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

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Institute for Safe Medication Practices Canada
Institut pour l'utilisation sécuritaire des médicaments du Canada

info@ismp-canada.org
www.ismp-canada.org

4711 Yonge Street, Suite 501
Toronto, ON M2N 6K8

telephone: 416-733-3131
toll free: 1-866-54-ISMPC
(1-866-544-7672)
fax: 416-733-1146

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency committed to the advancement of medication safety in all health care settings. ISMP Canada works collaboratively with the health care 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.

ISMP Canada also facilitates the implementation of medication reconciliation in acute care, long-term care, primary care and in the home care settings. ISMP Canada works with stakeholders across the continuum of care and also leads an international collaborative project in order to share learning at the global level.

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Key Report Contacts:

Michael Hamilton BSc, BEd, MD, Consultant and Medication Safety Specialist
Carol Lee CHIM, Analyst
Jessica Ma BScPhm, ACPR, RPh, Project Manager

Institute for Safe Medication Practices Canada
4711 Yonge Street
Suite 501
Toronto ON
M2N 6K8

Telephone: 416-733-3131 or toll free 1-866-544-7672
Fax: 416-733-1146
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info@ismp-canada.org

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Acknowledgement

The collaborating parties of the provincial critical incident reporting program include the Ontario Ministry of Health and Long-Term Care, Canadian Institute for Health Information (CIHI), Ontario Hospital Association (OHA) 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.

Special thanks are offered to those individuals and facilities in the Ontario health care community who report medication incidents and who share learning and feedback from their own organizational reviews.

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 October 2011. 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. 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 analysed by an ISMP Canada multidisciplinary team to ensure elucidation of the contributing factors, determination of vulnerabilities or learning opportunities, and identification of opportunities to share strategies for mitigating risks, and to inform medication safety efforts in Ontario.

Thirty-six Ontario critical incidents were included in this report. Twenty-six incidents (72%) were associated with severe harm while 10 incidents (28%) were reported to have contributed to death. Half of the critical medication incidents were reported to have occurred during the medication administration process (50%) and 19.4% were indicated to have occurred during the prescribing process. The most common medication/IV fluid problem associated with an outcome of severe harm or death is incorrect rate/frequency (25%). Incorrect product and incorrect quantity both accounted for 13.9%. Incorrect product errors were associated with high alert medications, and the incorrect quantity errors involved significant overdoses.

The top medications contributing to severe harm or deaths include opioids (i.e., hydromorphone, fentanyl, morphine, oxycodone), heparin, norepinephrine and oxytocin. These medications are all considered high-alert medications and therefore are known drugs that bear a heightened risk of causing significant patient harm when they are used in error. Top therapeutic classes reported as contributing to severe harm or deaths include opioids, anticoagulants, and adrenergic agonists. High potency opioids accounted for the majority of opioid overdose incidents. Factors contributing to opioid overdose include pump/infusion rate issues, the availability of multiple dosage formats or concentrations, and deficits in knowledge related to prescribing practices.

Communication, drug product confusion, and distractions/frequent interruptions were the top 3 contributing factors cited in the submitted incidents. Also of note, the reported contributing factors of incorrect use of infusion pump, calculation error, and infusion pump design together present a theme of interest surrounding the use of infusion pumps. The medications involved are high-alert medications, and the problem involved is usually incorrect rate/frequency resulting in overdose. The issues cited include incorrect programming of pump relating to pump library not being regularly reviewed, calculation error associated with not using an existing pump library, and incorrect pump programming associated with bolus dose work-around.

Qualitative analysis of the critical incidents identified a number of themes that may suggest potential areas of focus for improvement. The themes included medication pairs involved in reported mix-ups, care areas with low or decreased operational service support, care of mental health patients in acute care settings, and readiness in the management of potential complications.

Learning from analyses of the reported incidents is shared in bulletins designed for Ontario use and through presentations. The bulletins describe results of incident analysis, focus on priority areas for future quality improvement work, and provide outcome-directed recommendations for system safeguards. The presentations are done both through webinars and on site, and serve to highlight medication safety issues and to provide education to health care workers.

Through bulletins and presentations ISMP Canada developed and disseminated learning on the provincial critical incident reporting program as there is opportunity to improve both the quantity and the quality of reports submitted. It is anticipated that comprehensive reporting will improve as awareness and support increases.

In the critical incident dataset opioids were the most common medication classes noted. A webinar focusing on opioid-related deaths was presented and hydromorphone, a high-alert drug and potent opioid, was the subject of a bulletin that highlighted the risks involved with the medication.

Transitions of care within a facility are well known as times when medication errors occur. A bulletin was created to highlight a medication incident at a facility where a transition of care led to patient harm and a deficit in the medication reconciliation process was identified as a contributing factor.

Analysis of the incident reports that contained narrative description on future strategies/ recommendations revealed a majority of person-based recommendations being proposed or being initiated. When examining the processes that lead to errors, it is fundamental to recognize that both person-based and system-based strategies work hand-in-hand in contributing to a successful quality program. It is essential that appropriate system-based fail safes are developed and implemented to support person-based risk-reduction efforts. Also important is that these strategies are audited and assessed on an ongoing basis, and used as critical measures to reflect the learning from these incidents. The development of effective recommendations was a topic addressed in an issue of the Ontario Critical Incident Learning bulletin. This bulletin was disseminated with the intent of providing a theoretical background to the creation of effective safety strategies.

The new provincial directive on reporting critical incidents involving medications and IV fluids supports the increased awareness of the value of reporting and learning. The overall aim of the program is to strengthen Ontario's ability to minimize and prevent harmful medication incidents. Success will be measured by the engagement of stakeholders, the capacity for analysis, the responsiveness to issues, the development of effective recommendations, and for the dissemination of knowledge. Medication safety increases quality of services and quality of life across the continuum of care and is a key component of Ontario's patient safety and healthcare quality improvement efforts.

Once contacted, most organizations are open to sharing further details and information. Facilities often do a more complete analysis than what is reflected in the NSIR report. We have responded to a number of calls/emails requesting clarification and or elaboration and have developed strong relationships with numerous healthcare organizations. Additional communication strategies will be reviewed over the next year in order to increase participation. Engaging healthcare organizations, safety organizations, regulatory bodies, and professional associations will increase visibility, awareness, and effectiveness of this important patient safety program.

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 developing 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 from the NSIR are reviewed by an ISMP Canada 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 will periodically conduct aggregate analysis 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 will develop and disseminate 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 analyses of the reported incidents is shared in bulletins designed for Ontario use and through presentations. The bulletins describe results of incident analysis (both in-depth analysis of individual incidents and aggregate or multi-incident analyses), focus on priority areas for future quality improvement work and provide evidence-based recommendations for system safeguards. The presentations are done both through webinars and on site, and serve to highlight medication safety issues and to provide education to health care workers.

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

Data requests were submitted to CIHI from ISMP Canada and an anonymous dataset of Ontario specific incidents were extracted from NSIR on a regular basis for ISMP Canada analysis. All critical incident reports were reviewed and analysed by a multidisciplinary team to the extent allowed by the data. Attempts were made to follow-up with all critical incident reporters. Further information was elucidated from the reporter and/or health care facility where possible. Within the broad categories, further categorization of error factors was performed and outlined below. When and if permission was obtained to share learning from these incidents and where there were identified emerging issues in medication safety the process of bulletin development and dissemination ensued.

Results

A total of 36 Ontario critical incident reports were released into the NSIR with a submission date range between October 1, 2011 and December 31, 2012.[5] All of the reporters of these incidents were contacted for follow-up and a response was received from 15 incidents (42 %). This ongoing contact was used to elaborate on initial reports, to provide further background information, to better understand the factors that lead to the incident, and to better identify 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 balance of probabilities, the incident was considered to have played a role in the patient's death.[6]

26 incidents (72%) were associated with **severe harm** while 10 incidents (28%) were reported to have contributed to **death**.

Table 1: Critical Incidents by Degree of Harm

Degree of Harm	Number of reports	Percentage %
Severe harm	26	72
Death	10	28
Total	**36**	**100**

Medication/IV Fluid Use Process

The medication use process is divided into a number steps. Half of the critical medication incidents were categorized by reporters as having occurred during medication **administration** (50%). Approximately 29% of these critical medication incidents contributed to death.

The **prescribing** process was selected in 19.4% of critical medication incidents. However, none of these incidents contributed to death. This may perhaps be attributed to the opportunities for prescribing errors to be discovered and corrected further along the patient care process. Administration errors, on the other hand, are relatively less likely to be intercepted as administration is the last step in the medication use process before an error reaches the patient.

The **preparing/dispensing** process was reported in 11.1% of cases.

Table 2: Critical Incidents by Medication/IV Fluid Use Process

Medication/IV Fluid Use Process	Number of Incidents				
	Severe Harm	Death	Percentage of process type accounting for death	Total	Percentage of total reports
Administration	11	7	(29% = 7/18)	18	50.0
Prescribing	7	0		7	19.4
Preparing/dispensing	3	1	(25% = 1/4)	4	11.1
Other	1	2		3	8.3
Delivery	2	0		2	5.6
Monitoring	2	0		2	5.6
Supplying	0	0		0	0
Storage/location	0	0		0	0
Order documentation	0	0		0	0
Presentation/packaging	0	0		0	0
Advising/counselling	0	0		0	0
Total	**26**	**10**		**36**	**100**

Medication/IV Fluid Problem

Medication errors can be divided into a number of types. The most common medication/IV fluid problem associated with an outcome of severe harm or death is **incorrect rate/frequency** (25%). This result is reflective of the knowledge and skills required to properly operative infusion devices, and the need for communication amongst providers.

The medication/IV fluid problems of incorrect product and incorrect quantity both accounted for 13.9%. Both contributed to severe harm or death, as the **incorrect product** errors were associated with high alert medications, and the **incorrect quantity** errors involved significant overdoses.

Table 3: Critical Incidents by Medication/IV Fluid Problem

Medication/IV Fluid Problem	Number of Incidents			
	Severe Harm	Death	Total	Percentage %
Wrong rate/frequency	7	2	9	25
Wrong product	4	1	5	13.9
Wrong quantity	4	1	5	13.9
Other	3	2	5	13.9
No order	2	1	3	8.3
Extra dose	2	0	2	5.6
Wrong formulation	1	1	2	5.6
Wrong patient/resident	1	1	2	5.6
Omitted dose	0	1	1	2.8
Wrong route/technique	1	0	1	2.8
Wrong time	1	0	1	2.8
Expired/deteriorated product	0	0	0	0
Wrong storage/location	0	0	0	0
Total	**26**	**10**	**36**	**100**

Patient Care Areas

The majority of reported critical incidents associated with severe harm or death came from critical, high-intensity patient care areas such as **surgical units** (17.1%), **ICU** (14.6%), **emergency departments** (9.8%), as well as from the complex patient care environment of **general medical units** (19.5%). These care areas are often associated with patients that require rapid assessment and treatment, and this acuity can increase the probability of errors.

Table 4: Critical Incidents by Patient Care Areas

Patient Care Area	Frequency	Combined Frequency	Percentage %
General medical unit	8	8	19.5
General surgical unit	4	7	17.1
Other surgical unit	1		
Operating room	2		
Other intensive care unit	6	6	14.6
Emergency	4	4	9.8
Rehabilitation unit	3	3	7.3
Ambulatory care-unspecified	1	2	4.9
Other specialty clinic	1		
Hematology/oncology unit	1	2	4.9
Radiation oncology	1		
Obstetrical suite (labour & delivery)	2	2	4.9
Other functional area	2	2	4.9
Central distribution/main pharmacy	1	1	2.4
Inpatient services-unspecified	1	1	2.4
Long-term care unit	1	1	2.4
Palliative unit	1	1	2.4
Unit-based automated dispensing system	1	1	2.4
Total	**41**	**41**	**100**

Medication / IV Fluid

The top medications contributing to severe harm or deaths include opioids (i.e., hydromorphone, fentanyl, morphine, oxycodone), heparin, norepinephrine and oxytocin. This is not surprising as these medications are all considered high-alert medications and therefore are known drugs that bear a heightened risk of causing significant patient harm when they are used in error.

Table 5: Critical Incidents by Medication / IV Fluid

Generic Name	Frequency			
	Severe Harm	Death	Total	Percentage %
Hydromorphone	3	2	5	11.1
Fentanyl	2	1	3	6.7
Heparin	2	0	2	4.4
Morphine sulphate	2	0	2	4.4
Norepinephrine	0	2	2	4.4
Oxycodone	2	0	2	4.4
Oxytocin	2	0	2	4.4
Acetaminophen	1	0	1	2.2
Acetylsalicylic acid	1	0	1	2.2
Clonzaepam	1	0	1	2.2
Clopidogrel	1	0	1	2.2
Dalteparin	0	1	1	2.2
Dexamethasone	1	0	1	2.2
Dextrose	1	0	1	2.2
Diazepam	1	0	1	2.2
Diltiazem	1	0	1	2.2
Enoxaparin	0	1	1	2.2
Epinephrine	1	0	1	2.2
Furosemide	0	1	1	2.2
Indomethacin	1	0	1	2.2
Insulin	0	1	1	2.2
Ketamine	1	0	1	2.2
Lidocaine	1	0	1	2.2
Magnesium sulfate	1	0	1	2.2
Metformin	1	1	1	2.2
Methotrexate	1	0	1	2.2
Midazolam	1	0	1	2.2
Prednisone	1	0	1	2.2
Propofol	0	1	1	2.2
Ramipril	0	1	1	2.2
Sodium bicarbonate IV	1	0	1	2.2
Tinzaparin	1	0	1	2.2
Triamcinolone	1	0	1	2.2
Warfarin	1	0	1	2.2
Total	**33**	**12**	**45**	**100**

Therapeutic Drug Class

Top therapeutic classes reported as contributing to severe harm or deaths include opioids, anticoagulants, and adrenergic agonists. High potency opioids (HYDROmorphone and fentanyl) accounted for the majority of opioid overdose incidents with an outcome of severe patient harm or death. Reported factors contributing to opioid overdose include pump/infusion rate issues, the availability of multiple dosage formats or concentrations, and deficits in knowledge related to prescribing practices.

The majority of the anticoagulant incidents involved low molecular weight heparin (LMWH). Overall, the types of error include prescribing to patients who should not have received the medication, dose omission, and inappropriate dosing due to inadequate drug level monitoring, or due to incorrect use of an infusion pump. Because there is a narrow difference between an effective dose and a toxic dose for this class of medications, inappropriate dosing or prescribing of this group of high-alert medications can lead to patient harm.

Table 6: Critical Incidents by Therapeutic Drug Class

Therapeutic Class	Frequency			
	Severe Harm	Death	Total	Percentage %
Opioid	9	3	12	26.7
Anticoagulant	4	2	6	13.3
Adrenergic agonist	1	2	3	6.7
Anaesthetic	2	1	3	6.7
Analgesic/anti-inflammatory	3	0	3	6.7
Anxiolytic-sedative	3	0	3	6.7
Corticosteroid	3	0	3	6.7
Electrolyte	3	0	3	6.7
Antihypertensive	1	1	2	4.4
Pituitary hormone	2	0	2	4.4
Antidiabetic (oral)	0	1	1	2.2
Antineoplastic	1	0	1	2.2
Diuretic	0	1	1	2.2
Insulin	0	1	1	2.2
Platelet aggregate inhibitor	1	0	1	2.2
Total	**33**	**12**	**45**	**100**

Contributing Factors

The NSIR interface allows reporters to select from a list of contributing factors that played a role in the incident. In the 36 critical incidents 162 factors were identified to have contributed to the outcome.

Communication, drug product confusion, and distractions/frequent interruptions were the top 3 contributing factors cited in the submitted incidents.

Also of note, the reported contributing factors of incorrect use of infusion pump, calculation error, and infusion pump design together present a theme of interest surrounding the use of infusion pumps. The medications involved are high-alert medications, and the problem involved is usually incorrect rate/frequency resulting in overdose. The issues cited include incorrect programming of pump relating to pump library not being regularly reviewed, calculation error associated with not using an existing pump library, and incorrect pump programming associated with bolus dose work-around.

Table 7: Top 15 Contributing Factors Reported for Critical Incidents

Top 15 Contributing Factors Reported	Frequency		
	Severe Harm	Death	Total
Communication factors	5	3	8
Drug product confusion	4	4	8
Distractions/frequent interruptions	5	3	8
Application of poor procedure/protocol	7	0	7
Attention issues - failure to remember	4	2	6
Workflow design	4	1	5
Misapplication of standard procedure/protocol	4	1	5
Calculation error	1	3	4
Incorrect use of infusion pump	3	1	4
Organizational factors	3	1	4
Medication reconciliation process	3	1	4
Stress	2	2	4
Insufficient knowledge	3	1	4
Quality control-double/independent check processes	3	1	4
Work-around/shortcut	3	1	4

Patient Age Group

The age groups of **45 to < 65 years** (34.2%), **65 to < 85 years** (36.8%), and **over 85 years** (10.5%) together accounted for almost 82% of the persons affected by critical incidents contributing to severe harm and death. Approximately 75% of these critical incidents involving elderly patients over 85 years contributed to death, versus 28.6% for patients in the 65 to < 85 years age group.

Table 8: Critical Incidents by Patient Age Group

Age Group	Frequency			
	Severe Harm	Death	Total	Percentage %
Paediatric	0	0	0	0
18 to < 45 years	4	1 (20% = 1/5)	5	13.9
45 to < 65 years	11	2 (15% = 2/13)	13	36.1
65 to < 85 years	10	4 (28% = 4/14)	14	38.9
85+ years	1	3 (75% = 3/4)	4	11.1
Total	**36**	**10**	**36**	**100**

Qualitative Themes

Qualitative analysis of the 36 critical incidents identified a number of themes, and may suggest potential areas of focus for improvement.

Medication Pairs Involved in Reported Mix-ups

Medication names that sound or look similar are prone to mix-ups, particularly when the dosage ranges are similar. In contrast, the medication pair mix-ups involving oxytocin injection listed in the chart below occurred due to similar looking pre-mixed IV bags and pre-drawn syringes present in the obstetric suite.

Table 9: Examples of Medication Pairs Involved in Reported Critical Incident Mix-ups

Drug Product Mix-ups
Diltiazem Injection 5mg/mL ↔ Diazepam Injection 5mg/mL
Ketamine Injection 10mg/mL or 50mg/mL ↔ Kenalog (triamcinolone) 10mg/mL or 40mg/mL
Lasix (furosemide) Injection 40mg/4mL ↔ Levophed (norepinephrine) 4mg/4mL
Oxytocin Injection ↔ Magnesium Sulfate Injection
Oxytocin Injection ↔ Morphine Sulfate Injection

Care Areas with Low or Decreased Operational Service Support

Another notable finding is the potential for medication errors associated with the selection of medications from floorstock, night cupboard, and automated dispensing cabinets (ADCs). Patient care areas such as outpatient clinics and obstetric suites select medications from floorstock or ADCs for quick access to essential and frequently used medications. During pharmacy department closures, staff select medications either from floorstock, night cupboard, or ADCs. The convenient quick access and rapid initiation of drug therapy are often associated with the bypass of safety procedures such as pharmacy order verification and oversight and clinical checks that come with computerized order entry. These checks are especially crucial when initiating new drug therapy. Another risk factor is the override of ADC alerts, whether due to "alert fatigue", or insufficient assessment of the significance and implication of the alert. With patient safety in mind, risk-reduction strategies include regular careful assessment of the medications to include on floorstock and ADC lists, and to make reference information readily available to all staff.

Care of Mental Health Patients in Acute Care Settings

Patients with pre-existing addiction and/or psychiatric issues require acute healthcare services as with other patient populations. Caring for this patient group in the acute care setting can be challenging, as both their mental health and physical wellness need to be addressed. Health care staff may have limited experience in managing psychiatric illnesses. Overlooking these considerations may have contributed to some of the reported critical medication incidents covered in this report.

Compromised decision making ability on the part of the patient can create a patient safety risk. Guidelines and legal requirements related to the treatment of mentally ill persons are in place to ensure full and proper treatment. Incident data suggest not all healthcare workers are aware of these

guidelines, and systems need to be in place to ensure the proper and adequate care of persons with mental health illness in acute care areas.

Patients with addiction issues often have associated physical co-morbidities or health conditions resulting from their high risk lifestyle. Healthcare professionals should closely monitor potential drug-disease interactions and contraindications in these patients. Also, some of these patients may exhibit opioid tolerance to high doses of opioid medications, but may be susceptible to a subsequent opioid crisis later on. Awareness of these considerations and close monitoring, in combination with assessing best practices and other risk reduction strategies may prevent the recurrence of similar incidents.

Readiness in the Management of Potential Complications

There are various levels and elements of risk associated with different processes that involve medication use within the acute care setting. It is important to proactively identify potential risks, and to mitigate these risks through implementation of comprehensive safety strategies. The review of critical incidents revealed how knowing how to intervene when possible complications arise during routine procedures may reduce patient harm.

For example, in the oncology clinic setting, treatments regularly involve the administration of pre and post medications to protect patients from chemotherapy toxicity. The monitoring of drug levels before assessing the next dose is often an integral component of the protocol as well. Incident analysis determined that laboratory reporting delays contributed to patient harm. A delay in result reporting, a need to use an outside lab, or the need for specialized lab testing may introduce delays in monitoring. The management of these delays must be done in a way that minimizes the risk of toxicity, and could manifest as withholding doses until the result is known or instituting reversal or rescue agents in anticipation of a toxic result. Ideally, the scheduling of a drug regimen takes these known delays into account.

In the surgical or obstetric suite environment, IV bags and pre-draw of syringes are often prepared in anticipation of urgent need. In addition to implementing safeguards to prevent potential errors (e.g. labeling all IV bags and syringes), incident review identified the need to develop protocols to manage possible complications stemming from potential errors involving frequently used high alert medications during routine procedures.

Shared Learning

Critical Incident Reporting

Many of the reports of critical incidents received through the NSIR did not include sufficient detail to allow for meaningful analysis or to allow sharing of quality improvement strategies, notwithstanding detailed follow-up with the reporter. There are opportunities to improve both the quantity and the quality of reports submitted.

Through a bulletin, an Ontario Hospital Association webcast, and a presentation at a Toronto Regional Patient Safety and Quality Leadership Network meeting, Ontario hospitals and practitioners were encouraged to review their reporting processes to enhance participation in this important program. It is anticipated that reporting will improve as awareness and support increases. Comprehensive reporting through the NSIR, including detailed descriptions of the medication incident and actions taken at the hospital level, will support the MOHLTC focus on improving patient safety and will allow for sharing of recommendations. This bulletin is available at: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2012-1_MandatoryReporting-CanWeDoBetter.pdf.

High-Alert Medications

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when used in error. Although mistakes may or may not be more common with these drugs, the consequence of an error with these medications has the potential to be serious. The most common high alert medications are opioids, insulin, and anticoagulants.

This review additionally highlights drug product confusion concerning high-alert and critical medications that are available in regular as well as high potency concentrations (e.g. hydromorphone, epinephrine, sodium bicarbonate IV), and high-alert oral medications supplied in both regular and slow release formulations (e.g. oxycodone). These findings in turn can assist hospitals in focusing their system improvement efforts within their medication safety programs.

In the critical incident dataset opioids and anticoagulants are the most common medication classes noted. Another high-alert medication, insulin, has also been associated with a death. A webinar focusing on opioid-related deaths was presented and hydromorphone, a high-alert drug, was the subject of an Ontario Critical Incident Learning bulletin that highlighted the risks involved with the medication. This bulletin is available at: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-2_HYDROmorphoneRemainsAHighAlertDrug.pdf.

Medication Reconciliation

Admissions, discharges, and transfers within a facility are well known as times when medication errors occur. This is often a result of incomplete documentation or the lack of a well-communicated plan. Medication reconciliation is a systematic process that improves the transfer of medication information accurately and safely across these transitions. Much focus from healthcare safety organizations and governmental authorities has been directed towards this issue.

A bulletin was created to highlight a medication incident at a facility where a transition of care led to patient harm and a deficit in the medication reconciliation process was identified as a contributing factor. This bulletin is available at: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-3_MedicationReconciliation.pdf.

Developing Effective Recommendations

A qualitative analysis of the incident reports that contained narrative description on future strategies/ recommendations revealed a mix of both person-based and system-based recommendations being proposed or being initiated.

The majority of these appear to be person-based strategies that rely on individual awareness and vigilance. One area of focus cited is the re-education of staff about existing policies and procedures. Other person-based strategies mentioned include emphasis on the independent double-check process, the labelling of medications, and the updating of existing policies or the addition of new protocols.

The system-based recommendations cited include increased access to information via active communication tools during critical task junctures (e.g., prescribing stage, order entry stage, infusion pump setup, etc.), the limit of access to high-alert medications, limiting admissions of patients to nursing areas where the resources do not match the required level of patient care, and the ongoing standardization of computer systems and medication use processes to address and mitigate the factors that contribute to the incidents.

When examining the processes that lead to errors, it is fundamental to recognize that both person-based and system-based strategies work hand-in-hand in contributing to a successful quality program. It is essential that appropriate system-based fail safes are developed and implemented to support person-based risk-reduction efforts. Also important is that these strategies are audited and assessed on an ongoing basis, and used as critical measures to reflect the learning from these incidents.

A number of reporters had noted the recommendations arising from their facility's internal review. Organizations often perform high quality incident investigations and derive important safety strategies from these analyses. The sharing of these recommendations is an important method to increase safety of patients around the province.

The development of effective recommendations was a topic addressed in an issue of the Ontario Critical Incident Learning bulletin. This bulletin was disseminated with the intent of providing a theoretical background to the creation of effective safety strategies. This bulletin is available at: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-4_EffectiveRecommendations.pdf

Moving Forward

The overall aim of the program is to strengthen Ontario's ability to minimize and prevent harmful medication incidents. Harmful medication 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 has investigated and analyzed contributing factors and underlying causes of many medication incidents. This in turn has allowed the generation of recommendations that can be used proactively to reduce the likelihood of harmful incidents occurring.

The number of incident reports requiring analysis and knowledge translation of findings is increasing as a result of the raised awareness of the value of reporting and learning. This has been further supported by the new provincial directive on reporting critical incidents involving medications and IV fluids. Success will be measured by the engagement of stakeholders, the capacity for analysis, the responsiveness to issues, the development of effective recommendations, and for the dissemination of knowledge. Medication safety increases quality of services and quality of life across the continuum of care and is a key component of Ontario's patient safety and healthcare quality improvement efforts.

Once contacted, most organizations are open to sharing further details and information. Facilities often do a more complete analysis than what is reflected in the NSIR report. ISMP Canada has been the beneficiary of this knowledge, and it has been used to advance improvements in patient safety.

We have responded to a number of calls/emails requesting clarification and or elaboration and have developed strong relationships with numerous healthcare organizations. However despite efforts, ISMP Canada has not been able to engage a number of organizations in colloquy. Additional communication strategies will be reviewed over the next year in order to increase participation.

Incident analysis has helped clarify previously unrecognized patient safety issues that are worthy of further exploration, such as psychiatric patients in non-psychiatric care areas, concerns with infusion pump programming and use, the development of robust and effective safety strategies, and the need to better disseminate learning from incident analysis.

It has also become apparent that opportunities exist to dialogue with other patient safety organizations in Ontario. Engaging healthcare organizations, safety organizations, regulatory bodies, and professional associations will increase visibility, awareness, and effectiveness of this important patient safety program.

[1] ECFAA and a new directive on medication incidents/IV fluids. Toronto (ON): Ontario Ministry of Health and Long-Term Care; 2011 [cited 2013 Apr 29]. 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 2012 Oct 11]. 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 2012 Oct 11]. 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 18 Jan 2013]

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