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

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

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Demystifying Medication Incident Reporting

Introduction

To fulfill its commitment to patient safety, the Institute for Safe Medication Practices Canada (ISMP Canada) receives information about preventable adverse drug events from individual health care practitioners and health service organizations. Reporters send the information voluntarily and ISMP Canada uses its analysis of the medication incident reports to develop recommendations for enhancing patient safety.

In 2005, ISMP Canada was part of a research team[1] that obtained funding from the Canadian Patient Safety Institute to conduct a scan of legislation from across Canada that might apply to the reporting (or, in the term used by most statutes, "disclosures") of medication incident data to external organizations, such as ISMP Canada. We used the term "sharing" to refer to external incident reporting that is voluntary. Although the same statutory rules might apply to all kinds of incident reporting, we focused on types of information that are specific to medication incidents.

Reporters and reporting organizations in various provinces often ask questions about the landscape of privacy legislation across Canada and about the limits that such legislation might place on the sharing of medication incident data. As it happens, some of the key messages that came out of our legislative scan may be helpful to reporters with questions about privacy, confidentiality and the sharing of incident data.

Medication Incident Data Defined and Illustrated

For consistency, we used an accepted definition of the term "medication incident"*: any preventable subset of potential and actual adverse drug events.

*Medication Incident: Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. Similar Term: medication error.[3]

ISMP Canada asks those who are reporting medication incidents to provide the following categories of information[2]:

- a description of the incident
- the outcome of the incident
- the medication involved
- the type of incident (e.g. incorrect dose, incorrect route of administration etc)
- the stage of the medication-use system involved
- the type of health care area or facility
- the type of health care professional who discovered the incident

The following optional information may also be submitted:

- the age category and gender of the patient involved in the incident
- a description of how the incident was discovered
- any actions taken, or recommendations that the practitioner or institutional representative may have to prevent similar incidents in the future
- contact information for the person reporting the incident to ISMP Canada

The following types of information are not required and are excluded from all of the categories of information listed above:

- the name, contact and any other identifying information of the patient who was the subject of the incident
- unique identifying numbers (such as provincial health card number or a local hospital file number) used for the purpose of providing treatment
- information about the professional or treatment relationship between the person reporting the incident and the patient who was the subject of the incident (for example, if the person reporting provided treatment to the patient)

As these lists illustrate, the information elements required for medication incident reporting to ISMP Canada are from the level of individual records, but they do not identify individual patients. Each combination of elements is known to be about a particular incident, but not about a particular individual. Indeed, ISMP Canada's activities do not require any information that identifies patients; rather, what we need are non-identifying facts about the incident. As well, the type of information we ask to be shared cannot be used to link incident information directly with other information sources that could ultimately lead to identification of a patient.

Findings from an Examination of Statutory Rules

Information that is both non-identifying and factual is sharable

In the course of our work, we found that limits on the sharing of incident information stem from a variety of sources, including at least two types of statutory provisions:

i) provisions that limit the sharing of information that identifies individuals (i.e., "personal information" or "personal health information", which, by most statutory definitions, is also information that identifies individuals, in other words, "identifying information"); and

ii) provisions that place limits on sharing of *opinions* from professionals about the nature of an incident (for example, information protection legislation relating to quality assurance, which restricts the disclosure of information collected by or prepared for quality assurance purposes to limited circumstances.)

What counts for determining the permissibility of sharing are the *characteristics of the data*. Medication incident information is both *non-identifying* and *factual*—it is not "personal information" or "personal health information", nor is it protected information (as is the case for some quality assurance information.) Because of these characteristics, where the statutory privacy rules that apply to a reporter are like the two described above, medication incident information is also highly "sharable", because it falls outside of the statutory rules that limit sharing.

In short, we found that if medication incident information is both non-identifying (i.e., cannot be used to identify an individual patient) and factual, then the limits on sharing information that stem from privacy rules and other types of confidentiality provisions and that apply to statutorily protected information (for example, through quality assurance protections) are not applicable to medication incident data as defined above.

Standardized categories are needed

If there can be a national consensus about which non-identifying information elements are necessary for medication incident reporting, then standardizing the data set itself would make for a harmonized approach to medication incident reporting that would satisfy privacy rules across all of the provinces and territories. Where there is consistent use of a universal set of categories by everyone and every organization that collects and uses incident data, and where all such data are foreseeably both non-identifying and factual, the collection of data according to a "standard" would help to overcome both privacy and other confidentiality concerns. Recognizing that sharing is greatly facilitated through harmonization of characteristics according to an accepted standard or format, ISMP Canada has developed such a data set for individual practitioner reporting within the Canadian Medication Incident Reporting and Prevention System (CMIRPS).

Transparency has benefits and is ethical

When information falls outside of statutory rules because it is both de-identified and factual, it would be difficult from an *ethical* perspective to justify placing limits on the sharing of incident data. The feasibility of sharing reported data publicly has been demonstrated by the US-based Manufacturer and User Facility Device Experience Database[4] (known as MAUDE), which provides incident information related to medical devices on a publicly available website. Although this database is not Canadian, we think it is a good example for demonstrating that events can be shared openly to facilitate learning.

Case Examples

Examples of reported incidents and the shared learning that can result from these reports appear regularly in ISMP Canada's *Safety Bulletin*.[5] As just one example, ISMP Canada has published information about 4 instances of inadvertent administration of neuromuscular blocking agents to patients who were not intubated.[6] Information about these incidents was submitted voluntarily to warn others and to help develop and promote recommendations to prevent similar incidents in the future. Pharmaceutical manufacturers have also implemented changes to product packaging and labelling as a result of the learning that incident reporting allows.[7,8]

Conclusions

Reporters must assure themselves that any legislation applying to them permits the sharing of incident information with ISMP Canada. To do this, reporters should include two important questions: (1) Is the information identifiable "personal information" or "personal health information" according to the legislation that applies in my province or territory? (2) Is the information protected because it is confidential (i.e., such as an in-house *opinion* about why an incident occurred which may be protected quality assurance information?) A "no" answer to both questions is important in determining that certain information is "sharable."

The benefits of medication incident reporting and learning systems have been eloquently outlined in a World Health Organization report.[9] Reporters must, of course, comply with local rules, such as those on the privacy of personal and personal health information. But it is our considered opinion that, in all the jurisdictions in Canada, the general rules related to privacy of personal and personal health information and of quality-assurance-related opinions mean that *non-identifying facts* about an incident *are* sharable. We hope that the results of our study will aid health care practitioners and health service organizations in reassuring themselves about sharing of important information about preventable adverse drug events.

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References:

1. Weisbaum K, Hyland S, and Morton E. Striking a balance: Facilitating access to patient safety data while protecting privacy through creation of a national harmonized standard. In press. Toronto (ON): Institute for Safe Medication Practices Canada.
2. CMIRPS core data set for individual practitioner reporting. Canadian Medication Incident Reporting and Prevention System (CMIRPS): A collaborative initiative of the Institute for Safe Medication Practices Canada, the Canadian Institute for Health Information and Health Canada. Toronto (ON): Institute for Safe Medication Practices Canada; 2006 April [cited 2007 Mar 8]. p. 19-28. Available from: http://www.ismp-canada.org/download/CMIRPS%20Core%20Data%20Set%20for%20Individual%20Practitioner%20Reporting%20April%202006%20ISMP%20Canada.pdf
3. Definition of terms [internet]. Toronto (ON): Institute for Safe Medication Practices Canada; 2001[cited 2007 Dec 10]. Available from: http://www.ismp-canada.org/definitions.htm
4. Manufacturer and User Facility Device Experience Database [internet]. Rockville (MD): Food and Drug Administration (FDA); [updated 2007 Dec 10; cited 2007 Dec 10]. Available from: http://www.fda.gov/cdrh/maude.html
5. ISMP Canada Safety Bulletins [internet]. Toronto, (ON): Institute for Safe Medication Practices Canada; c2000-2007 [cited 2007 Dec 10]. Available from: http://www.ismp-canada.org/ISMPCSafetyBulletins.htm
6. "Paralyzing" mix-ups in the operating room: Opportunity to improve safety with neuromuscular blockers. ISMP Med Saf Bull. 2004[cited 2007 Dec 16];4(7):1-2. Available from: http://www.ismp-canada.org/download/ISMPCSB2004-07.pdf
7. Neuromuscular blocking agent labelling and packaging initiative. In: ISMP Can Saf Bull. 2006[cited 2007 Dec 10];2(2):2. Available from: http://www.ismp-canada.org/download/ISMPCSB2006-02PotassiumPhosphates.pdf
8. Enhanced labelling of neuromuscular blocking agents makes a difference. In: ISMP Can Saf Bull. 2007[cited 2007 Dec 10];7(5):3. Available from: http://www.ismp-canada.org/download/ISMPCSB2007-05Fentanyl.pdf
9. World Alliance for Patient Safety. WHO draft guidelines for adverse event reporting and learning systems: From information to action. WHO/EIP/SPO/QPS/05.3. Geneva (Switzerland): World Health Organization; 2005 [cited 2007 Dec 10]. Available from: http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf

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

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

(i) through the website http://www.ismp-canada.org/err_report.htm or

(ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.

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

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