Critical Incident Review Process

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1. Overview/procedure description

This procedure outlines the

(a) the process and methods to investigate a clinical incident.

(b) the responsibilities of RCH managers throughout and following the investigation.

(c) governance and monitoring of completion of recommended actions, following an investigation.

2. Related Policy & Procedure.

Quality Improvement & Risk ManagementPolicy

Open DisclosureProcedure

Incident Reporting and ManagementProcedure

3. Definition of Terms

- **Clinical Incident:** An event or circumstance that could have resulted, or did result, in unintended or unnecessary harm to a person receiving care (Australian Commission on Safety and Quality in Healthcare, ACSQHC 2006). Clinical incidents include adverse events, near misses and hazards in the environment that pose a clinical risk.
- A clinical incident can be an **adverse event:** An incident in which harm resulted to a person receiving health care (ACSQHC 2006).
- A clinical incident can be a **near miss** : An incident that did not cause harm (ACSQHC 2006). Near miss encompasses incidents that had potential to cause harm but did not, due to timely intervention and/or luck/chance.
- **Sentinel Events** are relatively infrequent, clear-cut events that occur independently of a patient's condition, commonly reflect hospital system and process deficiencies and result in unnecessary outcomes for patients. Please refer to Appendix One below for management of a Sentinel Event.
- **Incident severity rating (ISR)** is a score of 1, 2, 3, or 4 that measures the severity of the impact caused to either a person or organization following an incident, ISR 1 being the highest or most severe and ISR 4 a near miss.

  The ISR is derived from response to three consequence descriptor category questions related to
  - Degree of impact
  - Level of care

- Treatment required

Rating	Severity/Rating
ISR 1	Severe - Death / Severe
ISR 2	Moderate
ISR 3	Mild
ISR 4	No Harm / Near Miss

- **Critical Incidents (non local)**
  a) **An incident rated ISR 1** is always a critical incident.
  b) **An incident rated ISR 2** is classified as a critical incident if it meets the following criteria:
    - Resulted in moderate harm to a patient
    - Involved a 'process error' or 'failure of a process'
    - Involved more than one department within the hospital
  c) **Any incident (ISR 2,3 or 4)** where there is potential for learnings for the organization.
- **Critical Incident (Local) is an ISR 2 incident that meets to following criteria:**
  - Resulted in moderate harm to a patient
  - Involved a 'process error' or' failure of a process'
  - Involved only one department within the hospital

  These incidents are managed at the local level with a Strategy and Improvement quality manager to work with the local manager to assist in the review of the incident. Outcomes and recommendation will be documented in VHIMS for transmission to the Department of Health and Human Services (DHHS)
- **Critical Incident Review** is a detailed investigation utilizing the in-depth case review methodology. This involves a group of staff members convened by the quality manager to review the timeline of the incident, identification of factors contributing to the incident and formation of recommendations for system change
- **Root Cause Analysis (RCA):** a systematic process where the factors that contributed to an incident are identified
- **Open Disclosure** refers to the process of open communication with patient and their families following an adverse event or an unexpected event that may or may not result in harm to the patient Department of Health and Human Services (DHHS)
- **Date Closed:** An incident closed is referring to the fact that the incident has been reviewed and there is an agreed plan that is place to address the issues identified from the incident, or that there is no need to initiate a mitigation plan.

4. Procedure details

The Victorian Health Information System (VHIMS) has been established by the Department of Health and Human Services (DHSS), Victorian health services and other key stakeholder groups, for collection and review of statewide incident information. At RCH, VHIMS is used to collect information on clinical, OH&S and non-

clinical incidents.

When a clinical incident occurs, the local manager (heads of departments/ nurse unit managers) is responsible for ensuring the following actions are carried out in VHIMS:

- Review incidents within two working days of receipt
- Debrief with the staff involved in the incident, clarify information if required and provide support if required
- Ensure patient and families are notified of the incident and treatment required in accordance with the Open Disclosure procedure and record that 'next of kin' notified in VHIMS is checked
- Ensure the incident location and department is recorded accurately according to the incident
    - Incident Location = where the incident occurred (i.e. where the patient was located at the time of the incident)
    - Department = the department responsible for investigating the incident
- Ensure the primary incident type (classification) reflects the nature of the event
- The severity rating reflects the incident according to the impact, treatment required and changes to the level of care provided to the patient involved in the incident
- Where the incident has been rated 1 or 2 by the staff member entering the incident it can only be change by a member of the Strategy and Improvement. Any changes to the severity rating are done in consultation with the department manager and following presentation of evidence to the Executive Director or Director Quality Systems.

Note: The ISR is assigned by an algorithm set into the VHIMS program based on answers to a set of questions. The ISR will be shown in the severity section of VHIMS.

4.1 Investigation and follow-up for ISR 1 or 2

All ISR 1 and 2 are automatically distributed (via VHIMS) to the line manager of the area, Strategy and Improvement quality managers, divisional directors and members of the executive. The quality manager will review the incident to determine if the incident is defined as:

- a sentinel event
- a critical incident
- a critical incident (local)

ISR 1 and 2 incidents are reported to:

- CEO, Executive and Board / Board Quality and Service Planning Committee
- Patient Safety Committee
- Clinical Quality and Safety Committee

a) **Sentinel event:**
If a sentinel event has occurred, the Strategy and Improvement quality managers will notify the Department of Health and Human Services. A time-line, a root cause analysis and a final report is to be provided to the DHSS within 60 days of notification.

The Strategy and Improvement team will contact the department and provide a copy of the process for managing a Sentinel Event. The quality managers will work though the Sentinel Event Process with the department managers to ensure that there is clarity around how to manage the event and that patients, families and staff are supported through the process.

Refer to Appendix 1 – Process for Managing a Sentinel Event.

b) **Critical incident**

If the incident requires a critical incident review, the Strategy and Improvement quality managers will organize an incident investigation with key stakeholders and recommendations from this review process will be presented to Patient Safety Committee. Once the PSC has endorsed the recommendations, the incident is 'closed' but the recommendations remain open until completed.

Note: All RCH staff are expected to contribute to the Critical Incident review process or root cause analysis if required.

c) **Critical incident – Local (refer to definition above)** If the incident requires a 'local' review it is the responsibility of the local managers to investigate the incident and document investigation findings in the follow-up section in VHIMS. Managers are required to:

- determine the underlying causes of the incident
- describe the patient outcome
- outline steps/recommendations implemented to prevent re-occurrence of incident
- close all 'local' critical incidents within 60 days of notification

Note: The Strategy and Improvement quality managers will provide support to the local manager when investigating the incident. Closure rate for critical incidents are reported as a Key Performance Indicator (KPI) to the Clinical Quality and Safety Committee.

4.2 Investigation and follow-up for clinical (non-critical) incidents

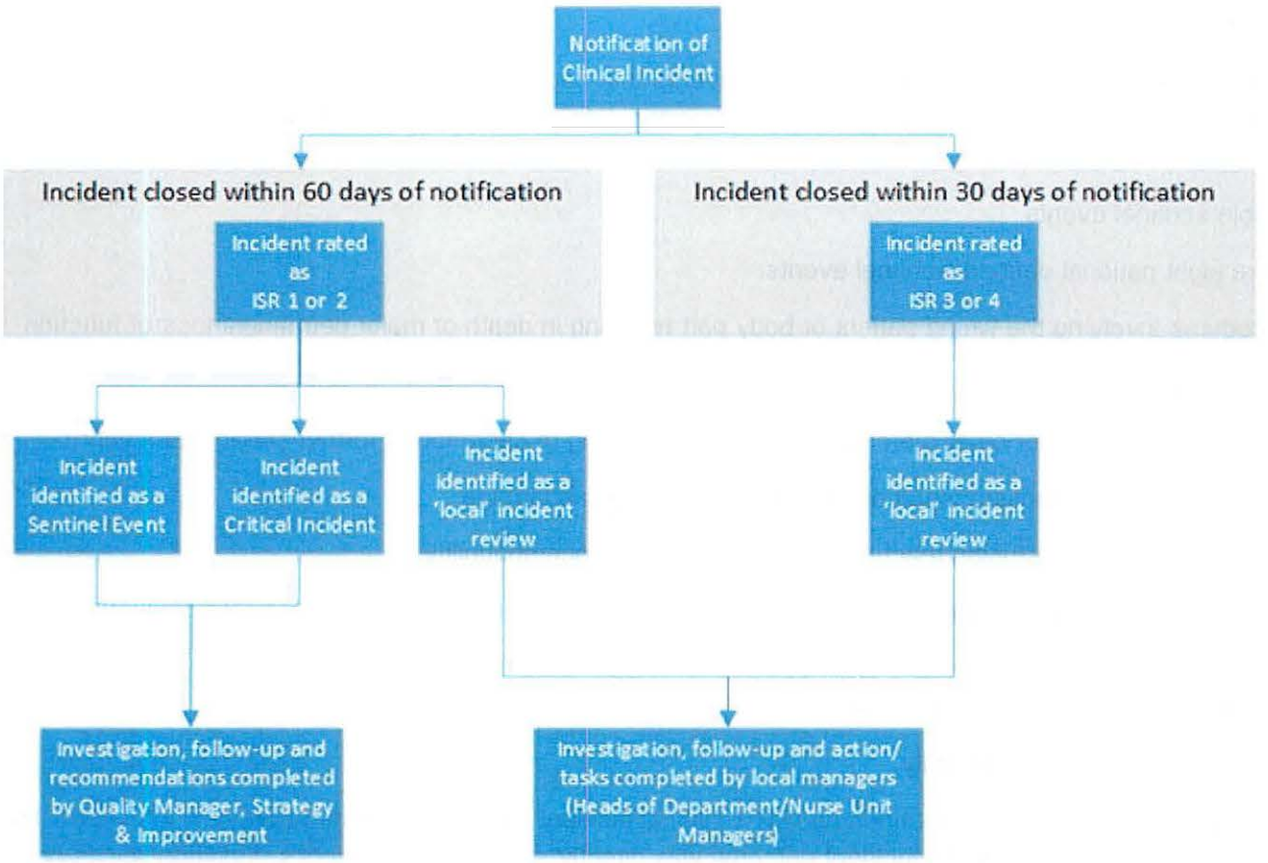
These are investigated by the local managers. It is the responsibility of the managers to determine the underlying cause of the incident and assign corrective actions/tasks to address the identified issues.

The local managers are responsible for providing objective evidence that the corrective actions/tasks have been completed. These incidents are required to be closed within 30 days of incident notification.

Incident analysis through the monitoring of trend and aggregate data occurs at the appropriate national standard committee. Local level analysis is conducted with department manager in consultation with a quality manager.

Note: Closure rate for ISR 3 and 4 are reported as a KPI to the Clinical Quality and Safety Committee.

The Clinical Incident Review Process for managers comprises a series of steps. These steps are depicted below.



Appendix One

Process for Managing a Sentinel Event

1	2	3	4	5	6
Reporting the incident	Notification to Department of Health (DH)	Incident review and interviews	Timeline and Root Cause Analysis	Recommendations and submission to Patient Safety Committee (PSC)	Prepare final report for DH –within 60 days of the incident.
• Record incident in VHIMS • ISR1 could indicate a sentinel event • Strategy and Improvement will lead the incident investigation • You will be contacted by a Quality Lead / Quality Manager to identify an investigation team *Refer to Critical Incident Management Procedure for more information about sentinel events*	• We are required to notify DH within 7 days of a reportable incident. • DH will advise if the incident is be reported as a sentinel event (if it is not one of the 8 defined criteria) • Strategy and Improvement will prepare a report to be sent to DH	• Strategy and Improvement will work with the Dept Manager to arrange staff interviews: • The purpose of the interviews are to: - Focussed on systems and processes, not on individual performance or blame - Determine sequence of events - Ascertain the staff member's involvement - Identify any difficulties or problems they observed or experienced *Refer to Critical Incident Management Procedure for more details about staff interviews*	Investigation team to develop: - Timeline of events - Cause and effect analysis (brainstorming and mindmap) - Root cause analysis *Strategy and Improvement will set up meetings with the investigation team to develop the above documents*	• Prepare report including identified issues and recommendations for PSC • Presentation at the next scheduled PSC • Endorsement of recommendations by PSC	Strategy and Improvement to prepare and submit report. The report includes: • Executive summary of incident • Conclusions • Recommendations • Timelines • Cause and effect chart • Risk reduction strategies (recommendations) • Sign-off by CEO *Strategy and Improvement will submit the signed document to DH*

What is a sentinel event?

Sentinel events are relatively infrequent, clear-cut events that occur independently of a patient's condition, commonly reflect hospital (or agency) system and process deficiencies; and result in unnecessary outcomes for patients.

Reportable sentinel events

There are eight national defined Sentinel events:

1. Procedures involving the wrong patient or body part resulting in death or major permanent loss of function
2. Suicide in an inpatient unit
3. Retained instruments or other material after surgery requiring re-operation or further surgical procedure
4. Intravascular gas embolism resulting in death or neurological damage
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility
6. Medication error leading to the death of patient reasonably believed to be due to incorrect administration of drugs
7. Maternal death or serious morbidity associated with labour or delivery
8. Infant discharged to wrong family.

Additionally: If a health service identifies an ISR 1 clinical incident they are requested to review the event. This review is to determine whether the incident outcome was directly related to the patient's condition/illness or due to a breakdown in health service systems or processes. If the review identifies that a breakdown in system or process issues contributed to the incident outcome, the incident is to be reported to the Sentinel event program

Management of Sentinel Events at RCH

If a sentinel event is identified in your department the following actions will occur. The process is coordinated by the Strategy and Improvement team. The diagram above provides an overview of the process.

Report incident to DHSS

The incident is reported to DHSS and is assigned a unique identification number. The notification is to be made within three days of notification to the RCH of the incident.

Interviews

The department manager is required to provide the Strategy and Improvement team with a list of all staff involved and when the staff will next be available for interview. Staff will be interviewed by a member of the Strategy and Improvement team (or other designated member of the investigating team) as soon as possible.

The interview will focus on

- The sequence of events related to the incident
- What is the normal process or sequence of events
- Their involvement in the incident
- Any difficulties or problems they experienced or observed

Prior to the interview

- The interviewees is given a clear explanation of the investigation process and the purpose of the

discussion and how the information will be used

- The interviewees are offered the opportunity to bring a colleague or support person with them to the interview.
- Interviews are to be held in a private place with no interruptions
- If it becomes clear that a professional shortcoming or error has occurred this will be discussed without judgment or adverse comment.
- Staff will be offered ongoing support and counseling

Timeline of Events

After conducting the interviews with staff, and using all evidence and information gathered during the investigation; a timeline of events is created. This timeline is used to inform the root cause analysis.

Root Cause Analysis (RCA)

The RCA phase is used to establish the course of events and identify contributing factors. The quality managers will utilize one of several tools to assist in identifying the root cause of the incident (eg cause and effect process, fishbone diagram).

- An investigating team will be established which will be multi-disciplinary and members should be familiar with the area but not directly involved in the incident
- The focus is on systems and processes not on individual performance or blame
- Both clinical and organisational processes will be reviewed

Recommendations

Once the team have completed a timeline of events and a root cause analysis, the next step is to develop recommendations which address contributory factors.

Recommendations are presented to the RCH Patient Safety Committee for endorsement. A schedule for completion of the recommendations is also established and recorded in the incident report and in VHIMS.

Once endorsed the mandatory report, including timeline, cause and effect diagram and endorsed recommendations is submitted to the CEO for review and sign-off, prior to being submitted the DHSS. This final report is to be submitted within 60 days of notification of the incident.

Feedback on the recommendations will be provided to all staff involved in the incident, staff involved in the investigation, other relevant providers and patient and family as allowed.

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