Chapter 6 Health—Using Critical Incident Reporting to Improve Patient Safety

1.0 MAIN POINTS

In healthcare, a critical incident is a serious adverse health event that did or could have resulted in serious harm or death of a patient. Critical incidents can cause emotional strain and stresses on both patients and healthcare providers, and significant costs on the overall health system (e.g., longer stays in hospitals). Critical incident reporting is a recognized tool in improving patient safety in the healthcare sector.

Since 2004, Saskatchewan healthcare organizations must, by law, report critical incidents to the Ministry of Health, and take steps to address their causes. The Ministry is responsible for overseeing critical incident reporting, evaluating whether steps that healthcare organizations identify are likely to prevent recurrence of similar future incidents, and help address system-wide concerns affecting patient safety.

As of December 2020, the Ministry needs to better utilize critical incident reporting as a tool to improve patient safety.

The overall number and types of critical incidents reported in Saskatchewan are not trending downwards. In recent years, the Saskatchewan Health Authority has reported the majority of critical incidents (884 critical incidents between April 2017 and March 2021). In 91 of the 290 incidents reported in 2019–20, a patient died.

The Ministry does not determine whether it is notified of all critical incidents. Our analysis of adverse events reported suggests it is not. For example, between December 2019 and September 2020, the Authority reported 17 medical device critical incidents to the Ministry as compared to 24 incidents related to medical device failures it reported to Health Canada for the same period. Some of these failures may meet the definition of a critical incident—the most serious subset of adverse events—and should have been reported to the Ministry.

The Ministry does not monitor whether the Authority sufficiently addressed causes of reported critical incidents, and improved patient safety. For example, 68 percent of planned corrective actions included in the critical incident reports we tested were reported as not implemented. Not knowing whether timely corrective actions are taken increases the likelihood of the reoccurrence of similar incidents resulting in patient harm or death.

In addition, the Ministry does not do enough analysis to identify system-wide improvements needed to keep patients safe, or determine if those improvements occur. Patient safety alerts are to communicate urgent patient safety information to healthcare providers for the benefit of the broader healthcare system. Between April 2017 and September 2020, the Ministry issued 10 patient alerts. However, the content of its alerts are not consistent with good practice, and the Ministry does not determine whether they improved patient safety.

Through effective use of critical incident reporting, the degree of injury and the types of critical incidents that occur in Saskatchewan healthcare facilities should reduce over time.

2.0 INTRODUCTION

This chapter reports the results of our audit of the Ministry of Health's processes for using critical incident reporting to improve patient safety.

Critical incident reporting refers to reports healthcare organizations must, by law, make to the Ministry of Health about a serious adverse health event, including, but not limited to, the actual or potential loss of life, limb, or function related to a health service provided by the organization.^{1,2}

2.1 Most Serious Adverse Events are Critical Incidents

The concept of medical harm has existed since antiquity. The term adverse event comes about when medical harm has come to a patient as a consequence of healthcare management. An adverse event can be defined as unintended physical injury resulting from, or contributed to, by medical care (including the absence of medical treatment). Adverse events may be preventable or non-preventable.³

Thousands of adverse events occur in the Saskatchewan health sector each year. According to *The Canadian Adverse Events Study* in 2004, 7.5 percent of all hospital patients experience an adverse event, where an unintended injury or complication arising from healthcare management lead to a longer hospital stay, disability, or death. Of these injuries, the study deemed 37 percent to be preventable.⁴ Applying this study's parameters to Saskatchewan's population results in an estimate of 5,800 adverse events would occur in Saskatchewan hospitals on an annual basis—a percentage of these events would be critical incidents.⁵

A critical incident is defined as the most serious subset of adverse events.

2.2 Critical Incident Reporting in Saskatchewan

Reporting of critical incidents is a recognized tool in improving patient safety.⁶ The role of critical incident reporting is to capture the most serious adverse events or potential adverse events.

In Canada, eight of 13 provincial and territorial jurisdictions have legislation pertaining to mandatory patient safety incident reporting, including Saskatchewan.⁷

⁶ Patient Safety and Incident Management Toolkit, Canadian Patient Safety Institute, (<u>www.patientsafetyinstitute.ca/</u> en/toolsResources/PatientSafetyIncidentManagementToolkit/Pages/default.aspx) (05 November 2020).

¹ Ministry of Health, Saskatchewan Critical Incident Reporting Guideline, 2004.

² Healthcare organizations include the Saskatchewan Health Authority, healthcare affiliates (e.g., long-term care operators) contracted by the Saskatchewan Health Authority, the Saskatchewan Cancer Agency, eHealth Saskatchewan, and Health Shared Services (3sHealth).

³ www.psnet.ahrq.gov/primer/adverse-events-near-misses-and-errors (02 March 2021)

⁴ Baker, Norton et. al, *The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada*, (2004).

⁵ Population as of January 1, 2021, per the Saskatchewan Bureau of Statistics: Saskatchewan 1,178,832 divided by Canada 38,048,738 times 2,500,000 Canadian hospital admissions times 7.5 percent of adverse events equals about 5,800 for Saskatchewan.

⁷ Mandatory reporting legislation in Canada: improving systems for patient safety? Health Economics, Policy and Law, (2021). The other seven jurisdictions with mandatory reporting legislation include British Columbia, Manitoba, Ontario, Quebec, New Brunswick, Newfoundland and Labrador, and Northwest Territories.

Saskatchewan was one of the first provinces to mandate in law the reporting of critical incidents in the health system in 2004. It requires the Saskatchewan Health Authority (with over 40,000 employees and physicians), the Saskatchewan Cancer Agency (about 800 employees), eHealth Saskatchewan, 3sHealth, and other health service providers (e.g., long-term care homes) to report critical incidents, and the results of their investigation of reported incidents to the Minister of Health.^{8,9} We refer to these entities collectively as healthcare organizations. Given other health service providers have contracts with the Saskatchewan Health Authority to provide health services, the Authority is responsible for reporting critical incidents that occur in these facilities to the Ministry of Health.

The Ministry of Health is responsible for:

- Overseeing and evaluating the comprehensiveness and completeness of the investigation of a reported critical incident
- Evaluating the adequacy and appropriateness of the steps identified for improvement, that is, whether they are likely to prevent recurrence of similar future incidents
- Preparing patient safety alerts to address system-wide concerns

The Ministry considers it important to maintain a trusting relationship with the reporting healthcare organizations and makes great effort to foster the relationship. The Ministry has assigned responsibility for overseeing and evaluating critical incident reporting to three provincial quality of care coordinators within its Quality and Safety Unit.

During the 2019–20 fiscal year, healthcare organizations reported 290 critical incidents to the Ministry of Health. In 91 of these 290 reported critical incidents, a patient died.

In addition to the emotional strain and stresses harmful incidents cause on patients and healthcare providers, harmful incidents have a significant cost on the overall health system. A 2016 Canadian patient safety report estimates patients who experienced harm spent more than half-a-million additional days in hospital beds in 2014–2015.¹⁰ This equates to an estimated additional \$685 million of costs.¹¹

Critical incident reporting and investigations of such incidents is one method of promoting patient safety. Identifying incidents that have resulted or could have resulted in patient harm, and recommending and implementing actions to improve systems makes healthcare safer.

3.0 AUDIT CONCLUSION

We concluded that for the 12-month period ended December 31, 2020, the Ministry of Health had effective processes, except in the following areas, for using critical incident reporting to improve patient safety.

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⁸ Healthcare organizations (also called healthcare system partners) are to generate a report setting out the results of their investigation, and including recommendations for improvement/corrective actions. They are then responsible for implementing these recommendations.

 ⁹ Health service providers have contracts with and are funded by the Saskatchewan Health Authority to provide health services.
 ¹⁰ B. Chan, D. Cochrane, *Measuring Patient Harm in Canadian Hospitals. What can be done to improve patient safety*? (2016), pp. 28–29.
 ¹¹ Ibid.

The Ministry needs to:

- Reassess what adverse events it wants reported as critical incidents and assess whether all critical incidents are reported as expected
- Consider root causes of critical incidents and use criteria to determine whether corrective actions will improve patient safety
- Monitor whether critical incident corrective actions are implemented in a timely manner
- Analyze critical incidents reported for system-wide concerns that put patient safety at risk
- Issue appropriate patient safety alerts and monitor their effectiveness and continued relevance
- Follow up when critical incident reports are not submitted by established deadlines

Figure 1—Audit Objective, Criteria, and Approach

	dit Objective: to assess whether the Ministry of Health, for the period ending December 31, 2020, had ective processes for using critical incident reporting to improve patient safety.
Auc	dit Criteria:
Pro	cesses to:
1.	 Maintain a framework for reporting and investigating critical incidents Work with healthcare system partners to promote a patient safety culture Communicate clear requirements for reporting and investigating critical incidents (e.g., expected timing and content of critical incident reports) Centrally record critical incidents in a timely manner Periodically evaluate the effectiveness of reporting system to identify improvements
2.	 Analyze critical incidents to prevent reoccurrence Assess critical incident reports for adequacy Monitor implementation of improvements recommended in a critical incident report Compare consistency of the nature and types of critical incidents reporting to other data sources (e.g., hospital system adverse events) Determine trends (e.g., system-wide, by facility, by organization) in critical incidents to identify systemic patient safety improvements needed Coordinate systemic patient safety improvements needed with key internal and external parties
3.	 Analyze critical incidents to prevent reoccurrence Monitor implementation of systemic patient safety improvements Communicate to key internal and external parties lessons learned and improvements made as a result of reporting
Auc	dit Approach:
Har crite	conduct this audit, we followed the standards for assurance engagements published in the CPA Canada ndbook—Assurance (CSAE 3001). To evaluate the Ministry of Health's processes, we used the above eria based on our related work, reviews of literature, and consultations with management and external risors. Ministry management agreed with the above criteria.

We examined Ministry of Health's guidelines, procedures, IT system, and reports relating to critical incident reporting. We consulted with an independent consultant with subject matter expertise in the area. The consultant helped us identify good practice. We examined patient safety alerts, and tested a sample of critical incident reports received and reviewed by the Ministry.

4.0 Key Findings and Recommendations

4.1 Legislation in Place for Confidential Reporting of Critical Incidents

The assignment of responsibilities in law for healthcare organizations (e.g., Saskatchewan Health Authority) to report and investigate critical incidents, and the Ministry of Health to oversee this reporting are clear.

Saskatchewan introduced mandatory critical incident reporting legislation in 2004. *The Provincial Health Authority Act* along with *The Critical Incident Regulations, 2016* outline requirements for reporting and investigating critical incidents. The Regulations refer to the Ministry's *Saskatchewan Critical Incident Reporting Guideline, 2004.*¹² The Regulations and Guideline detail how to report a critical incident, what to report, who makes the report, and to whom and by when.

The law explicitly prohibits recording the name of the patient or the names of the healthcare providers that were involved in the patient's care leading up to the event. The information gathered in the course of investigating a critical incident is privileged and protected by legislation. This is consistent with the six other Canadian provinces that have mandatory patient safety incident reporting in law. The purpose of reporting of critical incidents is not to lay blame on individuals. Rather, critical incident reporting is used to look at what can be done differently and what improvements can be made to the way health care providers work.

Responsibilities of healthcare organizations: The law makes healthcare organizations, like the Saskatchewan Health Authority, responsible for reporting to the Ministry the occurrence of all critical incidents that arise as a result of health services provided or not provided.¹³ The laws and Guideline also make a health organization responsible for investigating each reported incident, identifying corrective actions for improvement, and reporting the results including corrective actions to the Ministry. The laws make a healthcare organization responsible for implementing those corrective actions.

The Guideline defines critical incidents as a serious adverse health event including, but not limited to, the <u>actual or potential</u> loss of life, limb or function related to a health service provided by, or a program operated by, a health care organization. We found this definition of a critical incident aligns with international best practice.¹⁴

Responsibilities of the Ministry: The law makes the Ministry responsible for overseeing and evaluating the comprehensiveness and completeness of a healthcare organization's investigation of a reported critical incident, and the adequacy and appropriateness of the actions the organization has identified for improvement. Hence, the Ministry's role is providing oversight in the healthcare sector to achieve patient safety by preventing the reoccurrence of critical incidents.

¹²When a patient is harmed or where there is a potential for harm, professionals (e.g., nursing staff or physicians) in the health system are to notify (excluding the identity of the patient) the provincial quality of care coordinators in the Ministry of Health of the incident. Harmful events can occur in both primary care (e.g., hospitals, long-term care) and secondary care settings (e.g., home care) in the health care system.

¹³ Section 8.2 of *The Provincial Authority Act*.

¹⁴ The World Health Organization defines a patient safety incident as an event or circumstance that resulted, or could have resulted, in unnecessary harm to a patient.

The Ministry primarily oversees, for the purposes of critical incident reporting, the Saskatchewan Cancer Agency and the Saskatchewan Health Authority—since the 2017 amalgamation of the 12 former regional health authorities into the Authority. These two provincial government agencies directly deliver health services to patients. The mandatory reporting process makes the Authority responsible for reporting occurrences of critical incidents occurring at any provider with a contract with the Saskatchewan Health Authority (e.g., affiliate—long-term care home operator).

In general, Saskatchewan's mandatory critical incident reporting process is intended to help identify those cases that are the most serious subset of adverse events and allow those events to receive an in-depth review. It is also intended to help identify any necessary system-wide improvements to keep patients safe. Having a process for reporting in confidence fosters reporting of incidents which otherwise might not be reported through fear of blame or punishment.

4.2 Opportunity to Centrally Track and Learn from Critical Incidents

There are multiple adverse health event tracking IT systems in place across the health sector that create recording inefficiencies and do not support information sharing and learning.

The Ministry has an IT system for tracking and compiling critical incidents reported to it. The Ministry receives critical incident information from the healthcare organizations through a standardized reporting form (see **Section 4.4**). One of the three Ministry provincial quality of care coordinators then manually enters the reported information in the Ministry's critical incident tracking IT system.

Even though the Saskatchewan Health Authority amalgamated its operations, it continues to have 12 separate IT systems for tracking all adverse events, including critical incidents. In 2020, the Authority created another IT system for recording adverse events classified as critical incidents (critical incident system). The Authority manually enters critical incident information from its 12 separate IT systems into its critical incident system to support central compilation, and recommendation monitoring made on critical incidents. This means both the Ministry and the Authority duplicate critical incident data entry in multiple IT systems.

The Saskatchewan Cancer Agency also has a separate IT tracking and learning system for adverse health events.

Establishing a single, central knowledge base for tracking adverse events, including critical incidents, could support organization learning and enhance safer patient care delivery. One IT system could also support improved investigations of reported incidents, sharing of information, learning across the provincial health system, and strengthening a culture of patient safety.

4.3 Types of Critical Incidents Not Fully in Line with Good Practice

The types of critical incident events outlined in the *Saskatchewan Critical Incident Reporting Guideline, 2004* do not fully align with good practice, as defined by the Canadian Patient Safety Institute and Canadian Institute for Health Information.^{15,16}

The Guideline outlines the types of events that would normally be a critical incident and therefore reported to the Ministry (see **Figure 2**). The Ministry last revisited and updated the critical incident Guideline in 2004.

Figure 2—List of Adverse Health Events to be Reported to the Ministry of Health

The Guideline defines the types of adverse health events to report to the Ministry, and characterizes these events into six categories and 40 subcategories:

- **Surgical** (e.g., surgery performed on the wrong body part or the wrong patient)
- > **Product or device** (e.g., use of contaminated drugs or devices)
- > Patient protection (e.g., patient suicide or attempted suicide, death or disability associated with patient disappearance)
- > Care management (e.g., medication errors, acquired pressure ulcers, error in diagnosis)
- > Environmental (e.g., patient falls, transportation occurrences, burns)
- > Criminal (e.g., sexual or physical assault)

Source: Ministry of Health, Saskatchewan Critical Incident Reporting Guideline, 2004.

The Guideline defines 40 subcategories (i.e., types) of adverse health events within six categories. **Figure 2** lists the categories and gives examples of subcategories (i.e., types of critical incidents that may occur in the health sector). The Ministry included a summary of critical incidents in its 2019–20 Annual Report.¹⁷

We found, unlike good practice, the Guideline does not consider some of the 15 never events, that the Canadian Patient Safety Institute notes as adverse health events, to report as critical incidents.¹⁸ Our comparison of the Guideline against the Canadian Patient Safety Institute's never events found the Guideline does not include reporting of two types of never events:

- Patient death or serious harm due to uncontrolled movement of a ferromagnetic object in an MRI area (e.g., moving metal projectiles such as a pair of scissors)
- Patient death or serious harm as a result of transport of a frail patient or patient with dementia, where protocols were not followed to ensure the patient was left in a safe environment

¹⁵ The Canadian Patient Safety Institute is a not-for-profit organization funded by Health Canada. Established in 2003, the Canadian Patient Safety Institute works with governments, health organizations, leaders, patients and healthcare providers to inspire extraordinary improvement in patient safety and quality.

¹⁶ CIHI is an independent, not-for-profit organization that provides essential information on Canada's health system and the health of Canadians.

⁷⁷ www.pubsaskdev.blob.core.windows.net/pubsask-prod/119946/2019-20HealthAnnualReport.pdf (04 March 2021).

¹⁸ Never events are patient safety incidents that result in serious patient harm or death, and are preventable using organizational checks and balances. *The Never Events for Hospital Care in Canada* was created by the Canadian Patient Safety Institute, last updated in September

^{2015. (}www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care %20in%20Canada.pdf) (19 March 2021).

In addition, our comparison found the Guideline does not consider serious health-care associated infections as critical incidents. The Canadian Patient Safety Institute includes these as hospital harm events.¹⁹ Certain health-care associated infections, such as pneumonia, post-procedural infections, sepsis, infection of Clostridium difficile, MRSA (Methicillin-resistant staphylococcus aureus) or VRE (vancomycin-resistant enterococcus) can cause death or disability. Some subsets of these infections would be preventable and considered critical incidents. We found Ontario's critical incident reporting guideline includes healthcare associated infections as an incident type.

Without requiring incident reporting of the above two types of never events and potentially the above types of infections, the Ministry does not know the root causes or contributing factors of these types of critical incidents occurring in the Saskatchewan healthcare sector. In turn, it does not know whether Saskatchewan healthcare organizations are doing enough to keep patients safe from the occurrence of these types of events.

1. We recommend the Ministry of Health reassess the types of adverse health events it requires healthcare organizations to report as critical incidents.

4.4 Standardized Incident Reporting Form Could Be Improved

A standardized critical incident reporting form has been developed for reporting incident information to the Ministry of Health. However, it does not include sufficient information requirements to enable the Ministry to understand the root causes of a reported incident.

The Ministry developed the standard critical incident reporting form in consultation with the Saskatchewan Health Authority. Healthcare organizations have designated staff responsible for patient safety to report critical incident information to the provincial quality of care coordinators in the Ministry using this form in two stages—the notification stage, and completion of investigation stage.²⁰ The notification stage is when a healthcare organization first informs the Ministry of a critical incident. The completion of investigation stage is once a healthcare organization has investigated an incident and determined actions for improvement.

As **Figure 3** shows, the form includes requirements set out in *The Critical Incident Regulations, 2016.* It contains specific information requirements a reporting healthcare organization must give the Ministry for each stage.

Figure 3—Information Requirements of Standard Critical Incident Reporting Form

The reporting form requires the following information:
 Upon first notification:

 Patient information (age and gender but not patient name, health status prior to incident)

- Patient outcome (current status of patient)
- Location where the incident occurred (e.g., hospital versus long-term care and area of the province but not specific facility see **Section 4.11**)
- Event category (one of the six event categories in the Ministry's Guideline)
- Date of the incident
- Date the incident was classified as a critical incident (region aware date)
- Summary of the incident

¹⁹ CIHI and CPSI issued a joint publication in 2016 *Measuring Patient Harm in Canadian Hospitals.* (secure.cihi.ca/free_products/cihi_cpsi_hospital_harm_en.pdf) (19 March 2021).

²⁰ At December 2020, the Saskatchewan Health Authority had about 50 staff located throughout the province responsible for patient safety, including critical incident reporting.



However, we found the critical incident reporting form does not require a healthcare organization to provide the root causes behind the reported critical incident even though it expects reporting of the contributing factors.

The Guideline expects recommended actions for improvement to address the contributing factors and root causes identified—this is key to prevent further similar incidents from happening.

As **Figure 4** shows, good practice draws a distinction between contributing factors and root causes.

Figure 4—Identifying Contributing Factors and Root Causes

Contributing Factor: Conditions or actions that, if removed, would likely prevent the incident or hazard from happening, or reduce the severity of its consequences.

EXAMPLE: AN EMPLOYEE MISTAKENLY SKIPPED A STEP IN THE SAFE WORK PROCEDURE, WHICH LED TO AN INCIDENT.

Root Cause: The underlying weaknesses ultimately leading to an incident or the existence of a hazard.

EXAMPLE: THE EMPLOYEE HAS NOT RECEIVED FORMAL TRAINING ON THE PROCEDURE BECAUSE THE PROCEDURE WAS NOT ADDED TO THE TRAINING CURRICULUM.

Source: SMCX OnePager Determining Contributing Factors and Root Causes Mar2019.pdf (smscx.org) (21 March 2021).

An effective incident analysis process needs to identify both contributing factors and root causes to determine what led to the incident and recommend appropriate solutions. The root causes of a critical incident are often multifactorial and inter-related. Not asking healthcare organizations to report information on root causes limits the Ministry's ability to effectively oversee whether the healthcare sector does enough to prevent the reoccurrence of similar critical incidents.

2. We recommend the Ministry of Health ask healthcare organizations to include root causes of the incident when reporting critical incidents.

4.5 Incident Reporting Form Not Always Complete

The Ministry of Health does not always confirm the critical incident reporting form is properly completed, or obtain missing information from the reporting healthcare organization.

The Ministry has assigned responsibility for overseeing and evaluating critical incident reporting to three provincial quality of care coordinators within its Quality and Safety Unit. Provincial quality of care coordinators are to assess the critical incident reports as they are sent in at each stage (i.e., at the notification stage, and at the completion of the investigation stage) to ensure they contain the required information.

Upon receipt of critical incident notification reports from healthcare organizations (often via email), the Ministry assigns the incident a unique critical incident report number, and shares the number with the Authority for ongoing reference.

Our testing of critical incidents found the Ministry does not always confirm the completeness of the critical incident reports. We found:

For three of the 25 critical incident reports tested, the location field was blank. We further investigated and found that for critical incidents reported from April 2019 to September 2020, 58 or 12 percent of reports submitted did not have the location field filled out.

The lack of location information about where the incident occurred (e.g., hospital, long-term care) reduces the usefulness of data when looking for trends and problems in specific healthcare locations (see **Section 4.11** – facility location needed to identify and address systemic issues).

- For two of 30 critical incidents tested, contrary to the regulatory requirements, the patient outcome section was blank. *The Critical Incident Regulations, 2016* requires the critical incident notification to the Ministry to indicate the health status of the patient after the critical incident. These patients outcome information was included in the final reports received upon completion of the investigation stage.
- For nine of 30 critical incidents tested, the date the Authority classified the event as a critical incident (region aware date) was blank. We further investigated all critical incidents reported from April 2019 to September 2020 and found that 107 of them or 26 percent did not have this region aware date filled out.

Without having all dates required in the reporting forms, the Ministry cannot monitor if it is receiving the incident notification from the healthcare organization within three business days as required by law (see **Section 4.6** – incident notifications need monitoring for timeliness).

Missing data impacts the ability of the Ministry to do reliable analysis and draw valid conclusions about whether systemic issues exist that may impact patient safety, and whether planned actions are sufficient and put into place within a reasonable time to reduce the risk of similar incidents from occurring.

3. We recommend the Ministry of Health obtain missing critical incident information from reporting healthcare organizations.

4.6 Ministry Notified of Critical Incidents Later than Required

The Ministry of Health is not monitoring or enforcing compliance with reporting deadline dates set in *The Critical Incidents Regulations, 2016*. It frequently receives critical incident reports from healthcare organizations later than the timeframes required by law.

The Ministry's IT system tracks the status of each critical incident reported (e.g., investigation underway, final report received, incident closed). The Ministry can generate queries from the IT system to determine the status of critical incidents at various points in time and to determine how long it is taking healthcare organizations to submit incident reports.

The Critical Incident Regulations, 2016 set out timeframes by which a healthcare organization is required to notify and report the results of its investigation to the Ministry (see **Figure 5**).

Figure 5—Regulatory Timeframes for Reporting Critical Incident Reports to the Ministry

Notification: healthcare organizations must give notice to the Ministry of Health **within three days** of becoming aware of a critical incident (region aware date).

Final Report: healthcare organizations must conduct an investigation on each critical incident and submit final report on the investigation (including recommendations for improvement/corrective actions) **within 60 days** of becoming aware of the critical incident. The Ministry **may allow extensions** for submitting final reports (up to 180 days of the healthcare organization becoming aware of the critical incident).

Source: Adapted from The Critical Incident Regulations, 2016.

Our analysis of reported critical incidents over the last four years found the majority of critical incidents reported to the Ministry have come from the Saskatchewan Health Authority.²¹

Our analysis of initial notifications of critical incidents, as shown in **Figure 6**, found the Ministry often receives around 30 percent of them later than the three business days required by law.

Year	Number of Critical Incident Notifications	Number of Notifications Later than Three Business Days	% of Notifications Received Late
2017–18	187	55	29%
2018–19	213	52	24%
2019–20	231	101	44%
2020–21 (first two quarters only)	37	11	30%

Figure 6—Critical Incident Notifications Later Than Required by Law from 2017-18 to 2020-21

Source: Critical incident report data provided by the Ministry of Health.

^A As noted in **Section 4.5**, not all critical incidents reports had the date the Authority became aware of the incident so those incident notifications are not included in the above numbers.

Our analysis of reports of completed investigations (i.e., final reports), as shown in **Figure 7**, found the Ministry often receives over 30 percent of them later than the 60 business days required by law. On average, the Authority takes over 100 days to provide the Ministry with these reports. The Ministry may have authorized reporting extensions (up to 180 days) for these final reports as allowed by law. However, we note the percentage of reports of completed investigations received after 180 days increased from 2017–18 to 2019–20. Untimely receipt of final reports means the Ministry is not able to undertake timely assessments of corrective actions and analyze for system-wide issues.

²¹ During those same four years, the Saskatchewan Cancer Agency reported three critical incidents, the Athabasca Authority reported one incident, and other healthcare organizations such as eHealth and 3sHealth reported six critical incidents to the Ministry.

	Total Number of Final		Final Reports Received Later than 60 days but Less than 180 Days			Final Reports Received Later than 180 Days		
Year	Incident Reports Received	Number of Final Reports	% of Final Reports Received	Average Days to Submit Final Reports	Number of Final Reports	% of Final Reports Received	Average Days to Submit Final Reports	
2017–18	188	61	32%	126	16	9%	215	
2018–19	221	95	43%	115	26	12%	331	
2019–20	290	129	44%	107	85	29%	314	
2020–21 (first two quarters only)	Not available ^A	65		104	13		195	

Figure 7—Critical Incident Final Reports Received Later Than Required by Law

Source: Critical incident report data provided by the Ministry of Health.

^A Shaded are indicates the total number not available as year not complete.

We also note that as of October 31, 2020, the Ministry had not received 107 final reports for an average of 221 days since the critical incident occurred. The Ministry noted delays have occurred in receiving final critical incident reports from the Authority in 2020 because of the COVID-19 pandemic.

The Ministry indicated it does not follow-up with the Authority to determine why it takes longer than the required deadline of three business days to notify it of a critical incident. In addition, we found that the Ministry does not follow up on final critical incident reports not received within 60 days of the notification of the incident.

While the Ministry grants extensions to the deadlines (as the law permits), we found it does not record the reasons for extensions granted, even though the law requires reasons for requesting an extension to be provided.

One of the main purposes of critical incident reporting notifications is to inform senior and executive management within the Ministry about serious harm or death that has come to a patient in care. Delays in receipt of initial notifications of critical incidents causes delay in Ministry becoming aware of the most serious events of harm to patients in the health sector.²²

As noted earlier, critical incident reports include results of investigating the incidents (including contributing factors and planned corrective actions to reduce the likelihood of serious harm or death occurring to another patient in the healthcare system). Delays in receiving results of investigations means the Ministry does not undertake timely assessment of planned actions for improvement. This increases the risk that factors contributing to a critical incident continue to exist in the healthcare system, and similar patient harm events reoccur.

4. We recommend the Ministry of Health follow up when receipt of critical incidents reports are beyond established reporting deadlines.

²² When the provincial quality of care coordinators receive notification of a new critical incident, they prepare and distribute a notification email to certain individuals in the Ministry (e.g., Deputy Minister, Associate and Assistant Deputy Ministers). The provincial quality of care coordinators typically send these emails the same day or next day following initial notification.

4.7 Insufficient Analysis of Extent of Underreporting of Critical Incidents

The Ministry of Health has no mechanism to determine if it receives reports of all critical incidents expected.

Healthcare organizations, by law and through policies, track and report on a number of different types of adverse events. For example each year, they report the number of deaths resulting from falls, medication errors, and self-harm incidents occurring in hospitals to the Canadian Institute of Health Information.²³ In addition, since December 2019, federal law requires reporting of medical device events to Health Canada.²⁴ Both the Canadian Institute of Health Information and Health Canada publish this information. In addition, the Saskatchewan Health Authority tracks various types of incidents occurring in its facilities.²⁵

We found the Ministry does not use available data about reported adverse events to determine if it is receiving the expected reports of critical incidents.

Our analysis suggests underreporting of critical incidents to the Ministry. As shown in **Figure 8**, we found significant differences between the number of adverse events tracked and reported, and critical incidents reported to the Ministry.

For example, as **Figure 8** shows, the Authority reported 24 medical device failures to Health Canada but only reported 17 medical device critical incidents to the Ministry, during the same timeframe.

Figure 8—Analysis Results of Sources of Health Data about Adverse Events Compared to Critical Incidents Reported

Category Analyzed (Source of Data for Adverse Events)	Number or Percentage of Adverse Events (Related period)	Number of Related Reported Critical Incidents ^A (Related period)
Deaths as a result of falls in Saskatchewan hospitals (Canadian Institute of Health Information)	20 (2019–20)	7 (2019–20)
Number of self-harm incidents while in care in Saskatchewan hospitals (Canadian Institute of Health	11 (2018–19)	7 (2018–19)
Information)	14 (2019–20)	8 (2019–20)
Medical devices events reported under Vanessa's Law [®] (Saskatchewan Health Authority)	24 (Between December 2019 and September 2020)	17 (Between December 2019 and September 2020)
Level 4 incidents in Saskatoon and Regina and surrounding area reported to the Ministry $^{\rm C}$	101 [□] (2019–20)	35 (2019–20)
(Saskatchewan Health Authority)		

²³ Canadian Institute of Health Information is an independent, not-for-profit organization that provides essential information on Canada's health system and the health of Canadians.

²⁴ As of December 2019, *The Protecting Canadians from Unsafe Drugs Act* (Canada) (known as Vanessa's law) requires the Saskatchewan Health Authority to report certain incidents to Health Canada. The Ministry does not receive reports under Vanessa's law. The Authority is required to report any incident related to a failure or misuse of a medical device under the federal Act.

²⁵ The Saskatchewan Health Authority has its own rating scale for incidents.

Category Analyzed (Source of Data for Adverse Events)	Number or Percentage of Adverse Events (Related period)	Number of Related Reported Critical Incidents ^A (Related period)
Medication or fluid errors in Saskatchewan hospitals (Canadian Institute of Health	65% of 695 errors occurring in Regina and Saskatoon hospitals	49% of 35 critical incidents occurring in Regina and Saskatoon hospitals
Information)	(2019–20)	(2019–20)

^A Critical incident report data provided by the Ministry of Health.

^B The Protecting Canadians from Unsafe Drugs Act (Canada) is known as Vanessa's law and requires reporting on medical device events to Health Canada.

^c The Saskatchewan Health Authority records adverse events in its own system It considers Level 4 incidents to be the most severe and include unanticipated death or potential loss of function or major injury.

^D In 2019–20, the Authority recorded 51 Level 4 incidents in Saskatoon in its adverse events recording system and reported 22 of them to the Ministry as critical incidents. In 2019–20, the Authority recorded 50 Level 4 incidents in Regina and reported 13 to the Ministry as critical incidents.

Our assessment of critical incidents due to medication errors occurring in hospitals between 2017 and 2020 suggest underreporting of critical incidents occurring in Regina and Saskatoon hospitals. We found 80 percent of medication errors in this period occurred in hospitals. Regina and Saskatoon area hospitals reported 26 percent of these critical incidents yet they provide at least 50 percent of hospital care in Saskatchewan.

Underreporting of critical incidents could be reflective of several elements including the culture of safety within the reporting healthcare organizations, insufficient awareness of or understanding of the legislative requirement to identify and report critical incidents (training), and the inability to identify and report critical incidents as they occur within the healthcare system.

The Authority completed its first patient safety culture survey of Authority staff in December 2020. The Authority plans to use these results as a benchmark to evaluate future survey results. The survey indicated that 53 percent of respondents see the culture in their work setting makes it easy to learn from errors of others and 50 percent feel it is difficult to discuss errors. A culture of safety reflects the underlying beliefs and values of an organization as they relate to safety as a priority. Lack of feedback and fear of personal consequences to staff are often common barriers to incident reporting.²⁶

Lack of complete critical incident data compromises the validity of the Ministry's analysis of critical incidents and limits its ability to determine patient safety improvements needed.

Not receiving reports about all critical incidents means the Ministry does not have sufficient or complete information to identify whether systemic issues exist that may affect patient safety. As such, the Ministry cannot not assess if healthcare organizations are doing enough to keep patients safe.

5. We recommend the Ministry of Health analyze the nature and types of critical incidents reported as compared to other health data sources.

4.8 Critical Incident Training in Conjunction with Authority Planned

At February 2021, the Ministry of Health planned to participate in the delivery of online training for certain Authority staff—the key healthcare organization reporting critical incidents. However, due to the COVID-19 pandemic the timing of this training is uncertain.

²⁶ www.ncbi.nlm.nih.gov/pmc/articles/PMC4675258/ (27 October 2020).

At December 2020, the Saskatchewan Health Authority had about 50 staff located throughout the province responsible for patient safety, including critical incident reporting. They determine whether adverse events reported by front line workers meet the definition of a critical incident, and require reporting to the Ministry.

As noted in **Section 4.7**, the Ministry frequently receives initial notification of a critical incident long after it first happened. This may suggest a lack of understanding of what constitutes a critical incident by healthcare organization staff. During the audit, we observed instances where the provincial quality of care coordinators did assist Authority staff in determining whether serious adverse events met the definition of a critical incident.

Since 2017, the Ministry has not undertaken any critical incident training with healthcare organizations (e.g., the Saskatchewan Health Authority). We note the Authority formed in December 2017, and the Ministry indicated it was waiting for the Authority to set its structure.

The Ministry plans to co-facilitate patient safety fundamentals online training for Authority staff responsible for critical incident reporting (i.e., patient safety staff). It expects this training to occur in 2021. The training was delayed as of February 2021, due to COVID-19 pandemic priorities at the Authority.

Providing training regularly would improve awareness and understanding of critical incident analysis and reporting requirements for patient safety staff of healthcare organizations.

4.9 Not Documenting the Use of Defined Criteria When Assessing Incident Corrective Actions

The Ministry of Health's assessment of planned corrective actions included in individual critical incident reports adds limited value to improving patient safety.

The Ministry has established a medical review committee (referred to as the Critical Incident Review Committee) to review planned corrective actions in critical incident reports. The Committee is comprised of individuals from various disciplines (e.g., physician, nurse and pharmacist). The Committee is governed by a terms of reference that was last updated in 2016. The provincial quality of care coordinators provide the Committee with support.

Through written terms of reference, the Ministry has made the Committee responsible for evaluating whether a healthcare organization's planned corrective actions included in a critical incident report effectively address the underlying causes of the incident or warrant additional corrective actions to the healthcare organization for its consideration. The Committee is also responsible for establishing whether there is value in distribution of critical incident corrective actions on a system-wide level via a patient safety alert (an official notice with advice or instructions to healthcare providers about preventing specific types of incidents).

The Committee meets once a week to review critical incident reports and their applicable contributing factors and planned corrective actions for improvement. The Committee may have further questions of the Saskatchewan Health Authority after review of the report, and prior to closing the critical incident case. The Ministry typically sends these questions via email to the Authority.



We found the Committee does not follow good practice in that it does not have written guidance to aid its review of whether corrective actions effectively address the underlying causes of the incident or warrant additional corrective actions. Good practice, recommended by the Canadian Patient Safety Institute, includes using the hierarchy of effectiveness (see **Figure 9**) to aid in determining if a corrective action will be strong enough to modify behaviour and improve patient safety. The Institute also recommends using 'SMART' criteria to write (and therefore assess) corrective actions. The criteria expects corrective actions should be Specific, Measurable, Attainable, Relevant and Time-based.²⁷

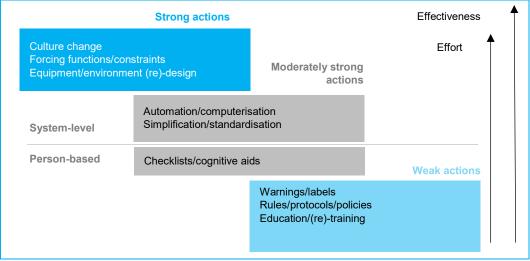


Figure 9—Hierarchy of Effectiveness

Source: Modified from graphics produced by the Institute of Safe Medication Practices and the US National Patient Safety Agency.

We found the Committee tries to take a persuasive but informal approach to assessing the adequacy of planned corrective actions in the reports. The Committee does not formally document its analysis of critical incident reports. The Ministry often seeks clarification or suggests improvements to corrective actions in critical incident reports (e.g., through emails to reporting healthcare organizations). However, the Ministry does not always require the reporting healthcare organizations to change the corrective actions in the final critical incident reports to align with the Ministry's suggestions.

Also, the Ministry does not require the Authority to summarize good practice used to devise corrective actions. It would be valuable for the Ministry to know if the Authority has looked for what actions are known to be effective in other locations. For example, a search of ISMP Canada safety bulletins would often provide relevant strategies for addressing critical incidents related to medication incidents.²⁸

²⁷ **Specific** – Tackle a clearly defined issue and have a clear scope, **Measurable** – can demonstrate impact on process and outcomes, **Attainable** – can be achieved with available resources, **Realistic** – do a reality check to predict if it will be accepted, implemented, and **Timely** – have a timeframe for implementation. Doran GT. There's a S.M.A.R.T. way to write management objectives. *Management Review*. 1981; 71 (11, AMA Forum); 35–36.

²⁸ ISMP Canada – the Institute for Safe Medication Practices Canada is a national, independent, and not-for-profit organization committed to the advancement of medication safety in all healthcare settings.

Our assessment of planned corrective actions of 21 critical incident reports found the planned corrective actions included in eight reports did not sufficiently address all of the contributing factors noted in the report. In each of these eight reports, the Ministry did not ask the Authority to add any corrective actions. For example, we found:

For one report tested, the planned corrective action was to develop a plan for safetyrelated tasks for an instance where a resident fell while being transferred with a mechanical lift while being bathed.

Using the hierarchy of effectiveness set out in **Figure 9**, we found this planned action weak in that it does not promote implementing the plan, result in staff training and/or confirm staff adherence to the plan or new policies.

For another report tested, the report listed several planned corrective actions but did not include one about redesigning a mental health unit even though the report noted that one of the root causes of the incident is the design of the mental health unit that did not allow for adequate monitoring and visual control of patients' whereabouts.²⁹ In this incident, a patient without pass privileges left the mental health unit undetected which may have put the patient at risk of self-harm.

The Ministry indicated that it does not expect or propose corrective actions with significant cost implications. We recognize budgetary constraints exist. However, not making corrective actions about the need for redesigning spaces to reduce the occurrence of further similar incidents may reduce the likelihood of the Authority considering such needs in future capital budget proposals. Furthermore, it may not sufficiently prevent another similar critical incident happening again.

We did not see evidence of the Committee asking for information about the root causes of incidents where this information was not evident in the report. See **Recommendation 2** about asking healthcare organizations to include information about root causes in incident reports.

Using formal criteria to assess corrective actions would aid in determining their adequacy. It would also help determine whether planned corrective actions sufficiently address the contributing factors and root causes, and whether there is a need for further actions. Having robust and documented analysis of the adequacy of planned corrective actions is consistent with the aim of critical incident reporting systems to improve patient safety.

With the 2017 creation of the Authority, there may be an opportunity to reassign the Ministry's role of evaluating the comprehensiveness and completeness of a healthcare organization's investigation of a reported critical incident. As noted in **Section 4.6**, since 2017, the vast majority of reported critical incidents have come from the Authority. As such, sharing such criteria with the Authority would help it identify planned corrective actions that address contributing factors and root causes of critical incidents.

6. We recommend the Ministry of Health (or responsible healthcare organization) apply consistent criteria to assess whether planned corrective actions effectively address causes of critical incidents.

²⁹ Corrective actions in the report included: discontinue using the Nursing Station Prox [security pass] to open the doors, requiring either a unit staff or security to use their Prox [security pass] to allow each patient/visitor in and off the unit individually; and station laptops at desks by each unit entrance door to assist security in monitoring those entering/exiting the units.

4.10 Implementation of Critical Incident Corrective Actions Not Monitored

The Ministry of Health does not know whether planned corrective actions that healthcare organizations include in critical incidents reports are implemented and improve patient safety.

Typically, the Saskatchewan Health Authority indicates in each critical incident report whether it has implemented the actions for improvement noted in the report at the time of its reporting.

Sixty-eight percent of planned corrective actions for improvement included in the 21 critical incident reports we tested were reported as not implemented. Some of these unimplemented planned actions have clear potential to reduce the risk of further similar critical incidents. For example, in one critical incident report about an attempted suicide, the Authority notes it planned to retrofit all patient room doors in a particular unit of a facility so patients cannot tie objects around them as a ligature point.

Our further investigation found the Authority could not provide us with a summary of critical incident corrective actions not implemented (e.g., at March 31, 2020). The Authority mentioned it was developing a new IT system to record and track the status of planned corrective actions related to critical incidents.

The Ministry views health care organizations as being solely responsible for implementing planned corrective actions and monitoring their implementation. As such, the Ministry does not record the planned corrective actions and their status in its critical incident IT system. Also, it does not require the Authority to routinely report back on status of implementation of corrective actions. As a result, the Ministry does not know the extent of critical incident corrective actions not implemented at any point.

We agree healthcare organizations are responsible for implementing planned corrective actions related to reported critical incidents.

However, we think the Ministry needs information about the implementation status of planned actions to fulfill its present role. That is, its role to oversee and evaluate the comprehensiveness and completeness of a healthcare organization's investigation (e.g., Saskatchewan Health Authority) of a reported critical incident, and the adequacy and appropriateness of the actions the organization has identified for improvement.

Not following up and monitoring the status of implementation of planned corrective actions may lead to the same critical incident occurring again. Identifying delays in implementing planned corrective actions would provide the Ministry with important information to help it determine whether it needs to support healthcare organizations in preventing specific types of incidents.

7. We recommend the Ministry of Health monitor the status of implementation of corrective actions set out in critical incident reports.

4.11 Analysis to Identify and Address Systemic Issues Limited

The Ministry of Health does limited analysis to identify whether systemic issues are causing reported critical incidents and to support its issuance of patient alerts—an official notice with instructions to healthcare providers.

As noted in **Section 4.9**, the Ministry's Critical Incident Review Committee is responsible for evaluating the corrective actions resulting from critical incident investigations to establish whether there is value in further dissemination of the corrective actions on a broader system level. Where it thinks there is value, the Ministry uses patient safety alerts to disseminate this information to necessary areas of the health sector (see **Figure 10**). The Ministry also makes its patient safety alerts available to the public through a government website.³⁰

Consistent with good practice, Ministry limits number of patient alerts issued: The Ministry tries to limit the number of patient safety alerts it issues in a given year. The Ministry notes it is important to balance the need for further guidance against the number of alerts issued, as too many alerts may overwhelm healthcare providers and can lead to healthcare providers not using them. We find this view reasonable.

See **Figure 10** for a list of the patient safety alerts issued by the Ministry in the past four years.

Alert Number	Alert Topic			
2017–18				
2017-18-01	Correct Patient Identification Prior to Any Care Interaction			
2017-18-02	Hydromorphone-Related Administration Errors			
2017-18-03	Preventing Pressure Ulcers in Acute Care			
2017-18-04	Safe Use of Four-Wheeled Walkers			
2017-18-05	Patient Referrals to Saskatchewan Cancer Agency			
2018–19				
2018-19-01	Ensuring Automated External Defibrillators (AEDs) are Operational			
2018-19-02	Pre-Operative Pregnancy Testing			
2018-19-03 Ensuring Fetal Wellbeing While Providing Unrelated Medical Care				
2019–20				
2019-20-01	Bed Entrapment Prevention			
2019-20-02	Decanting and Labelling Guidelines (for hazardous products)			
2020–21				
	No Patient Safety Alerts Issued to Date (as of December 30, 2020)			
Source: Ministry of Healt	h. www.ehealthsask.ca/services/resources/Pages/Patient-Safety.aspx (23 March 2021)			

Figure 10—List of Patient Safety Alerts Issued by the Ministry of Health between 2017 and 2020

³⁰ www.ehealthsask.ca/services/resources/Pages/Patient-Safety.aspx (04 March 2021).

The Ministry's provincial quality of care coordinators support the Committee in preparing patient safety alerts.

Content of patient safety alerts inconsistent with good practice: Our testing of four patient safety alerts issued between 2017 and 2020 found the alerts did not provide healthcare providers with specific guidance for reducing the risk to patients. Instead, they required the Authority to develop the guidance (e.g., create procedures or policies) to address the risk identified in the alert.

For example, in the Bed Entrapment Prevention patient safety alert, the Ministry recommended the Authority and health care organizations have policies and/or work standards in place in to ensure bed safety plans are communicated, implemented, and reviewed. The patient safety alert did not outline guidance to include in the bed safety plan. For example, the Ministry could have directed clinical guidelines at caregivers to help assess whether bed rails are appropriate or dimensional guidelines to help caregivers identify the dangerous zones within the bed system where entrapment may occur. Instead, the Ministry's alert expected the Authority to formulate this guidance.

Good practice expects a patient safety alert to be an official notice of advice or instructions to healthcare providers on how to prevent specific incidents known to occur and cause serious harm or death. Some jurisdictions (e.g., Alberta Health Services) use "safer practice guidance" as a reminder of safer and improved patient care practices not being followed but that should be.

Unlike good practice, no written guidance to guide decisions about patient safety alerts: The Ministry does not have written guidance to aid in deciding when incidents of harm to patients warrant the creation of a patient safety alert and the content of the alert.

Good practice suggest the use of written guidance to guide key decisions foster sufficient analysis to warrant an alert, and promotes consistent practice (see **Figure 11**).

Limited analysis as to whether the patient safety issue is under-recognized: We found that the Ministry, before issuing alerts, did not determine whether the Authority had already taken action to reduce the risk of patient harm. Nor did it have a process for identifying and tracking other patient safety alerts issued to healthcare providers from other sources such as medical device manufacturers and drug companies.

The Saskatchewan Health Authority has its own process to create and issue patient safety alerts. The Ministry is not part of the Authority's process, and does not track patient safety alerts issued by the Authority. The Ministry vets its patient safety alerts with the Authority before issuing them. As noted in **Figure 11**, good practice for issuing patient safety alerts includes considering whether the patient safety issue is new or under-recognized. Being aware of whether other parties have issued alerts helps determine if the issue is already recognized within the health sector.

A coordinated approach to reviewing alerts from all sources and centrally issuing only those alerts meeting defined criteria would reduce the risk of contradictory alerts and aid in reducing the number of alerts issued, to limit overwhelming healthcare providers.

Not using standard criteria to determine when a patient safety alert is warranted, increases the risk that an alert is made for a minor or localized issue, or that an alert is not made for a systemic issue and incidents continue to reoccur. Patient safety alerts must effectively communicate urgent patient safety information to healthcare providers.

8. We recommend the Ministry of Health (and/or responsible healthcare organization) utilize criteria to determine when to issue patient safety alerts.

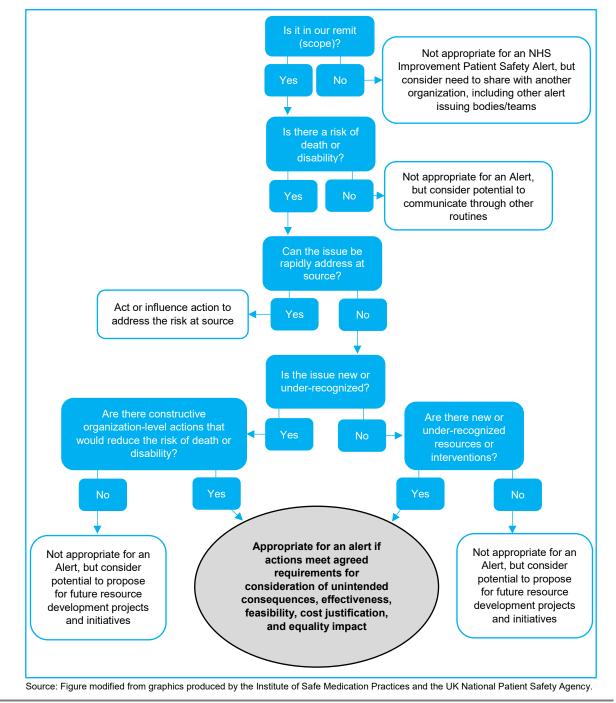


Figure 11—Patient Safety Alert Decision Tree, UK National Health Service



Trends and analysis of critical incidents limited: Our analysis also found the Ministry does not issue patient safety alerts in areas where a significant number of critical incidents continue to occur on a consistent basis.

We looked at the four highest subcategories of reported critical incidents in 2019–20 (stage 3-4 pressure ulcers, falls causing death, suicides while in care, and medication errors) and found that very few patient safety alerts issued by the Ministry related to these subcategories over the last three years (see Figure 10).³¹

In addition, while it does analyze some trends, the Ministry does not assess trends by facility location (e.g., specific long-term care home) to determine if a localized problem exists that warrants further investigation. We found the critical incident reporting form does not include where the patient died or was harmed (the specific location of the facility like Royal University Hospital). This information would allow the Ministry to determine if a facility is having a higher number of critical incidents and facing challenges in providing adequate patient care.

The Ministry's IT system allows the Ministry to generate critical incident summary information including the number of critical incident by outcome and by category. As Figure 12 shows, the number of critical incidents occurring overall and in the various categories are not trending downwards over the last five years. While it is not expected that the rate of reported critical incidents will ever be zero, the degree of injury and the kinds of critical incidents that occur in specific facilities should reduce over time if sufficient actions are taken to improve patient safety.

Category (including brief description)	2019– 20	2018– 19	2017– 18	2016– 17	2015– 16
Surgical Events					
(e.g., retention of a foreign object in a patient after surgery)	14	9	7	8	19
Product and Device Events					
(e.g., use or function of a device in patient care in which the device is used or functions other than as intended)	15	8	11	6	8
Patient Protection Events					
(e.g., patient disappearance, patient suicide or attempted suicide)	42	47	29	15	48
Care Management Events					
(e.g., medication or fluid error, error in diagnosis, Stage 3 or 4 pressure ulcers acquired after admission to a facility)	182	105	106	101	126
Environmental Events					
(e.g., patient death from a fall, delay or failure to reach a patient for emergent or scheduled services)	35	44	31	49	44
Criminal Events					
(e.g., sexual or physical assault of a patient)	2	8	4	7	4
Total Critical Incidents Reported	290	221	188	186	249

Figure 12—Critical Incidents Reported to Ministry of Health Between 2015 and 2020

ource: Ministry of Health, 2019–20 Annual Report, p. 28

³¹ The patient safety alerts related to the four highest reported subcategories included 2017-18-02 - PSA – Hydromorphone-Related Administration Errors, 2017-18-03 - PSA - Preventing Pressure Ulcers in Acute Care, 2017-18-04 - PSA - Safe Use of Four-Wheeled Walkers.

Our analysis of the incidents reported over the last five years found the trends in various categories and subcategories are not moving downward. For example, as indicated in **Figure 13**, the number of reported critical incidents for suicides and attempted suicides (within Patient Protection Events category) has not improved over the past five years.^{32, 33}

Figure 13—Reported Critical Incident Suicides and Attempted Suicides While in Care from 2015 to 2020

2019–20	2018–19	2017–18	2016–17	2015–16
28	33	25	10	24

Source: Ministry of Health 2019-20 Annual Report, p. 28.

Furthermore, as noted in **Section 4.10**, the Ministry does not monitor the status of implementation of planned corrective actions, or consider where unimplemented actions contribute to recurrence of similar critical incidents. For example, the Authority had a planned action to create a standard operating procedure document for checking the quality of future laboratory software downloads because of a critical incident at one laboratory facility. The planned corrective action did not include sharing this information across the health sector, which increases the risk such an incident could occur at another laboratory facility. We found the Ministry did not issue a patient safety alert on this incident. The Ministry indicated that this information was shared provincially across the Authority and Saskatchewan Cancer Agency but did not have documented evidence of the communication.

Without documented analysis of incidents, the Ministry staff must rely on their recall of whether similar critical incidents and/or planned corrective actions have occurred.

Not sufficiently analyzing reported critical incidents and corrective actions limits the ability to identify systemic issues in the healthcare system. It also increases the risk of the critical incident reporting system not contributing to patient safety and being more administrative in nature.

9. We recommend the Ministry of Health analyze critical incidents for systemic issues.

Unlike good practice, no follow-up of ministry patient safety alerts: The Ministry does not follow up patient safety alerts to determine if they are effective in improving patient safety. For example, the Ministry does not complete an assessment several years after the patient safety alert was issued (to allow time for impact) to see whether reported critical incidents in the area improved (e.g., did the number of bed entrapments reduce).

Good practice, from Alberta Health Services, requires a review of patient safety alerts every three years to confirm recommended practice in the alerts aligns with best practice. Otherwise, patient safety alerts are reissued. The review may also determine if the patient safety alert is no longer applicable as the issue has been resolved.

Without following up on the patient safety alerts, the Ministry cannot determine if they are implemented and successful.

³² This subcategory excludes deaths resulting from self-inflicted injuries that were the reason for admission to a hospital.
³³ This subcategory represents about 9 percent of all reported critical incidents in 2019-20.

10. We recommend the Ministry of Health work with the Saskatchewan Health Authority to monitor the effectiveness of patient safety alerts.

4.12 Critical Incidents Reported Internally and to the Public

The Ministry of Health shares key information about critical incidents internally with its branches and the Saskatchewan Health Authority. It also publishes the detailed results of critical incidents reported to it in its annual report.³⁴

See **Figure 12** for summary of published critical incident information. As **Figure 12** shows, almost half of the critical incidents reported fall into the category of care management events that include medication errors and pressure ulcers.

Our review of the Ministry's planning documents show it is focusing its strategic priorities on key areas of weakness in patient care. For example, the Ministry has set, in its 2019– 20 accountability document with the Saskatchewan Health Authority, a key action for establishing strategies to improve two high critical incident areas: patient falls and medication safety.

Also, our analysis of total critical incidents reported over the past few years found the acute care sector and the long term care sector continue to report the most critical incidents, accounting for 88 to 91 percent of the critical incidents reported. Higher rates of critical incident reporting in these sectors is expected as the complexity of care and interaction with patients is significantly increased in both of these sectors.

We also found the Ministry prepares, each quarter, critical incident trend analysis. It shares this trend analysis with other branches of the Ministry (see **Figure 14**). This analysis generally outlines the extent and types of critical incidents occurring (see **Recommendation 9** about need for better analysis of critical incidents to identify systemic issues).

We also identified instances where the Ministry prepared specific critical incident statistics at the request of other branches (e.g., specifics on suicides and attempted suicides) and the Authority.

In addition, each quarter, the Ministry gives the Authority the number of reported critical incidents and the top five reported subcategories.

Figure 14—Quarterly Critical Incident Trend Analysis Prepared by Ministry

> Total critical incidents reported by fiscal year for past 15 years

For the past five years:

- # of incidents reported by month
- # of incidents reported per year by organization (e.g., former health region area, Saskatchewan Cancer Agency)
- > # of incidents reported by outcome (death, disability/harm, close call, unknown)
- > # of incidents and percent reported by category (surgical event, product or device event, patient protection

³⁴ www.saskatchewan.ca/government/government-structure/ministries/health#:~:text=The%20Ministry%20of%20Health %27s%202019-20%20Annual%20Report%20presents,made%20and%20other%20key%20accomplishments%20of%20 the%20ministry. (04 March 2021).

event, care management event, environmental event, criminal event) and subcategory (e.g., medication or fluid error, patient suicide or attempted suicide, patient death associated with a fall, error in diagnosis, stage 3–4 pressure ulcer)

- # of top five reported subcategories
- Status of all critical incidents reports received (e.g., investigated, report incomplete, issue alert pending, closed)

Source: Adapted from Ministry of Health reports.

Periodic reporting internally, to the Authority, as well as the public, increases the transparency of critical incidents occurring in the healthcare system.

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