Case Study of the Institute for Safe Medication Practices Canada's Work on HYDROmorphone and Other Opioids

Final Report

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Prepared for:

The Institute for Safe Medication Practices Canada

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Table of Contents

Table of abbreviations	
ADC	Automated dispensing cabinet
CAPHC	Canadian Association of Paediatric Health Centres
CCSA	Canadian Centre for Substance Abuse
CIHI	Canadian Institute for Health Information
CIL	Critical Incident Learning
CMAR	Computerized electronic medication record
CMIRPS	Canadian Medication Incident Reporting and Prevention System
COPD	Chronic obstructive pulmonary disease
CPhIR	Community Pharmacy Incident Reporting
CPOE	Computerized prescriber order entry
CPSI	Canadian Patient Safety Institute
FMEA	Failure Mode and Effects Analysis
HFE	Human factors engineering
ICU	Intensive Care Unit
IMSN	International Medical Safety Network
IPR	Individual Practitioner Reporting System
ISMP	Institute for Safe Medication Practices
LASA	Look-alike, sound-alike
MSSA	Medication Safety Self-Assessment
MSSS	Medication Safety Support Service
NSIR	National System for Incident Reporting
OCCO	Office of the Chief Coroner for Ontario
PCA	Patient-controlled analgesia
PSRC	Patient Safety Review Committee
RCA	Root Cause Analysis
ROP	Required Organizational Practices
SBAR	Situation, Background, Assessment, Recommendation

1.0 Introduction

Established in 1999, the Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national non-profit organization dedicated to gathering and analyzing information related to medication incidents and developing recommendations to improve medication safety practices (PRA Inc, 2010). ISMP Canada seeks to promote safe medication use and system strategies, develop and disseminate information on safe medication practices, create tools and educational programs to improve medication and patient safety, and offer expert consultation on medication systems for health care facilities (ISMP Canada, n.d.-b). In doing its work, ISMP Canada engages with numerous stakeholders spanning the continuum of safe medication practices, including health care facilities and providers, regulators, policy makers, industry, patient safety organizations, and the public (ISMP Canada, n.d.-b).

ISMP Canada has hired PRA Inc., an independent research firm, to conduct a case study of its work related to opioids, more specifically HYDROmorphone. Opioids, such as HYDROmorphone and morphine, are used to relieve moderate to severe pain, including chronic cancer pain (Murray & Hagen, 2005; Quigley & Glare, 2009). While opioids can be a highly effective method for treating pain, They are classified as a high-alert medication because they pose a heightened risk of causing significant patient harm when used in error (ISMP Canada, 2003a; ISMP US, 2012).

The case study considers ISMP Canada's work related to opioids, in part, through the lens of a 2011 HYDROmporphone incident at an Ontario hospital. The purpose of this case study is to examine ISMP Canada's overall activities related to opioid medication safety in an effort to understand the organization's ability (and potential ability) to influence health care organizations' and practitioners' opioid medication safety practices.

The case study focuses on four questions:

- How has earlier ISMP Canada opioid-related work informed how ISMP Canada could assist facilities experiencing a medication safety incident?
- How has a facility managed a HYDROmorphone incident, and how have the changes been directly or indirectly influenced by ISMP Canada?
- How has the learning from the incident been used in other ISMP Canada work?
- What are possible future priority areas that ISMP Canada should focus on in its work on opioids?

The case study report is organized into seven sections.

- Section 2 describes the methodology used for the study.
- Section 3 describes the risk of opioid medication incidents.
- Section 4 considers the role of ISMP Canada in medication safety with a focus on its work related to opioids.
- Section 5 describes the 2011 HYDROmorphone incident, the response, and the use of learning from that incident.
- Section 6 offers possible future priority areas for ISMP Canada's work, particularly related to opioids.
- Section 7 presents conclusions.

2.0 Methodology

The case study comprised three lines of evidence and was guided by a research matrix (see Appendix A). Data collection instruments (interview guides and survey questionnaire) used for the case study are in Appendix B. The methodological approach and the instruments were developed in consultation with representatives of ISMP Canada. This section of the report describes each of the lines of evidence.

2.1 Document review

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

The document review included several types of documents:

- ISMP Canada documents (e.g., safety bulletins and alerts, Ontario Critical Incident Learning bulletins, webinar materials, tools and products related to opioids)
- selected documents related to the 2011 HYDROmorphone incident
- scientific and grey literature on opioid safety

2.2 Interviews

In-depth interviews were conducted with stakeholder groups that had knowledge of ISMP Canada's work on opioids, including some stakeholders with knowledge of ISMP Canada's work with the facility that experienced the HYDROmorphone incident in 2011. PRA conducted 18 interviews with a total of 27 individuals. Key informants were chosen based on their detailed knowledge of some aspect of ISMP Canada's work on opioids. ISMP Canada and the facility that experienced the HYDROmorphone incident identified the appropriate key informants. The interviewees included ISMP Canada staff (n=2 interviews with 8 individuals); facility staff (n=4), and partners/external stakeholders (n=12 interviews with 15 individuals). The interviews were conducted by telephone, and each interview lasted approximately one hour.

2.3 Survey of facility staff

An online survey was conducted with staff of the health care facility that experienced the HYDROmorphone incident. PRA worked with ISMP Canada and facility representatives on the survey design and distribution. The method for distribution chosen was a general distribution email invitation to all facility staff, which numbered approximately 2,000. The survey was offered online between May 13, 2014, and June 7, 2014. Reminder emails were sent by the facility to encourage participation. The survey experienced some technical issues that could not be resolved, which may have affected the response. A total of 62 individuals completed the survey. Of those, 44 began working at the facility before the HYDROmorphone incident.

Table 1: Survey respondents

Category	#
Nurses/Nurse Manager/Nurse Director	31
Physicians	16
Pharmacists/Pharmacy Managers	4
Laboratory Technician/Technologist	3
Risk Manager	3
Physiotherapist	2
Personal Care Assistant	1
Manager (unspecified)	1
Other	1
Total	62

3.0 Risk of opioid medication incidents

ISMP Canada's work related to opioids (narcotics) was chosen for this case study because medication incident data demonstrate that opioids are one of the drugs most frequently associated with patient harm when used or administered incorrectly or in error. This section provides further details of this context for the study.

Medication incident data indicate that despite the attention paid to opioid safety, there continues to be a risk of opioid-related incidents. As shown in Figure 1, opioid incidents continue to be reported through the various reporting mechanisms available.[1]

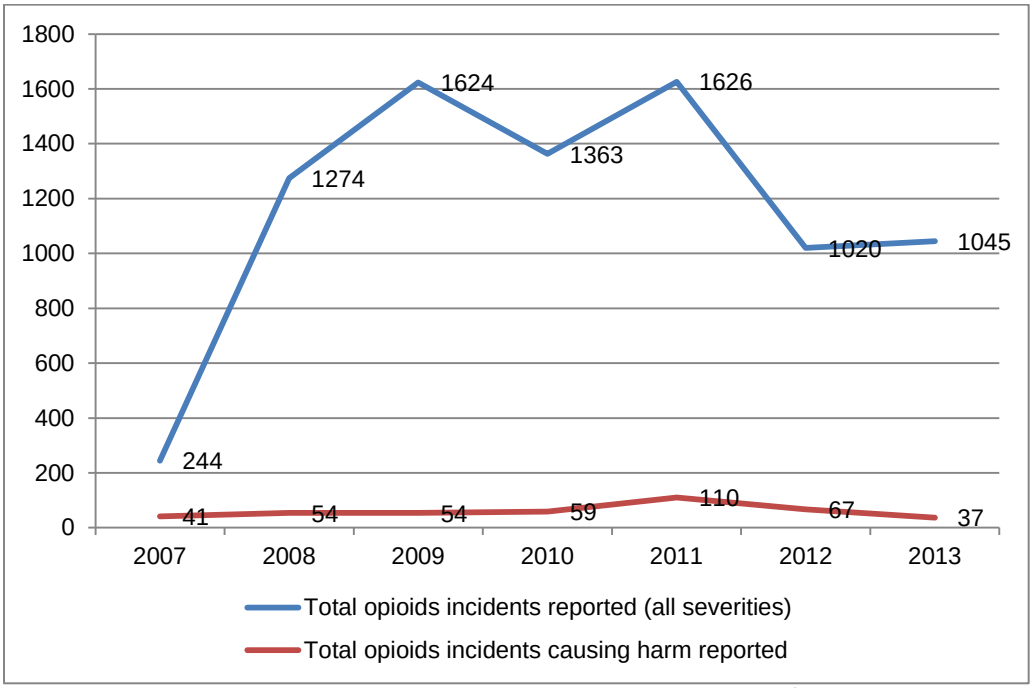

Figure 1. Opioid incidents reported 2007–13[2]

Examining the data from each reporting mechanism separately provides additional information on the nature of the risk associated with opioids. The Canadian Medication Incident Reporting and Prevention System (CMIRPS) began collecting reports from community pharmacies in 2010, and since 2011, community pharmacy reporting has made up by far the largest number of reported medication incidents. For CPhIR, the percentage of incidents related to opioids is 3.7% (2,108) for all severities (57,423), and the percentage of incidents resulting in harm that were

[1] Definite conclusions, however, on the level of risk or trends in risk cannot be made because reporting of medication incidents is voluntary, with many incidents remaining unreported. In 2012, CIHI reported the estimate that between 2% and 20% of incidents are reported. In addition, an increase in reporting over time could reflect a greater willingness to report incidents rather than a less safe environment (CIHI, 2012, p. 4).

[2] The data on medication incidents used for Figure 1 were collected from a variety of sources through multiple reporting databases. Incidents were reported by individual practitioners, hospitals, and coroners through the Individual Practitioner Reporting System (IPR), Analyze-ERR, and Ontario Medication Incident Database (OMID). Community pharmacies reported incidents through the Community Pharmacy Incident Reporting (CPhIR) system since 2010. Consumers reported medication incidents through the SafeMedicationUse.ca Consumer Reporting System since 2009.

related to opioids is 0.3% (26) of 8,069 incidents causing harm. These data do not necessarily indicate that opioid incidents are infrequent in the community pharmacy setting; opioid incidents may be infrequently detected or infrequently reported.

The other reporting mechanisms showed much higher rates of patient harm among reported incidents. Individual practitioners, hospitals, and coroners (IPR, Analyze-ERR, OMID) reported that opioids made up 15.6% (6,076) of all medication incidents (39,012) from 2007–13. Opioids were disproportionately likely to result in harm: 20.7% (388) of all incidents causing harm (1,872) were related to opioids. In some years, this figure was higher: in 2012, opioids accounted for 25.9% (57) of all reported incidents causing harm (220). Consumer reporting (SafeMedicationUse.ca) showed similar risks associated with opioids. Overall 4.7% (12) of all reported incidents (258) were related to opioids. However, 15.1% (8) of all incidents causing harm (53) were related to opioids.

In addition, a study conducted by the Office of the Chief Coroner for Ontario (OCCO) on medication incidents involving death provides additional insight into the occurrence and nature of opioid medication errors and confirms the need to classify opioids as a high-alert medication. Nearly half (47%) of the cases included in this study involved an opioid medication, with HYDROmorphone (n=19) being the most commonly-listed drug (ISMP Canada, 2013a).

Table 2: Medication classes most commonly involved in incidents associated with death

Medication Class	Number (%) of incidents (n=115)	
Opioids	54	47%
Psychotherapeutic agents	28	24%
Anticoagulants	24	21%
Cardiovascular agents	11	10%
Insulin	8	7%

Source: (ISMP Canada, 2013a)

Table 3: Medications most commonly involved in incidents associated with death

Medication	Number of incidents
HYDROmorphone	19
Morphine	13
Warfarin	11
Fentanyl	8
Insulin	8
Oxycodone	7
Amitriptyline	4
Methadone	4
Acetylsalicylic acid	3
Moxfloxacin	3
Olanzapine	3
Potassium	3
Tissue plasminogen activator (tPA)	3

Note: Some incidents involved more than one medication.
Source: (ISMP Canada, 2013a)

The Coroner data confirms earlier ISMP Canada findings that listed the opioids morphine, HYDROmorphone, and fentanyl as three of the top 10 drugs most frequently reported by individual practitioners as causing harm (ISMP Canada, 2006c).

In addition to the well-documented risks of error associated with opioid use, studies of medication incidents involving opioids show a distinct pattern in the most common types of errors. Table 4 below illustrates the following:

- The most frequent errors in opioid medication incidents involve incorrect dose, strength, frequency, or rate, with these errors accounting for 35% of all reported opioid incidents and nearly half (47%) of all errors associated with incidents causing harm.
- Using the wrong drug was the next most common type of error, accounting for 17% of all errors and 19% of all errors causing harm.
- Dose or medication omissions were the third most frequent error, accounting for 14% of all errors and 13% of all errors resulting in harm.

Table 4: Type of error related to opioid medication incidents

Type of error	Total (all opioid incidents)	Total (opioid incidents causing harm)
Incorrect dose/strength/frequency/rate	2,727 (34.8%)	192 (47.1%)
Incorrect drug	1,339 (17.1%)	79 (19.4%)
Dose or medication omission	1,119 (14.3%)	53 (13.0%)
Incorrect quantity	489 (6.2%)	1 (<1%)
Incorrect patient	231 (2.9%)	13 (3.2%)
Incorrect route of administration	209 (2.7%)	7 (1.7%)
Incorrect duration	188 (2.4%)	3 (0.7%)
Incorrect formulation or dosage form	185 (2.4%)	5 (1.2%)
Incorrect time	183 (2.3%)	-
Monitoring problem	51 (0.7%)	7 (1.7%)
Other	1,115 (14.2%)	48 (12%)
Total	**7,836**	**408**

Note: The number of reported incidents does not equal the number of incidents that occurred because not all incidents are discovered and not all incidents that are discovered are reported. CIHI estimates that between 2% and 20% of incidents are reported. It is not possible to determine the total number of incidents based on the number of reports (CIHI, 2012, p. 4). Percentages are rounded to one decimal place and may not sum to 100%.
Source: (ISMP Canada, 2014d)

4.0 Role of ISMP Canada

ISMP Canada's sustained work in the area of medication safety reflects its specialized role and its work related to opioids demonstrates its ability to identify issues, propose solutions, and influence health care organizations' and practitioners' opioid medication safety practices.

4.1 Source for medication safety information and strategies

ISMP Canada remains the primary resource for medication incident analysis and medication safety strategies, according to key informants. Other bodies, such as Health Canada, professional regulatory bodies, and other non-governmental safety organizations, have done work in the area of opioid safety, but their roles are considered to be different from ISMP Canada's. For example, Health Canada develops and implements the federal regulatory framework for human drugs, including opioids, to ensure that products authorized for sale in Canada are safe for use. Health Canada also has a role in communicating safety and risk information related to human drugs. The professional regulatory bodies and professional associations offer education and share best practices on medication use, and, as key informants pointed out, some of this content is informed by ISMP Canada. Accreditation Canada goes beyond medication safety and influences organizational practices more generally through its accreditation standards. In terms of non-governmental safety organizations, the other organization most often mentioned was the Canadian Patient Safety Institute (CPSI), which was seen as fulfilling a different role than ISMP Canada with a broader mandate related to patient safety more generally and with a focus more on disseminating knowledge on patient safety strategies.

Key informants consider ISMP Canada to fill a unique role, or niche, of providing analyses of medication safety incidents and offering specific recommendations on how to improve medication safety and reduce the potential for error. In terms of reporting medication safety incidents, several key informants pointed out that a key benefit to the health care system is the national distribution of information and analysis provided by the Canadian Institute for Health Information (CIHI) and ISMP Canada through CMIRPS.

ISMP Canada is seen as offering a specialist approach that is informed by a detailed understanding of the environment in various health care settings in which opioids are used. ISMP Canada's recommendations and safety strategies take the health care environment into account and offer feasible solutions, according to key informants. Key informants used language to describe ISMP Canada that highlighted its independent status when analysing medication incidents, commenting that ISMP Canada is "evidence-based," "the vanguard in terms of impartial and unbiased review," and offers "independence and neutrality." Several key informants pointed to ISMP Canada's expertise in systemic and latent errors that lead to medication incidents as a reason why they are a "go-to organization for medication safety information" and why health care organizations, particularly hospitals, take stock of their own processes when an ISMP Canada alert is published. Key informants pointed to ISMP Canada's direct engagement with hospitals and its role as a diffuser of knowledge about medication safety strategies and best practices as ways in which ISMP Canada has facilitated and supported positive changes in the safe use of opioid medications.

4.2 ISMP Canada work related to opioids

This section of the report provides an overview of ISMP Canada's work related to opioids and demonstrates the scope and breadth of the work. It also shows how ISMP Canada's recommendations related to opioids have been consistent and remain relevant today.

Since ISMP Canada's inception, opioid safety has been a major medication safety topic. The consistent attention paid to opioids and the variety of methods used by ISMP Canada to conduct and disseminate its work is shown in Table 5 and will be discussed in more detail below.

Table 5: ISMP Canada opioid-related work

Bulletins and alerts	
23 ISMP Canada safety bulletins and/or alerts related to opioids	2002–14
2 Ontario Critical Incident Learning bulletins	2013
2 Safemedicationuse.ca newsletter/alerts (consumer website)	2012–13
Projects	**Years**
Ontario Medication Safety Support Service (MSSS) Narcotics Project	2003–05
Alberta Medication Safety Collaborative Opioids (Narcotics) Project	2006–10
Collaboration with the Office of the Chief Coroner for Ontario	2004–present
Coroners' Project: Development of a Model to Translate Learning from Fatal Medication Incidents into Evidence-Based Interventions (collaboration with four provincial Offices of the Chief Coroner or Chief Medical Examiner)	2012–present
Advancing Medication Safety in Paediatrics (Phase 1 and Phase 2) (national collaborative)	2006–08 (Phase 1) 2009–10 (Phase 2)
HYDROmorphone Knowledge Assessment Survey	2012
HYDROmorphone Demonstration Project	2012–13
Products	
Medication Safety Self-Assessment (MSSA)	
community/ambulatory pharmacies	2006
complex continuing care and rehabilitation	2007
long-term care	2007, updated 2012
hospitals	2001, updated 2006
HYDROmorphone MSSA	2013
Paediatric Opioid Safety Resource List	2012
Presentations and workshops	
Conference on Ontario MSSS Narcotics Project	2005
National Guidelines for Opioid Medication Delivery in Paediatrics (Webinar)	2011
Tenfold medication errors in paediatrics (Webinar)	2011
HYDROmorphone Discovering What We Don't Know (Webinar in English and French)	2012
Hospital related deaths — The Role of the Coroner's Office in Enhancing Patient Safety (Webinar)	2013
Medication Safety Learning from Ontario Coroners' Cases — Focus on Opioids (Webinar)	2013
Protecting the living: How death investigations contribute to safe medication use (Webinar)	2013
Identifying Knowledge Deficits Related to HYDROmorphone (Webinar)	2013
Implementing Opioid Safety Guidelines: Successes and Challenges at Health Sciences, North	2013
A Year in Review: Critical Medication/IV Fluid Incident Reporting Through the National System for Incident Reporting (NSIR) (webcast)	2014
Managing Medication Standards and ROPs" High Alert Medications and Opioids	2014
Videos	
Consumers can Help Prevent Harm from Opioid Use (Youtube videos with English and French with subtitles)	2013
Publications	
25 publications, posters, and position statements related to opioids	2002–present
Other collaborations with external stakeholders	
Accreditation Canada	
Canadian Centre for Substance Abuse	
Note: Other ISMP Canada products can be used for issues related to opioids but do not specifically address opioids (e.g., Canadian Failure Mode and Effects Analysis Framework)	

4.2.1 Bulletins and alerts

ISMP Canada — in collaboration with CIHI and Health Canada — developed and implemented CMIRPS to coordinate the capture, analysis, and dissemination of voluntary medication incident reports reported by medical practitioners, hospitals, coroners, pharmacies, and the public through five databases: NSIR, IPR, Analyze-ERR, the CPhIR system, and the SafeMedicationUse.ca Consumer Reporting System (ISMP Canada, 2006c, 2014b).

ISMP Canada uses data collected through CMIRPS to develop safety bulletins and disseminate medication safety information to health care practitioners in an effort to reduce the risk of medication errors and encourage best practices in safe medication use (ISMP Canada, 2013e, p. 3). The safety bulletins summarize the results of ISMP Canada's research and analysis of medication incidents and may provide recommendations for improving medication management practices.

Early in its first full year of offering safety bulletins, ISMP Canada reported that it had "received several reports of serious medication errors involving narcotic medications" (ISMP Canada, 2002b). The bulletin described two errors with opioids (morphine and oxycodone) and offered suggestions stemming from a roundtable discussion at the Canadian Society of Hospital Pharmacists Professional Practice Conference of narcotic errors and possible safeguards (ISMP Canada, 2002b). Several of the suggestions have recurred throughout the following twelve years and formed recommendations made by ISMP Canada to reduce medication incidents involving opioids, in particular using independent double checks, installing automated dispensing units, limiting the choices of narcotic floor stock, removing high potency from wards, and standardizing pain relief choices and/or protocols.

Since it began disseminating safety bulletins in 2001, ISMP Canada has published 23 medication safety bulletins and alerts related to analyses of incidents involving opioid medication errors or other safety issues (ISMP Canada, 2014d). Appendix C contains a full list of the bulletins related to opioids. HYDROmorphone has figured prominently in the safety bulletins at certain key points in time:

- In 2003, ISMP Canada issued a safety bulletin to address a cluster of 22 medication incidents involving confusion between long-acting and regular release oral narcotics (ISMP Canada, 2003c).

- In 2004, a safety bulletin was devoted to a fatal incident involving a HYDROmorphone-morphine mix-up. This incident was the subject of a Root Cause Analysis (RCA) and served as an impetus for the Alberta Medication Safety Collaborative Opioids project, which is discussed in more detail Section 4.2.2 (ISMP Canada, 2004a).

- In 2005, ISMP Canada issued a safety bulletin devoted to the importance and method of performing independent double checks using two incidents of errors in programming patient-controlled analgesia (PCA) pumps as examples (ISMP Canada, 2005b).

- In 2006, ISMP Canada reviewed the first five years of CMIRPS data and reported on the top 10 drugs associated with causing harm as a consequence of medication error — HYDROmorphone was third after insulin and morphine (ISMP Canada, 2006c). Following up on those findings, later that same year, ISMP Canada conducted an aggregate analysis of incidents involving HYDROmorphone (ISMP Canada, 2006b). The

analysis found errors in all stages of the medication use system, but the most occurred during administration, followed by order entry and transcription errors. The most common errors were incorrect drug (e.g., substitution errors between HYDROmorphone and morphine), incorrect dose, and dose omission. ISMP Canada offered eight main recommendations, of which many reasserted and reinforced recommendations made by ISMP Canada in 2004 and 2005 (see Ontario MSSS Narcotics Project and Table 7 under the Alberta Medication Safety Collaborative Opioids (Narcotics) Project below).

- In 2012–13 (the years immediately following the HYDROmorphone incident that is the subject of this case study), ISMP Canada issued three bulletins focused on its work related to opioids and, more specifically, HYDROmorphone. These bulletins highlighted knowledge gaps related to HYDROmorphone among health care professionals (ISMP Canada, 2012b), the continued existence of HYDROmorphone as one of the top medications associated with incidents involving death (ISMP Canada, 2013c), and the results of ISMP Canada's HYDROmorphone Targeted Demonstration Project to assess existing safety strategies and follow up on implementation of improvements (ISMP Canada, 2013h). The project work related to these bulletins (the HYDROmorphone Knowledge Assessment Survey, the Coroner's Project, and the HYDROmorphone Targeted Demonstration Project) are all discussed in more detail below.

In addition to the safety bulletins, ISMP Canada also produced two Ontario Critical Incident Learning bulletins that address opioid safety and draw directly on learnings from the 2011 HYDROmorpohone case study, see Section 5.4 for a discussion of these bulletins. Also, more recently, ISMP Canada has included opioid safety information in its consumer newsletter and safety alerts (ISMP Canada, 2012e, 2013d).

4.2.2 Opioid safety projects

Beginning shortly after its establishment and in response to the evidence obtained through various reporting mechanisms of the level and severity of opioid medication incidents, ISMP Canada also became involved in several opioid safety projects. These projects also demonstrate how learning from one ISMP Canada project can inform its later work, as well as that of other health care organizations.

Ontario MSSS Narcotics Project

In 2003, ISMP Canada hosted a consultation with about 140 attendees from Ontario hospitals and all participant focus groups identified opioids as an area of concern (Colquhoun, Koczmara, & Greenall, 2006). Given the reports received by ISMP Canada and the level of concern of health care professionals, the Ontario MSSS Advisory Group made opioids ISMP Canada's focus for the MSSS safety initiative for 2005–06, which was funded by the Ontario Ministry of Health and Long-Term Care. The initiative aimed to reduce the risks associated with the use of opioids in Ontario hospitals by surveying Ontario hospitals to determine the extent to which system safeguards for narcotic distribution and administration were in place pre- and post-initiative. The survey resulted in 11 priority recommendations within the themes of culture and communication; storage and standardization; independent double checks; and PCA and epidural (see Table 6 below). ISMP Canada developed a resource binder and a communication strategy to support the implementation of the priority recommendations (ISMP Canada, 2007b).

A follow-up survey, in which 140 hospitals participated, found that almost all (94%) of the hospitals were implementing at least some of the recommended safety improvements, and most found ISMP Canada's resource binder (83%) and presentations (67%) helpful in those efforts (Colquhoun et al., 2006). Statistically significant results in safety improvements included reductions in the availability of high-potency narcotics from patient care area stock, increases in the percentage of hospital respondents documenting independent double checks for opioid medication and dosage via the epidural route (adult), and increases in the utilization of error-reduction strategies for epidural infusions. Most frequently, respondents identified implementing ISMP Canada strategies such as revising narcotic administration records to incorporate safe design principles, reducing the number of opioid stock items in patient care areas and reorganizing patient care area opioid stock, and standardizing opioids used for pain management and enhancing how long- and short-acting opioid oral products are differentiated. Opportunities for improvement included continued removal of high-potency ampoules or vials from patient care area stock and the development of processes to conduct risk audits of narcotic storage areas.

Table 6: ISMP Canada Priority Recommendations 2005

	Culture and Communication
1.	Educate staff regarding the system-based causes of medication error.
2.	Educate staff about the hierarchy of effectiveness of error-reduction strategies.
3.	Include the patient/family in the narcotic medication-use process.
	Storage and Standardization
4.	Remove the following stock items from patient care areas: ○ HYDROmorphone ampoules or vials with concentration greater than 2 mg/mL (exceptions may include palliative care) ○ Morphine ampoules or vials with concentration greater than 15 mg/mL ○ Morphine ampoules or vials greater than 2 mgmL in paediatric patient care areas ○ Sufentanil (exceptions may include Operating Room and Labour and Delivery)
5.	Assess risk associated with narcotic stock in patient care areas.
6.	Restrict as much as possible the admixing of narcotic solutions outside of pharmacy.
7.	Standardize infusion concentrations of parenteral narcotic medications and selection of medications for pain management.
	Independent Double Check
8.	Implement a policy of independent double checks for PCA infusions. The policy should include a clear process for an independent double check and documentation when the following occur: ○ Initial pump programming ○ Changes in pump programming ○ Solution changes ○ Patient transfers
9.	Consider a policy of independent double checks for: ○ All opioid infusions (continuous or intermittent) ○ Epidural infusions
	PCA and Epidural
10.	For PCA, develop and follow patient selection criteria (inclusion and exclusion).
11.	For epidural, identify and implement multiple error prevention strategies to enhance differentiation of epidural infusions from other infusions.

Source: (ISMP Canada, 2005a)

Alberta Medication Safety Collaborative Opioids (Narcotics) Project

In 2006–07, the Ontario MSSS work was replicated in Alberta as part of the Alberta Medication Safety Collaborative Opioids (Narcotics) Project. This project was prompted by a June 2004 HYDROmorphone error caused by a HYDROmorphone/morphine mix-up in an Alberta emergency room. Although derived from morphine, HYDROmorphone is considered to be five to ten times more potent than morphine (Quigley & Glare, 2009) and therefore must be delivered in considerably smaller doses than morphine.

Initially, ISMP Canada was involved by conducting a RCA for the hospital. The RCA is a retrospective analysis focused on a critical medication incident and near-miss event. The goal of the RCA is to understand what happened, why it happened, and what can be done to reduce the potential of a reoccurrence (ISMP Canada, 2005c). RCAs focus on the underlying causes and factors that contributed to an event, examining organizational, environmental, or regulatory factors that control individuals, and may not be immediately recognizable as being causal (ISMP Canada, 2005c). Rather than focusing on the need to educate staff and update organizational polices, the RCA's recommendations emphasize process-related changes, such as standardization, simplification, and careful automation (ISMP Canada, 2004b, p. 6).

Table 7: RCA in Action — HYDROmorphone/morphine incident, 2004

In 2004, ISMP Canada conducted a RCA after a hospital patient accidentally received HYDROmorphone instead of morphine resulting in a fatal overdose. The hospital contacted ISMP Canada to undertake an external review of the hospital's medication safety processes and to conduct a RCA of the identified HYDROmorphone event to identify the system-based causes of the event and to make targeted recommendations to avoid a similar adverse event in the future (ISMP Canada, 2004b, p. 5).

The RCA identified a number of human factors issues throughout the event. The triggering event — incorrect drug selection — was strongly influenced by look-alike packaging, sound-alike drug names, and workplace distraction. Other environmental factors included narcotics distribution, medication storage conditions, and handling practices commonplace in various health care settings. In addition, communication and medication safety process issues were identified, which reduced the likelihood of early discovery of the overdose once the event occurred.

The RCA developed recommendations based on the medication and patient safety and human factors engineering literature, as well as the experience of the review team with medication safety. Recommendations included the following:

- reduce stock amounts of HYDROmorphone or eliminating floor stock
- avoid stocking morphine and HYDROmorphone in the same strength
- use TALLman lettering to emphasize the HYDROmorphone on pharmacy labels, auxiliary labels, medication administration records, and drug listings, and consid adding label reminders indicating the brand name equivalent (Dilaudid)
- require an independent double check before administering narcotic doses intravenously, especially when obtaining narcotics from floor stock
- provide safety information to staff and patients on the use of potent narcotics and the differences between HYDROmorphone and morphine
- use technological solutions to help reduce the risk of mix-ups
- have and use policies that specify the nature of monitoring required before discharge a patient who received a parenteral narcotic (ISMP Canada, 2004a)

Recommendations were also made to help the hospital support a culture of patient safety to ensure appropriate organizational changes were implemented (ISMP Canada, 2004b, p. 4).

The subsequent Alberta Medication Safety Collaborative Opioids (Narcotics) Project aimed to develop and implement best practices for the safe handling of narcotics in Alberta's acute care facilities (Wright, 2010). The project teamed the Health Quality Council of Alberta, the Alberta Regional Pharmacy Directors, and ISMP Canada. ISMP Canada used learnings from the 2004 HYDROmorphone RCA in customizing its Survey of Opioid (Narcotics) Management in Hospitals for Alberta.[3] The results led to summary recommendations that included priority areas similar to those identified in the MSSS for narcotics (Colquhoun et al., 2006; Wright, 2010).

As with the Ontario project, ISMP Canada developed a resource binder to support the implementation of the priority recommendations, and, in February 2006, individual health regions began to implement changes. For example, the Calgary Health Region developed new storage and labelling guidelines that were applied to more than 500 areas where medications were stored as part of its enhanced patient safety strategy (Shultz, Harvie, McDonald, Manley, & Cole, 2007a), which tackled challenges identified in medication storage practices. Improvements included standardizing how medications are organized, clustering medications into logical groups, using colour coded storage bins, clearer bin labelling, use of generic drug names, and standard fonts. In addition, in 2007 an Opioid Checklist was created to assess progress, and the Health regions began documenting their progress using the Checklist and other reporting (Wright, 2010).

The Health Quality Council of Alberta reported on the overall outcomes of the Alberta project in 2010 (Wright, 2010). While there was not the desire for developing a collaborative province-wide project, the regional departments of pharmacy had established priorities for local action and made some system improvements. Initial priorities focused on improving the safety of PCA and epidural narcotics, and narcotic storage in patient care areas. One lesson learned from the project was that networks are both an important impetus for change, as well as a support for sustaining the momentum of medication system improvements. In addition, tools such as the Opioid Checklist and the ISMP Canada Survey of Opioid (Narcotics) Management in Hospitals are critical supports for medication system change (Wright, 2010).

Work with Office of the Chief Coroner for Ontario and the Coroners' Project

In addition to these early projects related to opioids in Ontario and Alberta, in 2004, ISMP Canada began collaborating with the OCCO on retrospective studies into deaths associated with medication errors. This work led to the creation of the Patient Safety Review Committee (PSRC), which was established in 2005 to assist with (and improve on) the Chief Coroner's investigation and review of deaths within the health care system where system-based errors appear to have occurred (ISMP Canada, 2013e; Office of the Chief Coroner for Ontario, 2011). Since the committee was established, ISMP Canada had been involved in various key roles, such as providing case review expertise, commentary in reports, and further disseminating their opioid management materials (Office of the Chief Coroner for Ontario, 2014).

The work with the OCCO demonstrated that Coroners and Medical Examiners Offices could offer an important source of data on some of the most serious medication incidents. Coroners and Medical Examiners currently investigate about 35,000 deaths in Canada per year (Statistics

[3] The original survey was used for the Ontario MSSS Narcotics project.

Canada, 2012) However, there is no coordinated effort to share learning or recommendations nationally.

Consequently, ISMP Canada has developed a collaborative relationship with Offices of the Chief Coroner or Chief Medical Examiner in four provinces — Ontario, Quebec, Saskatchewan, and Nova Scotia (known as the "Coroners' Project"). The project has reviewed individual case files from 2007–12 pertaining to medication incidents. By analyzing individual cases, conducting multi-incident (aggregate analyses), and reviewing and expanding upon recommendations that were made, the Project is intended to develop a model to translate this learning from fatal medication incidents into evidence-based interventions (ISMP Canada, 2013e, p. 12). One of the multi-incident analyses conducted related to opioids. As discussed in Section 3.0, the project has shown that since 2007, opioids have made up nearly half (47%) of the Coroners' Project's 115 cases where a medication incident may have contributed to or resulted in a patient's death, with HYDROmorphone and morphine being the most commonly-listed medications associated with death (ISMP Canada, 2013a, 2013e). The results of the Coroner's Project have received substantial interest (see Section 4.3.1) and have provided ISMP Canada with additional evidence to support its work on HYDROmorphone.

Advancing Medication Safety in Paediatrics

The goal of this project — which was a collaboration with the Canadian Association of Paediatric Health Centre and CPSI— was to enhance the safety of paediatric medication use, with a particular focus on opioids (ISMP Canada, 2014a). Phase I (2006–08) identified morphine as the most common medication causing harm, accounting for 8.8% (26) of all incidents causing harm (294). Fentanyl, another opioid, was among the top 5 medications reported as causing harm (ISMP Canada, 2009b). Phase I research also identified two of the most common types of medication incidents as "wrong drug" and "wrong dose," which mirrors the types of incidents seen outside of the paediatric setting.

Phase II, 2009–10, focused on transforming opioid delivery in paediatrics and resulted in the development of Paediatric Opioid Safety Consensus Guidelines (Consensus Guidelines) (ISMP Canada, n.d.-f). A key focus of these recommendations and guidelines was the adoption of standard concentrations of opioids for continuous infusions and the use of these standard concentrations in combination with smart pumps to maximise patient safety. The guidelines also included recommendations for intermittent opioid dosing, preparation and labelling of oral and parenteral opioids, development and dissemination of institution-wide opioid dosing and monitoring guidelines, appropriate storage and segregation of opioids, and implementation of independent double checks before administration of opioids to paediatric patients. The opioid safety recommendations support standardizations that are customized for the different needs of community and tertiary hospital settings. Section 4.3.1 shows the ongoing interest in the reports, guidelines, and tools from this project.

HYDROmorphone Knowledge Assessment Survey

ISMP Canada received funding from Health Canada in December 2011 to implement a project that would enable a better understanding of the significance of knowledge deficit among health care professionals as a factor contributing to medication incidents involving HYDROmorphone (ISMP Canada, 2012a).

ISMP Canada developed a Knowledge Assessment Survey on HYDROmorphone with the support of expert advisors (ISMP Canada, 2012a). A total of 3,476 respondents completed all or most of the knowledge assessment questions in the survey. Respondents included individuals from all provinces and territories and from the primary health care disciplines involved in prescribing, dispensing, preparation, administration, and/or monitoring of HYDROmorphone.

To assess the magnitude of knowledge deficit as it relates to HYDROmorphone use, the knowledge assessment questions were grouped into six categories: pharmacology, indication, adverse effects, dosing, difference, and calculations.

- The greatest area of knowledge deficit appeared to be in *pharmacological properties* and was represented in responses from all disciplines. The lowest scores were obtained for questions related to onset, peak effect, and duration of action of the various sustained-release and immediate-release formulations, as well as the relationship of these properties to patient monitoring and the use of rescue agents.

- The second most common area of knowledge deficit appeared to be related to conducting *mathematical calculations* by respondents within the nursing discipline. Respondents were asked to calculate the volume of HYDROmorphone to be administered intravenously to a paediatric patient from the lowest-concentration parenteral formulation available in Canada (HYDROmorphone 2 mg/mL, 1 mL ampoule). This is an important question because the starting dose for an opioid-naïve individual, even an adult, is less than a full 2 mg ampoule.

- Within the category of usual *dosing* the following were identified as greater knowledge deficits within the disciplines listed:

Table 8: Knowledge deficits related to dosing

Area of knowledge deficit	Discipline
Ability to identify opioid tolerance	All disciplines
Recognition that obese patients do not require higher doses	All disciplines
Recognition that chronic obstructive pulmonary disease (COPD) patients do not require the same doses as those without COPD	All disciplines
Recognition that patients on a benzodiazepine do not require higher or same doses as those not on a benzodiazepine	Nursing and Pharmacy
Recognition that the elderly do not require the same doses as younger patients	Nursing and Pharmacy
Ability to convert oral dose of HYDROmorphone to equi-analgesic parenteral dose of HYDROmorphone	Nursing

Source: (ISMP Canada, 2012a, p. 8)

- Within the *adverse effects* category, respondents across all disciplines were not able to discern that an adverse effect, or predictable side effect, of morphine would not preclude treatment with HYDROmorphone. Respondents from medicine scored lowest in recognizing signs of HYDROmorphone overdose.

- Within the *difference* category (differences between HYDROmorphone and morphine, especially in potency), a large majority of respondents correctly identified HYDROmorphone and morphine and their different potencies; however, some respondents (4.8%) from all disciplines demonstrated a knowledge deficit in differentiating between morphine and HYDROmorphone. This shows that the relationship between morphine and HYDROmorphone is not universally understood.

- There did not appear to be a knowledge deficit in recognizing *indications* for use of HYDROmorphone (ISMP Canada, 2012a, pp. 7–9, 2012b).

To summarize, the Knowledge Deficit Survey revealed key areas for concern in the use of HYDROmorphone:

- pharmacologic properties, especially sustained release vs. immediate release
- dose calculations
- ability to identify opioid tolerance
- comorbidities requiring lower doses
- distinction between side effects and allergies
- recognition and management of overdose (ISMP Canada, 2013f, p. 40)

To follow up on these findings and determine the effects of knowledge deficits related to HYDROmorphone, ISMP Canada conducted an aggregate analysis of the relationship between HYDROmorphone incidents and knowledge deficit. This analysis confirmed some of the key findings and informed the recommendations that came from the Knowledge Assessment Survey. The aggregate analysis identified two key areas of knowledge deficit: the pharmacological and pharmaceutical properties of HYDROmorphone, and the HYDROmorphone medication-use process (ISMP Canada, 2012a, p. 9).

These results confirm that education and training cannot be the sole response to prevent medication incidents, particularly with high-alert drugs where risks of patient harm are greater. Over the years, ISMP Canada recommendations have covered many of these areas (e.g., importance of monitoring patients, educate staff about error-reduction strategies, removal of high-concentration HYDROmorphone in patient care areas, use of standardized mixtures), yet knowledge deficits remain. ISMP Canada urged Canadian health care facilities and individual practitioners to examine the processes in their organizations where knowledge gaps related to HYDROmorphone could increase the potential for error (ISMP Canada, 2012b, p. 3).

This survey clearly gained attention, as the report of results was the second-most-downloaded ISMP Canada product in the last three years (see Section 4.3.1). In addition, several organizations have indicated their desire to incorporate use of the survey and resulting local findings into educational programs (ISMP Canada, 2012b, p. 2).

HYDROmorphone Demonstration Project

In 2012, the persistent appearance of HYDROmorphone in the list of drugs most often associated with medication incident involving harm or death caused ISMP Canada to develop the HYDROmorphone Demonstration Project, which included the design of a HYDROmorphone-specific MSSA. The MSSA tool considers key elements related to HYDROmorphone that affect its safe use and is intended to help health care facilities assess their medication systems on these key elements. The HYDROmorphone medication incident that is the subject of this case study informed the development of the MSSA and the demonstration project.

First, after a comprehensive review of the international literature, ISMP Canada developed a hierarchy of recommendations based on effectiveness and the area of the medication-use system they targeted. Second, a team of medication safety experts used this hierarchy to develop five actions to address areas that had not previously been recommended by ISMP Canada and could be implemented within a three-month period (ISMP Canada, 2013h).

The five interventions addressed tenfold overdoses (related to 10 mg/mL vials), starting doses too high, and monitoring for signs of toxicity (ISMP Canada, 2013f, p. 46). See Table 9.

Table 9: HYDROmorphone Demonstration Project — Recommended Actions and Rationale

#	Action to improve system safety	Rationale
1	Preparation by pharmacy of doses less than 1 mg in prefilled syringes	To prepare, in advance, doses that are commonly used in practice, reducing the risk of inadvertent overdose
2	Availability of a standard-volume chart for usual doses withdrawn from a 2 mg/mL vial or ampoule	To reduce the risk of dose miscalculation in the preparation of doses
3	Creation of an electronic alert in computerized prescriber order entry (CPOE) screens, pharmacy information systems, and automated dispensing cabinet (ADC) screens for initial doses greater than 1 mg IV/IM/SC/PO	To minimize the risk of an initial dose that is too high and to ensure assessment of opioid tolerance and comorbidities that might necessitate a dose reduction
4	Performance of a weekly audit to remove high-dose HYDROmorphone (i.e., parenteral dose greater than 2 mg) from patient care areas	To prevent inadvertent administration of tenfold overdoses by limiting availability of 10 mg/mL concentration
5	Distribution of an opioid information sheet to patients and families	To assist patients and families in becoming part of the monitoring process, thus supporting the ability of health care staff to recognize and respond to overdoses

Note: Listed according to hierarchy of effectiveness.
Source: (ISMP Canada, 2013h)

The ISMP Canada project team worked directly with participating hospitals to provide support. Of the 10 hospitals that initially expressed interest in the project, six completed the HYDROmorphone assessment, and results showed substantial room for improvement as the average response was less than 50% of the achievable score for each category. Five hospitals completed a project evaluation survey at the end of the three-month period to assess their progress and to describe any barriers encountered. Of these hospitals, all had implemented at least one of the recommended actions, with provision of a standard-volume chart for withdrawal of doses of HYDROmorphone from a 2mg/mL vial (Action 2) and implementation of weekly audits of narcotic stock for removal of high-dose HYDROmorphone from patient care areas (Action 4) being the two recommendations most frequently undertaken. Based on these selections, the preference of the hospitals was to implement recommendations that could be done easily and were completely within the control of the pharmacy department.

Participating hospitals found the exercise useful, reporting that they now had a baseline for their future improvement efforts and had identified priority areas for action (ISMP Canada, 2013h). The results of the study formed the basis of the most downloaded safety bulletin between January 2012 and February 2014 (see Section 4.3.1).

4.2.3 Medication safety products and tools

In addition to the ISMP Canada safety products and tools developed as part of opioid-specific projects discussed above, there are also many ISMP Canada safety products and tools designed to help health care facilities and practitioners handle any type of medication incident rather than specifically tailored to address one type of medication. One example described in Table 7 is the use of the RCA to determine the causes of a fatal opioid medication incident and develop safety recommendations.

Another example is the Failure Mode and Effects Analysis (FMEA), which is "a team-based systematic and proactive approach for identifying the ways that a process or design can fail, why it might fail, the effects of that failure, and how it can be made safer" (Nickerson, Jenkins, & Greenall, 2008). Working with experts in the area of human factors engineering (HFE), ISMP Canada developed the *Canadian Failure Mode and Effects Analysis Framework*, which can be applied to all health care processes. In 2006, the FMEA was used to analyze medication safety issues in Nova Scotia. The analysis accomplished what it intended, but also resulted in unexpected improvements to the delivery of narcotics.

Table 10: FMEA in action – Annapolis Valley Health, 2006

In 2006 Annapolis Valley Health, along with another district health authority in Nova Scotia, engaged ISMP Canada to provide training and support for a facilitated FMEA for two health care processes associated with significant risks for patient safety: the management of in-patient medication orders (known as the transcription process) and ongoing concerns over the at- or near-capacity status of the emergency department (known as Code Purple).

The FMEA exercise uncovered numerous potential failure modes, which highlighted multiple areas for improvement. An unexpected benefit of the exercise was that while nursing and pharmacy staff discussed the medication process issues, they discovered a simple change in timing could improve the delivery of narcotics (Nickerson et al., 2008).

As noted earlier, MSSA tools are intended to help Canadian health care facilities build their awareness of safe medication systems, while also providing a tool for quality improvement and evaluation (ISMP Canada, n.d.-d). ISMP Canada offers four versions of the MSSA tools designed for specific health care settings: hospitals, long-term care, pharmacy and ambulatory care, and complex continuing care and rehabilitation. These MSSAs, unlike the HYDROmorphone MSSA discussed above, do not focus on opioids but do cover protocols, system checks, and other processes related to high-alert drugs, which would include opioids.

4.2.4 Conclusion

ISMP Canada's research and reporting produced between 2002 and 2014 revealed opioids as the largest category of drugs causing error-related patient death or harm, with HYDROmorphone being the most common opioid associated with these incidents (ISMP Canada, 2006c, 2013a; Koczmara & Hyland, 2004). The factors that frequently contributed to these opioid-related incidents include the following:

- **Wrong drug errors:** including mix-up of HYDROmorphone and morphine (ISMP Canada, 2003c, 2004a, 2004e, 2006b, 2010b)
- **Wrong dose errors**: including tenfold errors from using 10 mg/mL concentration and too-high starting doses (Colquhoun et al., 2006; ISMP Canada, 2006b, 2007b, pp. 2–3, 2010b, 2011, n.d.-c; Wright, 2010)
- **Availability of high-concentration opioids in wards** (Colquhoun et al., 2006; ISMP Canada, 2005a, 2007b, pp. 2–3; Wright, 2010)
- **Administered to person who should not receive the drug** (ISMP Canada, 2007b, pp. 2–3, 2008, 2010b)
- **Storage and labelling issues:** including look-alike and sound-alike packaging (ISMP Canada, 2004a, p. 1, 2004e; Shultz et al., 2007a)
- **Lack of independent double checks** (Gosbee, 2004; ISMP Canada, 2002a, 2005a, 2005b; U, 2003)
- **Errors with PCA pumps** (ISMP Canada, 2004c, 2006b; Shultz et al., 2007a)
- **Failure of monitoring for signs of overdose or toxicity** (ISMP Canada, 2006b, n.d.-c)

ISMP Canada's work also stressed the need for safety strategies to employ HFE principles, which anticipates that individuals will make errors, and therefore designs systems that reduce over-reliance in areas of human limitations, such as memory. ISMP Canada's project work has frequently proposed HFE-based strategies in their recommendations to improve the safety of opioid medication safety. These recommendations can be grouped into nine categories.[4]

[4] For a more complete collection of ISMP Canada's recommendations 2002–2014 see Appendix D.

Summary of ISMP Canada recommendations related to opioids

Limit availability: this includes limiting the accessibility of HYDROmorphone by reducing stock or eliminating floor stock, and avoiding stocking morphine and HYDROmorphone in the same strengths (ISMP Canada, 2004a).

Packaging: this includes using TALLman letters for look-alike and sound-alike (LASA) names (ISMP Canada, 2003a), keeping different opioid formulations separate (ISMP Canada, 2004a), using auxiliary labels when high-potency preparations are dispensed (ISMP Canada, 2002b), and ensuring long-acting opioids are labelled as such (ISMP Canada, 2003c).

Double checks: independent double checks be used for high alert drugs, especially those administered by infusion pumps (ISMP Canada, 2004c).

Standardization: this includes standardized prescribing and terminology (ISMP Canada, 2006b), restricting admixing narcotic solutions outside the pharmacy (ISMP Canada, 2005a), and limiting the choice of floor stock narcotics (ISMP Canada, 2002b).

Prescribing: this includes using pre-printed order forms, avoiding abbreviations (ISMP Canada, 2003a), discouraging the use of verbal orders, except in emergency situations, where orderer should repeat back the entire order to the prescriber (ISMP Canada, 2002b).

Monitoring: this includes assessing, monitoring, and documenting use of opioids and implementing guidelines or standardized forms, and includes clear criteria for identifying and treating toxicity (ISMP Canada, 2006b).

Educate: staff needs to be educated about the use of potent narcotics, differences between LASA opioids (ISMP Canada, 2004a), system-based causes of medication errors, and the hierarchy of effectiveness in error reduction strategies (ISMP Canada, 2005a). Staff should also be provided with clear instructions and a safety checklist on infusion pumps (ISMP Canada, 2004c).

Inform: the patient and family should be consulted about the risks and benefits when prescribing an opioid, and all involved should be able to clearly read the prescription (ISMP Canada, 2002a, 2005a).

Technology: facilities should implement bar coding and electronic order entry systems with built in checks to prescribing, selection, and administration (ISMP Canada, 2002b; Koczmara & Hyland, 2004). Automated dispensing cabinets can be used to provide automatic narcotic counts, alerts, and relevant drug/dose information (Koczmara & Hyland, 2004). Furthermore, facilities should conduct a risk assessment process when implementing new technology to integrate safeguards previously in practice (ISMP Canada, 2008).

4.3 Dissemination of ISMP Canada's work related to opioids

Dissemination, uptake, and use of learning are critical components of the knowledge translation cycle (Straus et al., 2009). This section primarily focuses on the dissemination of ISMP Canada's work related to opioids as data on uptake and use tend to be based more on anecdotal evidence. The strongest evidence of uptake and use comes from ISMP Canada's influence on standards of practice, which will be discussed below.

4.3.1 Dissemination of products

The primary product used by ISMP Canada to deliver medication safety analyses, information, and safety recommendations is its safety bulletin.[5] ISMP Canada disseminates its safety bulletins to a distribution list that has grown from 5,868 in 2010 to 11,463 in 2012 (PRA Inc., 2013; PRA Inc, 2010). According to ISMP Canada, the distribution list now has about 18,000 contacts. Safety bulletins are sent as email attachments to all the addresses on ISMP Canada's distribution list, so as a result each bulletin is sent to thousands of health care professionals and other stakeholders. Unfortunately, information on the downloading of the bulletins from the website is limited to the last few years. Consequently, the data are incomplete in that they do not include the initial interest for the bulletins initially distributed prior to 2012. This is important, as Table 11**Error! Reference**

[5] Safety bulletins are published approximately 10 to 13 times each year.

source not found. demonstrates that, for bulletins published in 2012–13, the interest in bulletins is highest in the year of publication. However, the data on downloads show the enduring interest in safety bulletins that contain content related to opioids. For example, the 2006 bulletin on the Top 10 Drugs Reported as Causing Harm through Medication Error was the third most downloaded bulletin related to opioids in 2013. In addition, the 2006 Shared Learning — Reported Incidents Involving HYDROmorphone was downloaded almost 143 times in 2013, eight years after its publication. Of the recent bulletins, the most downloaded are: the 2013 Safeguards for HYDROmorphone — Results of a Targeted Demonstration Project (the sixth most-downloaded bulletin in 2013) and the 2012 Opioid-Related Incident Long-Term Care Home (the fifth most-downloaded bulletin in 2012). Overall, ISMP Canada's safety bulletins that have content related to opioids have been downloaded 43,083 times in 2012–14.

Table 11: Number of downloads of ISMP Canada safety bulletins with content related to opioids, 2012–14

	2012 (Jul–Dec)	2013	2014 (Jan–Feb)	Total
2002 Narcotic Safeguards – The Challenge Continues	310	560	33	903
2002 Codeine Syrup – Dangerous 'Near miss' in the Community	223	394	20	637
2003 Methadone: Not your typical narcotic	457	880	82	1,419
2003 Safeguard against errors with long-acting oral narcotics	272	483	33	788
2004 Morphine Ampoule Look-Alike Packaging ALERT	270	498	53	821
2004 An Omnipresent risk of Morphine-HYDROmorphone mix-ups	284	529	35	848
2004 High Alert Drugs and Infusion Pumps: Extra Precautions Required	543	823	56	1,422
2004 Meperidine (Demerol): Issues in medication safety	1,144	1,587	159	2,890
2005 Lowering the Risk of medication errors – Independent Double Checks	833	1,634	107	2,574
2006 Top 10 Drugs Reported as Causing Harm through Medication Error	1,438	1,703	114	3,255
2006 Shared Learning – Reported Incidents Involving HYDROmorphone	888	964	44	1,896
2006 Transdermal Fentanyl: A Misunderstood Dosage Form	397	876	50	1,323
2007 Fentanyl Patch Linked to Another Death in Canada	757	754	55	1,566
2008 HYDROmorphone Intended for an Adult Patient Inadvertently Administered to an Infant	263	532	41	836
2009 Analysis of International Findings From Incidents Involving Fentanyl Transdermal	327	684	46	1,057
2009 National Collaborative – Top 5 Drugs Reported as Causing Harm through medication safety in Paediatrics	667	1,119	88	1,874
2010 Medication Incidents Occurring in Long-Term Care	415	822	62	1,299
2012 Identifying Knowledge Deficits – HYDROmorphone	2,616	1,211	53	3,880
2012 Opioid-Related Incident Long-Term Care Home	2,009	1,289	90	3,388
2012 Recall of Morphine 2 mg/mL (1 mL Ampoules) and Medication Safety Strategies in a Drug Shortage Situation	692	708	47	1,447
2013 Deaths Associated with Medication Incidents: Learning from Collaborative Work with Provincial Offices of the Chief Coroner and Chief Medical Examiner	n/a	3,698	172	3,870
2013 Safeguards for HYDROmorphone – Results of a Targeted Demonstration Project	n/a	2,696	236	2,932
2014 Deaths Associated with Medication Incidents Occurring Outside Regulated Healthcare Facilities	n/a	n/a	2,158	2,158
Total	**14,805**	**24,444**	**3,834**	**43,083**

Source: (ISMP Canada, 2014d)

While safety bulletins are ISMP Canada's main mechanism for delivering the results of its incident analyses, it is interesting to note that, based on available data, ISMP Canada's single-most-downloaded product related to opioids since 2011 is the 2004 HYDROmorphone/Morphine RCA Report 2004, which was downloaded a total of 20,607 times since 2011 (April–December) (see Table 12). Not all RCA reports are made publicly available, as this is dependent on the willingness of the facility conducting the RCA to release the report. The openness of the facility involved in the 2004 incident to having its RCA available online continues to benefit the health care system, as demonstrated by the sustained interest in the 2004 report. The 2012 HYDROmorphone Knowledge Assessment Survey Report has also received a high level of interest, with over 14,000 downloads.

Table 12: Number of downloads of other ISMP Canada products and tools related to opioids, 2011–14

	2011 (Apr–Dec)	2012	2013	2014 (Jan–Feb)	Total
HYDROmorphone-specific reports					
HYDROmorphone / Morphine RCA Report 2004	2,582	10,815	6,255	955	20,607
2012 HYDROmorphone Knowledge Assessment Survey Report	N/A	6,870	5,795	1,394	14,059
Ontario					
2005 Priority Recommendations from the Ontario Hospital Narcotic (Opioid) Collaborative Project	189	453	714	41	1,397
Ontario Critical Incident Learning					
Designing Effective Recommendations	N/A	N/A	1,095	206	1,301
HYDROmorphone remains a high-alert drug	N/A	N/A	1,727	307	2,034
Paediatrics					
Paediatrics Opioid Consensus Guidelines	N/A	384	575	63	1,022
Phase I Report	N/A	101	97	17	215
Phase II Report	N/A	1,542	2,051	356	3,949
Phase II Report Appendices	N/A	1,638	1,188	170	2,996
Paediatric Opioid Safety Resource Kit	N/A	n/a	187	76	263
SafeMediationUse.ca					
Informed Consumers Can Help Prevent Harm from Opioid Use!	N/A				
Opioid Resources for Practitioners and Consumers					
Information for Patients and Families about Opioid Pain Medicines	N/A	N/A	1,334	239	1573
Consumer video on opioid safety: English (with and without subtitles)	N/A	N/A	N/A	384	384
Consumer video on opioid safety: French (with and without subtitles)	N/A	N/A	N/A	69	69
Other reports					
2013 Ontario Hospital Critical Incidents Related to Medications or IV Fluids Analysis Report	n/a	n/a	1672	684	2,356
Implementing System Safety Guards to Prevent Error-Induced Injury with Opioids (Narcotics), (Article)	314	465	432	44	1,255
2006 ISMP Canada Independent Double Check Usability Test Report (Report)	286	478	440	103	1,307

Source: (ISMP Canada, 2014d)

As noted earlier, MSSAs are tools for health care facilities to assess their medication safety practices. Data are available on the use of three of the MSSAs: the Hospital MSSA and the Long-Term Care MSSA that address high-alert drugs generally and the HYDROmorphone MSSA. Uptake for the Hospital and HYDROmorphone MSSAs programs is limited.

- From 2007 to 2014, the Hospital MSSA was completed and results submitted 132 times by 100 hospitals in six provinces, although Ontario hospitals accounted for the vast majority of the MSSAs completed (77). Interest in the MSSA appears to have dropped after 2007.

- Between 2007 and February 2014, 366 facilities have completed the Long-Term Care MSSA a total of 1377 times. As with the Hospital MSSA, Ontario facilities are the majority of those completing the Long-Term Care MSSA.

- The HYDROmorphone MSSA was made available in 2013. Uptake for this MSSA has been minimal, with only seven facilities completing it (i.e., submission of results into the program). Of those, six are in Ontario and one is in Prince Edward Island.

Table 13: MSSA uptake (number of facilities submitting results)

	2007	2008	2009	2010	2011	2012	2013	2014 (Jan–Feb)	Total
Hospital MSSA									
British Columbia	2		1						3
Saskatchewan	5	1		1	2				9
Manitoba	5								5
Ontario	35	14	4	5	7	9	2	1	77
Quebec			1		1				2
Nova Scotia	4								4
Total	**51**	**15**	**6**	**6**	**10**	**9**	**2**	**1**	**100**
Long-Term Care MSSA									
British Columbia	26	37		1			1		65
Alberta		26			1	151			178
Saskatchewan							1		1
Manitoba	3		7			8			18
Ontario	3	81	16	4	57	69	87	49	366
Total	**32**	**144**	**23**	**5**	**58**	**228**	**89**	**49**	**628**
HYDROmorphone MSSA									
Ontario	N/A	N/A	N/A	N/A	N/A	N/A	5	1	6
Prince Edward Island	N/A	N/A	N/A	N/A	N/A	N/A	1		1
Total							**6**	**1**	**7**

Source: (ISMP Canada, 2014d)
Note: If a facility has submitted an MSSA in more than one year, only the most recent year of submission is reflected in the table.

Other ways that ISMP Canada disseminates the results of its work are by publishing in external journals and by hosting webinars and conferences. In terms of publications, between 2002 and 2012, ISMP Canada published over 20 articles and position statements related to opioid incidents. These articles appeared in journals, such as *Hospital News, Canada Journal of Hospital Pharmacy, Dynamics* (official journal of the Canadian Association of Critical Care Nurses), *Healthcare Quarterly*, and *Pharmacy Connection.* A complete listing of ISMP Canada's publications is found in Appendix E.

Another method for disseminating its work is through educational opportunities presented by conducting workshops and webinars. ISMP Canada hosted a workshop related to opioids with the Ontario Hospital Association, which, as described in Section 4.2.2, helped lead to the Ontario MSSS Narcotics Project. Since then, ISMP Canada has relied primarily on webinars as a cost-effective method of providing information on its work related to opioids. In the last four years, ISMP hosted seven webinars (one in English and French) and had over 1,200 lines connected to the sessions. Actual attendance figures, however, were likely higher, since multiple people could participate on each line.

Table 14: Number of lines / attendance of ISMP Canada Education Webinars and Conferences

	Lines / Attendance
OHA/ISMP Canada Workshop: Medication Safety Support Service – High Alert Drugs Narcotics (opioids) Project 2005 (conference)	150
2005 Total	**150**
Opioid Safety in Paediatrics National Consensus Guidelines for Opioid Medication Delivery in Paediatrics 2011 (webinar)	23
Tenfold Medication Errors: The elephant in the paediatric hospital 2011 (webinar)	23
2011 Total	**46**
HYDROmorphone Discovering What We Don't Know 2012 (webinar)	480
HYDROmorphone: Discovering What We Don't Know 2012 (webinar FR)	62
2012 Total	**542**
Hospital related deaths - The Role of the Coroner's Office in Enhancing Patient Safety 2013 (Webinar)	103
Medication Safety Learning from Ontario Coroners' Cases – Focus on Opioids 2013 (webinar)	114
Protecting the living: How death investigations contribute to safe medication use 2013 (webinar)	8
A Year in Review: Critical Medication/IV Fluid Incident Reporting Through NSIR 2013 (webcast)	96
2013 Total	**321**
Managing Medication Standards and ROPs" High Alert Medications and Opioids 2014 (webinar)	170
Identifying Knowledge Deficits Related to HYDROmorphone 2014 (webinar)	202
2014 Total	**372**
2005–14 Total	**1,431**

Source: (ISMP Canada, 2014d)

4.3.2 Awareness of ISMP Canada's activities

While ISMP Canada's activities since 2002 demonstrate that it has a sustained agenda related to raising awareness of the potential medication safety issues related to opioids and its dissemination efforts show interest in many of its products and publications, the facility staff survey and interviews with key informants show a lack of awareness of several key ISMP Canada products and tools. As Table 15 shows, about one-fifth of facility respondents were very aware of ISMP Canada's safety bulletins on HYDROmorphone and opioids and its priority recommendations related to narcotics for hospitals. More than half of those surveyed were not at all aware of the HYDROmorphone Knowledge Assessment Survey, the Hospital MSSA, the Ontario Critical Incident Learning bulletins, and opioid safety tools for paediatrics. Because of the small sample size of the survey, these results should be treated with caution. However, the results are somewhat consistent with the findings of other surveys with stakeholders, where awareness of ISMP Canada products and tools were highest for safety bulletins and dropped off for other products (PRA Inc., 2013; PRA Inc, 2010).

Key informants provided some insights into possible reasons for the low level of awareness. They noted that knowledge of ISMP Canada and its products, tools, and services are highest for pharmacists (of which, the survey only had four respondents) and risk or safety managers (of

which, the survey had three respondents). Key informants also reported that managers working in these areas would review bulletins to determine if there were recommendations or suggestions that should be applied to their facilities' processes. Consequently, ISMP Canada's information may be filtered through managers to frontline staff. The advice and medication safety solutions may, therefore, be used within facilities without staff having an awareness of the influence or use of the actual ISMP Canada recommendations, safety solutions, or products. That being said, a potential benefit of staff having direct awareness of ISMP Canada's work is that it could lead to increased understanding of the value of reporting mediation incidents, which in turn could encourage frontline staff to use the IPR to report incidents.

Table 15: How would you rate your level of awareness of ISMP Canada's work related to opioids and HYDROmorphone? (n=62)

	Not at all aware	→	→	→	Very aware	Don't know
Safety bulletins on HYDROmorphone and opioids	42%	8%	7%	16%	21%	7%
Making Hospitals Safer: Priority recommendations for narcotics	36%	15%	11%	16%	18%	5%
Paediatric Opioid Safety Resource Kit	57%	7%	5%	10%	8%	15%
Paediatric Opioid Consensus Guidelines	58%	8%	2%	10%	8%	15%
2012 HYDROmorphone Knowledge Assessment Survey Report	55%	11%	5%	7%	11%	11%
Acute Care/Hospital MSSA	50%	8%	7%	10%	19%	7%
Ontario Critical Incident Learning Bulletin	53%	10%	5%	13%	15%	5%

Source: Survey of facility staff
Caution: Small sample size.

4.3.3 Influence on standards

As noted above, the best example of uptake is when ISMP Canada recommendations and medication safety products and tools influence professional standards. Accreditation standards require compliance, so ISMP Canada's influence has system-wide effects when its medication safety recommendations and strategies are incorporated into these standards.

A major example of this influence involves Accreditation Canada. This professional health care regulatory association works with health care organizations to help them improve quality, safety, and efficiency. Accreditation Canada develops Required Organizational Practices (ROPs) that define a practice that facilities are expected to implement in order to maintain their accreditation. Each ROP is accompanied by Tests for Compliance (major and minor), which set out expected practices that surveyors assess on-site to determine compliance with the ROP. In its handbook, Accreditation Canada defines major tests for compliance as having "an immediate impact on safety, while minor tests for compliance support longer-term safety culture and quality improvement activities and may require additional time to be fully developed and/or evaluated" (Accreditation Canada, 2014, p. 1).

ISMP Canada served on Accreditation Canada's standards working group when it revised its standards in 2013. The result of that work was Accreditation Canada's *Required Organizational Practices* handbook for 2014, which included two topics that relate to ISMP Canada's work on opioids: High-Alert Medications and Narcotics (Accreditation Canada, 2014, pp. 41–2, 45–7). The handbook also directs facilities to refer to ISMP Canada materials in optimizing the safe use

of opioid products. For example, "Organizations serving paediatric populations are encouraged to implement recommendations from the Canadian Association of Paediatric Health Centres and the ISMP Canada Paediatric Opioid Safety Resource Kit, including the use of standardized concentrations for opioid infusions" (Accreditation Canada, 2014, p. 46).

High-Alert Medications

Accreditation Canada's ROPs related to high-alert medications align closely with ISMP Canada's recommendations for the handling of high-alert medications. Accreditation Canada requires that the organization have a policy for the management of high-alert medications. ISMP Canada has provided many recommendations that altogether constitute policy for the management of high-alert medications. Moreover ISMP Canada has recommended that each facility evaluate the precautions that it requires for high-alert medications. The following, more specific tests for compliance which Accreditation Canada requires incorporate many of ISMP Canada's recommendations for the handling of high-alert medications.

Table 16: Alignment of ISMP Canada recommendations with Accreditation Canada ROPs related to high alert medications

	Accreditation Canada ROP Tests for compliance	ISMP Canada recommendation
Major	The organization has a policy for the management of high-alert medications.	Evaluate the precautions required for high-alert medications that are commonly used (ISMP Canada, 2012c)
Minor	The policy names the individual(s) responsible for implementing and monitoring the policy.	n/a
Major	The policy includes a list of high-alert medications identified by the organization.	n/a
Major	The policy includes procedures for storage, prescribing, preparation, administration, dispensing, and documentation for each high-alert medication, as appropriate.	Limit the storage of high-potency narcotic preparations to the pharmacy, and review storage areas (ISMP Canada, 2002b) Standardize prescribing and terminology (ISMP Canada, 2006b) Development of institution-wide dosing and monitoring guidelines (ISMP Canada, 2014a) Careful review of how products are arranged on shelves to avoid similar packaging or sound-alike medications being side by side (ISMP Canada, 2003a) Require an independent double check for high-alert drugs, especially those administered by infusion pumps (ISMP Canada, 2004c)
Major	The organization limits and standardizes concentrations and volume options available for high-alert medications.	Limit access — reduce stock amounts of HYDROmorphone or eliminate floor stock (ISMP Canada, 2004a) Reduce the dosage and volume options for a medication, i.e., default dose/volume/rate for specified dose ranges (ISMP Canada, 2003a)
Minor	The organization regularly audits client service areas for high-alert medications.	Limit access — reduce stock amounts of HYDROmorphone or eliminate floor stock (ISMP Canada, 2004a)
Minor	The organization establishes a mechanism to update the policy on an ongoing basis.	n/a
Major	The organization provides information and ongoing training to staff on the management of high-alert medications.	Educate staff — provide safety information on the use of potent narcotics and the differences between HYDROmorphone and morphine (ISMP Canada, 2004a)

Source: (Accreditation Canada, 2014, pp. 41–2)

Narcotics Safety

Accreditation Canada's ROPs for narcotics safety likewise align closely with ISMP Canada recommendations. Key informants note that the development of these ROPs was informed by ISMP Canada's previous work on opioids.

Table 17: Alignment of ISMP Canada recommendations with Accreditation Canada ROPs related to narcotics (opioids)

	Accreditation Canada ROP Tests for compliance	ISMP Canada recommendation
Major	The organization has completed an audit of narcotic (opioid) storage areas. The audit includes a review of products and quantities stored and identification and removal of unnecessary products.	Assess risk associated with narcotic stock in patient care areas (ISMP Canada, 2005a) Limit the storage of high-potency narcotic preparations to the pharmacy, and review storage areas (ISMP Canada, 2002b)
Major	The organization has removed the following products (exceptions include palliative care): HYDROmorphone ampoules or vials with concentration greater than 2 mg/ml; and morphine ampoules or vials with concentration greater than 15 mg/ml.	Remove the following stock items from patient care areas: – HYDROmorphone ampoules or vials with concentration greater than 2 mg/mL (exceptions may include palliative care) – Morphine ampoules or vials with concentration greater than 15 mg/mL (ISMP Canada, 2005a)
Major	The organization standardizes and limits the number of parenteral narcotic (opioid) concentrations available.	Standardize infusion concentrations of parenteral narcotic medications and selection of medications for pain management (ISMP Canada, 2005a)

Source: (Accreditation Canada, 2014, p. 45)

4.3.4 Examples of uptake

In addition to ISMP Canada recommendations informing the latest set of Accreditation Canada ROPs on high-alert drugs and narcotics, there are a number of more specific documented examples where ISMP Canada's activities have influenced the decisions of health care facilities and organizations. For example, a 2002 roundtable discussion at the Canadian Society of Hospital Pharmacists Professional Practice Conference adopted recommendations influenced by ISMP Canada materials (ISMP Canada, 2002b). In 2004, ISMP Canada's safety bulletin on two errors caused by administration of higher-than-intended doses of morphine (due to look-alike packaging) helped influence the manufacturer to redesign their packaging to better differentiate between its 10 mg/ml and 2 mg/mL products (ISMP Canada, 2004e).

Other examples previously noted in Section 4.2.2, include the results of the follow-up survey to the Ontario MSSS Narcotics project, which showed statistically significant improvements in compliance with key safety strategies (e.g., reductions in the availability of high-potency narcotics [opioids] in patient care area stock; statistically significant increases in the percentage of respondents documenting independent double checks for opioid medication and dosage; and statistically significant increases in the utilization of error-reduction strategies for epidural infusions) (Colquhoun et al., 2006). The use of a follow-up survey helped close the knowledge translation cycle by showing the uptake of the knowledge and the changes in practice. In addition, the Alberta Medication Safety Collaborative Opioids project reported some system-wide outcomes, including improving safety of PCA systems and epidural narcotics, as well as narcotic storage in patient care areas, including differentiating look-alike/sound-alike products (Wright, 2010).

More recently, Sunnybrook Health Sciences Centre in Toronto has developed an Opioid Task Force informed by ISMP Canada's research and recommendations on opioids, including the HYDROmorphone Knowledge Assessment Survey (Sunnybrook Health Sciences Centre, 2013). For instance, the Task Force prepared an education campaign titled "Less is Morphine" to educate people that HYDROmorphone is five times more potent than morphine. This was placed on Sunnynet, incorporated into e-learning, spread through ambient marketing, and presented at Health Achieve 2012. Since the implementation of the Task Force (Fiscal Year 2011–12), the frequency of opioid incidents of moderate and critical harm has markedly decreased. From October 2010 to September 2011 there were five major or critical events reported involving opioid analgesics. From October 2011 to September 2012, there were no major/critical events documented (Sunnybrook Health Sciences Centre, 2013, p. 11).

Key informants from health care facilities commented that their organizations use ISMP Canada's products, tools, and publications. In particular, managers and directors review safety bulletins to determine if their processes align with recommendations. Bulletins focusing on specific incidents help raise awareness of the potential risks and demonstrate how "it could happen anywhere." Key informants acknowledged the difficulty in determining uptake and implementation of safety strategies even within a facility. Some key informants noted that facilities and the health care system typically do not have the tools/processes or the resources (i.e., staff time) to assess the use and efficacy of safe medication practices. Barriers are considered to exist at both the system and facility-level and include, in addition to resource constraints, continued hesitance to share experiences and learning from medication incidents.

4.4 Expansion of role

Until the last year, ISMP Canada's focus was on medication errors, and its work did not consider the issues of prescription drug misuse and abuse. The harms associated with the misuse and abuse of certain prescription drugs, including opioids, have become a leading public health and safety concern in Canada. These harms are well-documented and include personal harms (e.g., addiction, withdrawal, injuries due to accidents, overdoses, and suicide) and economic costs. The prevalence of this problem is rising. Ontario experienced an almost 250% increase in emergency room visits related to the use of narcotics between 2005–06 and 2010–11. Similarly, deaths related to opioids almost tripled from 168 in 2002 to 494 in 2010 (National Advisory Council on Prescription Drug Misuse, 2013, p. 24).

Considering the significant problems associated with the misuse and abuse of prescription drugs, ISMP Canada has begun working in this area in partnership with other stakeholders in the field, such as the Canadian Centre for Substance Abuse (CCSA). This expansion of ISMP Canada's role draws on its expertise in analyzing medication events from multiple sources as well as its work with consumers.

National Strategy for Prescription Misuse / Opioid Stewardship

CCSA has taken the lead on a national strategy to respond to prescription drug misuse and abuse. The National Advisory Council on Prescription Drug Misuse was formed in response to this growing problem. The Council developed a national strategy, First Do No Harm: Responding to Canada's Prescription Drug Crisis, to address the harms associated with prescription drugs, while

giving consideration to their therapeutic uses (National Advisory Council on Prescription Drug Misuse, 2013).

The Strategy presents 58 short- and long-term recommendations around five streams of action:

- Prevention
- Education
- Treatment
- Monitoring
- Surveillance (National Advisory Council on Prescription Drug Misuse, 2013, p. 1)

ISMP Canada is named as a proposed co-lead for five recommendations. These recommendations align with ISMP Canada's past work on product packaging and labelling, its work with consumers, and its experience gained through CMIRPS of building an approach to studying medication incident information compiled from various sources including the databases of Coroners and Medical Examiners, the multiple national systems of reporting, and Ontario's Critical Incident Reporting System (ISMP Canada, 2014e). The five recommendations are the following:

- "Review existing evidence and/or conduct objective and independent research on the effectiveness of tamper-resistant and abuse-deterrent technology and packaging and make recommendations as needed to reduce the harms associated with prescription drugs and pediatric exposure" (National Advisory Council on Prescription Drug Misuse, 2013, p. 30).

- "Develop and promote guidelines for individuals and families related to the use, safe storage and disposal of prescription medications. Guidelines should include family assessment, community medication disposal resources and strategies to address barriers to safe storage (e.g., locked boxes) and disposal" (National Advisory Council on Prescription Drug Misuse, 2013, p. 31).

- "Review existing patient brochures, product labels and inserts (including prescriber indications), auxiliary labels, and recommendations for specialist consultation and patient education. Revisions as needed should seek to standardize language, promote comprehension and prevent or reduce the harms associated with prescription drugs (e.g., operating a motor vehicle while using prescription medications, caution when combined with other medications or alcohol)" (National Advisory Council on Prescription Drug Misuse, 2013, p. 31).

- "Develop and promote the use of evidence-informed culturally appropriate individual, family and community resources to assess, prevent, reduce the harms associated with, and provide access to appropriate treatment for prescription drug problems, as well as adjunct therapies" (National Advisory Council on Prescription Drug Misuse, 2013, p. 41).

- "Standardize the key elements of a Canadian prescription drug surveillance system, such as:

    a. Data holders;
    b. Data streams (e.g., coroner reports, poison centre records, IMS Health data, losses and thefts data, post-market surveillance related to adverse events data, medication incidents);
    c. Definitions and common terminology;

d. Indicators (explore potential linkages with other projects such as the National Treatment Indicators, Drug and Alcohol Network of Surveillance Experts, Canadian Tobacco, Alcohol and Drugs Survey and existing provincial surveillance systems);
e. Collection methods;
f. Reporting;
g. Links with data systems for alcohol and other drugs, as well as risk factors and sentinel surveillance for local planning" (National Advisory Council on Prescription Drug Misuse, 2013, p. 44).

ISMP Canada has also provided its expert opinion to the House of Commons Standing Committee on Health, which has undertaken a study on 'The Role of Health Care Practitioners in the Prevention and Treatment of Prescription Drug Misuse, Abuse and Dependence," ISMP Canada presented to this Standing Committee on November 27, 2013 (ISMP Canada, Hamilton, & Ma, 2013).

ISMP Canada offered three strategies for reducing prescription drug misuse, abuse, and dependence.

- Improvements in prescribing skills in pain management and opioids. A coordinated effort needs to be undertaken by medical schools, regulatory bodies, professional organizations, and expert panels to enhance prescribing skills and develop expertise in pain management.

- Defining opioid dependence or abuse as an adverse event or medication error and enhancing associated surveillance and analysis systems. Opioid addiction resulting from the escalated use of prescribed drugs should be treated as an adverse drug reaction or preventable event and reported as such through adverse drug reaction reporting mechanisms.

- Recruiting patients and caregivers as both active monitors and active interveners in opioid use. Patients and families need to be an active part of the opioid use process: aware of the signs and symptoms of overdose, and also the risk factors and indicators of dependence and addiction. All parties in the process must have a plan, the resources, and the support to intervene when they detect and recognize alarming signs or behaviours.

It was suggested that ISMP Canada is well-situated to expand its role by addressing a critical gap in Canada related to post-market surveillance of opioids (i.e., monitoring, evaluating, managing risk) (Health Canada, n.d.). ISMP Canada's involvement in initiatives like First Do No Harm was seen as an opportunity to increase awareness of the organization and expand its partnerships to health care stakeholders that are not directly involved in providing patient care but work in areas related to prescription drugs.

5.0 2011 HYDROmorphone incident

Section 4.0 provides an overview of ISMP Canada's work related to opioids and, more specifically, HYDROmorphone. This section provides a case study of a HYDROmorphone incident in a hospital and the facility's response, including the involvement of ISMP Canada. The case study demonstrates how HYDROmorphone medication errors continue to occur despite well-documented learning on how to reduce the risk of these incidents, but also how openness of a facility can effect safety improvements, and what role ISMP Canada can play.

The incident: In October 2011 a fatal HYDROmorphone incident occurred in an Ontario hospital. The incident involved a 10-fold dosing error, whereby 4 mg of HYDROmorphone was administered instead of the prescribed 0.4 mg. The dose was drawn from a high-concentration vial of HYDROmorphone, which was not part of floor stock but had been borrowed from patient-specific stock.

After the fatal overdose, the facility conducted a full internal review of the incident. The incident was also reported to the OCCO through the Critical Incident Program and was referred by the investigating coroner to the PSRC on which ISMP Canada sits.

5.1 Medication safety culture

A patient safety culture depends on limiting the tendency to assess individual blame for adverse events, focusing on a systems approach to address the circumstances that lead to the event, and facilitating transparency and learning from adverse events and near misses (Emanuel et al., 2008). The existence of this culture is important to encourage reporting of medication incidents and sharing learning from those incidents. The case study results indicate that the facility has the potential to improve its fostering of a supportive, non-blaming culture.

When asked about the culture or attitude of the facility with respect to mediation incidents, both the survey respondents and key informants were divided, although their responses were more positive than negative. Interviewees noted improvement in the facility's medication safety culture in the last several years as attitudes are more open, supportive, and non-judgemental when errors occur. However, the level of openness was considered to be dependent on the unit within the facility as well as the category of staff. For example, it was noted that frontline staff in some units remain concerned that incident reports will be used punitively.

Table 18: How would you describe the facility's culture or attitude with respect to medication incidents? (n=62)

Very blaming	→	→	→	**Very supportive**
11%	10%	37%	24%	18%
Mostly reactive				**Mostly preventative**
16%	13%	39%	16%	16%

Source: Survey of facility staff
Caution: Small sample size.

Very few survey respondents who were employed at the facility at the time of the 2011 HYDROmorphone incident considered the facility's response to that incident to be blaming or damaging. Interestingly, more than half could not assess the response because they were not aware of the incident and/or how the facility managed it. This result may indicate a missed opportunity to further develop a culture of openness and remove the fear of retribution not only by demonstrating the constructive, process-oriented approach to investigating incidents and developing safety solutions but by making the incident more widely known in the facility. That being said, the facility demonstrated an open culture by its willingness to involve the OCCO's PSRC and ISMP Canada despite pending litigation related to the incident. The facility also allowed its experience to be the subject of two Ontario Critical Incident Learning bulletins, as discussed in Section 5.4.

Table 19: How would you describe the facility's response to the 2011 HYDROmorphone incident? (n=44)

Very blaming	→	→	→	**Very supportive**	**Don't know**
--	2%	21%	11%	7%	59%
Very damaging				**Very constructive**	**Don't know**
--	7%	18%	14%	2%	59%

Source: Survey of facility staff
Caution: Small sample size.

5.2 Actions taken by facility and ISMP Canada influence

Following the October 2011 HYDROmorphone incident, the facility conducted a full internal review of the incident. While the facility focused its review on the unit involved in the incident, it also looked at relevant practices in other units. The review showed that even though the facility had a policy that high-concentration HYDROmorphone be kept separate, with patient labels and returned to the pharmacy when the patient was discharged, practice did not conform to the policy.

The facility had already developed recommendations for safety procedures as part of its internal review, which were shared with the PSRC and ISMP Canada (as a member of the PSRC). The PSRC also noted the following as possible contributing factors:

- Availability of high-concentration (10 mg/ml) HYDROmorphone in unit stock
- Failure to conduct an independent double check, despite there being a facility policy to do so
- Lack of knowledge or instruction on how to obtain an appropriately diluted 0.4 mg dose from the 10 mg concentrate prescribed in the patient's medical administration record (PSRC, 2012).

On the basis of the facility's own internal review and the recommendations of the PSRC, the facility developed strategies that were expected to reduce the likelihood of a recurrence of this error and to enhance the safety of other aspects of care (Hyland, 2014). The facility's Quality Coordinating Committee made 13 recommendations, which are summarized in the table below (PSRC, 2012, pp. 4–6).

As Table 20 shows, the facility's internal review produced recommendations which align with recommendations produced by ISMP Canada. In particular, the facility followed ISMP Canada's recommendation for immediate removal of HYDROmorphone in high concentration: the facility recommended that this be removed from the unit immediately, and that narcotic drawers be audited to remove these medications when they are not being used. The facility followed ISMP Canada's priority recommendation to implement a policy of independent double checks — it appears that the facility already had such a policy, but recommended that that the policy be reviewed. The facility also followed ISMP Canada's recommendation to employ technology through implementing electronic ordering, record-keeping, and automatic dispensing cabinets. The facility moved towards implementing warnings and patient labels as recommended by ISMP Canada.

Table 20: Alignment of facility's recommendations with ISMP Canada's recommendations for opioid medication use

Hospital's Recommendations	ISMP Canada's recommendations
High Leverage	
Forcing functions and constraints	
That the high concentration of HYDROmorphone be removed from the unit immediately as there currently is no patient requiring this medication in this patient care area.	**Limit availability** Responds directly to ISMP Canada's recommendation to reduce stock amounts of HYDROmorphone or eliminate floor stock, and to the 2005 priority recommendation to remove HYDROmorphone ampoules or vials with concentration greater than 2 mg/mL
That the pharmacy explore mechanisms to physically separate morphine from HYDROmorphine.	**Limit availability; Packaging** Responds to the recommendation to avoid stocking morphine and HYDROmorphone together; to reduce look-alike potential, and to segregate and differentiate opioid formulations.
Automation/computerization	
That the computerized electronic medication record (CMAR) is implemented.	**Technology** Responds to the recommendation to implement electronic medication administration records.
Finalize time frame for roll out of ADCs and consider prioritization of placement of cabinets in areas that administer high-concentration narcotics.	**Technology** Responds to the recommendation to use ADCs.
Mid Leverage	
Reminders, checklists, double checks	
That additional warning is highlighted on the CMAR with regard to high-risk medications.	**Technology** Responds to the recommendation to use electronic order entry with system checks.
That the medication administration safety committee explores other means of adding patient labels to high-risk medications that are available in multiple concentrations.	**Packaging** Responds to the recommendation to add auxiliary labels when high potency preparations are dispensed, and to use visible coloured auxiliary warning labels.
That professional practice and medication administration safety committee review the current policy on independent double checks.	**Double checks** Responds to the recommendation to require an independent double check for high-alert drugs.
That pharmacy routinely audit narcotic drawers in patient care areas to remove high-risk medications that are not being used, grant pharmacy technician access to medication narcotic drawers.	**Limit availability** Responds to the recommendation to reduce stock amounts of HYDROmorphone and eliminate floor stock.

Table 20: Alignment of facility's recommendations with ISMP Canada's recommendations for opioid medication use	
Hospital's Recommendations	**ISMP Canada's recommendations**
Low Leverage	
Rules & Policies	
That pharmacy reviews the current practice of "borrowing" medications between patient care areas.	**Limit availability** Responds indirectly to the recommendation to reduce stock amounts of HYDROmorphone and eliminate floor stock.
Education & Information	
The nurse involved is to complete medication administration module through the College of Nurses of Ontario and reflective practice. The nurse manager and chief practice officer to follow up with regard to any additional actions.	**Education** Responds to the recommendation to educate staff, but only for the nurse involved. ISMP Canada recommends training for all staff because knowledge deficits are likely not limited to one individual.
That emotional support is offered to the staff.	n/a
That this incident be used in safety huddles within complex continuing care to discuss high-risk drugs and mitigating strategies.	**Education** Responds to the recommendation to educate staff on the use of potent narcotics; the system-based causes of error; and the hierarchy of effectiveness for error-reduction strategies. However, only done on an *ad hoc* basis, not a comprehensive strategy.
That risk management ensures that for any critical incident resulting in death the coroner has been notified.	n/a
Sources: For facility recommendations (PSRC, 2012). The sources for ISMP Canada recommendations are in Appendix D.	

ISMP Canada continued to communicate with the facility in 2013. For instance, the facility asked ISMP Canada if they have any resources or literature that they could share with physicians in order to promote dialogue and change prescribing and ordering practices, since HYDROmorphone was routinely ordered for surgical patients. ISMP Canada sent to the facility a the HYDROmorphone Knowledge Assessment Survey, an Emergency Department study that noted frequent desaturations in patients who were given 2 mg IV HYDROmorphone for pain, and a bulletin on HYDROmorphone from a US physician's organization (ISMP Canada, 2012a, 2012b; Chang, Bijur, Napolitano, Lupow, & Gallagher, 2009; Marcus, 2009). ISMP Canada suggested that the facility pick out elements of the Knowledge Assessment Survey as a learning tool for physicians and also provided grand rounds with physicians that covered the risks associated with HYDROmorphone.

Key informants who were aware of ISMP Canada's involvement commented that these supports were very helpful and well-received. ISMP Canada was seen as providing an "external pair of eyes with a different perspective" and having an awareness of the "bigger picture" given their awareness of what other organizations have done to address similar incidents. Key informants said they would not hesitate to contact ISMP Canada again for assistance should their facility experience another medication incident. The only suggestions for improvement were for ISMP Canada to expand its consultation practice, so it could provide direct assistance to more facilities experiencing medication errors.

Frontline staff were less aware of ISMP Canada's involvement. Only 10% (n=9) of survey respondents who were employed at the time of the incident were aware of ISMP Canada's involvement. Of those, four indicated that ISMP Canada's involvement had a positive effect on their level of confidence that an appropriate safety solution would be found. The other two respondents reported no effect.

5.3 Success in adopting safety strategies

Of the 44 staff who were employed at the facility at the time of the incident, 36% (n=16) believe that the method of managing HYDROmorphone and other opioids at the facility has improved since the incident. The majority could not assess whether there was an improvement (57%, or n=25) and the remaining (7%, or n=3) believe there has been no improvement. The respondents indicated the following safety measures have led to the improvements in managing HYDROmorphone and other opioids:

- increased awareness of dangers and safety measures (n=7)
- use of separate cart/drawer/location for HYDROmorphone (n=6)
- removal of high-concentration HYDROmorphone and other high-risk medications from patient care areas (n=2)
- use of high-alert flags/labelling (n=2)
- availability of patient-specific doses for high-concentration HYDROmorphone (n=2)
- separation of HYDROmorphone from morphine (n=1)

Of the 62 staff who completed the survey, few indicated that any safety strategies listed in the survey were not in use, but anywhere from 24% to 83% did not know if a particular safety strategy was in use. Given the small response to the survey, the results should not be considered representative of the facility staff. That being said, the results may indicate a low level of awareness of safety strategies employed for HYDROmorphone. Similarly, staff who indicated that a safety strategy was in use generally thought the facility had been successful in implementing the strategy with few indicating actual lack of success. Interestingly, strategies involving education tended to be seen as less successfully implemented.

Table 21: Implementation and success of safety strategies
Q13: Which of the following safety strategies for HYDROmorphone and other opioids are currently used at the facility?
Q14: On a scale of 1-5 with 5 being very successful, how successful has the facility been in implementing these strategies?

Strategies	Yes, in use (n=62)	Very successful/successful*	
		#	%
Use of patient selection criteria for PCA	45%	14	50%
Removal from floor stock of HYDROmorphone ampoules or vials with a concentration greater than 2 mg/mL	48%	27	90%
Removal from floor stock of morphine ampoules or vials with a concentration greater than 15 mg/mL	45%	25	89%
Removal from floor stock of morphine ampoules or vials with a concentration greater than 2 mg/mL in paediatric patient care areas	15%	8	89%
Removal from floor stock of sufentanil	11%	7	100%
Pharmacists conduct a risk assessment for each narcotic storage area with regular follow up to check for unapproved items in floor stock	24%	9	60%
Standardization of opioid infusion solutions/concentrations	45%	23	82%
Standardization of products approved for pain management	44%	20	74%
Restrictions on mixing narcotic solutions outside of the pharmacy	32%	16	80%
Routine use of independent double checks before medication	61%	23	61%

Table 21: Implementation and success of safety strategies
Q13: Which of the following safety strategies for HYDROmorphone and other opioids are currently used at the facility?
Q14: On a scale of 1-5 with 5 being very successful, how successful has the facility been in implementing these strategies?

Strategies	Yes, in use	Very successful/successful*	
administration			
Use of drug access mechanisms that reduce the need to borrow medications from other patients or other care areas	47%	20	69%
Availability of a standard chart for typical facility doses of HYDROmorphone with instructions for proper preparation of low doses	18%	7	64%
Repackaging of injectable HYDROmorphone into low-dose syringes or patient-specific doses	8%	5	100%
Education of staff regarding system-based causes of medication error involving opioids	44%	14	52%
Education of staff regarding the hierarchy of effectiveness of error-reduction strategies for opioids	36%	9	41%
Inclusion of the patient/family in the narcotic medication-use process	21%	11	85%
Routine use of two independent identifiers when identifying patients	61%	26	68%
Routine use of standardized pain control protocols or order sets	52%	24	75%
Availability and use of education tools about opioid use designed for patient/family	23%	7	50%

Source: Survey of facility staff.
* N varies based on number who respond yes to Q13.
Caution: Small sample size.

Survey respondents appear to believe that the facility has successfully implemented a number of safety practices related to HYDROmorphone, However, despite the best intentions to improve opioid medication safety, the facility experienced at least one near-miss incident and one harmful overdose involving high concentrate HYDROmorphone after the 2011 incident (ISMP Canada, 2013b). The facility had initially responded to the 2011 incident with policy and rule changes, but the experience of subsequent errors with the same medication revealed that these changes, implemented in isolation, were not providing the necessary improvement to patient safety. Follow-up investigation found that unused containers for discharged patients were not being removed and doses of high-concentration HYDROmorphone were being borrowed for use in other areas of the facility; two key safety strategies recommended after the 2011 incident.

Consequently, ISMP Canada recommended higher-leverage, system-based strategies, especially forcing functions and constraints (ISMP Canada, 2013b). In response to the continued incidents, the facility undertook enterprise-wide changes, including a going from biweekly to daily audits of high-concentration opioids to ensure staff could not borrow medication from patient stocks; installing automatic dispensing cabinets, implementing electronic medication records, and changes in medication management and delivery systems (ISMP Canada, 2013b).

Key informants who could comment pointed to several challenges or barriers to making changes. In particular, they mentioned financial constraints (e.g., for ADCs, physician order entry), technological barriers (e.g., IT structure does not support bar coding), human resource limitations (e.g., for independent double checks), and clinical inertia. For the latter, some key informants believed changes controlled by pharmacy were more consistently followed than those which required changes in clinical practice (e.g., physician practice in prescribing HYDROmorphone). Key informants emphasized that when safety strategies rely on changing people's behaviour,

they are more susceptible to inconsistent or incomplete implementation than when they are "hard-wired" into systems and processes, which echoes the underlying message to ISMP Canada's systems approach to addressing medication safety issues. In addition, as a lesson learned, key informants noted that facilities should beware of assuming that when a new system or process is put in place that the potential for error has been addressed, and they must continue to be vigilant to identify the potential for workarounds that circumvent the process.

Another challenge is measuring the effectiveness of the medication safety strategies — both in terms of having the resources available to audit compliance but also to incorporate a definition of success when designing the recommendations and build in a mechanism to measure it. ISMP Canada has begun developing performance measures for some safety strategies, such as medication reconciliation, but this was seen as an area in which ISMP Canada could do more.

5.4 Use of learning from the 2011 HYDROmorphone incident

The PSRC committee produced a series of recommendations arising out of the incident (PSRC, 2012, pp. 6–7). Those related specifically to the facility are discussed above (see Section 5.2). In addition to the recommendations for the facility, the PSRC in collaboration with ISMP Canada used the learning from the incident to offer system-wide recommendations directed at key professional associations and other stakeholders (see Table 22).

Table 22: PSRC recommendations to other stakeholders related to learning from the 2011 HYDROmorphone incident

Stakeholders directed at	Recommendation
Ontario Hospital Association Ontario College of Pharmacists Ontario Branch of Canadian Society of Hospital Pharmacists Ontario Long-Term Care Association Ontario Association of Long-Term Care Physicians	Consider pharmacy preparation of small doses of HYDROmorphone in the absence of a commercially available product.
	Provide a readily available standard dilution chart for usual doses of HYDROmorphone using the standard concentration available (usually 2 mg/mL).
	Consider the use of morphine as the drug of first choice in patients with low opioid needs and no contraindications.
	Review prescribing practices related to the use of dangerous abbreviations and dose designations. Refer to ISMP Canada's Do Not Use list available at: http://www.ismp-canada.org/download/ISMP CanadaanadaListOfDangerousAbbreviations.pdf.
	Review prescribing practices related to range dosing.
	Consider implementation of standardized palliative care admission orders.
	For Palliative Care areas in which higher concentration preparations of HYDROmorphone may be necessary, mechanisms must be in place to maintain a physical separation from lower-concentration preparations, and ideally to limit access to these preparations to prevent inadvertent administration.
	Consider using ISMP Canada's HYDROmorphone Knowledge Assessment Survey as a tool for education. It is available at http://www.ismp-canada.org/education/webinars/20120209_HYDROmorphone/Answers.pdf.
	Periodic checks / audits should be conducted to ensure compliance with existing policies, such as independent double checks.

Table 22: PSRC recommendations to other stakeholders related to learning from the 2011 HYDROmorphone incident

Stakeholders directed at	Recommendation
Canadian manufacturers of HYDROmorphone (Sandoz Canada and Hospira Canada) The Pharmaceutical Manufacturers Association of Canada	Lower-concentration preparations of HYDROmorphone should be produced, including prefilled syringes (0.5 mg/mL and 1 mg/mL) such as are being marketed in other jurisdictions.
OCCO	For future incidents investigated by coroners, encourage documentation of how the incident was discovered as this can provide valuable insight into system-based strategies to decrease risk and mitigate harm.

Source: (PSRC, 2012, pp. 6–7)

ISMP Canada has been involved in disseminating information related to the incident, including the PSRC recommendations. ISMP Canada published an Ontario Critical Incident Learning (CIL) bulletin about the medication incident (ISMP Canada, 2013c). Drawing on these learnings, the bulletin issued the following "call to action" for hospitals:

- "remove HYDROmorphone vials containing a total dose greater than 2 mg from floor stock (see Accreditation Canada ROPs and ISMP Canada recommendations [*Priority recommendations for Ontario hospital narcotic (opioid) project*, 2005]) and frequently audit compliance with this policy;
- if high-concentration HYDROmorphone must be dispensed for a specific patient, create a mechanism for the prompt and secure return to the pharmacy of unused doses;
- develop drug access mechanisms designed to reduce the need to borrow medications from other patients or other care areas;
- design a standard chart for typical facility doses of HYDROmorphone with instructions for proper preparation of low doses;
- require independent double checks before administration of high-alert medications;
- consider having pharmacy repackage injectable HYDROmorphone into low-dose syringes or patient-specific doses" (ISMP Canada, 2013c).

The bulletin received substantial interest as it has been downloaded 2,034 times between February 2013 and February 2014.

ISMP Canada published a second CIL bulletin sharing learnings from the facility's response to the medication error and to its subsequent incidents with HYDROmorphone (ISMP Canada, 2013b). The previous research had shown that organizations often responded to errors with policy and rule changes which, without higher-leverage strategies, are unlikely to provide meaningful benefit to patient safety over the long term. The bulletin highlighted this need and shared how this facility had implemented high-leverage, system-based strategies to introduce forcing functions and constraints, so that a large dosage error could not occur again because high-concentration HYDROmorphone would not be available (ISMP Canada, 2013b). This bulletin has been downloaded just over 1,300 times between April 2013 and February 2014.

The incident also informed subsequent ISMP Canada project work. In particular, the HYDROmorphone MSSA addressed the need for frequent auditing of HYDROmorphone to ensure the drug is not located in floor stock in patient care areas unless it is patient-specific (i.e., appropriately labelled and segregated). This self-assessment criterion reflected the learning gained from the facility's experience in needing to increase its audits from biweekly to daily. The Targeted Demonstration Project also used learning from the incident by recommending weekly audits as well as preparation by the hospital pharmacy of smaller doses (less than 1 mg) in prefilled syringes.

Key informants (ISMP Canada and facility) reported several best practices that they learned from the experience of working with the facility and that informed their later work:

- the effectiveness of system-based improvements over lower-leverage improvements, such as education and policies, which rely more on an individual health care practitioner's recollection and implementation of the safety approach
- the critical importance of sharing medication incidents, which was facilitated by the openness of the facility
- the usefulness of in person contact with the facility, particularly through a site visit, which was not done in the 2011 HYDROmorphone incident but was suggested as a future best practice by some key informants who noted that obtaining more background information through observation of the work would be helpful

The OCCO also made recommendations of further work for ISMP Canada to undertake. In the final review report for the incident that was distributed in advance of a PSRC meeting on February 21, 2014, the Office recommended:

- "ISMP Canada should identify medications which may be fatal if administered via intravenous (IV) push, and make recommendations to manufacturers and pharmacies regarding labelling or other markings to minimize the likelihood that such medicatiosn will be administered by IV push in error" (PSRC, 2014).

ISMP Canada is working to address this recommendation.

An aggregate analysis of incidents, including the 2011 HYDROmorphone incident was completed (ISMP Canada, 2013g). This report has been downloaded 2,356 times between May 2013 and February 2014.

In addition, the Ontario PSRC has made a preliminary proposal to collaborate with ISMP Canada on a study HYDROmorphone deaths as a focused review on causes of incidents and strategies to prevent recurrence (Greenall, 2014; ISMP Canada, Greenall, & Hamilton, 2013). This is a collaborative project with four provincial Offices of the Chief Coroner or Chief Medical Examiner. The 2011 incident has factored into discussion related to this new project, which is only recently underway and demonstrates the continued interest and effort in addressing medication errors related to HYDROmorphone.

6.0 Possible future priority areas for ISMP Canada on opioid medication safety

Part of this study included asking stakeholders about what should be the focus of future ISMP Canada work, related to medication safety generally as well as opioids more specifically.

When asked what are the top five medication safety issues that need to be addressed going forward, key informants most frequently mentioned opioids and, to a lesser extent, other high alert medications (specifically anticoagulants and insulin).[6] For opioids, key informants acknowledged improvements primarily through increased awareness of the issues related to opioids (better understanding of need for opioids and risks), but at the same time, they pointed to uninformed prescribing practices (i.e., over-dosing and under-dosing) and lack of knowledge about safe administration as a major threat. As one key informant stated, "The improvements and threats related to opioids are the same."

Several key informants stressed the importance of messaging and ensuring the right balance between concerns with opioid use and the need for opioids to treat chronic and severe pain. For these reasons, a few key informants suggested ISMP Canada be involved in opioid stewardship, similar to anti-microbial stewardship's focus on appropriate use but with an interest in reducing anti-microbial resistance.

Packaging and labeling continue to be considered a major threat to opioid safety. Several key informants suggested that ISMP Canada continue to work with manufactures and on single dose vials. Storage of high concentration narcotics in floor stock remains a threat to safety as well. As the above discussion shows, key informants continue to identify areas where ISMP Canada has made recommendations. Several key informants noted that ISMP Canada needs to "continue doing what it is doing."

After opioids and other high alert medications, key informants most often identified medication reconciliation and the risks involved in patient transitions between health care settings as areas on which ISMP Canada should continue to focus. As with opioids, there was recognition that ISMP Canada has done extensive work in this area, but key informants emphasized that organizations still required substantial support in order to develop and implement medication reconciliation processes.

The challenges and potential benefits of technological solutions were also identified by several key informants. Two solutions received the most comment – computerized order entry and bar-coding. The increased use of technology for medication management was considered to have benefits in terms of providing innovative approaches, but the benefits were accompanied by the risk of alert fatigue. It was suggested that ISMP Canada could study the quantity and type of alerts that are optimal.

[6] Very few survey respondents answered this question. The most-cited medication safety issues were each identified by four individuals: narcotics, packaging (look-alike, sound alike), unclear physician orders, and administration errors (wrong patient, wrong medication)..

Other areas were mentioned by two or three key informants. They included:

- managing polypharmacy issues (use of multiple medicines by one patient)
- managing anticoagulants and venous thromboembolism
- encouraging incident reporting
- becoming more involved in post-market surveillance activities and filling knowledge deficits related to medications approved for the Canadian market
- acting as a knowledge broker
- increasing involvement in public and patient education about pharmaceuticals and their risks
- increasing efforts directed at educating health professionals about issues related to prescribing practices and use of medication administration tools, such as infusion pumps
- continuing to emphasize the efficacy of the systems approach to safety.

7.0 Conclusions

ISMP Canada, through its role in analyzing data collected through CMIRPS, has produced the most comprehensive information available at a national level of the drugs most likely to cause harm. Over a twelve-year period (2002–14), ISMP Canada has continued to bring attention to medication incidents involving opioids, particularly HYDROmorphone, as CMIRPS data, in addition to Coroner's data from Ontario show that these drugs are one of the medications most commonly involved in mediation incidents, including those associated with death.

In response to opioids' status as a high alert medication, ISMP Canada has devoted sustained and multi-faceted efforts directed at opioid safety that began in 2002 and continues today. A review of both its project work and its analysis of incidents reflects a consistency in its safety recommendations — the solutions focus on a systems approach to addressing opioid safety issues and tackle weaknesses in the system that repeatedly lead to medication errors such as incorrect drug, dose, and/or method of administration.

The study found evidence that ISMP Canada's opioid work builds on its previous research and projects. This is evidence from its early work in Ontario informed later project work in Alberta on opioids safety. The 2011 HYDROmorphone incident that is the subject of this case study demonstrated this as well as the learning from this incident was reflected in the HYDROmorphone MSSA subsequently developed by ISMP Canada. Strategic partnerships with other health care system stakeholders are also critical to ISMP Canada's work. Working with Accreditation Canada and influencing content of its ROPs has meant that institutions will be required to follow some key ISMP Canada recommendations related to high alert medications (including opioids) as part of their accreditation.

Systematic evidence on dissemination is available, but not on uptake and use which is much more difficult and resource-intensive to track. ISMP Canada evidence of downloading of its products and publications as well as participation at its webinars shows interest in its work on opioids. The increase in offering webinars in recent years is an important method of expanding the access to its work. The one noted weakness was uptake of MSSAs. As these are important proactive methods of reducing the risk of medication errors, promoting these tools could be an area of focus. A noted strength is the continued interest in the 2004 RCA report. This shows the importance and utility of institution-specific examples of medication incident causes and responses.

The experience working with the facility in the 2011 HYDROmorphone incident provides an example of the various issues involved in medication incidents, the response to them, and the role and reputation of ISMP Canada. The openness to involvement of the PSRC and ISMP Canada by a facility that had experienced a fatal medication incident and was faced potential litigation is notable. At the same time, a medication safety culture of openness, while experienced by managers in the facility was less apparent to frontline staff. This dichotomy in a facility's understanding of medication safety culture is probably not unique to this facility but offers an opportunity for improvement.

The facility's initial recommendations for addressing the opioid medication error aligned with many of ISMP Canada's recommendations over the previous years reflecting what ISMP Canada has learned through its incident analyses — that solutions may be clear but their implementation is difficult, which is evidenced by the reoccurrence of these causes of opioid errors. While the facility

worked to address all of the recommendations, its experience also shows the difficulty in making system changes as workarounds occurred that caused risky medication practices to persist. The work with the facility also demonstrated how both ISMP Canada and the facility benefit from these interactions — facility representatives appreciated the independent, expert role of ISMP Canada and ISMP Canada learned more about the implementation pitfalls that facilities experience, which informed its later opioid work, particularly the HYDROmorphone MSSA.

An opportunity for improvement that has been identified in past evaluations of ISMP Canada too was raised again by stakeholders in this evaluation — awareness of ISMP Canada's work is limited to certain health care professionals and settings, particularly hospital pharmacists, risk/safety managers, and directors. Frontline staff are less aware. The importance of this lack of awareness of frontline staff of the source of safety improvements is debatable, as key informants emphasized that at the managerial levels within facilities ISMP Canada recommendations are reviewed and acted upon. The more limited knowledge of types of health care professionals, such as physicians, may be more important, particularly in the areas of opioids safety solutions as some are directed at prescribing practices that may lead the over- or under-use of opioids.

In general, the case study found that stakeholders place great value on the role of ISMP Canada in analyzing medication incident data and developing safety solutions. Stakeholders who are aware of its work through its products, tools, and services as well as representatives of the facility that experienced a medication safety incident with HYDROmorphone emphasize the expertise and objectivity that ISMP Canada brings to its study of medication errors. It is that outside, independent perspective that is grounded in the practical knowledge of how the health care environment works that gives ISMP Canada recommendations special weight with health care organizations and professionals.

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Appendix A — Research Matrix

Matrix for case study on opioid medication incident			
Research questions	**Indicators**	**Data sources**	**Responsibility**
Context			
1. What is the risk of opioid medication incidents (e.g., level, nature)?	• Number of opioid medication incidents reported by year, type, and severity (2007–13) • Opioid incidents as a percentage of total reported medication incidents by year (2007–13)	• CMIRPS data (NSIR, Community Pharmacy, IPR, and Consumer) • Data from Coroners Project	
2. Do stakeholders consider opioid medication incidents a priority area for ISMP Canada?	• Identified priority areas	• Interviews with facility representatives • Interviews with external stakeholders • Interviews with ISMP Canada	
3. Is ISMP Canada seen as a credible source of analysis, safety information and strategies?	• Stakeholder opinion on credibility of ISMP Canada • Number and percentage of Info@ requests related to opioids (2007-2013) • Number of hits/downloads of opioid-related products	• Interviews with facility representatives • Interviews with external stakeholders • Info@ • Web metrics	
4. What are the alternatives to ISMP Canada for medication incident analysis and medication safety information and strategies?	• Stakeholder opinion of alternatives	• Interviews with facility representatives • Interviews with external stakeholders	
How has earlier ISMP Canada work (2002 –11) informed how ISMP Canada could assist a facility in follow-up to an incident?			
5. What earlier project work (2002–11) has informed ISMP Canada's products and materials on opioid safety?	• Projects related to opioid safety • Bulletins related to opioids • Presentations related to opioids • Publications related to opioids • Products related to opioids (e.g., acute care MSSA)	ISMP Canada documentation including: • Ontario and CMIRPS bulletins • Ontario presentations • Draft work with Patient Safety Review Committee • Consumer publications • Presentations using Coroner's project data • Interviews with ISMP Canada	
6. What is the level of awareness of ISMP Canada's work related to opioids?	• Stakeholder awareness • Awareness of ISMP Canada's work by various key positions	• Interviews with external stakeholders • Interviews with facility representatives	
7. What was ISMP Canada's involvement with facilities that experienced opioid medication incidents between 2002 and 2011?	• Number of facilities assisted by ISMP Canada • Type and severity of opioid mediation incidents with which ISMP Canada assisted • Nature of ISMP Canada assistance • Learnings used in later opioid-related products	• ISMP Canada documentation • Interviews with ISMP Canada	
8. What has been the spread of ISMP Canada products related to opioids between 2002 and 2011?	• Number of bulletin downloads by location (P/T) and by year • Number of participants at presentations by location (P/T) and by year • Number of acute care MSSA completed by location (P/T) by location (P/T) and by year • Number of downloads of the opioid patient handout by location (P/T) and by year	• IT Statistics/Web metrics • ISMP Canada documentation (education sources, presentations)	

Matrix for case study on opioid medication incident			
Research questions	**Indicators**	**Data sources**	**Responsibility**
9. How have ISMP Canada's recommendations, products and educational materials related to opioids been used by external stakeholders?	• Role in informing policy (input into policy groups) • Use by health care facilities to inform practice • Other uses by external stakeholders	• Patient Safety Review Committee reports • Accreditation Canada (e.g., Required Organizational Practices) • Standing Committee on Health • Policy documents of other organizations • Interviews with external stakeholders • Interviews with ISMP Canada	
How has a facility managed a HYDROmorphone incident, and how have changes been directly or indirectly influenced by ISMP Canada's work related to HYDROmorphone and opioids?			
10. To what extent were the actions taken by the facility informed by ISMP Canada's work on opioids?	• Stakeholder opinion • Evidence of use of ISMP Canada recommendations in facility documentation	• Interviews with facility representatives • Facility documentation • Interviews with ISMP Canada	
11. How realistic and implementable are ISMP Canada's safety strategies related to opioids given resources and infrastructure constraints?	Stakeholder opinion on: • Successfully implemented recommendations • Unsuccessfully implemented recommendations • Barriers and enablers • Uptake of recommendations	• Interviews with facility representatives • Interviews with external stakeholders	
12. How effective is ISMP Canada in assisting facilities that have experienced a medication error?	• Stakeholder opinion on benefits of ISMP Canada involvement in investigative and analytic process • Stakeholder opinion on effectiveness of ISMP Canada assistance and recommendations • Improvements in safety metrics	• Interviews with facility representatives • Interviews with external stakeholders	
13. What are the challenges or difficulties in evaluating the effectiveness or utility of the medication safety strategies undertaken?	• Stakeholder opinion on challenges in evaluating effectiveness • Unanticipated problems with strategies	• Interviews with facility representatives • Interviews with ISMP Canada	
14. What factors are necessary to spread and sustain knowledge gained through medication incidents?	• Stakeholder opinion on factors (e.g., engaging hard to reach groups such as physicians)	• Interviews with facility representatives • Interviews with external stakeholders • Interviews with ISMP Canada	
Theme 3: How has ISMP Canada used the learnings from the HYDROmorphone incident in its other work, including in its collaborations with other partners? (2012–14)			
15. What ISMP Canada project work (2012-2014) has benefited from the learnings from the HYRDOmorphone incident?	• Projects related to opioid safety • Bulletins related to opioids • Presentations related to opioids • Publications related to opioids • HYRDOmorphone MSSA	ISMP Canada documentation including: • Ontario and CMIRPS bulletins • Ontario presentations • Draft work with PSRC • Consumer publications • Presentations using Coroner's project data • Interviews with ISMP Canada	

Matrix for case study on opioid medication incident			
Research questions	**Indicators**	**Data sources**	**Responsibility**
16. What are the benefits to the facility and the broader healthcare system from ISMP Canada's direct involvement with facilities that have experienced a medication incident?	• Examples of types of information shared • Spread of products that incorporate additional learnings • Use and assessment of products by other external stakeholders • Stakeholder opinion on benefits and barriers to sharing information	• IT Statistics/Web metrics • Available documentation of examples of information sharing and use and assessment of products (e.g., feedback from pilot hospitals on HYDROmorphone MSSA) • Interviews with facility representatives • Interviews with external stakeholders • Interviews with ISMP Canada	
17. What is ISMP Canada's role in knowledge diffusion to the broader health care system?	• Efforts undertaken by ISMP Canada related to diffusing knowledge • Feedback from stakeholders on ISMP Canada's role • Stakeholder opinion on how broader knowledge diffusion can occur/be encouraged	• Interviews with facility representatives • Interviews with external stakeholders • ISMP Canada documentation (e.g., quality initiatives, presentations)	
18. Do the efforts of ISMP Canada related to opioid safety align well with government or accreditation expectations about medication safety?	• Alignment of recommendations with accreditation requirements • Alignment of recommendations with provincial and national legislative directions • Stakeholder opinion	• Accreditation standards • Provincial and national legislation, directives, initiatives, and priorities • Interviews with facility representatives • Interviews with external stakeholders	
Theme 4: What are possible future priority areas that ISMP Canada should focus on in its work on opioids?			
19. What are areas of greatest improvement related to opioid safety?	• Trends in incident data • Stakeholder opinion on improvements	• CMIRPS data (NSIR, Community Pharmacy, IPR, and Consumer) • Data from Coroners Project • Interviews with facility representatives • Interviews with external stakeholders • Interviews with ISMP Canada	
20. What significant issues in opioid safety need to be addressed?	• Trends in incident data • Safety initiatives of external stakeholders related to opioids • Health care professional knowledge of opioid safety issues/practices • Stakeholder opinion on priority areas to address	• CMIRPS data (NSIR, Community Pharmacy, IPR, and Consumer) • Data from Coroners Project • Documentation on external stakeholders opioid safety initiatives (e.g., CCSA) • HYRDROmorphone Knowledge Assessment Survey • Interviews with facility representatives • Interviews with external stakeholders • Interviews with ISMP Canada • Survey on HYDROmorphone	

Appendix B — Data Collection Instruments

Institute for Safe Medication Practices Canada (ISMP Canada)
Case Study on Opioid Work
Interview Guide for Facility Representatives

ISMP Canada has hired PRA Inc., an independent research firm, to conduct a case study of its work related to opioids, more specifically HYDROmorphone. The case study focuses on the 2011 HYDROmorphone incident, which is described in the attached Ontario Critical Incident Learning Bulletins from February and April 2013.

The case study focuses on four questions:

- How has earlier ISMP Canada opioid-related work informed how ISMP Canada could assist facilities experiencing a medication safety incident?
- How has a facility managed a HYDROmorphone incident, and how have the changes been directly or indirectly influenced by ISMP Canada?
- How has the learning from the incident been used in other ISMP Canada work?
- What are possible future priority areas that ISMP Canada should focus on in its work on opioids?

The case study includes interviews with ISMP Canada staff, representatives of a facility with a critical HYDROmorphone incident, and stakeholders who are aware of ISMP Canada's work on opioids.

Context

1. How would you describe the culture or attitude in your facility with respect to medication incidents? Do you believe your organization experiences medication incidents at the same or different rate than other comparable facilities? How responsive is your facility to medication incidents?

2. What organizations does your facility rely upon for medication incident analysis and medication safety information and strategies? Please describe how your facility engages with each organization.

3. What is your general perception of ISMP Canada as a source of analysis, safety information, and strategies?

Opioid-related work conducted by ISMP Canada

4. Prior to this incident, what was the level of awareness of ISMP Canada's work related to opioids and, more specifically, HYDROmorphone? Does the level of awareness vary by type or position of health care professional? In your opinion, could ISMP Canada do anything to improve awareness among health care professionals of its work?

5. What safety strategies/products/policies related to opioids were in place at the facility prior to the incident? Were any of them informed by ISMP Canada's work? If so, which ones.

Response to the HYDROmorphone incident

6. What steps did the facility take to investigate and analyze the incident? What were the key findings?

7. How did the existence of the legal action and the involvement of the Coroner's office and the PSRC affect your facility's willingness or ability to engage and share information with ISMP Canada, if at all?

8. How did ISMP Canada directly assist the facility after the event? What were the benefits, if any, of ISMP Canada involvement?

9. What changes has the facility made since the adverse HYDROmorphone event? Please be as specific as possible.

10. In your opinion, to what extent were the changes made at your facility directly or indirectly influenced by ISMP Canada's work related to HYDROmorphone and opioids? Please be as specific as possible.

11. How successful has the facility been at implementing the changes? Was your facility unsuccessful in implementing any of ISMP Canada's recommendations/safety strategies? What have been the major barriers and enablers to change? To your knowledge, how were any barriers managed or enabling factors leveraged to achieve change?

12. To what extent did ISMP Canada's recommendations related to opioid safety align with legislative/regulatory requirements or accreditation expectations related to medication safety and management of opioids in your facility?

13. What do you consider to be the key lessons learned from your facility's experience?

14. In your opinion, have the changes had any early effects on the type or incidence of HYDROmorphone safety incidents in the facility?

15. What have been the main challenges or difficulties, if any, in evaluating the effectiveness or utility of the medication safety strategies undertaken by your facility after this incident?

16. How effective do you think the facility has been in spreading and sustaining the knowledge gained through this medication incident within its organization? Upon what evidence do you base your conclusion? What factors have facilitated or hindered knowledge diffusion and practice changes in your organization?

17. Based on your experience, what advice would you give other health care facilities that have experienced a serious medication safety incident in terms of how to respond and whether/how to seek outside assistance?

18. Would you contact ISMP Canada to request assistance or share learning should your facility experience another critical medication incident? Why or why not?

19. Based on your experience, do you have any suggestions for ISMP Canada on how it might improve or expand its work with facilities that have had a medication safety incident?

20. What do you think is needed to spread and sustain the learning from these kinds of medication incidents across the health care system? What role does/can ISMP Canada play?

Future priority areas

21. From your perspective, what are the top five medication safety issues that need to be addressed going forward?

22. In the past five years, what have been the greatest areas of improvement related to opioids in the Canadian health care system? What are the greatest gaps or threats to safe opioid use in the health care system?

23. Considering your responses to the above question, what do you think should be the future priority areas that ISMP Canada should focus on in its work on opioids?

Thank you for your participation.

Ontario CRITICAL Incident Learning

Improving quality in patient safety

HYDROmorphone remains a high-alert drug

Issue 2
February 2013

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy

Suggested action items:

- Refer bulletin to pharmacy and therapeutics committee for evaluation of pharmacy practices and for comment to the medical advisory committee
- Refer bulletin to nursing leadership committees for evaluation of nursing practices and for comment to senior administration
- Refer bulletin to quality/patient safety committees for evaluation of hospital practices
- Circulate bulletin to physicians and other front-line staff
- Use bulletin as an educational resource in your hospital safety huddles or rounds

The following report shares learning from a fatal HYDROmorphone incident that occurred in an Ontario hospital.

Background

- HYDROmorphone 0.2 to 0.4 mg subcutaneously every hour as needed for pain was prescribed for a patient.
- A 10-fold dosing error occurred, whereby HYDROmorphone 4 mg was administered instead of the 0.4 mg ordered.
- The dose had been drawn from a high-concentration (10 mg/mL) vial of HYDROmorphone.
- Although the facility did not maintain high-concentration HYDROmorphone as floor stock, it was not uncommon for nurses to borrow HYDROmorphone from patient-specific stock.
- The patient was found without vital signs shortly after administration of the HYDROmorphone.

Learning from Analysis

- Consistent with other reported HYDROmorphone administration errors, the availability of a high-concentration HYDROmorphone product played a significant role in the incident.[1]
- The practice of borrowing opioids from patient-specific stock, which sometimes occurred in this facility, may have introduced the risk of misidentifying the drug or the intended patient.
- An independent double-check,[2] which might have uncovered the error before administration, was not mandated by the facility's drug-administration procedures and was not performed in this case.

Call to Action for Hospitals

- Remove HYDROmorphone vials containing a total dose greater than 2 mg from floor stock, in accordance with Accreditation Canada's Required Organizational Practices[3] and ISMP Canada recommendations,[4] and audit compliance with this policy frequently.
- If high-concentration HYDROmorphone must be dispensed for a specific patient, create a mechanism for the prompt and secure return to the pharmacy of unused doses (e.g., after the patient is discharged or transferred to another care area).
- Develop drug access mechanisms specifically designed to reduce the need to borrow medications from other patients or other care areas.
- Design a standard chart for typical facility doses of HYDROmorphone with instructions for proper preparation of low doses.
- Require independent double checks before administration of high-alert medications.
- Consider having pharmacy repackage injectable HYDROmorphone into low-dose syringes or patient-specific doses.

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Ontario CRITICAL Incident Learning Issue 2, February 2013

Discussion

From October 1, 2011, to December 31, 2012, a total of 35 Ontario incidents involving HYDROmorphone were reported to the National System for Incident Reporting.[5,6] HYDROmorphone continues to be 1 of the top 3 medications involved in incidents associated with harm or death that are voluntarily reported to ISMP Canada.[7,8] Provincial ministries of health, Accreditation Canada, various offices of the chief coroner or medical examiner, and other organizations have supported initiatives such as removal of high-concentration HYDROmorphone from patient care areas, use of TALLman lettering, implementation of independent double checks, and development of commercial low-dose products by Canadian manufacturers.

In the case presented above, the availability of high-concentration HYDROmorphone in the patient care unit, the lack of a standardized independent double-check process, the practice of borrowing doses of medication from other units or from patient-specific stock, and frequent distractions in the work area were all identified as factors contributing to the error. In its report, the facility also identified other aspects of the medication-use process where improvements in medication safety could be realized, including segregation of morphine from HYDROmorphone in storage areas, increased automation and computerization, improvements in warnings on medication labels and medication administration records, routine audits of opioid storage areas, staff education, and policy review.

Conclusion

HYDROmorphone is a high-alert drug with substantial potential for harmful consequences if involved in medication incidents. ISMP Canada recommends high-leverage, system-focused safety strategies. In this case, removal of the high-concentration preparation of HYDROmorphone from the care unit would have made a 10-fold dosing error unlikely; in addition, a standardized, independent double-check procedure might have prevented the error from reaching the patient. The ideal scenario would be availability of a dosage form in the prescribed dose (e.g., as a prefilled syringe), prepared and administered with the support of an independent double-check process. Individual practitioners and administrators in Ontario healthcare facilities are encouraged to closely examine the processes for use of HYDROmorphone in their organizations and to take steps to improve patient safety.

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We gratefully acknowledge the review of this bulletin by the facility where the incident described took place.

[1] Report to the Attorney General – Public inquiry into the death of Lucy Lecavalier. Edmonton (AB): Alberta Justice and Solicitor General; 2012 [cited 2013 Jan 31]. Available from: http://justice.alberta.ca/programs_services/fatality/Publications_Sudden_death_investigation/Report-Lecavalier.aspx/DispForm.aspx?ID=150

[2] Lowering the risk of medication errors: independent double checks. ISMP Can Saf Bull. 2005 [cited 2013 Feb 25];5(1):1-2. Available from: https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2005-01.pdf

[3] Required organizational practices 2012. Ottawa (ON): Accreditation Canada; 2012 [cited 2013 Feb 4]. Available from: http://www.accreditation.ca/uploadedFiles/ROP%20Handbook.pdf

[4] Priority recommendations for Ontario hospital narcotic (opioid) project. Toronto (ON): Institute for Safe Medication Practices Canada; 2005 [cited 2013 Feb 4]. Available from: https://www.ismp-canada.org/download/Narcotic_Priority_Recommendations.pdf

[5] National System for Incident Reporting. Ottawa (ON): Canadian Institute for Health Information. Analysis generated on 2013 Jan 7.

[6] Minimum data set. In: National System for Incident Reporting. Ottawa (ON): Canadian Institute for Health Information; 2012.

[7] Top 10 drugs reported as causing harm through medication error. ISMP Can Saf Bull. 2006 [cited 2013 Feb 4];6(1):1-2. Available from: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2006-01Top10.pdf

[8] Shared learning – reported incidents involving hydromorphone. ISMP Can Saf Bull. 2006 [cited 2013 Feb 4];6(9):1-3. Available from: https://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2006-09Hydromorphone.pdf

Collaborating parties of the Ontario Critical Incident Reporting program

Canadian Institute for Health Information / Institut canadien d'information sur la santé — Ontario — Ontario Hospital Association — ISMP Canada

PRA

Improving quality in patient safety

Ontario CRITICAL Incident Learning

Issue 4
April 2013

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy

Suggested action items:

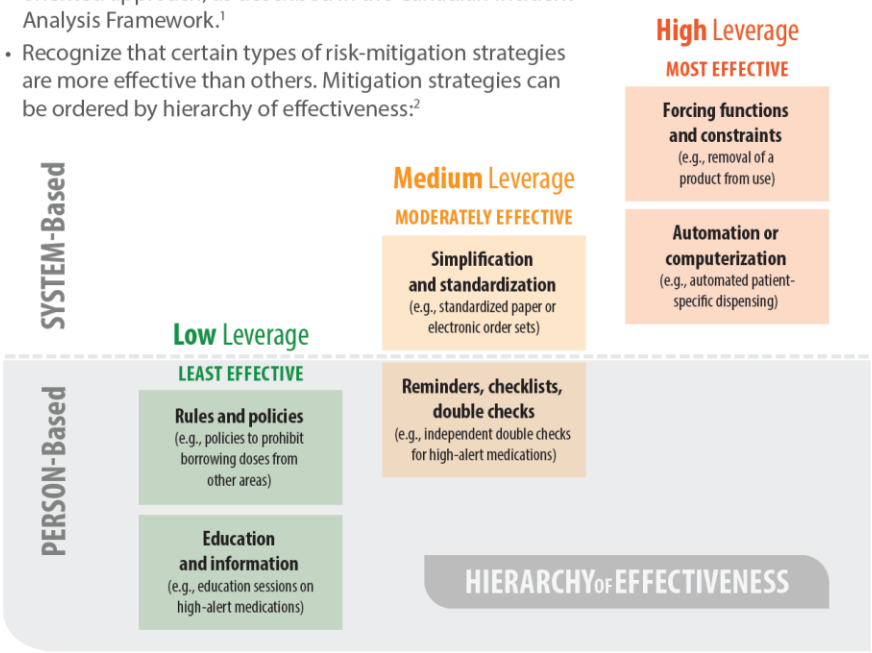
- Circulate bulletin to front-line staff and physicians
- Refer bulletin to quality and safety committees to encourage appraisal of effectiveness of hospital's recommendations and assessment of hospital's quality improvement initiatives
- Use bulletin as an educational resource in your hospital's safety huddles or rounds

Designing Effective Recommendations

The reporting, investigation, and analysis of medication incidents are important elements in improving patient safety, but these efforts must be accompanied by effective strategies to mitigate the contributing factors leading to the incidents.

Advice for Hospitals

- Review patient safety incidents using a systematic, team-oriented approach, as described in the Canadian Incident Analysis Framework.[1]
- Recognize that certain types of risk-mitigation strategies are more effective than others. Mitigation strategies can be ordered by hierarchy of effectiveness:[2]



- System-based recommendations have a higher likelihood of success because they do not rely on individual attention and vigilance.
- Appreciate that a small number of higher-leverage, more effective recommendations addressing the contributing factors determined from the incident analysis will be more likely to improve patient safety than a larger number of less effective strategies.
- Ensure that recommendations are specific, measurable, attainable, realistic, and timely (SMART).[3]
- Continuously monitor and assess the effectiveness of any recommendations arising from incident analyses.
- Provide feedback to staff about quality and safety improvement initiatives and achievements.

ISMP CANADA

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Ontario CRITICAL Incident Learning Issue 4, April 2013

Background

A hospitalized patient received a fatal overdose of an opioid prepared from a high-concentration product. The facility conducted a full internal review of the incident and developed a series of strategies that were expected to reduce the likelihood of recurrence of this error, as well as to enhance the safety of other aspects of care within the facility. The recommendations included providing staff education, changing medication policies, reducing availability of the particular product, improving the labelling and delivery of all high-concentration products, and reinforcing independent double-check practices. Despite these measures, the facility has since experienced one near-miss incident and one harmful overdose of the same product.

Learning from Analysis

Further analysis revealed that availability of the high-concentration product played a significant role in both of the subsequent errors, despite the institution's intent to develop and implement strategies specifically designed to address the identified contributing factors. For example, in areas where the product was still available, unused containers for discharged patients were being stored in drug carts until the next audit and collection opportunity. Doses of the high-concentration product were being borrowed for use in other areas of the facility, which led to opportunities for error. These actions reflected a desire for economy and efficiency on the part of staff members and were not performed out of carelessness or any intent to cause harm.

These findings emphasized that vulnerabilities in medication-use systems must be addressed with the most effective strategies that are reasonable and/or feasible to implement, given the particular circumstances. In this case, the facility ultimately opted to implement a *daily* audit of high-concentration opioids to ensure removal of items no longer required for admitted patients, effectively creating a high-leverage forcing function and constraint (i.e., the product would not be available for borrowing).

Organizations often respond to errors with policy and rule changes, but research and experience have clearly shown that such recommendations, implemented in isolation, are unlikely to provide any meaningful benefit to patient safety over the long term and that higher-leverage strategies are required. Hospital leaders are encouraged to analyze all recommendations proposed after review of a critical incident and to consider how effective they will be in preventing a future incident or mitigating harm from any incidents that do occur.

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We gratefully acknowledge the review of this bulletin by the facility where the incident described took place.

[1] Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework. Edmonton (AB): Canadian Patient Safety Institute; 2012. Incident Analysis Collaborating Parties are Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety Canada (a patient-led program of CPSI), Paula Beard, Carolyn E. Hoffman, and Micheline Ste-Marie. Available from: http://www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF

[2] Institute for Safe Medication Practices (ISMP). Medication error prevention "toolbox". ISMP Med Saf Alert. 1999 Jun; 4(11): 1-2.

[3] Doran GT. There's a S.M.A.R.T. way to write management objectives. Manag Rev. 1981;71(11,AMA Forum):35-36.

Collaborating parties of the Ontario Critical Incident Reporting program

Institute for Safe Medication Practices Canada (ISMP Canada)
Case Study on Opioid Work
Interview Guide for ISMP Canada

ISMP Canada has hired PRA Inc., an independent research firm, to conduct a case study of its work related to opioids, more specifically HYDROmorphone. The case study focuses on the 2011 HYDROmorphone incident, which is described in the attached Ontario Critical Incident Learning Bulletins from February and April 2013.

The case study focuses on four questions:

- How has earlier ISMP Canada opioid-related work informed how ISMP Canada could assist facilities experiencing a medication safety incident?
- How has a facility managed a HYDROmorphone incident, and how have the changes been directly or indirectly influenced by ISMP Canada?
- How has the learning from the incident been used in other ISMP Canada work?
- What are possible future priority areas that ISMP Canada should focus on in its work on opioids?

The case study includes interviews with ISMP Canada staff, representatives of a facility with a critical HYDROmorphone incident, and stakeholders who are aware of ISMP Canada's work on opioids.

Opioid-related work conducted by ISMP Canada

1. What project work related to opioids has ISMP Canada conducted since 2002? *(Probe for interviewer: establish work undertaken before and after 2011)*

2. How has the learning related to opioids from that project work been used by ISMP Canada in its products or educational materials?

3. To your knowledge, have ISMP Canada products or educational materials related to opioids been used by health care facilities? Please give specific examples without compromising confidentiality.

4. How has ISMP Canada been involved in assisting health care facilities after they have experienced an adverse drug event involving HYDROmorphone? *(Probe: type of issue, severity of incident; nature of assistance)* How has its earlier work informed how ISMP Canada assists a facility?

5. To what extent has ISMP Canada's work related to opioids, and specifically HYDROmorphone, informed the work of external stakeholders involved in health care policy (e.g., Canadian Centre for Substance Abuse, Patient Safety Review Committee, Accreditation Canada)?

Response to the HYDROmorphone incident

6. After the HYDROmorphone incident occurred in Facility A, how did ISMP Canada become aware of the incident?

7. What actions had Facility A already undertaken before contact was made with ISMP Canada? To what extent were the facility's initial responses informed, if at all, by ISMP Canada's work in reducing/responding to opioid adverse events?

8. Once contact was made by Facility A, how was ISMP Canada involved with the facility? To what extent did the facility follow ISMP Canada and Patient Safety Review Committee (PSRC) advice/suggestions? If any advice/suggestions were not followed, why not?

9. What changes has the facility made since the adverse HYDROmorphone event? In your opinion, to what extent were those changes directly or indirectly influenced by ISMP Canada's work related to HYDROmorphone and opioids?

10. Were the changes made by Facility A in alignment with recommendations/safety strategies of ISMP Canada regarding opioids? If any recommendations/safety strategies of ISMP Canada were not followed, do you know why not?

11. To your knowledge, what barriers or enabling factors to implementing change were experienced by the facility? To your knowledge, how were any barriers managed or enabling factors leveraged to achieve change? What do you consider to be the key lessons learned from this facility's experience?

12. How did the existence of the legal action and the involvement of the Coroner's office and the PSRC affect the facility's willingness or ability to engage and share information with ISMP Canada, if at all?

13. Based on your experience working with this facility and others, what are the challenges or difficulties in evaluating the effectiveness of the medication safety strategies? What has been or should be ISMP Canada's role in evaluating medication safety strategies? Are there any lessons that should be applied going forward?

Use of learning from the incident by ISMP Canada

14. What were the key lessons learned by ISMP Canada through the review of the HYDROmorphone incident with Facility A?

15. How has ISMP Canada used this learning in its products, educational materials, or other projects? To what extent has this new learning been used by other health care facilities and professionals?

16. How has ISMP Canada used this learning in its work with external stakeholders? What have been the results of this work?

17. How effective do you think ISMP Canada has been in spreading the knowledge gained through this medication incident? Upon what evidence do you base your conclusion?

18. What system-wide, facility-based, or individual-level factors have facilitated or hindered knowledge diffusion and practice changes related to opioids?

19. What is needed to sustain the learning from these kinds of medication incidents? What role does/can ISMP Canada play?

Future priority areas

20. From your perspective, what are the top five medication safety issues that need to be addressed going forward?

21. In the past five years, what have been the greatest areas of improvement related to opioids in the Canadian health care system? What are the greatest gaps or threats to safe opioid use in the health care system?

22. Considering your responses to the above question, what do you think should be the future priority areas that ISMP Canada should focus on in its work on opioids?

Thank you for your participation.

Improving quality in patient safety

Ontario
CRITICAL Incident Learning

Issue 2
February 2013

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy

Suggested action items:

- Refer bulletin to pharmacy and therapeutics committee for evaluation of pharmacy practices and for comment to the medical advisory committee
- Refer bulletin to nursing leadership committees for evaluation of nursing practices and for comment to senior administration
- Refer bulletin to quality/patient safety committees for evaluation of hospital practices
- Circulate bulletin to physicians and other front-line staff
- Use bulletin as an educational resource in your hospital safety huddles or rounds

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HYDROmorphone remains a high-alert drug

The following report shares learning from a fatal HYDROmorphone incident that occurred in an Ontario hospital.

Background

- HYDROmorphone 0.2 to 0.4 mg subcutaneously every hour as needed for pain was prescribed for a patient.
- A 10-fold dosing error occurred, whereby HYDROmorphone 4 mg was administered instead of the 0.4 mg ordered.
- The dose had been drawn from a high-concentration (10 mg/mL) vial of HYDROmorphone.
- Although the facility did not maintain high-concentration HYDROmorphone as floor stock, it was not uncommon for nurses to borrow HYDROmorphone from patient-specific stock.
- The patient was found without vital signs shortly after administration of the HYDROmorphone.

Learning from Analysis

- Consistent with other reported HYDROmorphone administration errors, the availability of a high-concentration HYDROmorphone product played a significant role in the incident.[1]
- The practice of borrowing opioids from patient-specific stock, which sometimes occurred in this facility, may have introduced the risk of misidentifying the drug or the intended patient.
- An independent double-check,[2] which might have uncovered the error before administration, was not mandated by the facility's drug-administration procedures and was not performed in this case.

Call to Action for Hospitals

- Remove HYDROmorphone vials containing a total dose greater than 2 mg from floor stock, in accordance with Accreditation Canada's Required Organizational Practices[3] and ISMP Canada recommendations,[4] and audit compliance with this policy frequently.
- If high-concentration HYDROmorphone must be dispensed for a specific patient, create a mechanism for the prompt and secure return to the pharmacy of unused doses (e.g., after the patient is discharged or transferred to another care area).
- Develop drug access mechanisms specifically designed to reduce the need to borrow medications from other patients or other care areas.
- Design a standard chart for typical facility doses of HYDROmorphone with instructions for proper preparation of low doses.
- Require independent double checks before administration of high-alert medications.
- Consider having pharmacy repackage injectable HYDROmorphone into low-dose syringes or patient-specific doses.

Ontario CRITICAL Incident Learning Issue 2, February 2013

Discussion

From October 1, 2011, to December 31, 2012, a total of 35 Ontario incidents involving HYDROmorphone were reported to the National System for Incident Reporting.[5,6] HYDROmorphone continues to be 1 of the top 3 medications involved in incidents associated with harm or death that are voluntarily reported to ISMP Canada.[7,8] Provincial ministries of health, Accreditation Canada, various offices of the chief coroner or medical examiner, and other organizations have supported initiatives such as removal of high-concentration HYDROmorphone from patient care areas, use of TALLman lettering, implementation of independent double checks, and development of commercial low-dose products by Canadian manufacturers.

In the case presented above, the availability of high-concentration HYDROmorphone in the patient care unit, the lack of a standardized independent double-check process, the practice of borrowing doses of medication from other units or from patient-specific stock, and frequent distractions in the work area were all identified as factors contributing to the error. In its report, the facility also identified other aspects of the medication-use process where improvements in medication safety could be realized, including segregation of morphine from HYDROmorphone in storage areas, increased automation and computerization, improvements in warnings on medication labels and medication administration records, routine audits of opioid storage areas, staff education, and policy review.

Conclusion

HYDROmorphone is a high-alert drug with substantial potential for harmful consequences if involved in medication incidents. ISMP Canada recommends high-leverage, system-focused safety strategies. In this case, removal of the high-concentration preparation of HYDROmorphone from the care unit would have made a 10-fold dosing error unlikely; in addition, a standardized, independent double-check procedure might have prevented the error from reaching the patient. The ideal scenario would be availability of a dosage form in the prescribed dose (e.g., as a prefilled syringe), prepared and administered with the support of an independent double-check process. Individual practitioners and administrators in Ontario healthcare facilities are encouraged to closely examine the processes for use of HYDROmorphone in their organizations and to take steps to improve patient safety.

Content reviewed by:

Debbie Barnard, MSc, CPHQ, Director, Quality and Patient Safety, Health Sciences North

Dan Cass, BSc, MD, FRCPC, Interim Chief Coroner, Office of the Chief Coroner, Ontario

Hal Fjeldsted, formerly CEO, Kirkland District Hospital

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Collaborating parties of the Ontario Critical Incident Reporting program

Canadian Institute for Health Information / Institut canadien d'information sur la santé — Ontario — Ontario Hospital Association — ISMP Canada

PRA

Improving quality in patient safety

Ontario CRITICAL Incident Learning

Issue 4
April 2013

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy

Suggested action items:

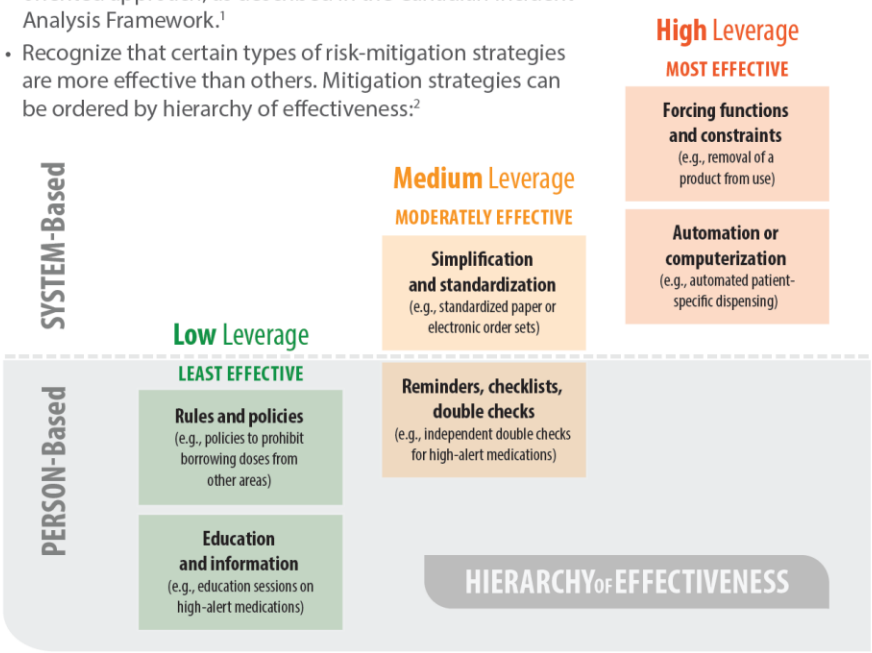
- Circulate bulletin to front-line staff and physicians
- Refer bulletin to quality and safety committees to encourage appraisal of effectiveness of hospital's recommendations and assessment of hospital's quality improvement initiatives
- Use bulletin as an educational resource in your hospital's safety huddles or rounds

Designing Effective Recommendations

The reporting, investigation, and analysis of medication incidents are important elements in improving patient safety, but these efforts must be accompanied by effective strategies to mitigate the contributing factors leading to the incidents.

Advice for Hospitals

- Review patient safety incidents using a systematic, team-oriented approach, as described in the Canadian Incident Analysis Framework.[1]
- Recognize that certain types of risk-mitigation strategies are more effective than others. Mitigation strategies can be ordered by hierarchy of effectiveness:[2]



- System-based recommendations have a higher likelihood of success because they do not rely on individual attention and vigilance.
- Appreciate that a small number of higher-leverage, more effective recommendations addressing the contributing factors determined from the incident analysis will be more likely to improve patient safety than a larger number of less effective strategies.
- Ensure that recommendations are specific, measurable, attainable, realistic, and timely (SMART).[3]
- Continuously monitor and assess the effectiveness of any recommendations arising from incident analyses.
- Provide feedback to staff about quality and safety improvement initiatives and achievements.

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Ontario CRITICAL Incident Learning
Issue 4, April 2013

Background

A hospitalized patient received a fatal overdose of an opioid prepared from a high-concentration product. The facility conducted a full internal review of the incident and developed a series of strategies that were expected to reduce the likelihood of recurrence of this error, as well as to enhance the safety of other aspects of care within the facility. The recommendations included providing staff education, changing medication policies, reducing availability of the particular product, improving the labelling and delivery of all high-concentration products, and reinforcing independent double-check practices. Despite these measures, the facility has since experienced one near-miss incident and one harmful overdose of the same product.

Learning from Analysis

Further analysis revealed that availability of the high-concentration product played a significant role in both of the subsequent errors, despite the institution's intent to develop and implement strategies specifically designed to address the identified contributing factors. For example, in areas where the product was still available, unused containers for discharged patients were being stored in drug carts until the next audit and collection opportunity. Doses of the high-concentration product were being borrowed for use in other areas of the facility, which led to opportunities for error. These actions reflected a desire for economy and efficiency on the part of staff members and were not performed out of carelessness or any intent to cause harm.

These findings emphasized that vulnerabilities in medication-use systems must be addressed with the most effective strategies that are reasonable and/or feasible to implement, given the particular circumstances. In this case, the facility ultimately opted to implement a *daily* audit of high-concentration opioids to ensure removal of items no longer required for admitted patients, effectively creating a high-leverage forcing function and constraint (i.e., the product would not be available for borrowing).

Organizations often respond to errors with policy and rule changes, but research and experience have clearly shown that such recommendations, implemented in isolation, are unlikely to provide any meaningful benefit to patient safety over the long term and that higher-leverage strategies are required. Hospital leaders are encouraged to analyze all recommendations proposed after review of a critical incident and to consider how effective they will be in preventing a future incident or mitigating harm from any incidents that do occur.

Content reviewed by:

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We gratefully acknowledge the review of this bulletin by the facility where the incident described took place.

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Collaborating parties of the Ontario Critical Incident Reporting program

Institute for Safe Medication Practices Canada (ISMP Canada)
Case Study on Opioid Work
Interview Guide for Stakeholders

ISMP Canada has hired PRA Inc., an independent research firm, to conduct a case study of its work related to opioids, more specifically HYDROmorphone. The case study focuses on the 2011 HYDROmorphone incident, which is described in the attached Ontario Critical Incident Learning Bulletins from February and April 2013.

The case study focuses on four questions:

- How has earlier ISMP Canada opioid-related work informed how ISMP Canada could assist facilities experiencing a medication safety incident?
- How has a facility managed a HYDROmorphone incident, and how have the changes been directly or indirectly influenced by ISMP Canada?
- How has the learning from the incident been used in other ISMP Canada work?
- What are possible future priority areas that ISMP Canada should focus on in its work on opioids?

The case study includes interviews with ISMP Canada staff, representatives of a facility with a critical HYDROmorphone incident, and stakeholders who are aware of ISMP Canada's work on opioids.

Context

1. What organizations are available in Canada for medication incident analysis and medication safety information and strategies?

2. What is your general perception of ISMP Canada as a source of analysis, safety information, and strategies?

3. A number of organizations, such as Health Canada, professional health care regulatory bodies and associations, and non-governmental safety organizations, have worked to reduce the harm associated with opioids. What do you see as the roles of each type of organization? Which efforts have resulted in positive change? Which have been less successful?

Opioid-related work conducted by ISMP Canada

4. What do you think is the general level of awareness of ISMP Canada's work related to opioids and, more specifically, HYDROmorphone? Does the level of awareness vary by type or position of health care professional? In your opinion, could ISMP Canada do anything to improve awareness among health care professionals of its work?

5. To what extent has ISMP Canada's work related to opioids, and specifically HYDROmorphone, informed the work of your organization in this area?

6. Has your organization worked directly with ISMP Canada on the issue of the safe use of HYDROmorphone or opioids more generally? What have been the results of this work?

7. To what extent has ISMP Canada's work related to opioids, and specifically HYDROmorphone, informed the work of other stakeholders involved in health care policy (e.g., CCSA, PSRC, Accreditation Canada)?

8. To your knowledge, how have ISMP Canada products or educational materials related to opioids been used by health care facilities?

9. Based on your experience, how realistic and implementable are ISMP Canada's opioid-related recommendations/safety strategies? What, if anything, has limited the ability of facilities to use ISMP Canada recommendations/safety strategies? Are any particular opioid-related recommendations/safety strategies difficult to implement and why?

10. What are the benefits, if any, to facilities and the broader health care system of ISMP Canada's involvement in the investigative and analytic process of medication safety incidents?

11. Do you have any suggestions for how ISMP Canada can improve or expand its work with and support facilities that have had a critical medication safety incident?

12. How effective do you think ISMP Canada has been in spreading the knowledge gained through opioid medication incidents? Upon what evidence do you base your conclusion?

13. What system-wide or facility-based factors have facilitated or hindered knowledge diffusion and practice changes related to opioids? What individual factors have been facilitators or barriers?

14. To what extent do ISMP Canada's recommendations related to opioid safety align with government or accreditation expectations related to medication safety?

15. What is needed to sustain the learning from these kinds of medication incidents? What role does/can ISMP Canada play?

Future priority areas

16. From your perspective, what are the top five medication safety issues that need to be addressed going forward?

17. In the past five years, what have been the greatest areas of improvement related to opioids in the Canadian health care system? What are the greatest gaps or threats to safe opioid use in the health care system?

18. Considering your responses to the above question, what do you think should be the future priority areas that ISMP Canada should focus on in its work on opioids?

Thank you for your participation.

Improving quality in patient safety

Ontario
CRITICAL Incident Learning

Issue 2
February 2013

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy

Suggested action items:

- Refer bulletin to pharmacy and therapeutics committee for evaluation of pharmacy practices and for comment to the medical advisory committee
- Refer bulletin to nursing leadership committees for evaluation of nursing practices and for comment to senior administration
- Refer bulletin to quality/patient safety committees for evaluation of hospital practices
- Circulate bulletin to physicians and other front-line staff
- Use bulletin as an educational resource in your hospital safety huddles or rounds

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HYDROmorphone remains a high-alert drug

The following report shares learning from a fatal HYDROmorphone incident that occurred in an Ontario hospital.

Background

- HYDROmorphone 0.2 to 0.4 mg subcutaneously every hour as needed for pain was prescribed for a patient.
- A 10-fold dosing error occurred, whereby HYDROmorphone 4 mg was administered instead of the 0.4 mg ordered.
- The dose had been drawn from a high-concentration (10 mg/mL) vial of HYDROmorphone.
- Although the facility did not maintain high-concentration HYDROmorphone as floor stock, it was not uncommon for nurses to borrow HYDROmorphone from patient-specific stock.
- The patient was found without vital signs shortly after administration of the HYDROmorphone.

Learning from Analysis

- Consistent with other reported HYDROmorphone administration errors, the availability of a high-concentration HYDROmorphone product played a significant role in the incident.[1]
- The practice of borrowing opioids from patient-specific stock, which sometimes occurred in this facility, may have introduced the risk of misidentifying the drug or the intended patient.
- An independent double-check,[2] which might have uncovered the error before administration, was not mandated by the facility's drug-administration procedures and was not performed in this case.

Call to Action for Hospitals

- Remove HYDROmorphone vials containing a total dose greater than 2 mg from floor stock, in accordance with Accreditation Canada's Required Organizational Practices[3] and ISMP Canada recommendations,[4] and audit compliance with this policy frequently.
- If high-concentration HYDROmorphone must be dispensed for a specific patient, create a mechanism for the prompt and secure return to the pharmacy of unused doses (e.g., after the patient is discharged or transferred to another care area).
- Develop drug access mechanisms specifically designed to reduce the need to borrow medications from other patients or other care areas.
- Design a standard chart for typical facility doses of HYDROmorphone with instructions for proper preparation of low doses.
- Require independent double checks before administration of high-alert medications.
- Consider having pharmacy repackage injectable HYDROmorphone into low-dose syringes or patient-specific doses.

Ontario CRITICAL Incident Learning Issue 2, February 2013

Discussion

From October 1, 2011, to December 31, 2012, a total of 35 Ontario incidents involving HYDROmorphone were reported to the National System for Incident Reporting.[5,6] HYDROmorphone continues to be 1 of the top 3 medications involved in incidents associated with harm or death that are voluntarily reported to ISMP Canada.[7,8] Provincial ministries of health, Accreditation Canada, various offices of the chief coroner or medical examiner, and other organizations have supported initiatives such as removal of high-concentration HYDROmorphone from patient care areas, use of TALLman lettering, implementation of independent double checks, and development of commercial low-dose products by Canadian manufacturers.

In the case presented above, the availability of high-concentration HYDROmorphone in the patient care unit, the lack of a standardized independent double-check process, the practice of borrowing doses of medication from other units or from patient-specific stock, and frequent distractions in the work area were all identified as factors contributing to the error. In its report, the facility also identified other aspects of the medication-use process where improvements in medication safety could be realized, including segregation of morphine from HYDROmorphone in storage areas, increased automation and computerization, improvements in warnings on medication labels and medication administration records, routine audits of opioid storage areas, staff education, and policy review.

Conclusion

HYDROmorphone is a high-alert drug with substantial potential for harmful consequences if involved in medication incidents. ISMP Canada recommends high-leverage, system-focused safety strategies. In this case, removal of the high-concentration preparation of HYDROmorphone from the care unit would have made a 10-fold dosing error unlikely; in addition, a standardized, independent double-check procedure might have prevented the error from reaching the patient. The ideal scenario would be availability of a dosage form in the prescribed dose (e.g., as a prefilled syringe), prepared and administered with the support of an independent double-check process. Individual practitioners and administrators in Ontario healthcare facilities are encouraged to closely examine the processes for use of HYDROmorphone in their organizations and to take steps to improve patient safety.

Content reviewed by:

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Collaborating parties of the Ontario Critical Incident Reporting program

Canadian Institute for Health Information / Institut canadien d'information sur la santé · Ontario · Ontario Hospital Association · ISMP Canada

PRA

Improving quality in patient safety

Ontario CRITICAL Incident Learning

Issue 4
April 2013

Distributed to:

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy

Suggested action items:

- Circulate bulletin to front-line staff and physicians
- Refer bulletin to quality and safety committees to encourage appraisal of effectiveness of hospital's recommendations and assessment of hospital's quality improvement initiatives
- Use bulletin as an educational resource in your hospital's safety huddles or rounds

Designing Effective Recommendations

The reporting, investigation, and analysis of medication incidents are important elements in improving patient safety, but these efforts must be accompanied by effective strategies to mitigate the contributing factors leading to the incidents.

Advice for Hospitals

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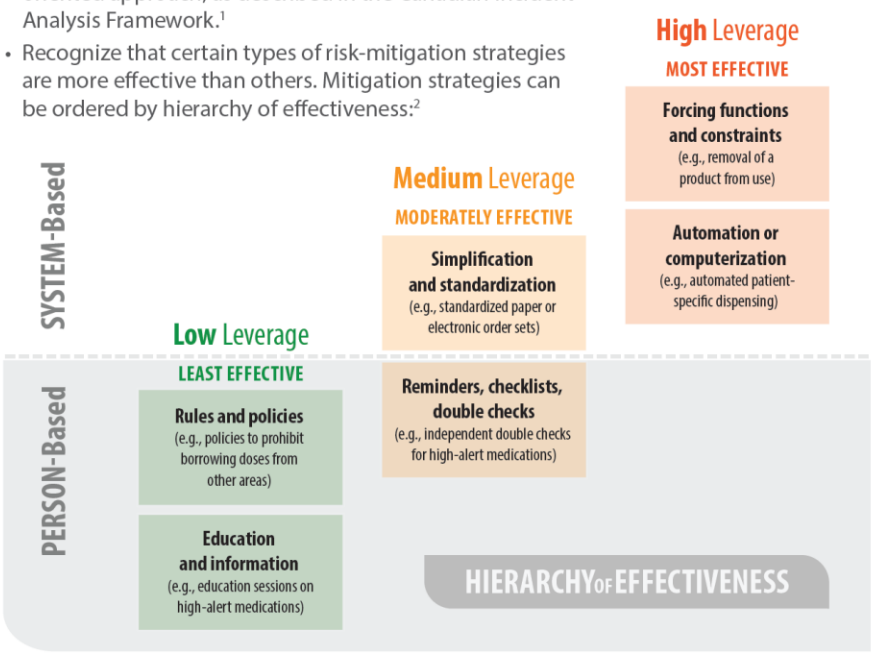

- System-based recommendations have a higher likelihood of success because they do not rely on individual attention and vigilance.
- Appreciate that a small number of higher-leverage, more effective recommendations addressing the contributing factors determined from the incident analysis will be more likely to improve patient safety than a larger number of less effective strategies.
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Ontario CRITICAL Incident Learning
Issue 4, April 2013

Background

A hospitalized patient received a fatal overdose of an opioid prepared from a high-concentration product. The facility conducted a full internal review of the incident and developed a series of strategies that were expected to reduce the likelihood of recurrence of this error, as well as to enhance the safety of other aspects of care within the facility. The recommendations included providing staff education, changing medication policies, reducing availability of the particular product, improving the labelling and delivery of all high-concentration products, and reinforcing independent double-check practices. Despite these measures, the facility has since experienced one near-miss incident and one harmful overdose of the same product.

Learning from Analysis

Further analysis revealed that availability of the high-concentration product played a significant role in both of the subsequent errors, despite the institution's intent to develop and implement strategies specifically designed to address the identified contributing factors. For example, in areas where the product was still available, unused containers for discharged patients were being stored in drug carts until the next audit and collection opportunity. Doses of the high-concentration product were being borrowed for use in other areas of the facility, which led to opportunities for error. These actions reflected a desire for economy and efficiency on the part of staff members and were not performed out of carelessness or any intent to cause harm.

These findings emphasized that vulnerabilities in medication-use systems must be addressed with the most effective strategies that are reasonable and/or feasible to implement, given the particular circumstances. In this case, the facility ultimately opted to implement a *daily* audit of high-concentration opioids to ensure removal of items no longer required for admitted patients, effectively creating a high-leverage forcing function and constraint (i.e., the product would not be available for borrowing).

Organizations often respond to errors with policy and rule changes, but research and experience have clearly shown that such recommendations, implemented in isolation, are unlikely to provide any meaningful benefit to patient safety over the long term and that higher-leverage strategies are required. Hospital leaders are encouraged to analyze all recommendations proposed after review of a critical incident and to consider how effective they will be in preventing a future incident or mitigating harm from any incidents that do occur.

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Collaborating parties of the Ontario Critical Incident Reporting program

Survey of Facility Staff

The Institute for Safe Medication Practices (ISMP) Canada has hired PRA Inc., an independent research firm, to conduct a case study of its work related to opioids, more specifically, HYDROmorphone. The case study focuses on a critical HYDROmorphone incident that occurred in 2011 at Facility.

Background

- HYDROmorphone 0.2 to 0.4 mg subcutaneously every hour, as needed for pain, was prescribed for a patient.
- A 10-fold dosing error occurred, whereby HYDROmorphone 4 mg was administered instead of the 0.4 mg ordered.
- The dose had been drawn from a high-concentration (10 mg/mL) vial of HYDROmorphone.
- Although the facility did not maintain high-concentration HYDROmorphone as floor stock, it was not uncommon for nurses to borrow HYDROmorhpone from patient-specific stock.
- The patient was found without vital signs shortly after administration of the HYDROmorphone

--Taken from Ontario Critical Incident Learning Bulletin (February 2013)

We would appreciate it if you could take the time to complete the following survey about this case.

The survey asks about awareness of ISMP Canada's work on opioid safety, how Facility handled the incident, and what learning has resulted.

Your responses will be kept confidential, although compiled data and survey responses will be used in reports. Information will be grouped together in the reports, and no individual responses will be identifiable. All personal information collected through the survey will be destroyed at the conclusion of the evaluation.

Responses will be accepted **until [date].**

Simply follow this link to complete the survey **(insert hyperlink here)**.

If you have any questions about this study, please call Amy Richmond of PRA at 1-888-877-6744 (toll-free) or email her at ismpc@pra.ca. You may also contact Dr. Michael Hamilton of ISMP Canada at 1-416-733-3131, ext. 232 or at MHamilton@ismp-canada.org.

1. Please indicate which of the following **best** describes your current position

- ☐ 01 Physician
- ☐ 02 Nurse
- ☐ 03 Pharmacist
- ☐ 04 Physician Assistant
- ☐ 05 Pharmacy Technician
- ☐ 06 Risk Manager
- ☐ 07 Nurse Administrator
- ☐ 66 Other _____

2. In what month and year did you begin working at Facility?

_____ _____
Month Year

The reason for this question is to determine if you would be able to respond to questions about the facility's response to the 2011 HYDROmorphone incident.

Awareness

3. How would you rate your level of awareness of ISMP Canada's work related to opioids and HYDROmorphone:

	Not at all aware				Very aware	Don't know
a. ISMP Canada safety bulletins on HYDROmorphone and opioids generally	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05	☐ 88
b. Making Hospitals Safer: ISMP Canada priority recommendations for narcotics (opioids)	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05	☐ 88
c. Paediatric Opioid Safety Resource Kit	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05	☐ 88
d. Paediatric Opioid Consensus Guidelines	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05	☐ 88
e. 2012 HYDROmorphone Knowledge Assessment Survey Report	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05	☐ 88
f. Acute Care/Hospital Medication Safety Assessment	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05	☐ 88
g. Ontario Critical Incident Learning bulletin	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05	☐ 88

Responses to medication errors and the HYDROmorphone incident

4. How would you describe the culture or attitude of Facility with respect to medication incidents?

Very blaming				Very supportive
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. Do you think of Facility as reactive (only deals with issues as they arise) or preventative (always looks for ways to improve safety even before incidents arise) in how it approaches medication safety?

Mostly reactive				Mostly preventative
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. Do you think Facility experiences medication incidents at the same or different rate than other comparable facilities? Lower rate=1; Same rate=2, Greater rate=3; DK=8

Lower rate	Same rate	Greater rate	Don't know
☐ 1	☐ 2	☐ 3	☐ 8

(Only asked of respondents who answer 2011 or earlier to Q2)

7. How would you describe Facility's response to the 2011 HYDROmorphone incident?

Very blaming				Very supportive
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Very damaging				Very constructive
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

(Only asked of respondents who answer 2011 or earlier to Q2)

8. Were you aware of ISMP Canada's involvement with Facility after the 2011 HYDROmorphone incident?

Yes	No	Don't know
☐ 1	☐ 2	☐ 8

(If yes to Q8)

9. Did ISMP Canada's involvement affect your level of confidence that an appropriate safety solution would be found so it would be less likely for this medication incident to occur again?

Negative effect	No effect	Positive effect
☐ 1	☐ 2	☐ 3

(Only asked of respondents who answer 2011 or earlier to Q2)

10. Do you think that the method of managing HYDROmorphone and other opioids at Facility has improved since the 2011 HYDROmorphone incident?

Yes	No	Don't know
☐ 1	☐ 2	☐ 8

11. **(If yes to Q10)** What has improved and to what do you credit that improvement?

12. **(If no to Q10)** What has not improved and why do think improvements have not occurred?

13. Which of the following safety strategies for HYDROmorphone and other opioids are currently used at Facility?

	Yes	No	Don't know
a. Use of patient selection criteria for Patient Controlled Analgesia	☐ 01	☐ 02	☐ 88
b. Removal from floor stock of HYDROmorphone ampoules or vials with a concentration greater than 2 mg/mL	☐ 01	☐ 02	☐ 88
c. Removal from floor stock of morphine ampoules or vials with a concentration greater than 15 mg/mL	☐ 01	☐ 02	☐ 88
d. Removal from floor stock of morphine ampoules or vials with a concentration greater than 2 mg/mL in paediatric patient care areas	☐ 01	☐ 02	☐ 88
e. Removal from floor stock of sufentanil	☐ 01	☐ 02	☐ 88
f. Pharmacists conduct a risk assessment for each narcotic storage area with regular follow-up to check for unapproved items in floor stock	☐ 01	☐ 02	☐ 88
g. Standardization of opioid infusion solutions/concentrations	☐ 01	☐ 02	☐ 88
h. Standardization of products approved for pain management	☐ 01	☐ 02	☐ 88
i. Restrictions on mixing narcotic solutions outside of the pharmacy	☐ 01	☐ 02	☐ 88
j. Routine use of independent double checks before medication administration	☐ 01	☐ 02	☐ 88
k. Use of drug access mechanisms that reduce the need to borrow medications from other patients or other care areas	☐ 01	☐ 02	☐ 88
l. Availability of a standard chart for typical facility doses of HYDROmorphone with instructions for proper preparation of low doses	☐ 01	☐ 02	☐ 88
m. Repackaging of injectable HYDROmorphone into low-dose syringes or patient-specific doses	☐ 01	☐ 02	☐ 88
n. Education of staff regarding system-based causes of medication error involving opioids	☐ 01	☐ 02	☐ 88
o. Education of staff regarding the hierarchy of effectiveness of error reduction strategies for opioids	☐ 01	☐ 02	☐ 88
p. Inclusion of the patient/family in the narcotic medication-use process	☐ 01	☐ 02	☐ 88
q. Routine use of two independent identifiers when identifying patients	☐ 01	☐ 02	☐ 88
r. Routine use of standardized pain control protocols or order sets	☐ 01	☐ 02	☐ 88
s. Availability and use of education tools about opioid use designed for patient/family	☐ 01	☐ 02	☐ 88

(Only asked for sub-parts to Q13 where indicated Y)

14. How successful has Facility been in implementing these safety strategies?

	Not at successful				Very successful
a. Use of patient selection criteria for Patient Controlled Analgesia	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
b. Removal from floor stock of HYDROmorphone ampoules or vials with a concentration greater than 2 mg/mL	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
c. Removal from floor stock of morphine ampoules or vials with a concentration greater than 15 mg/mL	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
d. Removal from floor stock of morphine ampoules or vials with a concentration greater than 2 mg/mL in paediatric patient care areas	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
e. Removal from floor stock of sufentanil	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
f. Pharmacists conduct a risk assessment for each narcotic storage area with regular follow-up to check for unapproved items in floor stock	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
g. Standardization of opioid infusion solutions/concentrations	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
h. Standardization of products approved for pain management	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
i. Restrictions on mixing narcotic solutions outside of the pharmacy	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
j. Routine use of independent double checks before medication administration	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
k. Use of drug access mechanisms that reduce the need to borrow medications from other patients or other care areas	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
l. Availability of a standard chart for typical facility doses of HYDROmorphone with instructions for proper preparation of low doses	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
m. Repackaging of injectable HYDROmorphone into low-dose syringes or patient-specific doses	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
n. Education of staff regarding system-based causes of medication error involving opioids	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
o. Education of staff regarding the hierarchy of effectiveness of error reduction strategies for opioids	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
p. Inclusion of the patient/family in the narcotic medication-use process	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
q. Routine use of two independent identifiers when identifying patients	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
r. Routine use of standardized pain control protocols or order sets	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05
s. Availability and use of education tools about opioid use designed for patient/family	☐ 01	☐ 02	☐ 03	☐ 04	☐ 05

15. Overall, what were the barriers, if any, to successful implementation of the safety strategies for HYDROmorphone and other opioids?

16. What factors, if any, enabled successful implementation of the safety strategies for HYDROmorphone and other opioids?

17. How effective has Facility been in spreading knowledge related to medication errors related to HYDROmorphone and other opioids within Facility since the 2011 HYDROmorphone incident?

Not at all effective				**Very effective**	**Don't know**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 8

18. How effective has Facility been at sustaining the knowledge gained through the 2011 HYDROmorphone incident?

Not at all effective				**Very effective**	**Don't know**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 8

19. What do you think is needed to spread and sustain the learning from these kinds of medication incidents

    a. Within Facility?

    b. Across all areas of health care (facilities, regions, types of care)?

Future priorities

20. What do you think should be the future priority areas that ISMP Canada should focus on in its work on opioids?

21. From your perspective, what are the top five medication safety issues in the Canadian health care system that need to be addressed going forward?

1

2

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4

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Appendix C — Opioid-related Safety Bulletins from ISMP Canada (2002–14)

Table 1: Opioid-related safety bulletins from ISMP Canada (2000–14)	
Year	**Description**
2002	A safety bulletin reported two errors with opioids (morphine and oxycodone) and offered suggestions stemming from a roundtable discussion at the Canadian Society of Hospital Pharmacists Professional Practice Conference (ISMP Canada, 2002b).
	Safety bulletin reported a dangerous near-miss incident involving codeine oral syrup. Factors contributing to the error included workload issues, lack of an independent check in the dispensing process, and the inability of the pharmacy to contact the prescribing physician. ISMP Canada proposed numerous recommendations (ISMP Canada, 2002a).
2003	A safety bulletin reported on two medication errors involving methadone and offered recommendations to healthcare practitioners, hospitals, and community pharmacies on the safe prescribing and dispensing of methadone (ISMP Canada, 2003b).
	ISMP Canada reported on three medication errors involving long-acting oral narcotics, including HYDROmorphone. The Safety Bulletin proposed system safeguards to prevent similar errors (ISMP Canada, 2003c).
2004	ISMP Canada reported a fatal incident where HYDROmorphone was administered instead of the prescribed morphine. The Safety Bulletin warned that "over the years, we've received many reports of confusion between HYDROmorphone and morphine, some of which have been fatal. In fact, mix-ups between these drugs are among the most common and serious errors that can occur involving two high-alert drugs". This incident was the subject of a RCA which produced recommendations for preventing HYDROmorphone / morphine incidents. (ISMP Canada, 2004a, p. 1)
	ISMP Canada reported three incidents involving infusion pumps. In one of these a patient received a tenfold overdose of morphine delivered from an infusion pump. The bulletin offered numerous recommendations (ISMP Canada, 2004c).
	A safety bulletin was issued to address concerns raised by healthcare professionals about the use of meperidine (Demerol®) in Canadian hospitals. It reported two adverse events and reported information suggesting restricting the use of meperidine to enhance medication safety (ISMP Canada, 2004d).
	A safety bulletin reported on multiple medication errors involving the substitution of morphine 10 mg/mL for morphine 2 mg/mL. ISMP Canada provided information on the errors to the supplier of the look-alike ampoules, which prompted the labels to be redesigned. ISMP Canada offered recommendations for hospitals in the interim, to prevent further errors until the new labelling was available (ISMP Canada, 2004e).
2005	ISMP Canada published a Safety Bulletin providing an overview of the importance and method of performing independent double checks. It cited two medication incidents which had been prevented by independent checks (ISMP Canada, 2005b).
2006	ISMP Canada shared learning from reported medication incidents involving HYDROmorphone Since 2001 ISMP Canada had received 17,320 incident reports, with 783 of these related to HYDROmorphone. Frequent causes of medication errors included substitution errors between HYDROmorphone and morphine, incorrect doses, errors in programming infusion pumps, and insufficient routine monitoring. ISMP Canada provided numerous recommendations for protocols (ISMP Canada, 2006b).
	A safety bulletin reported the top 10 drugs associated with causing harm as a consequence of medication error. Analysis of CMIRPS data showed an association between a large percentage of harmful errors and a small number of drugs, which led ISMP Canada to undertake further specific investigation of these drugs. Morphine and HYDROmorphone were among the top three drugs listed (ISMP Canada, 2006c)
	A safety bulletin was published providing warning and recommendations for the use of fentanyl patches, which drew on learnings from incident reports (ISMP Canada, 2006d).
2007	Another safety bulletin was published providing warning and recommendations for the use of fentanyl patches, which again drew on learnings from incident reports (ISMP Canada, 2007a).
2008	ISMP Canada reported on an incident where HYDROmorphone intended for an adult patient was inadvertently administered to an infant. The error was detected quickly and the infant recovered. The error was due to mistaken patient identification. ISMP provided numerous recommendations (ISMP Canada, 2008).

Table 1: Opioid-related safety bulletins from ISMP Canada (2000–14)	
Year	**Description**
2009	ISMP Canada reported findings from an analysis of aggregated data on fentanyl transdermal systems (patches) conducted by the International Medical Safety Network (IMSN). This study analyzed incidents reported in Canada, Ireland, the United Kingdom, and the United States (ISMP Canada, 2009a).
	ISMP Canada reported on phase one of the collaborative project with the Canadian Association of Paediatric Health Centres (CAPHC) to enhance paediatric medication safety (ISMP Canada, 2009b). This identified the top 5 medications most frequently involved in errors reported as causing harm in paediatric patients, and identified contributing factors. A previous review of the ISMP Canada medication incident database had also identified morphine, insulin, and fentanyl among the top 5 medications reported as causing harm, in both adult and paediatric patients, as a consequence of medication error (ISMP Canada, 2006c).
2010	ISMP Canada shared information about voluntarily reported medication incidents occurring in long-term care facilities. The majority of harmful incidents reported involved 1 of 3 classes of high-alert medications: anticoagulants, insulin, and opioids (ISMP Canada, 2010b).
2012	ISMP Canada offered safety strategies for handling the shortage of morphine that was exacerbated by a recall of one morphine product by a manufacturer. The safety strategies included drawing staff attention to the potential dosing errors that can occur when alternative dosage forms or concentrations are used, using independent double checks, avoiding relying on frontline practitioners to make the calculations, and relying on the pharmacy to prepare doses in advance rather than doing this in patient care areas (ISMP Canada, 2012d).
	ISMP Canada reported on the results of its HYDROmorphone Knowledge Assessment Survey that explored knowledge deficits or gaps with respect to HYDROmorphone that could potentially contribution to medication incidents. The lowest area of awareness among respondents related to the pharmacologic properties of HYDROmorphone and their relationship to patient monitoring followed by dosing calculations (ISMP Canada, 2012b).
	This safety bulletin shared findings of a opioid-related incident in a long-term care home that resulted in death. ISMP Canada conducted a review of the incident that included a visit of the facility. Recommendations included the use of independent double checks, work with the pharmacy service provider and physicians to limit the narcotics kept on site, and use of ADCs/packaging systems, and/or CPOE (ISMP Canada, 2012c).
2013	ISMP Canada summarized selected findings from the Coroner Project, which was a collaboration among ISMP Canada and four provincial Offices of the Chief Coroner or Chief Medical Examiner. The Project reviewed 523 death cases from 2007 to 2012 in which medication error was a potential cause. The medications most often involved (47%) were opioids with HYDROmorphone being the medication most frequently involved in incidents associated with death, followed by morphine, fentanyl, oxycodone, and methadone (ISMP Canada, 2013a).
	This safety bulletin outlined the results of the HYDROmorphone Targeted Demonstration Project, which involved a small number of hospitals completing a structured self-assessment of their existing HYDROmorphone safety strategies so that they could identify actions they could take to improve safety. At the end of the project, the hospitals completed a project evaluation survey to assess their progress (ISMP Canada, 2013h).
2014	The Coroners' Project also included a review of deaths associated with medication incidents occurring outside regulated healthcare facilities. Opioids were the most frequent medication class in these incidents (ISMP Canada, 2014c).

Appendix D — Table of ISMP Canada Recommendations for Opioids (2002–14)

Table 1: Table of ISMP Canada recommendations for opioids (2002–14)	
Recommendation	**Source**
Limit availability	
Limit access — reduce stock amounts of HYDROmorphone or eliminate floor stock	(ISMP Canada, 2004a)
Reduce options — avoid stocking morphine and HYDROmorphone in the same strength	(ISMP Canada, 2004a)
Remove high-concentration HYDROmorphone from patient areas whenever possible	(ISMP Canada, 2006b)
Limitations on opioid selection	(ISMP Canada, 2014a)
Limitations on availability of and access to opioids in ward stock	(ISMP Canada, 2014a)
Remove the following stock items from patient care areas: o HYDROmorphone ampoules or vials with concentration greater than 2 mg/mL (exceptions may include palliative care) o Morphine ampoules or vials with concentration greater than 15 mg/mL o Morphine ampoules or vials greater than 2 mgmL in paediatric patient care areas o Sufentanil (exceptions may include Operating Room and Labour and Delivery)	(ISMP Canada, 2005a)
Assess risk associated with narcotic stock in patient care areas.	(ISMP Canada, 2005a)
Limit the storage of high-potency narcotic preparations to the pharmacy, and review storage areas	(ISMP Canada, 2002b)
Limit the choices of floorstock narcotics and standardize pain relief choices	(ISMP Canada, 2002b)
Restrict access to HYDROmorphone, with independent double checks	(ISMP Canada, 2008)
Reduce the dosage and volume options for a medication, i.e. default dose/volume/rate for specified dose ranges	(ISMP Canada, 2003a)
Restrict stock of high-potency narcotics to pharmacy	(Koczmara & Hyland, 2004)
Eliminate infrequently used narcotics from stock	(Koczmara & Hyland, 2004)
Collaborate with the pharmacy service provider and physicians working in the long-term care home to identify and minimize the number and types of narcotic medications that must be kept on site	(ISMP Canada, 2012c)
Packaging	
Reduce look-alike potential — use TALLman lettering to emphasize the HYDROmorphone on pharmacy labels, auxiliary labels, medication administration records, and drug listings, and consider adding label reminders indicating the brand name equivalent Dilaudid	(ISMP Canada, 2004a)
Reduce look-alike potential	(ISMP Canada, 2006b)
Segregation of paediatric opioids from formulations intended only for adult use	(ISMP Canada, 2014a)
Segregation and differentiation of opioid formulations (by drug, by dose, or concentration)	(ISMP Canada, 2014a)
Labelling of opioids intended for oral or parenteral administration	(ISMP Canada, 2014a)
Child-resistant packaging is essential with high-risk drugs	(ISMP Canada, 2002a)
Oral syringes, with instructions on their use, should be provided when paediatric liquids are dispensed	(ISMP Canada, 2002a)
Consider cautionary auxiliary labels when high potency preparations are dispensed	(ISMP Canada, 2002b)
Ensure that labelling of long-acting preparations clearly identifies “CONTROLLED RELEASE” or “EXTENDED RELEASE” in uppercase or large type	(ISMP Canada, 2003c)
Use selective uppercase lettering and large type in the description field of the drug name in computer order entry systems	(ISMP Canada, 2003c)
Include both the generic name and brand name when writing orders and labelling re-packaged products to help differentiate between the regular release and extended release products	(ISMP Canada, 2003c)
Review the hospital formulary for sound-alike and look-alike medications	(ISMP Canada, 2003a)

Table 1: Table of ISMP Canada recommendations for opioids (2002–14)	
Recommendation	**Source**
Use of TALLman letters for sound-alike and look-alike names	(ISMP Canada, 2003a)
Careful review of how products are arranged on shelves to avoid similar packaged or sound-alike medications being side by side	(ISMP Canada, 2003a)
Use of visible coloured auxiliary warning labels	(ISMP Canada, 2003a)
Have pharmacy add labels to narcotic stock to differentiate narcotics with look-alike/sound-alike names, using, for example: TALLman lettering, such as “HYDROmorphOne” [sic]; familiar brand names such as “DILAUDID®”	(Koczmara & Hyland, 2004)
Dispense narcotic medications with labelling for individual residents	(ISMP Canada, 2012c)
Consider strategies to enhance the visibility to nurses of critical information during medication administration	(ISMP Canada, 2012c)
Consider the use of manufacturer-prepared control packs for narcotics and other controlled drugs, to enhance differentiation between medications	(ISMP Canada, 2012c)
Ensure that long-acting medications are identified as such	(ISMP Canada, 2012c)
Double checks	
Require redundancies — an independent double check before administering IV narcotic doses, especially when obtaining narcotics from floor stock	(ISMP Canada, 2004a)
Require redundancies — independent double checks and a witness when programming HYDROmorphone doses in ADCs	(ISMP Canada, 2006b)
Adoption of independent double checks at all stages of the medication-use process in paediatric settings	(ISMP Canada, 2014a)
Implement a policy of Independent Double Checks for PCA infusions. The policy should include a clear process for an independent double check and documentation when the following occur: o Initial pump programming o Changes in pump programming o Solution changes o Patient transfers	(ISMP Canada, 2005a)
Consider a policy of independent double checks for: o All opioid infusions (continuous or intermittent) o Epidural infusions	(ISMP Canada, 2005a)
Fail-safe process in pharmacy that ensures an independent double check before dispensing, comparing the original order with the final product being dispensed — ‘alarm bells’ should be ringing if the order requires more than one container of a drug	(ISMP Canada, 2002a)
Require an independent second check before administering high-alert drugs like parenteral narcotics	(ISMP Canada, 2002b)
Require an independent double check for high-alert drugs, especially those administered by infusion pumps	(ISMP Canada, 2004c)
Ensure a procedure for verification of pump settings during shift changes	(ISMP Canada, 2004c)
Enforce independent double checks on dosage calculation, and on the input of settings of infusion pumps being used for high-alert drugs	(ISMP Canada, 2003a)
Apply *independent* double checks for select narcotic administration, such as for PCAs and epidurals. Narcotic medications are usually obtained from stock and thus bypass the pharmacist/nurse independent check (note: *independent* double checks *must* be performed correctly in order to prevent approximately 95% of errors that would otherwise reach the patient)	(Koczmara & Hyland, 2004)
Review the feasibility of integrating an independent verification step before administration for as many high-alert medications as possible	(ISMP Canada, 2012c)
Standardization	
Standardize prescribing and terminology	(ISMP Canada, 2006b)
Move to standardized concentrations to reduce calculation and other errors	(ISMP Canada, n.d.-a)
Standardization of concentrations for continuous opioid infusions	(ISMP Canada, 2014a)
Adoption of standard methods for preparing and administering intermittent doses of opioids	(ISMP Canada, 2014a)

Table 1: Table of ISMP Canada recommendations for opioids (2002–14)	
Recommendation	**Source**
Inclusion of dosage by weight for all paediatric opioid orders	(ISMP Canada, 2014a)
Development of institution-wide dosing and monitoring guidelines	(ISMP Canada, 2014a)
Use of prefilled oral syringes for enteral administration of opioids	(ISMP Canada, 2014a)
Restrict as much as possible the admixing of narcotic solutions outside of pharmacy.	(ISMP Canada, 2005a)
Standardize infusion concentrations of parenteral narcotic medications and selection of medications for pain management.	(ISMP Canada, 2005a)
Limit the choices of floorstock narcotics and standardize pain relief choices	(ISMP Canada, 2002b)
Standardize concentrations of high-alert drugs to minimize manoeuvring tubing changes and to minimize possible confusion with various strengths being used	(ISMP Canada, 2004c)
Use standardized solutions for infusions such as intravenous (IV), patient-controlled analgesia (PCA) and epidural	(Koczmara & Hyland, 2004)
Use commercially available or pharmacy premixed solutions for infusions	(Koczmara & Hyland, 2004)
Use preprinted order forms with a standardized concentration	(Koczmara & Hyland, 2004)
Prescribing	
Risk/benefit analysis during prescribing, in consultation with the patient and family	(ISMP Canada, 2002a)
The patient/family and pharmacist should both be able to clearly read the prescription	(ISMP Canada, 2002a)
Hospital policy and practice should strongly discourage the use of verbal orders except in emergency situations — ensure there is an expectation to repeat back the entire order to the prescriber, and educate the prescriber to ask for a repeat-back	(ISMP Canada, 2002b)
Educate nurses to reconsider the appropriateness of an order when more than two containers of a drug are needed to prepare one dose — this may require an automatic independent second check regardless of medication	(ISMP Canada, 2002b)
Review the mechanisms in place to identify and resolve discrepancies between pharmacy order interpretation and nursing order interpretation	(ISMP Canada, 2003c)
Require that all medications ordered for paediatric patients include the dose per kilogram	(ISMP Canada, 2008)
In non-emergency situations, require that the medical assessment of patients be charted before administration of any medication	(ISMP Canada, 2008)
Stop using dangerous abbreviations such as “u”, and the trailing zero on a dosage (e.g. 5.0 mg)	(ISMP Canada, 2003a)
Use of a leading zero before a decimal place	(ISMP Canada, 2003a)
Use of preprinted order forms	(ISMP Canada, 2003a)
Do NOT use dangerous abbreviations such as “MSO4” for morphine sulphate	(Koczmara & Hyland, 2004)
Use preprinted order forms with a standardized concentration	(Koczmara & Hyland, 2004)
Monitor	
Monitor patients — specify by policy the nature of monitoring before discharge after receiving a parenteral narcotic	(ISMP Canada, 2004a)
Assess, monitor, and document — implement guidelines or standardized forms, with clear criteria for the identification and treatment of toxicity	(ISMP Canada, 2006b)
Development of institution-wide dosing and monitoring guidelines	(ISMP Canada, 2014a)
Monitor the patient frequently, including the overnight hours	(ISMP Canada, 2003c)
Educate	
Educate staff — provide safety information on the use of potent narcotics and the differences between HYDROmorphone and morphine	(ISMP Canada, 2004a)

Table 1: Table of ISMP Canada recommendations for opioids (2002–14)	
Recommendation	**Source**
Educate and inform staff — analgesic equivalencies, differences between HYDROmorphone and morphine	(ISMP Canada, 2006b)
Educate staff regarding the system-based causes of medication error.	(ISMP Canada, 2005a)
Educate staff about the hierarchy of effectiveness of error-reduction strategies.	(ISMP Canada, 2005a)
Educate staff about possible errors and share learnings from errors	(ISMP Canada, 2002b)
Educate staff about the potential for confusion between immediate and extended release products and the differences in dosing regimens	(ISMP Canada, 2003c)
Provide orientation and training in the use of infusion pumps for all nursing staff, especially new nurses and agency nurses who may not be familiar with the pumps	(ISMP Canada, 2004c)
Provide clear pump use instructions and a safety checklist with the infusion pump	(ISMP Canada, 2004c)
Provide quick, up-to-date references at narcotic cupboards such as a list of narcotic generic names with corresponding trade names. Consider posting equi-analgesic dose charts with common doses and dosing frequencies for each narcotic	(Koczmara & Hyland, 2004)
Ensure all practitioners know how to contact the on-call pharmacist after hours	(Koczmara & Hyland, 2004)
Educate staff (e.g. in-services and newsletters on narcotics, include examples of error reports)	(Koczmara & Hyland, 2004)
Provide education for nursing staff on recommended processes for recommencing medication administration if interrupted during the medication pass	(ISMP Canada, 2012c)
Patients	
Educate patients — prior to administration, repeat the name of the narcotic out loud	(ISMP Canada, 2004a)
Engage patients and their families as partners in medication safety	(ISMP Canada, 2006b)
Include the patient/family in the narcotic medication-use process.	(ISMP Canada, 2005a)
Technology	
Employ technology — technological solutions may reduce the risk of mix-ups	(ISMP Canada, 2004a)
Employ technology — CPOE, bar coding, and automated dispensing technology requiring pharmacy order review before retrieval of a narcotic dose	(ISMP Canada, 2006b)
Ideally, a pharmacy computer system should provide a warning when doses exceed the recommended dose limits	(ISMP Canada, 2002a)
Automatic dispensing units can build in an additional check	(ISMP Canada, 2002b)
Electronic order entry with built in checks and electronic medication administration records can add system checks to prescribing, selection, and administration	(ISMP Canada, 2002b)
Build the default dosing frequency for long-acting drugs in the order entry application	(ISMP Canada, 2003c)
Work toward a longer-term strategy of CPOE	(ISMP Canada, 2008)
Implement CPOE	(Koczmara & Hyland, 2004)
Implement bar coding	(Koczmara & Hyland, 2004)
Consider the purchase of *smart* pumps that utilize dose maximums/minimums and can provide special alerts	(Koczmara & Hyland, 2004)
Consider the use of ADCs which can provide an automatic narcotic count, alerts and pertinent drug/dose information	(Koczmara & Hyland, 2004)
Develop a comprehensive medication safety strategy that considers the applicability of technology options to enhance medication safety	(ISMP Canada, 2012c)
Other	
Define an optimal psycho-physiological state to deliver opioids	(ISMP Canada, n.d.-a)
For PCA, develop and follow patient selection criteria (inclusion and exclusion).	(ISMP Canada, 2005a)

Table 1: Table of ISMP Canada recommendations for opioids (2002–14)	
Recommendation	**Source**
For epidural, identify and implement multiple error prevention strategies to enhance differentiation of epidural infusions from other infusions.	(ISMP Canada, 2005a)
Address unsafe working conditions such as long hours without breaks and multitasking between phones, patients, and prescription dispensing	(ISMP Canada, 2002a)
Ensure drug information is readily available, easily accessible, and up-to-date in all areas where medications are administered	(ISMP Canada, 2002b)
Use 2 patient identifiers at every stage of the medication-use process	(ISMP Canada, 2008)
Ensure that all communications about any patient include patient identifiers — consider implementing a standardized approach, such as SBAR (Situation, Background, Assessment, Recommendation)	(ISMP Canada, 2008)
Ensure that pertinent and up-to-date paediatric drug information is readily available	(ISMP Canada, 2008)
Implement distinct processes for adult and paediatric patients — for instance, changing the appearance of paediatric Emergency Department charts or creating a separate area in the ED for paediatric patients	(ISMP Canada, 2008)
Conduct a risk assessment process when implementing new technology such as ADCs, to integrate safeguards previously in practice	(ISMP Canada, 2008)
Perform Failure Mode and Effects Analysis on all new protocols, procedures, as well as upon the addition of a new high-alert drug or new medication device	(ISMP Canada, 2003a)
Use only IV pumps with set-based anti-free-flow mechanisms — tubing is automatically clamped when removed from infusion pump and practitioner must conscientiously unclamp tubing to initiate fluid-flow by gravity	(Koczmara & Hyland, 2004)
Use tubing without injection ports for all epidural infusions	(Koczmara & Hyland, 2004)
Include vital patient safety strategies into preprinted orders, such as “use tubing **without** injection ports” for all epidural infusions	(Koczmara & Hyland, 2004)
Develop a triage process to ensure timely review of incidents with a potential to cause harm and to provide guidance for decision support	(ISMP Canada, 2012c)
Consider developing standard protocols for administration of the first dose of a reversal agent, such as naloxone	(ISMP Canada, 2012c)
Evaluate processes for reviewing residents’ medications	(ISMP Canada, 2012c)
Evaluate the precautions required for high-alert medications that are commonly used	(ISMP Canada, 2012c)
Develop a comprehensive medication safety strategy that considers the applicability of technology options to enhance medication safety	(ISMP Canada, 2012c)
Regularly assess the safety of the medication-use system through interdisciplinary audit and feedback programs such as the Medication Safety Self-Assessment for Long-Term Care	(ISMP Canada, 2012c)
Provide access to an on-call pharmacist	(ISMP Canada, 2012c)
Note: Some recommendations have been included under more than one category.	

Appendix E — ISMP Canada Opioid-related Publications (2002–14)

Table 1: ISMP Canada opioid-related publications (2002–14)		
Year	**Source**	**Description**
2003	*Hospital News*	Warns about the danger of errors involving high-alert medications It proposed several safeguards for the use of high-alert medications, including not using dangerous abbreviations, using a leading zero before a decimal place, using TALLman letters, among others (ISMP Canada, 2003a).
2003	*Canadian Journal of Hospital Pharmacy (CJHP)*	Addresses criticisms of the requirement of double-checking, indicating independent double checks should only be applied strategically to situations that most warrant their use—prescribing, dispensing, and administering select high-alert medications. The article states that fewer well-placed double checks will be more successful than an overabundance of double checks (U, 2003).
2004	*ISMP Canada*	Published the results of a usability test of two methods of independent double-checking constructed as part of the MSSS Narcotics project (Gosbee, 2004)
2004	*CACCN*[1] *Dynamics*	Discusses how to prevent narcotic adverse events in critical care units, drawing on the Canadian Adverse Events Study. Argues that efforts to enhance system safety must take into account not only the human factors perspective, but also combine these with high-leverage strategies throughout the medication-use process (Koczmara & Hyland, 2004).
2004	*ISMP Canada*	Reviews and provides recommendations on an incident involving a fatal overdose caused by incorrect drug selection (HYDROmorphone instead of morphine), look-alike, sound-alike characteristics, and other environmental distractions (ISMP Canada, 2004b)
2005	*CACCN Dynamics*	Reviews the safety of meperidine (Demerol®) for a variety of indications in critical care and identifying those patients at high-risk of adverse events (Koczmara, Perri, Hyland, & Rousseaux, 2005)
2005	*CJHP*	Shares the results and recommendations from ISMP Canada's Medication Safety Support Service (MSSS) project (Colquhoun & Koczmara, 2005).
2005	*CJHP*	Discusses safety recommendations for sedation in the Intensive Care Unit (ICU) (Perri, 2005).
2006	*CJHP*	Describes the University Health Network (Toronto) experience developing an equi-analgesic dosage chart to enhance the quality of patient care in pain management (Seki & Turner, 2006).
2006	*Hospital News*	Explains the danger of errors involving high-alert medications and outlines some safety initiatives undertaken (U, 2006).
2006	*Hospital News*	Highlights the independent double-check process targeting high-alert drugs as a cost-effective and low-tech safety initiative that can measurably reduce risk (Dueck, 2006). The article also described the Ontario MSSS Narcotics project and its results.
2006	*CPSO*[2] *Dialogue*	Discusses screening for inappropriate medications for the elderly and includes criteria for considering whether certain opioids are appropriate prescriptions for the elderly (ISMP Canada, 2006a).
2006	*Healthcare Quarterly*	Discusses the Ontario MSSS project and preliminary analysis of follow-up survey results from that province's efforts to increase awareness and create further national impetus for the enhancement of safeguards in the use and management of opioids (Colquhoun et al., 2006).
2007	*CJHP*	Two articles discussing standardizing the safe storage and labelling of medications due to LASA (look-alike, sound-alike) and look-alike packaging, as well as unsafe storage practices, which have been cited as contributing factors to the frequency of medication errors in hospitals. Article discusses Calgary Health Region's efforts to standardize and simplify the storage and labelling of medications (Shultz et al., 2007a; Shultz, Harvie, McDonald, Manley, & Cole, 2007b)..

[1] Dynamics is the official journal of the Canadian Association of Critical Care Nurses
[2] College of Physicians and Surgeons of Ontario

Table 1: ISMP Canada opioid-related publications (2002–14)		
Year	**Source**	**Description**
2007	*Hospital News*	Provides an outline of what patients and families should know about fentanyl patches (Kozcmara, Walsh, & Greenall, 2007).
2009	*CJHP*	Describes findings from an analysis of a HYDROmorphone incident and suggested opportunities for pharmacist intervention in the emergency department to reduce the likelihood of medication errors (Greenall, Santora, Koczmara, & Hyland, 2009).
2009	*ISMP Canada*	An ISMP Canada poster summarizing analysis of international medication incidents involving fentanyl patches (Cheng et al., 2009).
2010	*ISMP Canada*	An ISMP Canada poster summarizing the National Collaborative Advancing Medication Safety in Paediatrics, which identified morphine as the most common medication causing harm through medication errors in paediatric settings. Recommends safer opioid delivery is a combination of opioid safety tactics, human factors analysis, and psychological insights (ISMP Canada, 2010a).
2010	*ISMP Canada*	An ISMP Canada poster giving an overview of the Alberta project to enhance opioid medication system safety (Wright, 2010).
2011	*Pharmacy Connection*	The article examines medication safety in paediatrics, looking at the five-stage medication-use process: prescribing, order entry, dispensing, administration, and monitoring. Expired paediatric narcotics were among the cases examined. The article identified several themes in paediatric medication errors: general order entry errors; incorrect patient; allergy; error prone use of high-alert medications; reconstitution; and weight-based dosing (Poon & Ho, 2011).