



Institute for Safe Medication Practices Canada

Privacy Policy

Developed : June 30, 2004

Updated : March 5, 2010

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1.0 Introduction

The document is organized as follows:

- Section 1 describes ISMP Canada's Mandate, Data Holdings, and Privacy Program;
- Section 2 explains the legislative framework within which ISMP Canada operates;
- Section 3 outlines ISMP Canada's Privacy Policy with accompanying privacy principles for the protection of information to which the Institute is entrusted.

1.1 Mandate

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices.

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

Under its mandate, the goals of ISMP Canada are:

- To review and analyze medication incident and near-miss reports according to a hazard identification model, identify contributing factors and causes and make recommendations for the prevention of harmful medication incidents.
- To promote safe medication use and system strategies for reduction of adverse drug events.
- To publish and disseminate information on safe medication practices for knowledge translation.
- To develop and provide tools and educational programs for building capacity to enhance patient safety.
- To provide expertise and consultation on medication systems in health service organizations and other health care settings.
- To develop quality improvement programs for use by the healthcare community.
- To work with regulatory agencies, policy makers and manufacturers to promote enhancements to pharmaceutical product packaging and labelling.
- To facilitate patient safety research.

- To establish and maintain strong partnerships with the Institute for Safe Medication Practices (ISMP) in the US, and other key national and provincial organizations with an interest in patient safety.
- To achieve the outcomes envisioned by the Canadian Medication Incident Prevention and Reporting System (CMIRPS), a collaborative initiative of ISMP Canada, the Canadian Institute for Health Information (CIHI) and Health Canada (known as the collaborating parties for CMIRPS), in conjunction with the Canadian Patient Safety Institute (CPSI).

1.2 Data Holdings

ISMP Canada receives information on preventable adverse drug events from healthcare institutions and individual healthcare practitioners via telephone, email, fax and a web-based reporting function. ISMP Canada also receives information about medication incidents from consumers through an online reporting program available at www.safemedicationuse.ca or via telephone submissions. In addition, hospitals may report information on preventable adverse drug events through ISMP Canada's "Analyze-ERR", an electronic reporting tool designed by ISMP Canada to track and analyze medication errors in healthcare institutions. Detailed information on the purposes, data elements, data sources and data flows for Analyze-ERR are contained in a privacy impact assessment on Analyze-ERR completed in July 2004.

ISMP Canada uses information from its data holdings to help healthcare practitioners and institutions, consumers and caregivers, the pharmaceutical industry, as well as government and regulatory agencies to prevent future medication incidents. For example, ISMP Canada's data holdings are used to:

- Develop monthly medication safety alerts that describe, for example, problems with titrating drug doses or the link between first-dose delays of anticoagulants and antibiotics and patient morbidity or mortality.
- Develop monthly articles on safe medication practices for hospitals, including information on the patient's role in safe medication use.
- Understand the cost of preventable adverse drug events and make comparisons among reporting institutions to develop best practices to prevent similar medication errors.

Reliable, accurate and timely data are critical to support the above activities and to develop appropriate strategies that are designed to reduce the risk of future medication incidents. ISMP Canada works in partnership with its reporting institutions and healthcare practitioners to identify health information needs and to ensure that ISMP Canada's information protection practices comply with relevant privacy legislation. ISMP Canada also works directly with healthcare administrators and practitioners at reporting institutions to facilitate secure, responsible access to data.

1.3 ISMP Canada's Privacy Program

Respecting personal privacy, safeguarding confidential information, and ensuring security appropriate to the sensitivity of the data for which it is responsible are critical for carrying out ISMP Canada's mandate successfully.

The ISMP Canada privacy program includes:

- A privacy secretariat, headed by the Chief Privacy Officer, who reports directly to the President and Chief Executive Officer; and
- An external privacy consulting team, which includes a former Chief Privacy Officer at one of ISMP Canada's reporting institutions, a former member of the Privacy Secretariat with the Canadian Institute for Health Information (CIHI), leading privacy and security specialists in healthcare, and representatives from ISMP Canada's stakeholder organizations, such as risk management professionals, healthcare administrators, and hospital Privacy Officers. Key activities of the ISMP Canada privacy program include:
 - *Policy development, analysis and application:*
 - ◆ Development and implementation of ISMP Canada's Privacy Policy and related practices and procedures;
 - ◆ Conducting a privacy impact assessment of ISMP Canada's data holdings contained in Analyze-ERR (June 2004) and the Consumer Reporting and Learning Program (2010);
 - ◆ Monitoring relevant privacy and data protection legislation;
 - ◆ Reviewing and resolving privacy and security issues.
 - *Fostering a culture of privacy at ISMP Canada by:*
 - ◆ Supporting development activities to ensure that privacy and data protection issues are addressed;
 - ◆ Working with Information Technology staff and other areas of the organization to ensure adequate data protection tools and safeguards for data holdings;
 - ◆ Conducting staff training on privacy and communicating with staff on privacy and data protection policies and procedures;
 - ◆ Ensuring staff sign a confidentiality agreement that indicates that breaches of the ISMP Canada Privacy Policy may lead to disciplinary actions.
 - *Communications/Outreach:*
 - ◆ Developing user-friendly and accessible information about ISMP Canada's privacy program for the general public;
 - ◆ Addressing organizations, upon request, to explain privacy and data protection at ISMP Canada;
 - ◆ Liaising with privacy officials in the Ministries of Health and Privacy Commissioners' Offices, where appropriate;
 - ◆ Responding to privacy questions or complaints about ISMP Canada's privacy practices.

1.4 Scope

The principles and policy in this document are specific to ISMP Canada's handling of **medication incident information** ("incident information"), i.e., non-identifying, record-level information about a single medication incident. The medication incident information required by ISMP Canada in accordance with its mandate does not include information that identifies any patient who was the subject of a medication incident ("**identifying information**"), individual reporter, or reporting institution. Reporters and reporting institutions may consent to voluntarily identify themselves by providing **contact information** in order for ISMP Canada to verify and validate information about a medication incident. However, because of the format and characteristics of medication incident information, contact information of the reporter does not facilitate identification of the patient who was the subject of the incident. Limits on collection of identifying information are described at Principle 4 of this policy.

2.0 Legislative Framework

A complex framework of legislation at the federal/provincial/territorial levels governs the broad range of activity that takes place in the various Canadian hospitals that report data to ISMP Canada. Within this framework, it is important to note that there are currently no legislative provisions that actually *require* hospitals or individual healthcare practitioners to report data to ISMP Canada on medication errors, or that specifically govern how ISMP Canada should analyze the data it receives.

This places ISMP Canada in a unique situation from other major Canadian healthcare organizations, in which rules for the reporting of data may be specifically outlined in various statutes. Nevertheless, the Institute has created this privacy policy for the collection of data on preventable adverse drug events in partnership with Canadian hospitals and healthcare practitioners, as well as security practices for the handling of data for which it is responsible.

ISMP Canada encourages *voluntary* reporting of medication errors (e.g., any information ISMP Canada has on medication errors it receives from institutions and individuals which choose voluntarily to disclose this information). From a privacy perspective, ISMP Canada also retains only *non-identifiable* information – i.e., information that does not identify individuals or institutions. This system of voluntary reporting, in which ISMP Canada retains only non-identifiable information, provides the framework within which this privacy policy was developed.

3.0 Principles and Policy for the Protection of Information

3.1 Why ISMP Canada Requires a Privacy Policy

While ISMP Canada does not retain any identifiable information reported by institutions or individuals, the Institute still has data protection concerns, and, therefore, has developed a comprehensive privacy policy. For example, ISMP Canada may use contact information to follow-up with reporting institutions, healthcare practitioners and consumers about specific preventable adverse drug events (e.g., to clarify data). In addition, there may be rare cases when it is possible to infer the identity of an individual patient, healthcare practitioner or specific healthcare institution through the unique circumstances of a particular preventable adverse drug event (e.g., a death resulting from a rarely-used drug in a geographic location where there are only one or two healthcare practitioners or hospitals that could have administered the drug). For this reason, ISMP Canada also requires appropriate security safeguards to protect the sensitive data for which it is responsible (e.g., proper storage of data, encryption). These are outlined in the “Safeguards” section of the privacy policy.

Finally, ISMP Canada requires a privacy policy to: ensure confidence in its data handling practices as an increasing number of Canadian hospitals use the Analyze-ERR software; as the Institute develops future versions of the Analyze-ERR software with tabs for the capture of identifiable information (for internal use in hospitals); and as ISMP Canada contributes to the development of a future national medication error reporting system.

3.2 ISMP Canada’s Privacy Vision and Commitment

ISMP Canada is committed to protecting the privacy, confidentiality and security of all information with which it is entrusted in order to carry out its mandate. ISMP Canada’s privacy policy incorporates the ten provisions of Part 1 of the *Personal Information Protection and Electronic Documents Act* and includes the ten principles of the Canadian Standards Association (CSA) Model Code for the Protection of Personal Information (CAN/CSA-Q830-96), which was published in March 1996 as a National Standard of Canada. The ten principles, which form the basis of ISMP Canada’s privacy policy, are interrelated and ISMP Canada will adhere to the ten principles as a whole.

3.3 Purpose of the ISMP Canada Privacy Policy

The ISMP Canada Privacy Policy is a formal statement of principles concerning the minimum requirements for the protection of information provided voluntarily to ISMP Canada by healthcare institutions and individual healthcare practitioners. The objective of the ISMP Canada Privacy Policy is to promote responsible and transparent practices in

the management of information for which ISMP Canada is responsible in accordance with the national privacy standard.

ISMP Canada will continue to review its privacy policy to ensure it is relevant and remains current with changing technologies and laws. More importantly, ISMP Canada wants to ensure it continues to meet the evolving needs of the healthcare system and the patients to whom care is provided. ISMP Canada recognizes that privacy is a key component of its relationship of trust with the institutions and individuals who voluntarily report data to ISMP Canada on preventable adverse drug events.

3.4 Scope of the ISMP Canada Privacy Policy

The ISMP Canada Privacy Policy applies to all information received by the Institute for the purpose of fulfilling its mandate. The policy applies to information received in any format (e.g., via Analyze-ERR, telephone, email, fax, in-person conversations, web-based submissions), and applies to information stored in any medium (e.g., electronic, photographic, paper). This policy applies to all individuals associated with ISMP Canada, including staff, students, volunteers, board members, contractors, and third party suppliers.

3.5 Definitions in the ISMP Canada Privacy Policy

Accountable – means having clearly defined and understood responsibilities in connection with the protection of information for which ISMP Canada is responsible.

Aggregate Information – means information that has been rolled up or combined to summarize a population trend or statistic.

Audit – means the systematic review of a record showing who has accessed a computer system and what operations he or she has performed, including the creation, access, updating or deletion of information, during a given period of time.

Authorization – Permission of a reporter to collect, use or disclose incident information, or related data.

Collection – in relation to information, means to gather, acquire, receive or obtain the information by any means from any source. ISMP Canada *only* “collects” information through *voluntary* reporting of preventable adverse drug events by healthcare institutions and individual healthcare practitioners (also referred to as “receive”).

Confidentiality Agreement – is a signed agreement entered into by ISMP Canada employees or associates of the Institute (e.g., contractors) which requires that individuals agree to collect, use or disclose information in a manner consistent with the ISMP Canada Privacy Policy.

Consent – means the voluntary acceptance or approval of an individual to the collection, use or disclosure of his or her identifiable information for specifically identified purposes.

Disclose - in relation to information in the custody or under the control of ISMP Canada, means to make the information available or to release it to an individual or organization other than the institution or practitioner that originally reported the information, but does not include the “use” of information.

Healthcare practitioner – is any person who is registered and entitled by provincial or territorial law to practise or provide healthcare in that province or territory, including: doctors, pharmacists, optometrists, nurses, dentists, registered psychologists, and registered social workers.

Individual – in relation to information, means the individual or institution with respect to which the information was or is being collected or created.

Institution - is any organization that provides healthcare services and *voluntarily* reports information to ISMP Canada for the purposes identified in this policy (also referred to as healthcare institution).

Medication Error – means any preventable event that may cause or lead to inappropriate medication use or patient harm from medication, while the medication is in the control of the healthcare practitioners, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems including: prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.¹

Medication Incident – an alternative term for medication error.

Personal Information – is information that identifies an individual, or that could enable identification of an individual. This is in contrast with the more general term *information*, which, for the purposes of the ISMP Canada Privacy Policy, refers to information in any form that is *not* identifying.

Preventable Adverse Drug Event – means medication errors leading to patient harm and includes, for the purpose of this policy, near miss medication errors and hazardous conditions likely to create a medication error.

Purpose – means a reason or intent for which information is collected, used, disclosed (see ISMP Canada’s purposes for information in section 3.6.2 below).

Report – is the act of disclosing information pertaining to a preventable adverse drug event to ISMP Canada by an individual healthcare institution or practitioner; methods of reporting include: telephone, email, fax, a web-based reporting function and (in rare circumstances) in-person conversations with ISMP Canada staff.

Use – in relation to information in the custody or under the control of ISMP Canada, means to handle or deal with the information within ISMP Canada including access, manipulation or linkage to other sources of data, but does not include disclosing the information.

¹ National Coordinating Council for Medication Error Reporting and Prevention definition; available at: <http://www.nccmerp.org/aboutMedErrors.html>

3.6 The 10 Privacy Principles

Principle 1 – Accountability for Information

Principle 1.1: ISMP Canada is responsible for medication incident information with which it is entrusted. While unlikely, it is possible that reporters/reporting organizations might inadvertently disclose identifying information to ISMP Canada. Also, some incident reports might include information that is otherwise sensitive or confidential (for example, the name of the reporting hospital). Accordingly, ISMP Canada has developed privacy policies and procedures to ensure compliance with the 10 privacy best practices set out in the Canadian Standards Association Model Code (CSA Code) and Schedule 1 of the Protection Information Protection and Electronic Documents Act (PIPEDA). These same best practices underlie Canadian legislation that governs handling of personal health information.

Principle 1.2: Accountability for ISMP Canada's compliance with the principles set out in this document rests with the President and Chief Executive Officer (CEO), even though other individuals within ISMP Canada are responsible for the day-to-day processing of information. The Chief Privacy Officer of ISMP Canada is the delegate of the CEO with regard to privacy and security of information. The name of the Chief Privacy Officer and any other individuals designated by ISMP Canada to oversee compliance with the principles is made known upon request.

Employees or associates of ISMP Canada are required to sign a confidentiality agreement as an indication that they agree with the terms of this policy and accept responsibility for the protection of any information with which they may be entrusted in the course of performing job duties related to work for ISMP Canada.

Principle 1.3: ISMP Canada is responsible for information that has been transferred to a third party for processing. In such circumstances, ISMP Canada will use contractual or other means to ensure a comparable level of protection by the third party while the information is being processed.

Principle 1.4: ISMP Canada will implement corporate policies and practices to give effect to this policy, including:

- Establishing procedures to receive and respond to privacy complaints and inquiries.
- Training staff and communicating to staff information about ISMP Canada's policies and procedures.
- Developing public communications materials to explain the Institute's policies and procedures.

Principle 2 – Identifying Purposes for the Collection of Information

Principle 2.1: ISMP Canada will identify the purposes for which it receives information at or before the time reporters provide information to ISMP Canada.

This will be accomplished through the posting of this policy on the ISMP Canada web site, brochures for the public on ISMP Canada, and references to the ISMP Canada Privacy Policy in the licensing agreement for Analyze-ERR.

Principle 2.2: ISMP Canada receives information for the following purposes:

- To review medication errors and to make recommendations to reduce the probability that such errors will happen again.
- To publish and disseminate information to the healthcare community and practitioners through efficient electronic means in order to promote safe medication use and strategies for reduction of error-induced injury in Canada.
- To conduct, encourage, and participate in research and analyses on safe medication use and strategies for reduction of error-induced injury in Canada.
- To participate in cooperative programs with professional organizations in Canada in providing education about preventable adverse drug events and their prevention.
- To act as consultants, upon request, to institutions and other healthcare settings on safe medication use.
- To develop educational and quality improvement assessment tools for healthcare practitioners and institutions.
- To establish and maintain a strong partnership with the Institute for Safe Medication Practices (ISMP) in the United States, and other international, national and provincial patient safety initiatives, where appropriate.
- To provide educational programs for university and health professional constituents.
- To comply with legal and regulatory requirements.
- Where appropriate, to support research by sharing non-identifying information and/or aggregate data to researchers for the purposes of conducting research on medication incidents.

Principle 3 – Consent for the Collection, Use, and Disclosure of Information

Consent and Individual Patients

Principle 3.1(a): The purposes for which ISMP Canada collects medication incident information from reporters, as set out in Principle 2, do not require identifying information. Accordingly, ISMP Canada does not need to collect, nor does it use, retain, or disclose identifying information.

Principle 3.1(b): ISMP Canada recognizes that individuals or institutions reporting medication incident information must determine what actions are necessary to comply with any disclosure requirements in their jurisdictions.

Authorization of Reporters

Principle 3.2(a): All reporters provide medication incident information to ISMP Canada on a voluntary basis only.

Principle 3.2(b):

In cases where ISMP Canada believes that there is a risk of identifying an individual or institution in one of its safety bulletins or other publications, ISMP Canada will notify the reporting individual or institution of such a risk and will not publish any potentially identifiable information without the permission of the reporting individual or institution. ISMP Canada generally sends its safety bulletins and other publications on a specific medication incident to the reporting healthcare practitioner or health institution for review prior to publication. ISMP Canada respects the wishes of the reporters as to the level of detail to be included in ISMP Canada publications.

Principle 3.2(c): When information received by ISMP Canada is to be used for a purpose not previously identified, the new purpose will be identified prior to use. Unless law requires the new purpose, the authorization of the reporting individual or the institution will be obtained before information can be used for that purpose.

Principle 3.2(d): ISMP Canada will not, as a condition of the supply of a product or service, require a reporting individual or institution to consent to the collection, use, or disclosure of information beyond that required to fulfill the explicitly specified and legitimate purposes.

Principle 4 – Limiting Collection of Information

Principle 4.1: ISMP Canada takes steps to limit the collection of identifying information during the submission of incident data by requesting that reporters submitting incident information report only the information that is necessary for the purposes identified by ISMP Canada (i.e., no identifying information)

Principle 4.2: In cases where reporting individuals or institutions provide contact information, ISMP Canada will use that information only for the purpose of follow up.

Principle 4.3: Information will not be collected for purposes other than those for which it was received, except with the consent of the reporter, or as required by law. When information is to be used for new purposes, this policy will be updated to reflect these changes.

Principle 5 – Limiting Use, Disclosure, and Retention of Information

Limiting Use

Principle 5.1: ISMP Canada will only use information for purposes consistent with its mandate; see Principle 2 - “Identifying Purposes for the Collection of Information”. Information will not be used or disclosed for purposes other than those for which it was received, except with the authorization of the reporting individual or institution or as required by law. When information is to be used for new purposes, this policy will be updated to reflect these changes.

Limiting Use, Retention and Disclosure

Principle 5.2: ISMP Canada only uses, retains, discloses or publishes aggregated information in a manner designed to ensure that individuals and institutions cannot be identified, which requires a minimum of three observations per data cell or element. In cases where there are less than three observations per data cell or element, ISMP Canada will obtain authorization from the reporting individual or institution before publishing the aggregated information.

Limiting Use

Principle 5.3: Access to information at ISMP Canada will be limited to only those authorized to hold, view or handle such information for their current job duties. Access is to be determined by the individual's direct supervisor at ISMP Canada and is subject to approval by the Chief Privacy Officer. Information is to be maintained in the strictest of confidence and is not to be shared with unauthorized persons.

Limiting Retention

Principle 5.4: ISMP Canada will not retain contact information after it has used such information for data clarification purposes, or follow-up investigation purposes at the request of the reporting individual or institution.

Principle 5.5: ISMP Canada will develop guidelines and implement procedures with respect to the retention of information. These guidelines will include maximum retention periods. Information that is no longer required to fulfill the identified purposes will be shredded, erased, incinerated or made anonymous.

Limiting Disclosure:

Principle 5.6: ISMP Canada will not disclose any information that may foreseeably lead to the identification of any individual or institution.

Principle 6 – Ensuring Accuracy of Information

Principle 6.1: ISMP Canada depends on the individuals and institutions to report information that is as accurate, complete, and up-to-date as possible. In cases where ISMP Canada has questions about the accuracy of the information it receives, it will contact reporters for follow-up if the reporter has provided ISMP Canada with contact information.

Principle 6.2: In cases where ISMP Canada is not able to clarify information that it believes may be inaccurate or about which it has unanswered questions, ISMP Canada will not use that information to analyze a preventable adverse drug event (e.g., conduct root cause analysis) or include that information in any safety bulletins, reports or other publications.

Principle 7 – Ensuring Safeguards for Information

Principle 7.1: ISMP Canada will safeguard all incident information provided by reporters. A current, high standard of security will be implemented to protect information against loss or theft, as well as unauthorized access, disclosure, copying, use, or modification. ISMP Canada will protect information regardless of the format in which it is held.

The nature of the safeguards will vary depending on the sensitivity of the information that has been collected, the amount, distribution, and format of the information, and the method of storage. A higher level of protection will safeguard more sensitive information, such as financial and human resources records, which contain personal identifiers.

Principle 7.2: The methods of protection will include:

- 7.2.1. *Physical measures*, for example, locked filing cabinets, and restricted access to offices and other areas where ISMP Canada's data holdings are stored;
- 7.2.2. *Administrative measures*, for example, the ISMP Canada Privacy Policy, based on Schedule 1 of the *Personal Information Protection and Electronic Documents Act*, staff training on privacy, signing of confidentiality agreements, and limiting access to information on a "need-to-know" basis; and
- 7.2.3. *Technical measures*, for example, the use of passwords, encryption, firewalls, audits, and other technical security safeguards to minimize the risk of unauthorized individuals accessing ISMP Canada's data holdings.

Principle 8 – Openness about Information Policies and Practices

Principle 8.1: Upon request, ISMP Canada will make readily available to individuals and institutions specific information about its policies and practices relating to the management of information under its custody or control.

Individuals and institutions will be able to acquire information about ISMP Canada's policies and practices without unreasonable effort. This information will be made available in a form that is generally understandable.

ISMP Canada may make information on its policies and practices available in a variety of ways. For example, the Institute will make notices or brochures available in its place of business, and may mail information to its reporting individuals or institutions, as well as provide on-line access to information about its policies and practices with respect to the management of information.

Principle 9 – Access to Information

Principle 9.1: ISMP Canada does not retain identifying information on preventable adverse drug events. As such, individuals requesting information about a specific medication error should contact the healthcare institution or practitioner involved in the medication error. Since ISMP Canada does not retain the names of individual

patients, healthcare practitioners or institutions involved in preventable adverse drug events, the Institute cannot confirm whether a specific individual or institution has reported a particular medication error.

Principle 10 – Challenging Compliance with ISMP Canada’s Privacy Policy and Practices

Principle 10.1: An individual will be able to address a challenge concerning compliance with this policy to the Chief Privacy Officer at ISMP Canada.

Principle 10.2: ISMP Canada has procedures in place to receive and respond to complaints or inquiries about its policies and practices relating to the handling of information with which it is entrusted. The complaint procedures will be easily accessible and simple to use. ISMP Canada will inform individuals who make inquiries or lodge complaints of the existence of relevant complaint procedures.

Principle 10.3: ISMP Canada will investigate all complaints. If a complaint is found to be justified, ISMP Canada will take appropriate measures, including, if necessary, amending its policies and practices.