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

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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

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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-nine critical medication incidents occurring in Ontario during calendar year 2013 were included in the analysis reported here. Twenty-three (79%) of these incidents were associated with severe harm, and 6 (21%) were reported to have contributed to patients' deaths. Most of the critical medication incidents were categorized by reporters as having occurred during medication administration (38%) or prescribing (31%). The most common problem associated with an outcome of severe harm or death was wrong quantity (34%).

The medications most frequently identified as contributing to severe harm or death were hydromorphone, morphine, epinephrine, heparin, and desmopressin. The top therapeutic classes reported as contributing to severe harm or death were opioids, anticoagulants, and antineoplastics.

Communication, quality control (including double or independent check processes), and knowledge were the top 3 categories of contributing factors cited in the submitted incidents. In the category of "communication factors", use of verbal communication was commonly specified as contributing to critical medication errors. The 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 monitoring, cancer chemotherapy, infusion pumps, temporary or novice healthcare workers, and technology in healthcare. Further analysis of these identified themes is now underway to inform selection of future areas of focus.

Learning from individual and aggregate analyses of the reported incidents is shared through bulletins designed for use within Ontario, presentations, and knowledge translation projects. The bulletins, available from the ISMP Canada website, describe the results of incident analyses, outline priority areas for future quality improvements, and provide outcome-directed recommendations for system safeguards. Bulletins for this reporting year included promotion of the safe use of insulin in hospitals, analysis of a warfarin incident that highlighted the importance of monitoring, review of a pump programming incident with recommendation for full operationalization of pump safety features, and examination of an incident involving opioids in the emergency department.

Presentations delivered through webinars and on site at individual facilities have provided general medication safety education to healthcare workers and have highlighted particular issues identified through the critical incident learning program. A collaborative knowledge translation project has been undertaken as part of the critical incident learning program. The project's goals are to identify effective, evidenced-based interventions and to develop tools to support Ontario hospitals in safe medication use related to a focused area identified through the program. The knowledge translation process and the knowledge product tools of this project have been shared through a bulletin, a webinar, presentations, and a dedicated project page on the ISMP Canada website.

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.

Analysis of the critical medication incidents generated the following opportunities to improve medication safety in Ontario:

- Expand the existing reporting directive to include targeted reporting of the following types of incidents:
    - all incidents involving high-alert medications (i.e., those medications known to carry a heightened risk of harm if an error occurs)
    - all incidents involving technology (e.g., infusion pumps, automated dispensing cabinets, decision support software)
    - all incidents involving identified "theme" or "focus" medications 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)
- Expand the existing reporting directive to encompass long-term care.
- Require organizations to develop plans to support initial acquisition and continuous upgrading of technology known to reduce the likelihood of medication errors, such as computerized prescriber order entry, infusion pumps with error-reduction software (smart pumps), and wireless systems to support simultaneous updating of such devices.
- Provide grant support for capital funding for specific identified technologies (e.g., smart pumps).
- Provide funding for demonstration and pilot projects to evaluate "paperless" medication-use processes.
- Expand the development and delivery of medication safety training for undergraduate healthcare programs across Ontario.
- Undertake a multi-incident analysis of medication incidents involving temporary or agency workers to identify factors contributing to such incidents, and use this information to develop educational programs specifically targeting this provider group.
- In collaboration with stakeholders, create guidelines to standardize the labelling of constituents of solvents and solutes in compounded and reconstituted products (e.g., intravenous admixtures).

- Develop guidelines and training programs related to safe and effective monitoring protocols for high-alert medications.
- Optimize the integration of new staff by directing the use of experienced healthcare mentors or trainers during the initial orientation or when staff roles or work environments are changed.
- Provide resources to ensure availability of experienced and knowledgeable staff to accommodate sudden absences or periods of increased demand.

Productive and fruitful relationships with reporting facilities have both aided the individual facilities (through increased awareness of the safety advice and analysis available from ISMP Canada) and increased overall learning about the difficulties of implementing system-based changes associated with medication incidents and the efforts required to do so. The critical incident learning program has supported 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 second year of the critical incident learning program and demonstrates ongoing interest in and commitment to learning from medication incidents on the part of Ontario hospitals, so that future harms can be prevented. The first-year report is available from the ISMP Canada website. A multifaceted approach to improving both the quality and quantity of incident reporting, undertaken in late 2012 and early 2013, has led to continuing interest in the program. In the coming year, the program will continue to focus on emerging issues in medication safety as identified through analyses of reported incidents. Selection of a knowledge translation project is in progress. Initiatives are underway to increase the dissemination of bulletins through professional bodies and colleges, and there will be continued participation at conferences and meetings (including formal presentations), to take advantage of communication and outreach opportunities as they become available.

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 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 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 the reported incidents is shared in bulletins designed for Ontario use, through presentations, and knowledge translation projects. These bulletins, available from the ISMP Canada website, 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 and on-site for individual facilities, providing general medication safety education to healthcare workers, as well as highlighting particular issues identified through the critical incident learning program. A collaborative knowledge translation project has been undertaken during each year of the critical incident learning program. The goals of the project 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 of this project were shared through a bulletin, webinar, 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 fiscal year basis 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 29 Ontario critical incident reports were released into the NSIR with a submission date range between January 1, 2013 and December 31, 2013.[5] All incidents were analyzed by an interdisciplinary team at ISMP Canada in accordance with a medication incident analysis framework.

All of the reporters of these incidents were sent a follow-up communication. Nine facilities (31 %) indicated a desire to work with ISMP Canada to help analyze the incidents or review system improvement opportunities. This ongoing association was used to understand details about initial reports, to obtain further background information, to better elucidate the factors that lead to the incident, and to assist in identifying 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 (79%) were associated with **severe harm** while 6 incidents (21%) were reported to have contributed to **death.**

Table 1: Critical Incidents by Degree of Harm

Degree of Harm	Number of reports	Percentage %
Severe harm	23	79
Death	6	21
Total	**29**	**100**

The cumulative total numbers since the inception of the program are 65 incidents reported, with 49 (75%) thought to be a factor in severe harm and 16 (25%) reported as contributing to death.

Medication/IV Fluid Use Process

The medication use process is divided into a number of operational steps in order to facilitate analysis. (Table 2) Most of the critical medication incidents were categorized by reporters as having occurred during medication **administration** (37.9%). Approximately 27% of these critical medication incidents were determined to contribute to death.

The **prescribing** process was identified by the reporter in 31% of 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 the 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 the patient.

In 10.3% of cases, the incident was reported to have occurred during the **preparing/dispensing** stage of the medication/IV fluid use process.

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	8	3	(27% = 3/11)	11	37.9
Prescribing	8	1	(11% = 1/9)	9	31
Preparing/dispensing	2	1	(33% = 1/3)	3	10.3
Order documentation	2	0		2	6.9
Other	2	0		2	6.9
Monitoring	0	1	(100% = 1/1)	1	3.4
Presentation/packaging	1	0		1	3.4
Advising/counselling	0	0		0	0
Delivery	0	0		0	0
Storage/location	0	0		0	0
Supplying	0	0		0	0
Total	**23**	**6**		**29**	**100**

Medication/IV Fluid Problems

Medication incidents can be divided into a number of types. The most common medication/IV fluid problem associated with an outcome of severe harm or death was **wrong quantity** (34.5%), accounting for 33% of incidents associated with death.

Wrong rate/frequency accounted for 17.2% of incidents. Taken together, **wrong quantity and wrong rate/frequency** account for 51.7% of incidents. This suggests that overdose – the common outcome of **wrong quantity** and **wrong rate/frequency** – is a very common contributor to medication errors.

Incorrect product accounted for 17.2% of medication/IV fluid problems.

Table 3: Critical Incidents by Medication/IV Fluid Problem

Medication/IV Fluid Problem	Number of Incidents			
	Severe Harm	Death	Total	Percentage %
Wrong quantity	8	2	10	34.5
Wrong rate/frequency	4	1	5	17.2
Wrong product	4	1	5	17.2
Other	4	1	5	17.2
No order	1	0	1	3.4
Omitted dose	1	0	1	3.4
Wrong patient/resident	1	0	1	3.4
Wrong formulation	0	1	1	3.4
Expired/deteriorated product	0	0	0	0
Extra dose	0	0	0	0
Wrong storage/location	0	0	0	0
Wrong time	0	0	0	0
Wrong route/technique	0	0	0	0
Total	**23**	**6**	**29**	**100**

Patient Care Areas

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** (19.4%). These care areas are often associated with patients that require rapid assessment and treatment, and this acuity can increase the probability of errors.

The next most common areas were **general medical units** (16.1%) and **surgical units** (12.9%).

Table 4: Critical Incidents by Patient Care Areas

Patient Care Area	Frequency	Combined Frequency	Percentage %
Emergency	6	6	19.4
General medical unit	5	5	16.1
Surgical areas: General surgical unit	1	4	12.9
Other surgical unit	2		
Operating room	1		
Intensive care units: Coronary intensive care unit	1	3	9.7
Pediatric intensive care unit	1		
Other intensive care unit	1		
Hematology/oncology unit	1	3	9.7
Oncology clinic-pre and post treatment therapy	1		
Oncology clinic-pre and post treatment systemic therapy - home infusion	1		
Inpatient services-unspecified	3	3	9.7
Post-anesthetic recovery room	2	2	6.5
Alternate level of care	1	1	3.2
Ambulatory care-unspecified	1	1	3.2
Combined medical/surgical unit	1	1	3.2
Long-term care unit	1	1	3.2
Palliative unit	1	1	3.2
Total	**31**	**31**	**100**

Medication / IV Fluid

The top 5 medications contributing to severe harm or death were: hydromorphone, desmopressin, epinephrine, and heparin. This is not surprising as these medications are all considered high-alert medications, and are therefore drugs that are known to bear a heightened risk of causing significant patient harm if they are used in error.

Table 5: Critical Incidents by Medication / IV Fluid

Generic Name	Frequency			
	Severe Harm	Death	Total	Percentage %
hydromorphone	3	3	6	17.6
desmopressin	2	0	2	5.9
epinephrine	2	0	2	5.9
heparin	2	0	2	5.9
morphine	2	0	2	5.9
acetylsalicylic acid	0	1	1	2.9
amphotericin b	0	1	1	2.9
clopidogrel	0	1	1	2.9
enoxaparin	0	1	1	2.9
succinylcholine	0	1	1	2.9
amiodarone	1	0	1	2.9
bromazepam	1	0	1	2.9
captopril	1	0	1	2.9
carboplatin	1	0	1	2.9
citalopram	1	0	1	2.9
cyclophosphamide	1	0	1	2.9
dalteparin	1	0	1	2.9
dextrose	1	0	1	2.9
diltiazem	1	0	1	2.9
etoposide	1	0	1	2.9
fentanyl	1	0	1	2.9
fluorouracil	1	0	1	2.9
lidocaine	1	0	1	2.9
methadone	1	0	1	2.9
tobramycin	1	0	1	2.9
Total	**26**	**8**	**34**	**100**

Therapeutic Drug Class

The therapeutic classes most frequently reported as contributing to severe harm or death include **opioids** and **anticoagulants**. HYDROmorphone, a high potency opioid, accounted for the majority of opioid overdose incidents with an outcome of severe patient harm or death.

The anticoagulant incidents involved heparin, enoxaparin, and dalteparin. Because there is a narrow range between an effective dose and a toxic dose for this class of medications, dosing or prescribing errors with this group of high-alert medications can lead to patient harm. The reported errors involving anticoagulants included prescribing and monitoring issues surrounding anticoagulant guidelines/protocols, incorrect product selection in the peri-operative environment, and incorrect use of infusion devices.

Antineoplastic agents were highlighted in the list of medications this year partly owing to the chemotherapy incidents which garnered significant attention and resulted in a third-party review.[7]

It is notable that medications and therapeutic classes identified in the 2013 report[8] do not appear in this 2014 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.

Table 6: Critical Incidents by Therapeutic Drug Class

Therapeutic Class	Frequency			
	Severe Harm	Death	Total	Percentage %
Opioid Agonist	7	3	10	29.4
Anticoagulant	3	1	4	11.8
Antineoplastic	4	0	4	11.8
Anti-infective	1	1	2	5.9
Adrenergic agonist	2	0	2	5.9
Anti-hypertensive	2	0	2	5.9
Endocrine-metabolic agent	2	0	2	5.9
Neuromuscular blocking agent	0	1	1	2.9
Nonsteroidal anti-inflammatory agent	0	1	1	2.9
Platelet aggregation inhibitor	0	1	1	2.9
Anaesthetic	1	0	1	2.9
Antiarrythmic	1	0	1	2.9
Antidepressant	1	0	1	2.9
Anxiolytic-sedative	1	0	1	2.9
Parenteral solution	1	0	1	2.9
Total	**26**	**8**	**34**	**100**

Contributing Factors

NSIR allows reporters to select from a list of one or more contributing factors that played a role in the incident. In the 29 critical incidents 140 factors were identified to have contributed to the outcome.

Communication, independent check processes, and insufficient knowledge were the top 3 contributing factors cited in the submitted incidents.

In the contributing factor category of "Communication factors", verbal communication was commonly specified as contributing to critical medication errors. The critical medication errors 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 15 Contributing Factors Reported for Critical Incidents

Top 15 Contributing Factors Reported	Frequency		
	Severe Harm	Death	Total
Communication factors - unspecified	10	0	10
Quality control-double/independent check processes	8	1	9
Insufficient knowledge	6	1	7
Incorrect use of infusion pump	4	1	5
Misapplication of standard procedure/protocol	4	1	5
Application of poor procedure/protocol	3	1	4
Calculation error	3	1	4
Look alike drug products	3	1	4
Distractions/frequent interruptions	2	1	3
Drug product labelling-manufacturer	2	1	3
Inadequate staff training	2	1	3
Knowledge based/problem solving-unspecified	2	1	3
Verbal-incomplete or incorrect	2	1	3
Workflow design	2	1	3
Written/printed information/medical history-incomplete, incorrect or illegible	1	1	2

Patient Age Group

The age groups of **45 to < 65 years** (31%), **65 to < 85 years** (31%), and **over 85 years** (10.3%) together accounted for almost 72.3% of the persons affected by critical incidents contributing to severe harm and death. Again this year, critical incidents involving elderly patients over 85 years have a high proportionality of death.

Table 8: Critical Incidents by Patient Age Group

Age Group	Frequency			
	Severe Harm	Death	Total	Percentage of total reports
Paediatric	1	0	1	3.4
18 to < 45 years	2	1 (33 % = 1/3)	3	10.3
45 to < 65 years	6	3 (33% = 3/9)	9	31
65 to < 85 years	9	0	9	31
85+ years	1	2 (66 % =2/3)	3	10.3
Unknown	4	0	4	13.8
Total	**23**	**6**	**29**	**100**

Qualitative Themes and Discussion

Qualitative study of the 29 critical incidents along with analysis of the quantitative data identified a number of themes, and may suggest potential areas of focus for improvement.

Monitoring

Appropriate monitoring of patients after receiving a medication is an important part of safe healthcare. Deficiencies in monitoring were frequently identified as contributing factors in incidents causing harm or death and highlight the need for monitoring of high-alert medications such as opioids, anticoagulants, and insulin. These medications can cause measurable physiologic effects such as reduced respiratory rate or sedation with opioids, laboratory measurements with anticoagulants, and blood glucose levels with insulin, and these effects can be used to evaluate both intended effects of the drug and the potential for harm.

Certain medication overdoses can be corrected and the patient recovered from harm if timely and effective monitoring is in place. A number of incidents reported that it was only timely assessment by a healthcare worker 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.

Despite the importance of monitoring, not all facilities have standardized protocols to systematically assess the effect, intended or otherwise, once a high-alert medication is administered. Without an effective strategy to monitor these patients, opportunities to intervene may be lost.

- Responses to date
    - ISMP Canada published an Ontario Critical Incident Learning bulletin on anticoagulant monitoring[9]
    - ISMP Canada has identified monitoring as an important element in safe medication use[10]
    - ISMP Canada has created and made available an opioid safety handout designed to educate patients and family members[11]

- Future opportunities for response
    - Fund the development of evidence based and appropriate monitoring standards for high alert medications
    - Mandate organizations to develop safe and effective monitoring protocols for high alert medications
    - Direct the reporting of all medication incidents involving high alert medications
    - Commit resources and/or agencies to provide support and training for the development and implementation of monitoring protocols

Cancer chemotherapy

A significant medication error that captured the media's and the public's attention was the chemotherapy underdosing incident first brought to light in the spring of 2013. Due to the method by

which the drugs were prepared (use of overfill), certain chemotherapeutic agents were delivered at a lower dose than anticipated. Supporting the national importance and scope of this incident (more than 1200 patients impacted in 2 provinces), the Ontario critical analysis team participated in the development of a national ISMP Canada Safety Bulletin.

- Responses to date
    - ISMP Canada contributed to the Thiessen report[7]
    - ISMP Canada issued 2 news releases in April[12] and May 2013[13] about the chemotherapy incidents
    - ISMP Canada published a national Safety Bulletin in August 2013 about the chemotherapy incidents[14]
    - ISMP Canada worked with individual organizations behind the scenes to support safety and integrity of chemotherapeutic products

- Future opportunities for response
    - Standardize methods of labelling constituents of solvents and solutes
    - Create regulatory framework or agency to direct consistency and integrity of compounded products, or create a framework within an existing agency
    - Create a supervisory and monitoring agency to monitor and enforce standards in manufacturing and compounding products, or empower this task in an existing agency

Infusion pump errors

Multiple incidents reported to the NSIR involved the use of infusion pumps. The availability of programmable infusion pumps has contributed to the precision of the administration of parenteral medications but has also been associated with errors. Some of the errors associated with pumps include:

- transcription-type errors (e.g., decimal point is omitted or moved, numbers are transposed)
- concentration input errors (concentration manually entered does not match actual concentration of drug preparation)
- drug selection errors (pump is programmed correctly but wrong drug is selected for transfusion)
- multiple line confusion (more than one medication is being infused and drugs are infused on the wrong channel or circuit)
- pump set-up errors (medication infusion lines not set up properly or hung freely bypassing the pump)

"Smart" infusion pumps that incorporate drug error reduction software (DERS) increase safety by restricting parameters to those normally used in clinical care. In several cases these smart pumps were used as infusion devices, but the full capability of these pumps was not being utilized. Some of the contributing factors were lack of organizational consistency regarding limits and features of the pumps in use, lack of deployment of error reducing software, and lack of processes to update and assess pumps.
It is clear that most infused medications are being administered via infusion pump, but there is evidence that not all pumps are being used to their full capability in terms of enhancing patient safety.

- Responses to date

- ISMP Canada published an Ontario Critical Incident Learning bulletin on smart pumps[15]
- ISMP Canada continues to collaborate with HumanEra (formerly known as the Healthcare Human Factors Group – Centre for Global eHealth Innovation) on the multiple infusion lines project
- ISMP Canada continues to collect data on infusion pump errors

- Future opportunities for response
  - Fund capital purchases of infusion pumps with drug error reduction software
  - Fund capital purchases of infusion pumps with wireless updating and analysis capability
  - Ensure the full operationalization of smart pumps
  - Commit resources and/or agencies to provide support and training in pump use and continuous quality improvement
  - Mandate reporting of all pump incidents to safety organizations or through NSIR

Temporary or novice healthcare workers

In a number of cases of medication incidents reported to the program reporters identified staff education or experience as contributing factors to the error. In particular the selections "inexperienced staff", "agency/temporary/relief/float staff", "insufficient knowledge", and "insufficient/unavailable staff" were frequently highlighted. This may indicate that reporters feel lack of healthcare staff resources is seen as playing a significant role in medication errors or that the use of early career healthcare workers, or workers brought in from an outside agency may be insufficiently trained or experienced with the hospital system and processes. Furthermore, reporters may be concerned about the lack of institution specific training or acclimation when temporary workers are integrated onto a ward for the first time. This may overall reflect a general concern about the levels of staffing or the mechanism by which unavailable workers are replaced.

- Responses to date
  - ISMP Canada supports the standardization of medication use and management processes across wards and/or facilities to ensure consistency and simplification
  - ISMP Canada continues to collect data on healthcare staffing related errors
  - ISMP Canada provides training for healthcare students on general medication safety principles, supported by the MOHLTC program (currently limited to GTA, on an ad hoc basis by request)
  - ISMP Canada provides training workshops and educational products for institutions and practitioners upon request

- Future opportunities for response
  - Create standards of training and practice such that healthcare workers can more easily transfer between wards, organizations, or agencies
  - Provide resources to ensure availability of experienced and knowledgeable staff to accommodate sudden absences or times of increased demand

- Optimize the integration of new staff by directing the use of experienced healthcare mentors or trainers during the initial period of orientation or when changing roles or work environments
- Perform a review of the use of temporary or agency workers to identify usage patterns or educational needs to better utilize health worker resources
- Expand the ability of ISMP Canada to educate healthcare students by funding the development and delivery of safety training

Technology in Healthcare

Technology permeates healthcare, and the influence of technology is evident in the analysis of medication incidents. Advancements in healthcare technology such as computerized prescriber order entry (CPOE), automatic transmission of prescriptions to pharmacy, and computerized Medication Administration record (MAR) systems are tools that seek to improve order integrity and timeliness and eliminate the need for order transcription, while adding efficiencies and economy to the medication use process. However, protocols need to be developed and incorporated into the medication safety system to minimize the occurrence of CPOE-related prescribing errors. For example, forcing functions that require the user to input or view patient allergy status before proceeding further can avoid the prescribing of medications to which the patient has a documented allergy. The emerging use of CPOE and electronic MARs also requires the adaptation of the systems to support staff to conduct independent double checks of the CPOE orders in a convenient and timely manner. Regular order verification audits are needed to ensure quality of the independent double check, and identify potential system gaps in the process.

CPOE can provide users with opportunities to incorporate clinical decision support tools to guide a prescriber to best practices at the time medication decisions are made. For example, robust and responsive CPOE/decision support systems can potentially avoid prescribing errors such as incorrect antibiotic dosing in renal patients and drug-drug interaction errors.

The use of automated dispensing cabinets (ADC) has become prevalent in healthcare facilities, most commonly hospitals. Errors may still occur during product selection from the ADC. Linking full patient medication profiles via the ADC can minimize such medication errors. This access to information strategy can also potentially detect pre-existing medication errors such as dosing discrepancies. Another strategy to counter ADC product selection errors is to regularly review and update ADC stock lists, and remove high risk medications that should be under limited access status, such as concentrated hydromorphone.

It must be recognized that technology can become outdated and obsolete with time. In any technology program, there must be a commitment to continuously update and monitor software, and plan for the supporting resources needed to use, maintain, and upgrade technological capital.

- Responses to date
    - ISMP Canada supports the use of medication system technology to decrease the risk of error in healthcare systems

- ISMP Canada co-led the Canadian Pharmaceutical Bar Coding Project, including development of the Medication Bar Code System Implementation Planning Resource Guide[16]
- ISMP Canada continues to collect error data on medication incidents involving technology
- ISMP Canada provides training in proactive risk assessment using Failure Mode and Effects Analysis

- Future opportunities for response
  - Fund the development of evidence based and appropriate standards for the use of technology in healthcare
  - Mandate organizations to plan for and perform continuous technological capital assessment and upgrading
  - Direct the reporting of all medication incidents involving technology (pumps, automatic drug carts, decision support software) to safety organizations or NSIR
  - Fund demonstration/pilot projects for the evaluation of "paperless" medication use processes

Reporting, Analysis, and Knowledge Translation

The collection and analysis of incident reports remains the backbone of medication safety programming. Without a robust reporting and analysis system, there cannot be identification of contributing factors to medication incidents and the opportunity for investigation and improvement is lost. The development of recommendations and the dissemination of knowledge are keys to ensuring safe healthcare.

- 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
  - ISMP Canada continues to collect error 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

Promoting the Safe Use of Insulin in Hospitals

Insulin is a high-alert medication that continues to be one of the top drugs involved in incidents associated with harm or death that are voluntarily reported to ISMP Canada. Efforts to reduce the potential for harm with this drug have resulted in numerous recommendations on best practices for improving the safety of insulin use in hospitals. These strategies touch on all aspects of insulin use throughout the medication-use process. Although many of these interventions have been adopted by hospitals, harmful incidents involving insulin continue to occur.

ISMP Canada undertook a knowledge translation project to identify effective, evidenced-based interventions and to develop tools to support Ontario hospitals in ensuring safe insulin use, with the overall goal of decreasing potential patient harm. As part of this project, ISMP Canada convened an expert panel to select key insulin-use interventions and then asked expert working groups to develop specific guidelines and templates to support the selected key interventions. This bulletin shares the process and tools of this project. This bulletin is available at: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-5_Insulin.pdf.

Monitoring Processes Contribute to Safe Use of Warfarin

Warfarin is an effective, widely used anticoagulant that requires monitoring and dose titration. Monitoring involves a blood test that measures coagulation status in terms of the international normalized ratio (INR). A person's INR can change frequently and rapidly, particularly with initiation of treatment or in response to interactions with other medications or changes in diet or health. The need for monitoring and the variability in dosing contribute to warfarin's status as 1 of the top 10 medications involved in incidents leading to harm or death that have been voluntarily reported to ISMP Canada. Although it is widely acknowledged that the safe use of warfarin requires timely INR monitoring and dose adjustment, the complexities and tightly coupled nature of the processes involved may not be widely appreciated. Having systems in place to effectively identify, test, and treat patients who are receiving warfarin is an important method of improving patient safety. This bulletin is available at: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2013-6_SafeUseWarfarin.pdf.

Smart Pumps Need Smart Systems

The availability of programmable infusion pumps has contributed to the precision of the administration of parenteral medications. Smart infusion pumps that incorporate drug error reduction software (DERS) offer dose-limit functionality, but the specific limits must be programmed by individual facilities. "Soft" dose limits alert users when maximum dosing is inadvertently exceeded, but they can be overridden. "Hard" limits prevent the user from administering a dose that is beyond the predetermined range. Medication incidents with smart pumps can occur when the pumps are not used to their full capability or are not subjected to continuous quality improvement efforts. In particular, opportunities for errors exist when pump parameters must be input manually or when calculations must be performed before programming. Keys to the safe use of infusion pumps involve consistent use of preprogrammed drug libraries, including the use of safety limits, and availability of resources and processes to ensure that pump libraries are up to date. This bulletin is available at: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2014-7_SmartPumpsNeedSmartSystems.pdf.

Pain Control in the Emergency Department

The emergency department of any hospital is an area where healthcare practitioners can often be called upon to make urgent decisions based on incomplete information. This working environment makes the emergency department a frequent location of medication incidents. The control of pain in the early presentation of a patient's illness or accident is an important duty of clinical practitioners; however, the activity, the urgency, and the unknowns in emergency care can create situations where medication incidents can happen. ISMP Canada has received numerous reports from practitioners demonstrating the pitfalls of controlling pain in the emergency department. The contributing factors identified in these incidents included knowledge deficits related to opioids, over-frequent dosing of opioids, and problems with monitoring and assessing patients. This bulletin is available at: https://www.ismp-canada.org/download/ocil/ISMPCONCIL2014-8_EDpain.pdf

Program Limitations and Challenges

After an improvement in reporting towards the end of fiscal 2012-2013, the reporting rate has levelled off in 2013-2014 and approaches the number of cases reported in the previous year. An increased number of reports had been anticipated following interventions to increase awareness, emphasizing the importance of the data collected, and demonstrating the products of reporting and analysis, such as bulletins and presentations.

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 shared to advance patient safety in other organizations.

It has been noted that few reports 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 will 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 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.

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:
    - all incidents involving high-alert medications (i.e., those medications known to carry a heightened risk of harm if an error occurs)
    - all incidents involving technology (e.g., infusion pumps, automated dispensing cabinets, decision support software)
    - all incidents involving identified "theme" or "focus" medications 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)
- Expand the existing reporting directive to encompass long-term care.
- Require organizations to develop plans to support initial acquisition and continuous upgrading of technology known to reduce the likelihood of medication errors, such as computerized prescriber order entry, infusion pumps with error-reduction software (smart pumps), and wireless systems to support simultaneous updating of such devices.
- Provide grant support for capital funding for specific identified technologies (e.g., smart pumps).

- Provide funding for demonstration and pilot projects to evaluate “paperless” medication-use processes.

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 temporary or agency workers to identify factors contributing to such incidents, and use this information to develop educational programs specifically targeting this provider group.
- In collaboration with stakeholders, create guidelines to standardize the labelling of constituents of solvents and solutes in compounded and reconstituted products (e.g., intravenous admixtures).
- Develop guidelines and training programs related to safe and effective monitoring protocols for high-alert medications.

C/ Ontario hospitals:

- Optimize the integration of new staff by directing the use of experienced healthcare mentors or trainers during the initial orientation or when staff roles or work environments are changed.
- Provide resources to ensure availability of experienced and knowledgeable staff to accommodate sudden absences or periods of increased demand.

Medications have yielded tremendous benefits to the health of Canadians. 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 ISMP Canada’s authoritative and credible recommendations, will help to ensure the health of the people of Ontario today and into the future.

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