



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

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**Submitted to  
Health Quality Ontario**

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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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The collaborating parties of the provincial critical incident reporting program include Health Quality Ontario (HQO), the Ontario Ministry of Health and Long-Term Care, the Canadian Institute for Health Information (CIHI), the 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 healthcare community who report medication incidents and who share learning and feedback from their own organizational reviews.

## Background and Rationale and Methodology

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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).<sup>1</sup> This reporting requirement builds upon the patient safety and quality initiatives of the *Excellent Care for All Act*<sup>2</sup> and Regulation 965 under the *Public Hospitals Act*.<sup>3</sup> 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”.

A data-sharing agreement between CIHI and ISMP Canada provides ISMP Canada with access to data submitted to NSIR and a mechanism to connect with reporting facilities. All reporters of critical incidents are sent a follow-up communication from ISMP Canada and further details and information are elucidated from the reporter and/or healthcare facility where possible. Analyses are completed to identify medication system vulnerabilities, to share strategies for mitigating risks, and to inform medication safety efforts in Ontario. On the basis of these analyses, ISMP Canada disseminates recommendations in the Ontario Critical Incident Learning Bulletins. These bulletins are sent directly to Ontario practitioners who have signed up to receive this publication and are also available from the ISMP Canada website ([www.ismp-canada.org/ocil/](http://www.ismp-canada.org/ocil/)) and other dissemination strategies.

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.

## Results

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A total of 17 critical incident reports from Ontario hospitals were released into the NSIR with a submission date range between January 1, 2015 and December 31, 2015.<sup>4</sup> All incidents were analyzed by an interdisciplinary team at ISMP Canada in accordance with a medication incident analysis framework.

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

### Degree of Harm

The classification of harm is defined by the severity and duration of harm and the treatment implications that result from an incident. A severe harm 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.<sup>5</sup>

For this reporting year, 10 incidents (59%) were associated with **severe harm** while 7 incidents (41%) were reported to have contributed to **death**.

**Table 1: Critical Incidents by Degree of Harm**

Degree of Harm	Number of reports	Percentage (%)
<b>Severe</b>	10	59
<b>Death</b>	7	41
<b>Total</b>	<b>17</b>	<b>100</b>

Since the inception of the program, a total of 109 critical incidents have been reported, with 82 (75%) associated with severe harm and 27 (25%) reported as contributing to death.

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

The medication use process is divided into a number of operational steps in order to facilitate analysis (Table 2). In the first 3 years of this program, the majority of the critical medication incidents were reported to originate in the prescribing and administration stages, with these stages also being commonly associated with incidents involving death. This year, the administration and the preparing/dispensing stages were the most commonly cited processes, followed by prescribing.

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

<b>Medication/IV Fluid Use Process</b>				
	<b>Severe Harm</b>	<b>Death</b>	<b>Total</b>	<b>Percentage (%)</b>
<b>Administration</b>	1	3	4	23.5
<b>Preparing/dispensing</b>	3	1	4	23.5
<b>Prescribing</b>	1	2	3	17.6
<b>Order documentation</b>	1	1	2	11.8
<b>Order verification (pre-admission)</b>	1	0	1	5.9
<b>Delivery</b>	1	0	1	5.9
<b>Storage/location</b>	1	0	1	5.9
<b>Other</b>	1	0	1	5.9
<b>Total</b>	<b>10</b>	<b>7</b>	<b>17</b>	<b>100</b>

### **Medication/IV Fluid Problem Types**

Medication incidents can be divided into a number of types that describe error circumstances. In a number of cases “Other” was selected, limiting further classification.

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

<b>Medication/IV Fluid Problem</b>	<b>Number of Incidents</b>			
	<b>Severe Harm</b>	<b>Death</b>	<b>Total</b>	<b>Percentage (%)</b>
<b>Other</b>	4	4	8	47.0
<b>Wrong quantity</b>	3	1	4	23.5
<b>Wrong product</b>	0	1	1	5.9
<b>Omitted dose</b>	0	1	1	5.9
<b>Wrong formulation</b>	1	0	1	5.9
<b>Wrong rate/frequency</b>	1	0	1	5.9
<b>No order</b>	1	0	1	5.9
<b>Total</b>	<b>10</b>	<b>7</b>	<b>17</b>	<b>100</b>

## Patient Care Areas

Twenty-one patient care areas were noted for the 17 reported incidents; certain errors occurred in more than one environment. High-intensity patient care areas such as emergency departments often care for severely ill patients who require rapid assessment and treatment, sometimes based on incomplete information, and these characteristics can increase the potential for errors to occur.

**Table 4: Critical Incidents by Patient Care Areas**

Patient Care Area	Frequency	Combined Frequency	Percentage (%)
<b>Emergency</b>	7	7	33.3
<b>Intensive care units</b>	3	3	14.3
<b>Ambulatory</b>			
Unspecified	1	3	14.3
Oncology clinic	1		
Renal dialysis clinic	1		
<b>Central distribution/main pharmacy</b>	2	2	9.5
<b>Surgical Area</b>			
Operating Room	1	2	9.5
General surgical unit	1		
<b>Combined medical/surgical units</b>	1	1	4.8
<b>Inpatient services-unspecified</b>	1	1	4.8
<b>Mental health and addiction services</b>	1	1	4.8
<b>Palliative unit</b>	1	1	4.8
<b>Total</b>	<b>21</b>	<b>21</b>	<b>100</b>

## Medication / IV Fluid / Drug Class

A wide variety of medications were reported as causing harm through incidents (Tables 5 and 6). Although high-alert medications are more commonly associated with harm as a result of errors, no single medication or class is unaffected by this risk. In some cases, more than one drug or drug class was reported to contribute to harm or death resulting from an incident. In 2015, no single medication stood out as was the case in previous years. Although opiate agonists continue to be represented most frequently of all the therapeutic classes, this class did not predominate to the same degree as in the past.

**Table 5: Medication / IV Fluid Associated with Critical Incidents**

Generic Name	Frequency			Percentage of total incidents (%)
	Severe Harm	Death	Total	
<b>HYDROmorphine</b>		2	2	10.5
<b>alteplase</b>		2	2	10.5
<b>allopurinol</b>		1	1	5.3
<b>azathioprine</b>		1	1	5.3
<b>dalteparin</b>		1	1	5.3
<b>heparin</b>		1	1	5.3
<b>piperacillin/tazobactam</b>		1	1	5.3

Generic Name	Frequency			
	Severe Harm	Death	Total	Percentage of total incidents (%)
amphotericin B	1		1	5.3
bortezomib	1		1	5.3
dopamine	1		1	5.3
iron injection (sodium ferric gluconate complex in sucrose)	1		1	5.3
isoflurane	1		1	5.3
lithium citrate	1		1	5.3
methadone hydrochloride	1		1	5.3
naloxone	1		1	5.3
potassium chloride	1		1	5.3
prednisone	1		1	5.3
<b>Total</b>	<b>10</b>	<b>9</b>	<b>19</b>	<b>100</b>

**Table 6: Therapeutic Drug Class Associated with Critical Incidents**

Therapeutic Class	Frequency			
	Severe Harm	Death	Total	Percentage of total incidents (%)
Opiate Agonists	1	2	3	15.8
Thrombolytic Agents		2	2	10.5
Anticoagulants		2	2	10.5
Anti-infective Agents	1	1	2	10.5
Immunosuppressants		1	1	5.3
Xanthine Oxidase Inhibitors		1	1	5.3
Anaesthetics	1		1	5.3
Adrenergic Agonists	1		1	5.3
Antianemics	1		1	5.3
Antimanic Agents	1		1	5.3
Antineoplastic Agents	1		1	5.3
Corticosteroids	1		1	5.3
Electrolytes	1		1	5.3
Opiate Antagonists	1		1	5.3
<b>Total</b>	<b>10</b>	<b>9</b>	<b>19</b>	<b>100</b>



## Contributing Factors

Using a drop-down menu, the NSIR allows reporters to select one or more contributing factors that played a role in the incident. For the 17 critical incidents reported in 2015, 101 factors were identified as having contributed to the incidents. Table 7 lists the contributing factors for all the death cases and the most commonly identified factors for the severe harm incidents.

**Table 7: Top Contributing Factors Reported for Critical Incidents\***

Top Contributing Factors Reported	Frequency			
	Severe Harm	Death	Total	Percentage of total incidents (%)
Inexperienced staff	3	2	5	5.0
Other	2	2	4	4.0
Quality control-double/independent check processes	1	2	3	3.0
Communication factors-unspecified	6	1	7	6.9
Delay in action	3	1	4	4.0
Medication reconciliation process	2	1	3	3.0
Insufficient knowledge	2	1	3	3.0
Pathophysiological/disease-related factors	2	1	3	3.0
Performance factors-unspecified	2	1	3	3.0
Transcription inaccuracy	2	1	3	3.0
Written/printed information/medical history-incomplete, incorrect or illegible	2	1	3	3.0
Workflow design	1	1	2	2.0
Agency/temporary/relief/float staff	1	1	2	2.0
Attention issues-failure to remember	1	1	2	2.0
Inadequate staff training	1	1	2	2.0
Computer/fax equipment-hardware, software, network failure		1	1	1.0
Distractions/frequent interruptions		1	1	1.0
Products, technology and infrastructure-unspecified		1	1	1.0
Drug product confusion-unspecified		1	1	1.0
Look-alike drug products		1	1	1.0
Unknown		1	1	1.0
Organizational factors – unspecified	5		5	5.0
Knowledge-based / problem-solving - unspecified	3		3	3.0

\*Contributing factors are presented based first on severity of harm (death vs. severe harm) and then total number of critical incidents

## Qualitative Themes and Discussion

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Qualitative study of the 17 critical incidents along with analysis of the quantitative data identified a number of themes, and may suggest potential areas of focus for improvement and for future work within the Ontario critical incident reporting and learning program.

### **Theme: Likelihood of Recurrence and Risk-Mitigation Strategies**

In the NSIR, reporters are prompted to estimate the likelihood of recurrence of the incident. In the report for calendar year 2015, 8 reporters (47%) suggested that there was a possibility of recurrence, 6 reporters (35%) felt that the incident was unlikely to recur, and 3 (18%) did not select a response.

Eleven of the reports included a risk-mitigation strategy to prevent recurrence, 4 of which would be considered to be high-leverage on the hierarchy of effectiveness ([Designing Effective Recommendations](#) bulletin).

Three of the 6 'unlikely to recur' cohort did implement, or planned to implement, higher leverage risk-mitigation strategies that are more likely to be effective. The remaining 3 of the 'unlikely to recur' cohort did not plan to implement any high-leverage risk-mitigating strategies. Most of the contributing factors identified in the 6 'unlikely to recur' cohort tended to be person-based (performance factors, inadequate staff training, knowledge deficits, communication factors, behavioural factors, inexperienced staff, temporary staff, attention issues).

The relationship between the presumption of recurrence and the adoption of higher or lower leverage mitigation strategies is interesting and not yet clear. High reliability industries and organizations adopt a "preoccupation with failure", an acceptance that errors can happen any time, and a constant drive to improve.<sup>6</sup> There is benefit to patient safety when practitioners are aware of the risk and potential presence of error – resulting in increased vigilance and opportunity to intervene and to learn and progress. The danger in dismissing the likelihood of recurrence is an increased likelihood of ignoring the inherent perils of healthcare and becoming complacent in the drive towards better healthcare quality and patient safety.

### **Theme: Patient Engagement**

Patients and caregivers play vital roles in medication therapy, even in hospital settings where processes and controls direct medication management. Five of the incidents reported that patients were not engaged in discussions to validate or clarify previous usage, and that this lack of conversation was a contributing factor to harm. These incident reports make note of missed opportunities of direct patient or caregiver confirmation of medication regimens. Engaging patients and/or their caregivers during medication reconciliation is a vital step in the systematic process of compiling a best possible medication list.<sup>7</sup> Beyond the creation of a medication list, it is important to ask questions regarding the timing of the last medication dose taken, especially for high-alert medications (where a double dose can cause harm), or medications that require tapering.

Other incidents identified patients who received a medication to which there was a documented intolerance. When an adverse event happens, health care professionals must clarify with the patient the medication name and the nature of the reaction that occurred. Patients should be empowered to speak up if that medication is prescribed or attempted to be administered again.<sup>8</sup> Nurses can facilitate this process by engaging the patient in a conversation about a medication that has been ordered; for example "I am going to be giving you a medication called..... have you ever had this medication before?" Medication practice standards for nurses recommend nurses seek information

from the patient about their medications and also that they provide education to their patients about their medications.<sup>9</sup>

Patients and/or caregivers are also key observers for drug effects, both desired and adverse. Engaging them in a dialogue, when possible, about observing and reporting specific effects can subsequently prevent harm if noted in a timely manner. Early and continuing dialogue also enables the prescriber to assess patients' and/or caregivers' ability and willingness to watch for and report early signs of medication toxicities.

Patients and caregivers hold a wealth of information. Health care professionals need to engage them to gather and share medication information, though research is inconclusive on how to best accomplish this to improve safety.<sup>10</sup>

### **Theme: Failed Independent Double Check**

An independent double check is a process in which a second practitioner conducts a verification of a first practitioner's work. Double check processes should be in place when high-alert medications are ordered, prepared, and administered.<sup>11</sup> The goal of the independent double check is to prevent medication errors from reaching patients by providing a second layer of safeguards.

Four reports, all involving high-alert medications, illustrated that a double check process was in place at each site, but had failed to identify and resolve the error before it reached the patient. It is noteworthy that the errors were not isolated to a single discipline - pharmacists, nurses, and physicians were involved.

Contributing factors were dependency on technology, complacency, knowledge deficits and lack of pharmacist review prior to administration. The value and importance of high-quality independent double check needs to be incorporated into the culture of all hospitals. A number of incident narratives highlighted the complacency that can develop in the face of technology ("the computer is always correct"), and with familiarity and experience ("he has worked here a long time...he knows what he is doing"). This demonstrates the need for high quality independent processes for double checks and the need for continual refreshment and reinforcement of independent double check skills.

Hospitals are encouraged to review their processes for independent double checks and highlight the importance of these checks.

### **Theme: Delay in First Doses**

A delay in administering the first dose was identified as causing harm in three of the reported incidents. Identified contributing factors included missed processing of a new order, medications not readily accessible, queries about how to administer, and urgency of a situation not effectively communicated or interpreted.

In one case report, an antibiotic order for a septic patient was not noticed for approximately 10 hours after it was written. Delayed antibiotic administration in sepsis is a known predictor of mortality.<sup>12</sup> Hospitals need to examine how time-sensitive medications are ordered and processed (e.g., STAT) and how the urgency of a new order is communicated to the most responsible nurse.

In another case report, a complex dilution and administration rate appeared to delay the first dose of a critical medication. Subsequently, the hospital now anticipates such orders and has prepared dilution and rate charts to prevent such delays from happening in the future.

Hospitals should define policy and procedures surrounding the access to, and administration of, defined time-critical medications.<sup>13</sup> Ensuring up-to-date, easy-to-follow protocols is one method to facilitate timely and appropriate administration. The specific needs of each hospital unit should be reviewed frequently, with front line staff empowered to discuss near misses, errors, and vulnerabilities and to suggest improvements to processes.

## **Shared Learning through Ontario Critical Incident Learning (OCIL) Bulletins**

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### **High-Alert Medications Need Multiple Safeguards**

High-alert medications (e.g., opioids, insulin, and anticoagulants) may not be inherently more likely to be involved in medication errors, but they carry an elevated risk of more serious harm to patients if an error occurs with their use. The potential consequences of these errors necessitate multiple enhanced safeguards designed to prevent errors from occurring along the medication-use process continuum, from prescribing and dispensing through to administration and monitoring. Since a single type of intervention is insufficient to ensure the safe use of high-alert medications, a multimodal approach is needed.

### **Errors Continue with Amphotericin B**

Amphotericin B is an antimicrobial drug used in the treatment of severe fungal infections. It is available in 3 formulations for intravenous use in Canada: “conventional” amphotericin B (Fungizone), amphotericin B lipid complex (Abelcet), and liposomal amphotericin B (AmBisome). Lipid-based forms of the drug appear to have less severe toxic effects, but when the wrong formulation of amphotericin B is inadvertently administered, the patient may receive an overdose which can lead to severe adverse effects. ISMP Canada and ISMP (US) have published several bulletins and alerts on concerns about the risks of inadvertently substituting one formulation for another. This bulletin highlights a scenario where a patient received the wrong formulation of amphotericin B leading to an overdose of the drug, requiring an unexpected ICU admission and plasmapheresis.

### **Resources to Sustain Incident Learning**

Sharing of learning from critical incidents reported to the Ontario Critical Incident Learning (OCIL) program through the National System for Incident Reporting (NSIR) constitutes a vital component of healthcare quality improvement. Selected incidents reported and analyzed through the OCIL program are shared in safety bulletins. To aid in knowledge transfer and sustain learning from incident analyses, insight from these incidents has been incorporated into a variety of resources to assist healthcare providers and organizations in implementing system safeguards. These resources are designed to support continuous quality improvement and may also assist hospitals as they prepare for accreditation processes.

### **Effective Meetings with Patient and Families**

Creating a culture of patient safety requires that healthcare providers and patients/caregivers are able to openly and honestly communicate, including having discussions about medication errors. This bulletin is a result of a collaborative effort with Health Quality Ontario. It highlights a checklist to support the provider in the disclosure of a medication error, assuring that is done in a consistent,

caring manner, and involves the patient and family throughout the process. The bulletin also takes into account caring for staff involved in the incident and making sure lessons learned are shared not only with the patient, family and staff, but also spread further across organizations.

## **Additional Shared Learning**

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The OCIL safety bulletins are a primary method to disseminate learning from the analyses of critical incidents. In 2015, other avenues to share learning were provided for Ontario practitioners to support system safety, including presentations and webinars.

**Webinar:** *Supporting Medication System Safety and Preparing for your Accreditation Survey: Applying New Tools for Home and Community Care and Acute Care*

This webinar presented on June 23, 2015, highlighted information about 3 new safety tools developed through analyses conducted as part of the OCIL program:

- Updated [Hospital Medication Safety Self-Assessment](#)® Canadian Version III program
- [Hospital to Home: Facilitating Medication Safety at Transitions Toolkit and Checklist](#)
- [Epidural Label Safety Checklist](#)

This webinar also shared the development of 2 new Medication Safety Self-Assessment programs for the home care sector:

- [Home Care Organizations Medication Safety Self-Assessment](#)
- [Home and Community Care Personal Support Worker Organizations Medication Safety Self-Assessment](#)

Webinar handouts and recording can be found on the Ontario Critical Incident Learning webpage ([Handouts](#)) ([Recording](#)).

**Webinar:** *Demystifying the Critical Incident Reporting Process*

Based on discussions with facilities, findings from non-critical incidents, and results from previous evaluation work, a second webinar was broadcasted on October 21, 2015. The focus of this webinar was to help Ontario practitioners understand the reporting and analysis process, and the ultimate goal of improving system safety. The webinar handouts and recording are available for practitioners on the ISMP Canada website ([Handouts](#)) ([Recording](#)).

## **Program Limitations and Challenges**

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The interpretation of the definition of “critical incidents” has been identified as an underlying reason why the total number of reported critical incidents appears to be low. Through discussion with practitioners from various facilities, ISMP Canada has learned that facilities may not all be defining the characteristics of a critical incident the same way. One facility may code an incident as severe harm, while the other as mild harm.

Again this year, many reports were incomplete and did not include sufficient detail for analysis. A webinar directed to Ontario practitioners was provided in October 2015 to “demystify” the critical incident learning process and to help practitioners understand the value of submitting incident reports and the need to include complete information.

ISMP Canada attempts to contact all reporters through the Critical Incident Program via the NSIR communication tool. In general, the organizations who engage in communication with us are enthusiastic in their commitment to safety and are open to sharing further details and information.

## Moving Forward

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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 and dissemination 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 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.

ISMP Canada is keen to contribute to 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:

- Standardize the interpretation of degree of harm. There is evidence of variability in the assessment of harm.
- Improve the definition of a critical incident to capture more incidents causing harm.
- Expand the existing reporting directive to include targeted reporting of the following:
  - Incidents involving an identified “theme” or “focus” medication(s) or process(es); and
  - Incidents occurring in long-term care facilities.
- Expand the development and delivery of medication safety training for professionals and students across Ontario.
- Develop targeted medication safety-related education programs (e.g., webinars, on-demand teaching modules) that disseminate information about identified vulnerabilities in medication systems and strategies to support safe medication practices to front line staff on a regular basis.

The use of medications represents an important investment in health by both governments and individuals, and it is crucial that they be administered safely and effectively. The Ontario Critical Incident Learning program helps protect this investment and safeguards the health of Ontarians by identifying emerging areas of risk, generating invaluable knowledge in patient safety, and developing strategies to protect patients.

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