Ontario Hospital Critical Incidents Related to Medications or IV Fluids Analysis Report

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

ISMP Canada's mandate includes reviewing and analyzing medication incident and near-miss reports, identifying contributing factors and causes, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives. One of ISMP Canada's core competencies is identifying root causes of medication incidents which leads to identification of system safeguards and solutions for prevention of (or mitigation of harm from) medication incidents. This work is done in collaboration with key stakeholders to maximize the dissemination and translation of knowledge into practice.

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Acknowledgements

The collaborating parties of the provincial critical incident reporting program include the Ontario Ministry of Health and Long-Term Care, the Canadian Institute for Health Information (CIHI), the Ontario Hospital Association (OHA), Health Quality Ontario (HQO) and the Institute for Safe Medication Practices Canada (ISMP Canada). The analyses described in this report were prepared using data received from CIHI; however the opinions expressed are those of ISMP Canada only.

ISMP Canada expresses sincere appreciation to all of the organizations and individuals who provided input to the data collection program, the analysis of received data, and the drafting and dissemination of recommendations and bulletins.

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Executive Summary

To advance the patient safety agenda, the Ontario Ministry of Health and Long-Term Care issued a directive that hospitals must report critical incidents involving medications and intravenous fluids to the Canadian Institute for Health Information National System for Incident Reporting (NSIR) beginning in October 2011. Medication incidents are a leading cause of *preventable* adverse drug events, and Ontario has achieved a high level of stakeholder commitment to, and participation in, medication incident reporting and learning. ISMP Canada has been identified as the lead organization to support analysis work for the provincial critical incident reporting program. Anonymous data from the NSIR are reviewed and analyzed by an ISMP Canada multidisciplinary team to help elucidate the contributing factors, determine vulnerabilities or learning opportunities, and identify opportunities to share strategies for mitigating risks and also, more generally, to inform medication safety efforts in Ontario.

Twenty-seven critical medication incidents reported to the NSIR program as having occurred in Ontario hospitals during calendar year 2014 were included in the analysis reported here. It is not possible to determine if this number represents the actual total number of critical incidents occurring in Ontario hospitals during this time period. Twenty-three (85%) of the reported incidents were associated with severe harm, and 4 (15%) were deemed by the reporting hospitals to have contributed to patients' deaths. Most of the critical medication incidents were categorized by reporters as having occurred during medication administration (44%) followed by preparation/dispensing and verification, both at (11%). The most common distinguishable problem associated with an outcome of severe harm or death was wrong quantity (22%), while "other" accounted for one third of these incidents.

The medications most frequently identified as contributing to severe harm or death were HYDROmorphone, methadone, ondansetron, and alteplase. The top therapeutic classes reported as contributing to severe harm or death was opioids.

Quality control (double/independent check processes), communication, behavioural factors, and drug preparation errors were the top categories of contributing factors cited in the submitted incidents. The occurrence of critical errors involving inadequate independent check processes underscore the importance of this strategy of redundancy to verify crucial information at various stages of the medication-use process.

Qualitative analysis of the critical incidents revealed a number of themes that may suggest potential areas of focus for improvement, including naloxone rescue, awareness of patient-related factors that may increase the likelihood of error, high-concentration or diverse concentration products, and the need for continuing education of staff about medication safety strategies.

Learning from individual and aggregate analyses of reported incidents is shared through bulletins designed for use within Ontario, presentations, and knowledge translation projects. The Ontario Critical Incident Learning Bulletins, available from the ISMP Canada website (www.ismp-canada.org/ocil/), describe the results of incident analyses, outline priority areas for future quality improvements, and provide outcome-directed recommendations for system safeguards. Bulletin topics for this reporting year included: promotion of the safe use of insulin pens in hospitals; the importance of naloxone protocols in treating opioid overdoses, the need for a systematic approach to assessment, monitoring

and correction of fluid and electrolyte abnormalities, and potential safety strategies to reduce risks associated with administration of multiple concurrent intravenous fluids.

The overall aim of the critical incident learning program is to strengthen Ontario's ability to avoid or reduce the risk of harmful medication incidents. Such incidents carry a high price tag in terms of real treatment costs, impact on the health of Ontarians, and erosion of confidence in the healthcare system. ISMP Canada's investigation and analysis of contributing factors and underlying causes of the reported medication incidents have in turn supported the generation of recommended actions that Ontario hospitals can apply to reduce the likelihood of harmful incidents:

- Expand the existing reporting directive to include targeted reporting of:
    - incidents involving an identified "theme" or "focus" medication(s) or processes, with the ultimate goal of developing directed strategies and knowledge translation products for the drug or process (e.g., all medication incidents related to anticoagulants, to improve awareness of associated errors and develop recommendations related to safer use and monitoring of this drug class); and
    - incidents involving opioid overdose and naloxone use to enhance analysis and learning.
- Expand the existing reporting directive to encompass long-term care.
- Fund the development and dissemination of evidence-based and appropriate protocols for naloxone use.
- Develop regional or larger scale information sharing systems such that patient allergy and health history information is easily accessible to healthcare workers.
- Fund adoption and integration of bar-coding or other electronic identification methods to reduce product mis-identification and mis-selection.
- Protect and enhance the role of the staff educator to perform research and information gathering for front line workers and to disseminate this learning.
- Develop healthcare safety related education programs that disseminate information to front line staff on a regular basis.
- Ensure staff members have point-of-care access to information and protected time on a regular basis to study updates to policy and procedures, and to acquire specific information relevant to maintaining competence in their daily work.
- Develop work schedules that allow employees time to keep current with what change is happening in their facility, community, and around the world regarding healthcare and medication changes.
- Expand the development and delivery of medication safety training for undergraduate healthcare programs across Ontario.
- Undertake a multi-incident analysis of medication incidents involving the contributing factor of "insufficient knowledge" and use this information to understand the deficits in knowledge and how to approach remediation.

Follow-up with individual facilities about reported incidents has led to productive and fruitful relationships that have aided both the individual facilities and the ISMP Canada analysis team. Individual facilities have gained detailed support for incident analysis, leading to increased awareness of safety principles. ISMP Canada has gained an enhanced understanding of the difficulties with and effort required to implement large scale system-based changes subsequent to incidents. This has informed approaches to action development for subsequent cases. The critical incident learning program has

supported development of a network of partnering organizations and practitioners from all healthcare disciplines who are working collaboratively to increase safe and effective care.

This report reflects work completed in the third year of the critical incident learning program; the initial and second year reports are both available from the ISMP Canada website (www.ismp-canada.org/ocil). In the coming year, the program will continue to focus on emerging issues in medication safety as identified through analyses of reported incidents. Emerging issues help to identify topics for focused knowledge translation projects; for example, in 2014-15, a toolkit to facilitate medication safety at transitions from hospital to home and a checklist to evaluate the safety of labels for epidural products were developed. Initiatives are underway to enhance shared learning from incident analysis through increased dissemination of bulletins via professional regulatory colleges and associations, and in-person and virtual presentations by ISMP Canada.

Hospitals reporting critical incidents to the NSIR and participating in incident analysis with ISMP Canada demonstrate a strong commitment to quality improvement and patient safety. Learning from incident analysis shared through this program benefits all Ontario hospitals, contributes to protection of patients from harm, and validates the dedication to excellence of front-line providers and healthcare organizations.

Background and Rationale

In October 2011 the Ontario Ministry of Health and Long-Term Care issued a directive mandating that all critical incidents involving IV fluids and medications be reported to the Canadian Institute for Health Information (CIHI) National System for Incident Reporting (NSIR).[1] This reporting requirement builds upon the patient safety and quality initiatives of the *Excellent Care for All Act*[2] and Regulation 965 under the *Public Hospitals Act.*[3] Following disclosure of a critical incident, hospital boards are required to ensure that the hospital administrator establishes a system for analyzing the critical incident and develops a system-wide plan to avoid or reduce the risk of further similar incidents. According to Regulation 965, a critical incident is an "unintended event that occurs when a patient receives treatment in the hospital that results in death, or serious disability, injury or harm, and does not result primarily from the patient's underlying medical condition or from a known risk inherent in providing treatment".

Medication incidents are a leading cause of *preventable* adverse drug events and Ontario has achieved a high level of stakeholder participation in, and commitment to, medication incident reporting and learning. A medication incident is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.[4]

ISMP Canada has been identified as the lead organization to support analysis work for the provincial critical incident reporting program. Anonymous data received from the NSIR are reviewed by a multidisciplinary team to ensure effective identification of the contributing factors. Analyses are completed in a timely fashion to identify medication system vulnerabilities, to share strategies for mitigating risks, and to inform medication safety efforts in Ontario. In addition, ISMP Canada periodically conducts aggregate analyses of reported incidents to provide a more in-depth assessment of events involving a particular medication or care setting, or to highlight a particular vulnerability or learning opportunity. On the basis of these analyses, ISMP Canada develops and disseminates outcome-directed recommendations, with an emphasis on high-leverage actions that take into account human factors engineering principles and the need to design systems with integrated safeguards.

Learning from individual and aggregate analyses of reported incidents is shared in bulletins designed for Ontario use, as well as through presentations and knowledge translation projects. These Ontario Critical Incident Learning Bulletins, available from the ISMP Canada website (www.ismp-canada.org/ocil/), describe results of incident analysis, outline priority areas for future quality improvement work, and provide outcome-directed recommendations for system safeguards. Presentations have been delivered through webinars as well as on-site for individual facilities, providing medication safety education to frontline healthcare providers and hospital leaders, as well as highlighting particular issues identified through the critical incident learning program. Collaborative knowledge translation projects have been undertaken during each year of the critical incident learning program. The goals of these projects are to identify effective, evidenced-based interventions and to develop tools to support Ontario hospitals with safe medication use related to a focused area. The knowledge translation process and knowledge product tools developed through these focused projects are shared through bulletins, webinars/presentations and a dedicated project webpage on the ISMP Canada website.

ISMP Canada's work is done in collaboration with key stakeholders to maximize knowledge dissemination and support for translation of knowledge into practice. It is well recognized that knowledge translation activities require foundational investment in analysis and evidence generation, as well as input from experts. In Ontario, ISMP Canada has built effective and collaborative partnerships with stakeholders, including professional associations, regulatory colleges and the Office of the Chief Coroner for Ontario. Working collaboratively with key partners informs the analysis process, assists with expert review processes, and also creates mechanisms for dissemination of information. ISMP Canada will continue to work closely with provincial partners to develop an aligned and coordinated approach for medication safety in Ontario.

Methods

A data-sharing agreement between CIHI and ISMP Canada provides ISMP Canada with access to data submitted to NSIR under the terms of the Ministry directive and a mechanism to connect with reporting facilities. ISMP Canada submitted data requests to CIHI for an anonymous dataset of Ontario incidents. The data was extracted from NSIR every two weeks throughout the year for ISMP Canada analysis.

All critical incident reports were reviewed and analysed by a multidisciplinary team. The depth of analysis was variable and dependent on the level of detail provided in the report and the ability to follow-up directly with the reporting facility. All reporters of critical incidents were sent a follow-up communication from ISMP Canada. Further communication and information was elucidated from the reporter and/or healthcare facility, where possible. Within the broad categories, further categorization of error factors was performed.

Where emerging issues in medication safety were identified and permission was obtained to share learning from these incidents, processes were undertaken to disseminate learning via bulletins and other means.

Results

A total of 27 Ontario critical incident reports were released into the NSIR with a submission date range between January 1, 2014 and December 31, 2014.[5] All incidents were analyzed by an interdisciplinary team at ISMP Canada in accordance with a medication incident analysis framework.

A follow-up communication was sent to all of the reporting organizations. Eight facilities (30%) responded and indicated interest in working with ISMP Canada to help analyze the incidents or review system improvement opportunities. Follow-up communication with facility risk managers, department managers, administrators, and frontline staff provided opportunity to expand on details initially reported, obtain further background information, and better elucidate the factors that led to the incident, assisting in identification of potential system improvement strategies.

Degree of Harm

The classification of harm is defined by the severity and duration of harm and the treatment implications that result from an incident. A severe outcome is defined as symptomatic, requiring life-saving intervention or major surgical/medical intervention, or shortening life expectancy or causing major permanent, long-term or loss of function. An outcome of death is defined as, on the balance of probabilities, the incident was considered to have played a role in the patient's death.[6]

For this reporting year, 23 incidents (85%) were associated with **severe harm** while 4 incidents (15%) were reported to have contributed to **death.**

Table 1: Critical Incidents by Degree of Harm

Degree of Harm	Number of reports	Percentage
Severe	23	85
Death	4	15
Total	**27**	**100**

Since the inception of the program, a total of 92 critical incidents have been reported, with 72 (78%) associated with severe harm and 20 (22%) reported as contributing to death.

Medication/IV Fluid Use Process (Stage of the Medication Use System)

The medication use process is divided into a number of operational steps in order to facilitate analysis (Table 2).

The majority of the critical medication incidents were categorized by reporters as having occurred during medication **administration** (44.4%). One of the administration errors was determined to have contributed to death.

In 11.1% of cases, the incident was reported to have occurred during the **preparing/dispensing** stage of the medication/IV fluid use process.

The **prescribing** process was identified by the reporters of 2 critical medication incidents with one of these incidents determined to have contributed to death. The prescribing stage is one of the first opportunities to influence safety in the medication use process. Prescribing errors have a greater opportunity to be discovered and corrected because of the number of subsequent stages in the patient care process where errors may be identified. Administration errors, on the other hand, are less likely to be intercepted as administration is the last step in the medication use process before an error reaches a patient.

Table 2: Critical Incidents by Medication/IV Fluid Use Process (Stage of the medication use system)

Medication/IV Fluid Use Process				
	Severe Harm	**Death**	**Total**	**Percentage (%)**
Administration	11	1	12	44.4
Preparing/dispensing	2	1	3	11.1
Order verification (pre-admission)	2	1	3	11.1
Prescribing	1	1	2	7.4
Monitoring (post-admission)	2	0	2	7.4
Order documentation	2	0	2	7.4
Other	2	0	2	7.4
Storage/location	1	0	1	3.7
Total	**23**	**4**	**27**	**100**

Medication/IV Fluid Problem Types

Medication incidents can be divided into a number of types.

Wrong quantity was implicated in 6 critical incidents, **wrong rate/frequency** accounted for 1, and **extra dose** contributed to 2 of these harmful outcomes. Taken together, **wrong quantity, wrong rate/frequency, and extra dose** accounted for 9 (33.3%) harmful errors. This suggests that overdose – the common outcome of **wrong quantity** and **wrong rate/frequency** and **extra dose** – remains a very common contributor to medication errors.

The most common medication/IV fluid category associated with an outcome of severe harm or death was "**other"** (33.3%), accounting for one death.

Incorrect product accounted for 18.5% of medication/IV fluid problems, representing little change from previous years.

Table 3: Critical Incidents by Medication/IV Fluid Problem Type

Medication/IV Fluid Problem	Number of Incidents			
	Severe Harm	Death	Total	Percentage (%)
Other	8	1	9	33.3
Wrong quantity	5	1	6	22.2
Wrong product	4	1	5	18.5
Extra dose	2	0	2	7.4
No order	1	0	1	3.7
Omitted dose	1	0	1	3.7
Wrong patient/resident	1	0	1	3.7
Wrong rate/frequency	1	0	1	3.7
Wrong route/technique	0	1	1	3.7
Total	**23**	**4**	**27**	**100**

Patient Care Areas

Thirty patient care areas were noted for the 27 incidents; certain errors occurred in more than one environment.

The highest number of reported critical incidents associated with severe harm or death came from critical, high-intensity patient care areas such as **emergency departments** (30.0%), **surgical areas** (13.3%) and **intensive care units** (10.0%).

These care areas are often associated with severely ill patients who require rapid assessment and treatment. Healthcare practitioners can often be called upon to make urgent decisions based on incomplete information under enormous time pressure, which can increase the potential for errors to occur.

In some cases, more than one area was reported.

Table 4: Critical Incidents by Patient Care Areas

Patient Care Area	Frequency	Combined Frequency	Percentage (%)
Emergency	9	9	30.0
Surgical areas: Day surgery	1	4	13.3
Neurosurgical unit	1		
Operating room	2		
Intensive care units: Coronary intensive care unit	1	3	10.0
Other intensive care unit	2		
Combined medical/surgical unit	3	3	10.0
Oncology clinic-pre and post treatment therapy	1	2	6.7
Other oncology Unit	1		
Mental health and addiction services	2	2	6.7
Other functional unit	2	2	6.7
General medical unit	1	1	3.3
Other medical unit	1	1	3.3
Interventional/angiography studies	1	1	3.3
Diagnostic and therapeutic services – unspecified	1	1	3.3
Palliative unit	1	1	3.3
Total	**30**	**30**	**100**

Medication / IV Fluid

The top 4 medications contributing to severe harm or death in the 2014 dataset were: HYDROmorphone, methadone, ondansetron, and alteplase. As in previous years of this program, HYDROmorphone was the most common medication implicated in errors causing harm, and a range of opioids, anticoagulants, and cancer drugs were also found in the data, reflecting their status as high-alert drugs; i.e., more likely to cause harm if used in error. Similar to previous years, however, a wide variety of medications were reported as causing harm in incidents, suggesting that patient injury can occur with any drug.

In some cases, more than one drug was reported to contribute to harm or death in an incident.

Table 5: Critical Incidents by Medication / IV Fluid

Generic Name	Frequency			
	Severe Harm	Death	Total	Percentage of total incidents (%)
HYDROmorphone	4	1	5	18.5
methadone	2		2	7.4
ondansetron	2		2	7.4
alteplase	2		2	7.4
diltiazem	1		1	3.7
paclitaxel		1	1	3.7
sodium chloride		1	1	3.7
tacrolimus		1	1	3.7
amphotericin b	1		1	3.7
argatroban	1		1	3.7
cisplatin	1		1	3.7
diazepam	1		1	3.7
enoxaparin sodium	1		1	3.7
gentamicin	1		1	3.7
heparin sodium	1		1	3.7
ifosfamide	1		1	3.7
methylphenidate	1		1	3.7
morphine	1		1	3.7
norepinephrine	1		1	3.7
protamine	1		1	3.7
raltitrexed	1		1	3.7
acetaminophen	1		1	3.7
oxycodone	1		1	3.7
acetaminophen/oxycodone	1		1	3.7
Total	**27**	**4**	**31**	**100**

Therapeutic Drug Class

The therapeutic classes most frequently reported as contributing to severe harm or death included **opioids** and **antineoplastics**. HYDROmorphone, a high potency opioid, accounted for the majority of opioid overdose incidents with an outcome of severe patient harm or death. The opioid class of drugs continues to account for close to one third of harmful errors and this has been the case for some time. It is well accepted that opioids cause harm when used for illicit purposes, but data such as this demonstrate the risks associated with these medications even when used in a therapeutic context.

Antineoplastic agents and agents that affect blood clotting (**Anticoagulants, Anticoagulant Antagonists, Thrombolytic agents**, and **Platelet Aggregation Inhibitors**) are again represented in this list. Because there is a narrow range between an effective dose and a toxic dose for these classes of medications, and because these agents can have profound physiologic effects, dosing, prescribing, or administration errors with these groups of high-alert medications can lead to patient harm.

It is notable that some medications and therapeutic classes identified as causing harm in previous years do not appear in this report. This highlights the fact that there are many factors contributing to the likelihood of a medication incident and these factors are independent of the drug and class. Although there are some medications more commonly associated with harm as a result of errors, no single medication or class is unaffected by this risk.

In some cases, more than one drug class was reported to contribute to harm or death in an incident.

Table 6: Critical Incidents by Therapeutic Drug Class

Therapeutic Class	Frequency			
	Severe Harm	Death	Total	Percentage of total incidents (%)
Opiates	8	1	9	33.3
Antineoplastic Agents	3	1	4	14.8
Immunosuppressant Agents		1	1	3.7
Replacement Solutions		1	1	3.7
Anticoagulants	2		2	7.4
Anti-emetics	2		2	7.4
Thrombolytic Agents	2		2	7.4
Aminoglycosides	1		1	3.7
Benzodiazepines	1		1	3.7
Cardiac Drugs	1		1	3.7
Fungicides	1		1	3.7
Miscellaneous Analgesics and Antipyretics	1		1	3.7
Miscellaneous Analgesics and Antipyretics + Opiates	1		1	3.7
Platelet Aggregation Inhibitors	1		1	3.7
Anticoagulant Antagonist	1		1	3.7
Central Nervous System (CNS) Stimulant	1		1	3.7
Sympathomimetic Agents	1		1	3.7
Total	**27**	**4**	**31**	**100**

Contributing Factors

The NSIR allows reporters to select from a list of one or more contributing factors that played a role in the incident. In the 27 critical incidents reported in 2014, 186 factors were identified to have contributed to the incident.

Quality control (e.g., independent double checks), communication, behavioural factors, and drug preparation error were the top 4 contributing factors cited in the submitted incident reports.

The most commonly reported contributing factor associated with death was a communication issue. This highlights the importance of accurate and precise exchanges of information and the risk to patients if communication methods break down. This also emphasizes the need to continuously improve communication practices.

The critical medication incidents involving inadequate independent check processes underscore the importance of this strategy of redundancy to verify crucial information at various stages of the medication process.

Table 7: Top Contributing Factors Reported for Critical Incidents

Top Contributing Factors Reported	Frequency			
	Severe Harm	Death	Total	Percentage of total incidents (%)
Quality control-double/independent check processes	11	2	13	48.1
Communication factors-unspecified	7	3	10	37.0
Behavioural factors-unspecified	8		8	29.6
Drug preparation error	7	1	8	29.6
Attention issues-failure to remember	5	1	6	22.2
Drug product confusion-unspecified	5	1	6	22.2
Drug storage conditions	6		6	22.2
Drug delivery process	5		5	18.5
Electronic documentation-incomplete, incorrect or inaccessible	3	2	5	18.5
Insufficient knowledge	4	1	5	18.5
Other	5		5	18.5
Products, technology and infrastructure-unspecified	3	2	5	18.5
Automated dispensing systems	3	1	4	14.8
Calculation error	3	1	4	14.8
Distractions/frequent interruptions	3	1	4	14.8
Emergency situation	4		4	14.8
Misapplication of standard procedure/protocol	3	1	4	14.8
Transcription inaccuracy	3	1	4	14.8
Work-around/shortcut	3	1	4	14.8

Patient Age Group

The age groups of 65 to less than 85 years (26%), 45 to less than 65 years (22%), and 18 to less than 45 years (15%) together accounted for 63% of the persons affected by critical incidents contributing to severe harm and death. No pediatric cases were reported in this period.

A high number of unreported age classifications were noted in the data for this reporting period.

Table 8: Critical Incidents by Patient Age Group

Age Group	Frequency			
	Severe Harm	Death	Total	Percentage of total reports (%)
Paediatrics	0	0	0	0
18 to < 45 years	3	1	4	14.8
45 to < 65 years	4	2	6	22.2
65 to < 85 years	7	0	7	25.9
85 + years	0	0	0	0
Unknown	9	1	10	37.0
Total	**23**	**4**	**27**	**100**

Qualitative Themes and Discussion

Qualitative study of the 27 critical incidents along with analysis of the quantitative data identified a number of themes, and may suggest potential areas of focus for improvement, and for future work within the Ontario critical incident reporting and learning program.

Naloxone Rescue

Certain medication overdoses can be corrected and the patient recovered from harm if timely and effective monitoring is in place. Again this year, a number of incident reports noted that it was only timely assessment by a healthcare provider or a crucial observation by a family member that alerted the care team to a problem. Without this warning, some of these patients would have had worse outcomes.

In particular, naloxone is a life-saving reversal agent that can be used to rescue patients from an opioid overdose. A number of facilities this year reported having used naloxone after recognizing a potential opioid overdose. Some of these cases involved astute observations by family members, or a chance evaluation by a healthcare provider. It is unknown if the facilities involved employed systematic monitoring of patients receiving opioids in order to better determine if a patient is at risk. In some circumstances, analysis revealed there was no systematic approach to the use of naloxone.

Naloxone is a life-saving drug, and ISMP Canada encourages a systematic approach through predefined naloxone protocols.

- Responses to date
    - ISMP Canada published an Ontario Critical Incident Learning bulletin on naloxone.
    - ISMP Canada has identified the importance of systematic approaches to monitoring that can detect a patient at risk of opioid toxicity and trigger an appropriate response from the healthcare team.
    - ISMP Canada has created and made available an opioid safety handout designed to educate patients and family members that highlights some of the warning signs that require emergent care, such as naloxone.[7]

- Future opportunities for response
    - Fund the development and dissemination of evidence-based and appropriate protocols for naloxone use.
    - Mandate organizations to develop safe and effective monitoring processes that can trigger the use of naloxone protocols.
    - Direct the reporting of all medication incidents involving opioid overdose and naloxone administration to enhance analysis and learning.
    - Commit resources and/or agencies to provide support and training for the development and implementation of naloxone protocols.

Patient Factors

Multiple incidents reported to the NSIR involved medication errors related to factors pertaining to the patient, or a physiologic condition of the patient. One of the most obvious patient factors to take into account when prescribing is an allergy to the drug or a constituent of the drug.

In certain cases, drug doses must be altered in response to some characteristic inherent in the patient. For example, a number of antibiotics must be dosed differently in patients with chronic kidney disease, or doses must be decreased in the presence of liver failure. The use of social or illicit recreational drugs can also change the manner in which a drug is metabolized, may necessitate a different pharmaceutical approach than planned, or create the need for enhanced monitoring. These are examples of drug-disease interactions.

A number of cases this year highlighted the need to be vigilant about these patient-related factors.

- Responses to date
    - ISMP Canada endorses the reconciliation of medication allergies as well as medications, ensuring this crucial information is transferred from care area to care area.
    - ISMP Canada continues to recommend integration of medication interaction software and patient medical history into electronic prescribing modules and pharmacy software.
    - ISMP Canada continues to collect data on patient factor errors.

- Future opportunities for response
    - Ensure electronic clinical records capture patient factors such as allergies and medical history and disease and that this data is used to help prescribers and pharmacists safely use drugs with that patient.
    - Ensure prescribing software highlights medications that may need altered doses or schedules depending on clinical condition.
    - Develop regional or larger scale information sharing systems such that patient allergy and health history information is easily accessible to healthcare workers.

High Concentration or Diverse Concentration Product Errors

In a number of cases of medication incidents reported to the program, reporters identified either high dose/high concentration products or the availability of different concentrations of the same product as contributing factors to the error. Many medications come in more than one concentration to align with clinical need. Certain drugs also come in more than one formulation and each of these formulations can have different concentrations and may require different doses or have different indications.

This availability of several strengths of medications often causes confusion and error. Having the same drug available in different concentrations in the same care area leaves open the possibility of product mis-selection and harm to patients. Independent double checks can provide a level of protection, but standardization of a product line, availability of patient-specific unit dosing (in lieu of bulk products), and the removal of high concentration products from care areas provide more effective safeguards against harm.

Different formulations of drugs may provide some clinical benefit in certain situations, but must be adequately differentiated and/or segregated to reduce the risk of error. Certain facilities have decided to rationalize their product lines by using only one formulation of the drug.

- Responses to date
    - ISMP Canada partners with external agencies like Accreditation Canada to recommend removal of high dose/high concentration products from clinical care areas.
    - ISMP Canada supports the standardization of medication products to ensure consistency and simplification.
    - ISMP Canada endorses the use of patient-specific unit dose delivery devices.
    - ISMP Canada recommends the use of independent double checks for high-alert medications.
    - ISMP Canada has worked with facilities and safety organizations to reduce the risk of high dose/high concentration product errors.

- Future opportunities for response
    - Encourage drug manufacturers to create unit dose, patient-specific products.
    - Provide resources and training to ensure high level compliance with effective independent double checks.
    - Fund adoption and integration of bar-coding or other electronic Identification methods to reduce product mis-identification and mis-selection

Continuing Education

Healthcare is in a constant state of change as our knowledge about diseases increases, and our processes and procedures evolve. Keeping up to date can be difficult. There is an ever present demand to assimilate new information that is current and significant, but it is difficult to sift through and retain what is important. Education resources may not be available to healthcare teams and the pace and demands of delivering health care may leave little time for reading and researching new information. "Insufficient knowledge" is frequently cited as a contributing factor to medication errors and discussions with healthcare facilities highlight knowledge deficits on the part of staff at all levels.

- Responses to date
    - ISMP Canada recommends sustaining high-quality practice by ensuring staff members have point of care access to relevant information about best-practices and medications.
    - ISMP Canada recommends sustaining high-quality practice by ensuring staff members have timely access to educators and /or mentors for advice and guidance.
    - ISMP Canada distributes alerts and bulletins to individual healthcare providers, healthcare organizations and through collaboration with professional regulatory colleges and associations and encourages wide dissemination through these channels.
    - ISMP Canada recommends that organizations ensure they have a robust process that monitors staff education, competence and compliance in executing protocols and using related medication administration devices.

- Future opportunities for response
    - Ensure staff members have point-of-care access to information and protected time on a regular basis to study updates to policies and procedures, and to acquire specific information relevant to maintaining competence in their daily work.
    - Encourage healthcare-related education programs that disseminate information to frontline staff on a regular basis.
    - Develop work schedules that allow employees time to keep current with changes happening in their facility, community and around the world regarding healthcare and medication.
    - Protect and enhance the role of the staff educator to perform research and information gathering for frontline providers and to disseminate this learning in a relevant and effective form.

Reporting, Analysis, and Knowledge Translation

As in years previous, the collection and analysis of incident reports remains the backbone of medication safety programming. The identification of contributing factors to medication incidents relies upon a robust reporting and analysis system and this opportunity for investigation and improvement leads to the development of recommendations and the dissemination of knowledge.

- Responses to date
    - ISMP Canada is committed to the Ontario Critical Incident Reporting program, a foundational program that supports medication safety for Ontarians.
    - ISMP Canada is committed to supporting healthcare organizations and practitioners in Ontario by assisting with incident analysis and disseminating information.
    - ISMP Canada continues to collect data on medication incidents, develop recommendations, and share learning across the province and beyond.

- Future opportunities for response
    - Expand the scope of reporting to other sectors of healthcare (e.g., long-term care).
    - Identify “theme” or “focus” medications or processes that can benefit from enhanced reporting and use this data to develop directed strategies and knowledge translation products around the drug or process (e.g., report all medication incidents related to anticoagulants for one year to improve awareness of associated errors and develop recommendations related to safer use and monitoring).

Shared Learning through Ontario Critical Incident Bulletins

Sharing Insulin Pens is a High-Risk Practice

Insulin pens are injection devices that are designed to help patients administer their own insulin with greater ease, convenience, and accuracy relative to the traditional insulin vial, needle, and syringe. These advantages have led to a rise in the popularity of insulin pens in facilities, which has been paralleled by an increase in concerns about the high-risk practice of sharing insulin pens between different patients. Since insulin cartridges and reservoirs can be contaminated with blood and other biologic material after their first use, sharing insulin pens carries the potential for transmission of blood-borne pathogens (e.g., HIV, hepatitis B, hepatitis C). ISMP Canada, with support from the Ontario Ministry of Health and Long-Term Care, led a knowledge translation project to develop evidence-based interventions and resources promoting the safe use of these devices. A key resource developed is the "Safe Use of Insulin Pens" e-Learning module. The module is intended to help healthcare providers recognize the advantages and disadvantages of insulin pens, understand the risks associated with the use of these devices, and develop best-practice administration techniques while learning to use insulin pens safely. This bulletin is available at: http://www.ismp-canada.org/download/ocil/ISMPCONCIL2014-9_SharingInsulinPens.pdf

Naloxone Saves Lives

Opioids constitute a class of high-alert medications whose toxic effects can cause sedation, confusion, and respiratory compromise and can lead to death. Fortunately, an effective and life-saving reversal agent—naloxone—is available. Naloxone temporarily replaces the opioid at the site of action of the drug, counteracting the toxic effects. With appropriate monitoring, patients known or suspected to be experiencing toxicity can be identified and rescued from the effects of opioid overdose with timely administration of naloxone and the initiation of other medical interventions. Naloxone has a shorter duration of effect than some opioids, and once it has been metabolized by the body, there is a risk that the pharmacological effects of the opioid will re-emerge, causing harm to recur. Therefore, patients receiving naloxone must be monitored closely for a prolonged period to ensure that any re-emergence of toxic effects is immediately addressed. Further administration of naloxone along with a higher level of care and medical intervention may be required. Naloxone also antagonizes the opioid's analgesic benefits, potentially inciting severe pain or withdrawal effects. Health care providers must be aware of these attributes and must manage these variables to safely mitigate the toxicity of opioids while maintaining their desired effects. Predefined naloxone protocols can help practitioners to balance conflicting clinical priorities and address the potential for unfamiliarity with appropriate dosing of naloxone because of infrequent use. Such protocols are an important tool for safe opioid management. This bulletin is available at: http://www.ismp-canada.org/download/ocil/ISMPCONCIL2014-10_NaloxoneSavesLives.pdf

Multiple IV Infusions: Risks and Recommendations

Despite growing awareness of the factors that lead to errors in programming a single intravenous (IV) infusion, minimal research has been conducted into the errors that can result from administering multiple IV infusions to a single patient. The use of multiple IV infusions is often unavoidable, and the complexity of the processes involved in managing these infusions contributes to the risk for medication

errors. The Ontario Critical Incident Learning program recognizes the challenges that front-line practitioners face in managing multiple IV infusions and in preventing these types of errors. Over the long term, improvements in the design of infusion systems are needed to solve problems associated with administering multiple IV infusions to individual patients. However, over the short term, supporting clinicians with targeted strategies can reduce inherent hazards and improve safety. The following are examples of errors and selected strategies designed to reduce or eliminate the risks associated with managing multiple IV infusions. This bulletin is available at: http://www.ismp-canada.org/download/ocil/ISMPCONCIL2014-11_MultipleIV-Infusions.pdf

Fluid Management

Most patients who are receiving inpatient care require fluid and electrolyte management, a process that is often thought of as simple and routine. However, evaluation of fluid status and replacement of fluids are complex activities, and there can be profound clinical consequences for patients if these tasks are not well managed. Electrolyte disturbances and pulmonary edema are but a few of the potential adverse sequelae that may develop while managing a patient's illnesses, comorbid conditions, and requirements for hydration. Determining an optimal regimen for replacing fluids and electrolytes involves clinical assessment of fluid volume status and measurements of fluid input and fluid loss. Appropriate imaging and laboratory measurement of electrolytes and organ function are also required.
The safe use of replacement fluids and electrolytes requires a respect for the unique needs of each patient. It also demands a systematic approach to assessment, monitoring, and correction of any deficit. This bulletin is available at: http://www.ismp-canada.org/download/ocil/ISMPCONCIL2015-12_FluidManagement.pdf

Program Limitations and Challenges

After an improvement in reporting towards the end of fiscal 2012-2013, the reporting rate has levelled off and approaches the number of cases reported in the previous years.

The number of direct contacts with facilities was slightly lower than the last reporting period; however it has been our experience again this year that, once contacted, most organizations are enthusiastic in their commitment to safety and are open to sharing further details and information. Facilities often do a more complete analysis than what is reflected in the NSIR report and ISMP Canada has been able to enhance information sharing to advance patient safety in other organizations.

Through informal channels, it is noted that facilities often have their own reporting structures and requirements within their organizations and that secondary reporting to the NSIR may be burdensome or may simply be deferred indefinitely.

Again this year, many reports do not include the strategies recommended by the reporting facility to reduce the risk of experiencing a similar medication incident. The Ministry directive about reporting critical incidents does dictate the inclusion of these recommendations or strategies as well as a timeframe in which reporting is to occur. Despite this, many reports do not include any future strategies or recommendations. This may be due to lack of awareness of reporting requirements, inability to perform required internal reviews and analysis in the specified time, fear of violating other legislation about confidentiality and privacy, the duplication of reporting work, or simply an omission of follow-up once the incident has been reported.

Moving Forward

The overall aim of the Ontario critical incident reporting and learning program is to strengthen the province's ability to avoid or reduce the risk of harmful medication incidents. Such incidents carry a high price tag in terms of real treatment costs, impact on the health of Ontarians, and erosion of confidence in the healthcare system. Incident reporting is important to identify trends and emerging issues; however, critical learning requires analysis of this information. The ultimate benefit of the program is the generation of recommended actions to reduce the likelihood of recurrence in the reporting facility and elsewhere. Healthcare in the 21st century is a complex undertaking, and there will always be new opportunities for error – key to reducing harm is identifying system vulnerabilities so that preventive strategies can be developed and widely shared.

Through the critical incident learning program, ISMP Canada team members had the opportunity to present to and network with practitioners in all healthcare disciplines in a variety of settings. These networks support additional efforts toward wider dissemination of the bulletins through professional bodies and colleges, continued presence and presentation at conferences and meetings, and other communication and outreach opportunities.

Direct contact with reporting facilities again this year has aided the individual facilities through increased awareness of safety strategies as well as direct assistance from ISMP Canada. This contact with facilities has also yielded benefits to ISMP Canada's critical incident learning team through improved understanding of the difficulties that facilities face in their efforts to implement system-based changes. This enhanced understanding assists ISMP Canada to refine its recommendations for improved success. We were pleased to be able to reconnect with some facilities that had previously engaged with ISMP Canada through the Ontario Critical Incident Program. It speaks to the value of the program that these facilities continue to report incidents through the NSIR, enthusiastically allow ISMP Canada to more profoundly analyse the incident, and recognize the need to share learning from the error.

ISMP Canada is pleased to play such an important role in enhancing the safety of Ontario residents. To ensure the continued protection of patients, ISMP Canada has identified the following opportunities for future work within the Ontario critical incident reporting and learning program, based on vulnerabilities identified to date:

A/ Ministry of Health and Long-Term Care:

- Expand the existing reporting directive to include targeted reporting of the following types of incidents:
    - incidents involving an identified "theme" or "focus" medication(s) or processes, with the ultimate goal of developing directed strategies and knowledge translation products for the drug or process (e.g., all medication incidents related to anticoagulants, to improve awareness of associated errors and develop recommendations related to safer use and monitoring of this drug class); and
    - incidents involving opioid overdose and naloxone use to enhance analysis and learning.
- Expand the existing reporting directive to encompass long-term care.
- Fund the development and dissemination of evidence-based and appropriate protocols for naloxone use.
- Direct the reporting of all medication incidents involving opioid overdose and naloxone use to enhance analysis and learning.

- Develop regional or larger scale information sharing systems such that patient allergy and health history information is easily accessible to healthcare workers.
- Fund adoption and integration of bar-coding or other electronic Identification methods to reduce product mis-identification and mis-selection.
- Protect and enhance the role of the staff educator to perform research and information gathering for front line workers and to disseminate this learning.

B/ ISMP Canada:

- Expand the development and delivery of medication safety training for undergraduate healthcare programs across Ontario.
- Undertake a multi-incident analysis of medication incidents involving the contributing factor of "insufficient knowledge" and use this information to understand the deficits in knowledge and how to approach remediation.
- Develop healthcare safety-related education programs that disseminate information to front line staff on a regular basis.

C/ Ontario hospitals:

- Ensure staff members have point of care access to information and protected time on a regular basis to study updates to policy and procedures, and to acquire specific information relevant to maintaining competence in their daily work.
- Develop work schedules that allow employees time to keep current with what change is happening in their facility, community and around the world regarding healthcare and medication changes.
- Protect and enhance the role of the staff educator to perform research and information gathering for front line workers and to disseminate this learning.

Medications have yielded tremendous benefits to the health of Ontarians. Both lifespan and quality of life have increased over the past century, in large part because of medications effective against acute and chronic illness. The future holds promise of more potent, more effective, and more tailored treatments. The use of these medications represents an important investment in health by both governments and individuals, but it is crucial that they be administered safely and effectively. The Ontario critical incident reporting and learning program helps protect this investment and safeguards the health of Ontarians by identifying emerging areas of risk, thereby generating invaluable information and strategies to enhance medication safety. The presence of a robust and responsive surveillance and analysis system, coupled with thorough analysis of reported incidents and development of system-based safety strategies will help to ensure the health of the people of Ontario today and into the future.

[1] ECFAA and a new directive on medication incidents/IV fluids. Toronto (ON): Ontario Ministry of Health and Long-Term Care; 2011 [cited 2014 Mar 22]. Available from: http://health.gov.on.ca/en/pro/programs/ecfa/legislation/criticalincident/update_20110901.pdf

[2] The Excellent Care for All Act, 2010. Toronto (ON): Ontario Ministry of Health and Long-Term Care; 2010 [cited 2014 Mar 22]. Available from: http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_10e14_e.htm

[3] The Public Hospitals Act, 1990. R.R.O. 1990, Regulation 965: Hospital management. Toronto (ON): Ontario Ministry of Health and Long-Term Care; 1990 [cited 2014 Mar 22]. Available from: http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900965_e.htm#BK1

[4] Adapted with permission from the *National Coordinating Council for Medication Error Reporting and Prevention, What Is Medication Error?*

[5] National System for Incident Reporting, Canadian Institute for Health Information, [data requested 2015 Jan 6]

[6] Canadian Institute for Health Information, The CIHI National System for Incident Reporting (NSIR) Minimum Data Set (Ottawa, Ont.: CIHI, 2012)

[7] Information for patients and families about opioid pain medicines. ISMP Can. 2013[cited 2014 Mar 22];1-2. Available from : http://www.ismp-canada.org/download/HYDROmorphone/ISMPCanada_OpioidInformationForPatientsAndFamilies.pdf