug manufacturers, government, associations, etc. The system will accommodate up to 10,000 registered users and unlimited anonymous reporters. Registered users will log on an average of once per week.

Frequency of data transmission/queries: To ensure timeliness of the data, it is assumed that there would be monthly transmission of data from health organizations and community-based pharmacies. It is assumed that individual reporters can report and perform queries at any time. The period for follow-up purposes (e.g. root cause analysis) is 60 days after which time data is stripped of identifiers and stored in the central database.

Data transmission specifications: The custodian will establish standards for the format and content of transmitted data files. The assumption for costing purposes was that initially the custodian would need to do some conversion and/or mapping of data.

System outputs: The proposed system outputs are as described in Chapters 4 and 5 of this report. The web-based tools would require a number of summary tables. For costing purposes, the summary tables developed for Analyze-ERR product were used.

Estimated Costs

The estimated costs for the proposed system are presented in the table that follows. Should CMIRPS move forward these cost estimates will need to be reviewed and validated. Estimated costs include the anticipated start-up and ongoing annual costs for the CMIRPS based on the preferred governance and management model presented in Chapter 7. Estimated costs exclude any incremental costs related to developing and transmitting data to the CMIRPS (i.e. data reporter costs).

Estimated One-Time And Ongoing, Annual Costs ($)

ITEM	ISMP	CIHI	Health Canada	TOTAL
ONE-TIME COSTS				
CAPITAL				
Hardware	$31,000	$221,000	$16,000	$268,000
Software	$15,000	$164,000		$179,000
Leasehold improvements	$20,000	$32,000	$8,000	$60,000
Furniture/Equipment	$29,500	$40,000	$10,000	$79,500
Other				
Sub-total Capital Expenses	$95,500	$457,000	$34,000	$586,500
OPERATING				
Compensation	$200,000	$200,000	$100,000	$500,000
Consulting fees		$750,000		$750,000
Sub-total Direct Operating	$200,000	$950,000	$100,000	$1,250,000
Indirect Operating	$40,000	$190,000	$20,000	$250,000
Sub-total Operating Expenses	$240,000	$1,140,000	$120,000	$1,500,000
TOTAL ONE-TIME COSTS	$335,500	$1,597,000	$154,000	**$2,086,500**
ANNUAL OPERATING COSTS				
Compensation	$500,000	$460,000	$220,000	$1,180,000
Consulting	$150,000	$77,500		$227,500
Software maintenance	$7,000	$40,000		$47,000
Hardware maintenance	$10,000	$68,000		$78,000
Supplies	$10,000	$10,000	$10,000	$30,000
Travel - Staff	$20,000	$10,000		$30,000
Travel - Committees			$50,000	$50,000
Sub-total Operating Expenses	$697,000	$665,500	$280,000	$1,642,500
Indirect Operating Expenses	$139,400	$133,100	$56,000	$328,500
TOTAL ANNUAL OPERATING	$836,400	$798,600	$336,000	**$1,971,000**

ISMP – Canada's one-time and annual costs include expenses related to follow-up with root cause analysis for selected medication incidents, analysis, identification and dissemination of preventative strategies, analysis and dissemination of special studies.

CIHI's one-time and annual costs include expenses related to the development and maintenance of standards, data collection, scrubbing, processing, storage and standardized reporting (including web-based application technology), completion of ad hoc requests, development of annual statistical descriptive report, analytical studies and ongoing service support.

Health Canada's one-time and annual costs include expenses related to the establishment and ongoing service provision of CMIRPS Secretariat, and analysis related to post-market surveillance and medication incidents that relate to adverse drug reactions.

Funding

While consultations confirmed tremendous support and need for a CMIRPS, the availability of resources was identified as a critical barrier to the successful development and implementation of a system. Consultations also confirmed that there should be no financial barriers to reporting to and/or accessing information from a CMIRPS.

The project team identified the following potential options for a CMIRPS:

1. Federal government funding – CMIRPS funding provided by Health Canada.
2. Federal/provincial/territorial cost sharing – CMIRPS funding shared between Health Canada and the provincial and territorial Ministries of Health. Details of such cost sharing would need to be further investigated.
3. Blended approach – Core funding start-up and ongoing operations provided by government and a certain percentage (yet-to-be determined) of revenues generated from sale of products and services on a cost-recovery basis.

While much work remains to be done to further define the proposed system and sources of funding, consultations with the Coalition members supported pursuing a blended approach to funding. There was general agreement that revenues should be generated from products and services such as:

- ad hoc requests for information (i.e. custom tabulations) that require a significant amount of resources to complete;
- web-based reporting (such as that envisioned for institutional users); and
- implementation support services such as education, training and consultation services.

To minimize financial barriers and encourage as much participation from the field as possible, the pricing of these products and services should be determined on a cost-recovery basis.

Chapter 8 – Implementation

Consultations with key stakeholders identified a number of critical factors for the successful development and implementation of the proposed CMIRPS. The following chapter summarizes the key themes raised during the consultations relating to implementation and presents a high-level plan that presents the major phases and expected timelines related to the rollout of the proposed system.

Implementation – Critical Success Factors

The factors identified as being critical to the overall success of the proposed CMIRPS include:

- buy-in and support from key stakeholders;
- relevancy, utility, and credibility of information;
- communication and education;
- non-punitive use of the information;
- integrated approach;
- assurance of confidentiality of data; and
- national leadership and effective coordination of activities.

What follows is a brief description of each critical success factor.

a) Buy-In And Support From Key Stakeholders

Obviously the proposed CMIRPS will not move forward without the support and input of key stakeholders of the system. Key stakeholders were identified as being any organization or individual that would have an interest in the information produced by the proposed system. These include health professionals, health organizations, consumers, community-based pharmacies, governments, research agencies, academic institutions, drug manufacturers, standard-setting organizations, health professional licensing authorities, and others. The proposed CMIRPS must provide a mechanism for all stakeholders to provide input to, and contribute to the ongoing development of the system. While there are many individuals and organizations that may have an interest in the information produced by CMIRPS, key stakeholders will be those that report data, and can effect change. The proposed National Coordinating Council can provide a mechanism for all stakeholders to effectively contribute to the CMIRPS by providing input to its data standards, analytical priorities, information products, preventative strategies, and providing valuable assistance in disseminating information to their respective constituents.

b) Relevancy, Utility, And Credibility Of Information

The CMIRPS must provide information that is relevant and useful to users if it is to be successful. This means ensuring that the information is relevant to the roles of users and designed to support their decision-making processes. Therefore, the information must be *timely* and *targeted* to maximize its value to users. To ensure that the system meets evolving information needs, it must be dynamic and able to accommodate changes over time. Finally, the overall

quality of the information is critical if the system is to be credible to users. The CMIRPS must build-in verification mechanisms to ensure the accuracy of the data.

c) Communication And Education

The CMIRPS must provide effective communication to stakeholders regarding all aspects of the system. Further, to support its implementation across the continuum of service delivery, the CMIRPS must support efforts from key stakeholders such as health professional associations to provide ongoing education and training services to their members.

d) Non-Punitive

Clearly, the CMIRPS must foster a *culture of openness and safety,* in which medication incidents are voluntarily and anonymously reported and systematically analyzed to prevent future incidents.

e) Integrated Approach

In addition, to minimize the burden of data collection for reporters, the CMIRPS must use an integrated approach by being compatible with existing incident reporting systems and patient safety systems.

f) Assurance Of Confidentiality Of Data

The CMIRPS must provide assurance to stakeholders that the privacy, confidentiality and integrity of the data will be safeguarded. The system must include publicly available policies and procedures related to its privacy, confidentiality and security practices.

g) Leadership

Stakeholders confirmed that given the scope and magnitude of the proposed system, the provision of government support and leadership is critical to the success of the proposed CMIRPS. Provincial and territorial ministries of health have a critical role in effecting system-wide change related to the delivery of the health care system. Consultations also confirmed that national leadership from Health Canada is critical for ensuring the effective coordination of activities across the country related to the CMIRPS.

Rollout of CMIRPS

The major phases and timelines related to the development and implementation of CMIRPS are provided below. Obviously, should the CMIRPS move forward, a much more detailed plan would need to be developed including a review and validation of the cost estimates. The intent here is to provide a high-level plan that outlines the key phases of activities that would need to occur. While the vision is to implement the system across the continuum of service delivery settings, it is recommended that implementation be phased-in starting with the acute care sector. Specific aspects of the proposed CMIRPS that require further study such as certain types of medication products (e.g. blood products and radio pharmaceuticals) can be reviewed and further studied during the business requirements definition/validation phase of the project.

PHASE	Timelines
Project Initiation ▪ Establish steering committee ▪ Establish implementation committee/operations committee ▪ Develop detailed project plan including communication/promotional plan ▪ Establish National Coordinating Council	6 months
Business Requirements Definition/Validation ▪ Review information needs ▪ Review and validate data set including definitions ▪ Define proposed information products ▪ Develop functional specifications	6 months
Systems Development and Testing ▪ Develop technical requirements ▪ Develop data model ▪ Develop/test system applications	1 year
Evaluation: Pre-test and Pilot ▪ Develop pre-test materials, objectives, plan ▪ Select pre-test sites based on selection criteria ▪ Education/training pre-test sites ▪ Pre-test/analysis of results ▪ Revise system based on results of pre-test ▪ Develop pilot detailed plan ▪ Select pilot sites based on selection criteria ▪ Education/Training pilot sites ▪ Pilot ▪ Assessment of pilot and revision of system based of results	 Pre-test 2 mo. Pilot 6 mo.
Implementation ▪ Operational System	3 years from start date

Evaluation: Pre-test and Pilot

It is recommended that an evaluation of the CMIRPS be conducted that includes pre-test and pilot phases of the proposed system. The objectives of the pre-test are to:

i) evaluate the feasibility of collecting and transmitting the proposed data set;
ii) evaluate the system for transmitting and receiving the data;
iii) review proposed methods for conducting root cause analysis; and
iv) evaluate any benefits derived from implementation.

The pre-test should last no more than 2 months and be limited to a few representative sites (e.g. 6 hospitals).

The pilot should last at least 6 months and involve a representative sample of users and reporters from across the country. The purpose of the pilot is to evaluate the proposed CMIRPS by hospitals across the country. The objectives are to:

- evaluate the feasibility of the data collection process;
- evaluate the relevancy and utility of the data set;
- assess the user-friendliness of the web-based query reporting system;
- evaluate the orientation and education process and materials.

While a statistically valid sample is not required for purposes of the pilot, the sample should be representative of potential hospital reporters and should include teaching and community hospitals, urban and rural hospitals, and hospitals with different drug distribution and administration systems. All hospitals should be invited to participate in the pilot but the sample for pilot purposes should be limited to a manageable size (e.g. 30).

Communication and Promotion

A detailed communication and promotion plan will have to be developed and implemented early in the process. The National Coordinating Council and the Steering Committee will both play a key role in promoting the mandate and goals of the system. The Steering Committee will need to galvanize members of the Council to work together to ensure that the development and implementation of the CMIRPS is successful.

Chapter 9 – Future Considerations

The completion of this report represents a significant milestone in the evolution the proposed CMIRPS. It is recognized however, that much more work remains to be done to ensure the successful development and implementation of the system. In this regard, recommendations regarding future areas of additional investigation and discussion are presented below.

1. To review and further define the proposed governance and management models of CMIRPS. This should include but not be limited to:
   a) a legal review and opinion regarding proposed partnership model and formal administrative agreement and dispute resolution mechanisms;
   b) clarification of contracting requirements (including requests for proposals) related to (government) funding of such a partnership;
   c) discussions between CIHI, ISMP Canada and Health Canada to discuss potential roles and responsibilities.
2. To complete privacy impact assessment of the CMIRPS and obtain appropriate legal advice.
3. To review and refine the CMIRPS data set in the context of the information needs of potential users.
4. To develop detailed implementation plan for CMIRPS with objectives, activities, responsibilities, deliverables and costs identified by year. Implementation plan should include a significant communication and promotion component.
5. To develop clearly defined linkages/collaboration with other patient safety initiatives, in particular the National Advisory Committee on Patient Safety, being facilitated by the RCPSC, as well as others.
6. To review and further define funding options for CMIRPS.
7. To review and further define the roles, responsibility and accountability of the CMIRPS secretariat, in particular related to contractual agreements.
8. To conduct further investigation of alternate options that would maintain the anonymity of registered users if they so choose.
9. Recognition of special needs of some types of services and/or products will require further consultation to ensure that the CMIRPS effectively addresses the complete scope of possible situations and products (e.g. blood products and radio pharmaceuticals).

The development and implementation of a Canadian Medication Incident Reporting and Prevention System is a formidable challenge and a long-term project that will require participation and collaboration from a number of stakeholders across the country. The proposed *Canadian Medication Incident Reporting and Prevention System* calls for the involvement of all levels of health care delivery in order to improve patient safety and the effective use of health care resources. These efforts will further strengthen our healthcare system and benefit all Canadians.

Appendix A - People Consulted

Canadian Coalition For Medication Incident Reporting and Prevention

Richard Jones
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Deb Saltmarche
Director, Pharmacy
Canadian Association of Chain Drug Stores
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Janet Harding
(Canadian Healthcare Association representative)
Manager, Department of Pharmaceutical Services
Royal University Hospital
Saskatoon Health District
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Dr. Todd Watkins
Canadian Medical Association
Ottawa, ON

Janet Davies
Director of Public Policy
Canadian Nurses Association
Ottawa, ON

Janet Cooper
Senior Director of Professional Affairs
Canadian Pharmacists Association
Ottawa, ON

Bonnie Salsman
(Canadian Society of Hospital Pharmacists representative)
Halifax, NS

Linda Strand
Volunteer
Consumers Association of Canada representative
Parksville, BC

David U
President and Chief Executive Officer
Institute for Safe Medication Practices – Canada
Toronto, ON

Mira Gokhale
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Appendix B - Privacy Impact Assessment

Information that can be used to conduct a privacy impact assessment of the proposed CMIRPS is provided below. The information is presented in relation to the ten privacy principles set out in *Schedule 1 of the Personal Information Protection and Electronic Documents Act.*

System Overview

A successful medication incident reporting and prevention program is driven by the goal of reducing and preventing incidents, and thereby reducing patient harm and improving the utilization of health care resources, by identifying system weaknesses and by developing prevention strategies that should be disseminated to the health care community for learning. The development and implementation of the proposed Canadian Medication Incident Reporting and Prevention System will serve to further strengthen our health care system and benefit Canadians by enhancing the safety of the medication use system and the effective use of scarce resources.

Purpose of the CMIRPS

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

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

Ten Privacy Principles

(a) Accountability:

CIHI has designated its President and Chief Executive Officer as accountable for compliance with CIHI's *Privacy and Confidentiality of Health Information at CIHI: Principles and policies for the protection health information.*

ISMP - Canada has designated its President and Chief Executive Officers as accountable for compliance with its privacy policies and procedures.

(b) Identifying Purposes

The purpose of the proposed system is clearly identified and is in the interest of the public good.

(c) Consent

The proposed CMIRPS is a voluntary reporting system. Individual practitioners elect to report identifying information relating to them.

(d) Limiting Collection

The proposed system only collects information by fair and lawful means, which are deemed necessary for the purpose of the system.

(e) Limiting Use, Disclosure and Retention

The custodian will ensure that CMIRPS data is only used for the intended purpose. The custodian will review all files and reports before disclosure for potential for residual disclosure because of small cell sizes. Data will be aggregated to levels that do not permit the disclosure of individual patients, health organizations, community-based pharmacies, or health professionals.

The purpose of the proposed system requires permanent retention of electronic data twenty years.

(f) Accuracy

The system' custodian will apply sophisticated edit checks to the data. The custodian may follow-up with health organizations for verification and correction of data purposes. Changes to the proposed system's data will be made once communicated to the custodian by the reporters. ISMP Canada may enhance and/or correct data during root cause analysis. After a 60-day period for purposes of completing root cause analysis, ISMP Canada will destroy all identifiers and send data to central database managed by the custodian.

(g) Safeguards

Appropriate physical, technological, procedural and other safeguards such as implementation of staff confidentiality pledges and staff training will protect the proposed system's data.

(h) Openness

ISMP Canada, Health Canada, and CIHI will be open about the policies and procedures related to the data that will be contained in the proposed system. Policies and procedures will be posted on CMIRPS's portal.

(i) Individual Access

Because the proposed system will only include anonymous data, the custodian will be unable to identify an individual's data.

(j) Challenging Compliance

The public may challenge ISMP Canada, Health Canada, and CIHI's compliance with their respective policies and procedures regarding privacy, confidentiality and security.

Appendix C - Glossary

Medication

Any substance or mixture of substances used in i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms; and ii) restoring, correcting or modifying organic functions.[25] This includes but is not limited to, biological products such as bacterial and viral vaccines, blood, plasma and their derivatives, interferon and erythropoietin.

Medication Misadventures[26]:

A hazard or incident that:
- is an inherent risk when medication therapy is indicated
- is created through either omission or commission by the administration of a medicine or medicines during which a patient may be harmed, with effects ranging from mild discomfort to fatality
- whose outcome may or may not be independent of the pre-existing pathology or disease process
- may be attributable to incident (human or system or both), immunologic response, or idiosyncratic response
- is always unexpected or undesirable to the patient and health professional.

Medication Incident[26]:

Any *preventable* event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Adverse Medication Event[26]:

An injury to a patient from a medicine (or lack of an intended medicine).

Adverse Medication Reaction[26]:

Any unexpected, unintended, undesired or excessive response to a medicine that:
- requires discontinuing the medicine (therapeutic or diagnostic),
- requires changing the medication therapy,
- requires modifying the dose (except for minor dosage adjustments),
- necessitates admission to a hospital,
- prolongs stay in a health care facility,
- necessitates supportive treatment,

- significantly complicates diagnosis,
- negatively affects prognosis, or
- results in temporary or permanent harm, disability or death.

Appendix D - References

1. Wilson R. Quality improvement will require a major commitment. Hospital Quarterly Spring 2001: 20-4
2. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human. Building a safer health system. Washington (DC): National Academy Pres; 1999
3. Final report of the taskforce on quality in Australian health care. June 1996. http://www.health.gov.au/pubs/hlthcare/toc.htm
4. Bond CA, Raehl CL, Franke T. Medication incidents in United States Hospitals. Pharmacotherapy. 2001; 21(9): 1023-1036
5. Preventing fatal medical incidents. New York Times December 1, 1999:A22
6. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients. A meta-analysis of prospective studies JAMA 1998; 279: 1200-5
7. Bates DW, Cullen DJ, Laird N et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995 Jul 5;274(1):29-34
8. Bates DW. The costs of adverse drug events in hospitalized patients. JAMA 1997; 277: 307-11
9. Phillips DP, Christfeld N, Glynn LM. Increase in US medication-incident deaths between 1983 and 1993. Lancet 1998; 351: 643-4.
10. MacKinnon NJ. Seven strategies to strengthen our medication-use system.
11. Campbell SG. Medical incident in Primary Care. Medical Incident Symposium. Frontline approaches in clinical practice. Capital District Health Authority. Nova Scotia. Aug 11-12, 2001.
12. Estimates based on sales figures from http://www.imshealthcanada.com/
13. Phillips MAS. National program for medication incident reporting and benchmarking: Experience with MedMARx. Hospital Pharmacy 2001; 36: 509-13
14. Bootman J. L, Harrison LTC, Donald L, and Cox, E. The health care cost of drug-related morbidity and mortality in nursing facilities. *Arch Intern Med.* 157(18):2089–2096, 1997.
15. Baker GR, Norton P. Making patients safer! Reducing incident in Canadian healthcare. Hospital Quarterly Spring 2001; 21.
16. *Managing the Risks from Medical Product Use: Creating a Risk Management Framework*. (1999) United States Food And Drug Administration.
17. Vinen J. Monitoring and measuring incident. Medical Incident Symposium. Frontline approaches in clinical practice. Capital District Health Authority. Nova Scotia. Aug 11-12, 2001.
18. First Ministers' Meeting, Ottawa, ON, September 11, 2000. www.scics.gc.ca
19. ISMP Canada www.ismp-canada.org
20. United States Pharmacopoeia www.usp.org
21. Summary of the 1999 Information submitted to MedMARx. A national database for hospital medication incident reporting. U.S. Pharmacopoeia. www.usp.org/medmarx
22. VHA National Centre for Patient Safety http://www.patientsafety.gov/
23. www.synx.com

24. Anon. Discussion paper on adverse event and incident reporting in healthcare. Institute for safe medication practices. Jan 24, 2000. www.ismp.org/Pages/concept.html
25. Food and Drug Act.
26. American Society of Health-system Pharmacists.
27. Bhasale, Alice L.; Miller, Graeme C.; Reid, Sharon E., et al. Analysing Potential Harm in Australian General Practice: an Incident-Monitoring Study. *MJA*. 169:73–76, 1998.
28. Green S, Goodwin H, Moss J. Problems in general practice: medication incident. The MDU Risk Management 1996; 1-8.
29. Fernandez C. Pediatrics. Medical Incident Symposium. Frontline approaches in clinical practice. Capital District Health Authority. Nova Scotia. Aug 11-12, 2001.
30. Cox PM Jr, D'Amato S, Tillotson DJ. Reducing medication incidents. Am J Med Qual 2001 May-Jun; 16(3): 81-6
31. Anon. Final summary of Food and Drug Administration (FDA) action items – doing what counts for patient safety: Federal actions to reduce medical incidents and their impact. February 2000. www.fda.gov/cder/drug/MedIncidents/patientsafety.htm
32. Evidence Based Medicine Health Care Hospital Management http://www.evidence-based-medicine.org/
33. Orser B. Reducing medication incidents. Canadian Medical Association Journal. 2000; 162(8): 1150-1
34. Final report of the taskforce on quality in Australian health care. June 1996. http://www.health.gov.au/pubs/hlthcare/toc.htm
35. Australian Patient Safety Foundation www.apsf.net.au
36. Wilson R. Quality improvement will require a major commitment. Hospital Quarterly Spring 2001: 20-4