SA Health

Guideline

How to Conduct a Cluster Incident Review

Version 1.0
Approval date: 15 April 2024
PDS Reference No: G0205

Contents

List of Tables

1. Name of guideline

How to Conduct a Cluster Incident Review

2. Relationship to parent policy

The Clinical Incident Management Policy is the parent policy to this How to Conduct a Cluster Incident Review Guideline.

3. Guideline statement

This guideline provides information and resources to support the process of a cluster incident review and aligns with the requirements of the Clinical Incident Management Policy.

4. Applicability

This guideline applies to all employees and contractors of SA Health; that is all employees and contractors of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks and SA Ambulance Service (SAAS).

5. Guideline details

Cluster incidents place multiple patients at risk, are complex in nature, generate significant organisational interest, and often have potential to generate media interest. A response to this risk should include, immediate risk management, leadership and advisory groups, a cluster incident response plan, effective communication flows and incident review evaluation.

Staff should consider the following resources when responding to cluster incidents, Appendix 1: The Cluster Incident Review Process and Appendix 2 The Cluster Review Checklist.

5.1 What is a cluster incident?

- A cluster incident means an event or circumstance where a group of five or more patients (3 or more for a small or specialised service) could have or did experience harm, as a result of a system failure(s) or common issue(s). The commonality of these incidents may be related to time, place, and/or treatment.
  - A cluster incident can take place in one or multiple LHNs, SAAS or state-wide services.
- Cluster incidents can be:
  - simple i.e., patients are impacted with minimal or no harm.
  - complex i.e., patients are impacted with serious harm, or a large number of patients are impacted with minimal or no harm or where multiple patients are affected where significant safety implications are identified.

Case Study 1 – What is a cluster incident
System failure (simple – no harm): The LHN outpatient waiting room notification system failed for a 1 day. 20 patient's appointments needed to be rescheduled. **System failure (complex- no harm):** The Sunrise Enterprise Master Patient Index Database incorrectly adjusted 500 patient details in the SA Health Electronic Medical Record. The risk to patients was significant but no patients were harmed. **Issue (complex – harm):** A Therapeutic Goods Administration recall was in place for faulty continuous positive airway pressure masks. Approximately 20 patients experienced allergies, or respiratory infection from the breakdown of the mask seal before recall.

5.2 Cluster Incident Response

The cluster incident response is relative to the number of patients involved in the incident and/ or the degree of patient harm. A simple cluster requires a simple cluster response, and a complex cluster

requires a complex cluster response. The senior manager in conjunction with the Safety and Quality (S&Q) Director/Manager should determine whether a cluster incident is simple or complex to identify the health service response.

5.2.1 Simple Cluster Response

- A simple cluster does not require a cluster response team or a formal response plan but should involve discussions with the relevant manager and the local S&Q team to ensure that the incident response and open disclosure is appropriate.

5.2.2 Complex Cluster Response

- A complex cluster requires a Cluster Review Team (CRT) (see 5.3.1) and formal response plan.
- A complex cluster incident requires a parent incident to be entered in the Safety Learning System (SLS) titled 'cluster' and 'cluster' in the first name and surname fields. Individual patient incidents can be linked to this parent incident.
- A cluster response plan should be developed by the CRT.
    - Staff should consider Appendix 3: Cluster Incident Response Plan Template.
- The cluster response plan should include:
    - a description of the incident scope in one or two sentences.
    - clinical risk and management actions.
    - coordinated actions to address system failures or issues.
    - the response plan should be confirmed by the CRT prior to implementation with allocated owners for all actions.
    - incident escalation to executive leads and DHW CIB Escalation Guide.
    - a communication strategy for stakeholders e.g. executive leads, the Chief Executive for Health and Wellbeing, Chief Clinicians in DHW (Chief Medical Officer, Chief Child Protection Officer etc) patients/families/carers, staff, and the general public.
    - open disclosure with all patients/families/carers involved in the incident.
    - SA Health Privacy Committee reporting requirements for privacy breaches.
    - evaluation of the cluster review effectiveness.

Case Study 2 – Cluster Review Team Response Plan

A breakdown in cleaning processes for an endoscope was identified impacting 15 patients at one LHN. The local manager and LHN S&Q Director determined that a complex cluster incident response was required. A CRT was convened within 24 hours and included the LHN S&Q Director, unit consultant, Nursing Director, NUM, Executive lead, and Communications Team Representative. On the same day, the CRT virtual huddle invitations were distributed and the response plan drafted and sent. At the first CRT huddle the response plan was reviewed and the CRT identified three additional risks for inclusion in the response plan and two additional CRT members to include being Infection Control and Infectious Diseases.

Case Study 3 – Cluster Review Team Response Plan

A digital health incident was identified impacting 16,000 patients. The DHW S&Q Director determined that a complex cluster incident response was required. A Cluster Oversight Group was convened within 1 day and included the DHW S&Q Director, Digital Health Director and Manager, and Communications Team Representative. On the same day, the Cluster Oversight Group virtual huddle invitations were distributed to the impacted LHNs. At the Cluster Oversight Group (members: LHN S&Q Directors, LHN senior leaders, LHN digital health experts, and Outpatient Nursing Directors) huddle the response plan was reviewed and the Cluster Oversight Group identified three additional risks for inclusion in the response plan and two additional Cluster Oversight Group members.

5.3 Leadership and Oversight Groups

5.3.1 Cluster Review Team

The Cluster Review Team (CRT) is the leadership group responsible for review of a complex cluster incident. As a leadership group, they ensure the incident review is timely, coordinated and responsive.

- Local teams not the CRT are responsible for immediate safety measures following a cluster incident.
- The CRT should be convened as soon as practical and within one business day of a cluster incident being identified.
- Where a cluster incident involves only one health service (i.e., LHN, SAAS or a state-wide service), that health service will lead the CRT. Where there is significant harm, clinical risk and/or media involvement, DHW should be contacted who may participate as a member of the CRT.
- At a minimum the CRT should consist of a senior manager with governance for the incident issue(s) or system failure(s), the Safety and Quality (S&Q) Director/Manager, and a communications team representative; the CRT should have one member who is a trained open disclosure facilitator.
    - The senior manager should provide expert information about the scope of the incident that may include:
        - the number of patients affected (with or without harm)
        - the degree of harm experienced by patients.
        - the root cause of the incident, contributing factors and any other relevant information about the issue(s) or system failure(s) involved in the incident as known at the time
        - the best available advice on how to resolve the issues or system failures.
    - The S&Q Director/Manger or delegate should lead the CRT and coordinate incident review actions that may include:
        - development of a response plan.
        - scheduling and leading the CRT huddles.
        - comprehensive communication with the Cluster Oversight Group (where relevant).
        - a plan for verbal or written open disclosure with the impacted patients/families/carers.
        - review documentation and escalation to executive leads and the DHW.
    - The communications team representative should provide a communication strategy that may include:
        - key messages about the cluster incident for staff and the general public.
        - identification of a nominated spokesperson for media releases.
        - questions and answers for the nominated spokesperson.
        - key contacts for media requests.
        - recommendations on the communication approach with external organisations.

5.3.2 Cluster Oversight Group

Where the incident involves more than one health services or state-wide system, DHW will convene and lead the Cluster Oversight Group, as a leadership group responsible for the oversight and management of complex cluster incidents and performs similar functions to the CRT.

- The Cluster Oversight Group should be convened as soon as practical.
- Membership will be determined by the type and nature of the cluster incident and should have the following:
    - expertise to define and advise on the scope and risk of the cluster incident.
    - expertise to define the broader system impact/s.

- access to communication pathways for the flow of information to staff.
- Access to mechanisms for consumer involvement.

5.4 Communication

The flow of information throughout cluster incident review is crucial. Information flow supports coordination of the organisational response; the information flow should include executive leaders, safety and quality teams, staff, and patients.

5.4.1 Executive Leads

- A complex cluster requires communication with executive leads using a Clinical Incident Brief (CIB). An initial CIB is required, and close out CIB or report is required. CIB Template and CIB Guide.
  - The initial CIB is to alert executive leads about the incident scope, known risks, response plan, and any anticipated media interest.
  - The close out CIB or report outlines the review findings and implemented patient safety actions.

5.4.2 Safety and Quality Leads

- When complex cluster incidents occur, the DHW S&Q Team will create and distribute a SLS cluster title to affected health services, for seamless incident tracking.
- The S&Q Director/Manager as the CRT lead, should provide a continuous flow of information to the CRT about the cluster review progress.
- DHW as the Cluster Oversight Group lead, should provide a continuous flow of information to the Oversight Group and CRTs about the cluster review progress.

5.4.3 Staff

- Relevant staff should receive information about the incident facts, planned actions to address the issue(s) or system failure(s), any actions required by staff, and key messages to share with the public.
  - The CRT (and in conjunction with the Cluster Oversight Group where relevant) should determine how and when this information is provided to staff.

5.4.4 Patients / Open Disclosure

- Patients who have been impacted by a cluster incident will be informed and communicated with through an Open Disclosure process.
- Open disclosure to all impacted patients/families/carers requires careful planning.
- Complex cluster incidents may require a written apology.
- Considerations are required to ensure that communication is consumer centric and considers health literacy for vulnerable groups (e.g., culturally and linguistically diverse, mental health clients, National Disability Insurance Scheme participants), causes no additional distress and/or harm.
- A designated point of contact for patients/family/carers is recommended.
- If a large number of patients are impacted, it is recommended that a toll-free telephone hotline and/or webpage be considered.
  - The hotline provides opportunity for questions and additional consumer information.
  - The hotline should have access to interpreter services.
    - A webpage may be beneficial to provide information such as frequently asked questions and regular updates on incident review progress.
- Some patients/families/carers may request a face-to-face meeting for additional information.
- Patients/families/carers should not incur any cost from face-to-face meetings or other financial burden from the incident. The CRT should coordinate:
  - provision of costs associated with meeting attendance.

- consideration of payment for any additional treatments associated with the incident. (e.g., General Practitioners or Specialists Medical Practitioners appointments).
- Group meetings with affected patients/family/carers is not recommended due to confidentiality of patient information and privacy protections.

5.4.5 General Public

- Cluster incidents that involve a large number of patients may require a media release to the general public by the Chief Executive (CE) or the Minister for Health and Wellbeing. In these instances, the DHW Communications Team should coordinate statement preparation and release.
- Impacted patients should be advised in advance of public media releases.

5.5 Evaluation

- The CRT should evaluate the cluster incident review management.
  - Key measures of timeliness, coordination and communication should be considered.
- S&Q Directors/ Managers should:
  - communicate lessons learned from the cluster incident review at the DHW Clinical Governance Community of Practice.

6. Supporting Information

- Clinical Incident Management Policy
- Contributing Factors Tool
- How to Conduct a Clinical Incident Review Guideline
- How to Conduct Open Disclosure Guideline
- Incident Management Guide, Australian Commission on Safety and Quality in Healthcare 2022
- NHS Guide to responding proportionately to patient safety incidents
- NHS Serious Incident Framework
- NSW Health Quality Improvement Tools
- Privacy Guideline
- Privacy Policy
- Queensland Health Patient Incident Management

7. Definitions

- **Cluster incident:** means an event or circumstance where a group of five or more patients (3 or more for a small or specialised service) could have or did experience harm, as a result of a system failure(s) or common issue(s). The commonality of these incidents may be related to time, place, and/or treatment.
- **Complex cluster incident:** means a cluster incident where patients are impacted with serious harm, or a large number of patients are impacted with minimal or no harm or where multiple patients are affected where significant safety implications are identified.
- **Contributing factors:** means circumstances, actions or influences that have played a part in an incident. Contributing factors topic guide.
- **Harm:** means impairment of structure or function of the body. Harm includes disease, injury, suffering, disability, and death.
  - Harmful incidents can occur because an unplanned or unintended variation in care has occurred, the patients or medical team's expectations of care were not met, or a complication

of investigation, (e.g., colonoscopy) or treatment, (e.g., surgery) resulted in patient harm. (e.g., bowel perforation or pneumothorax).

- Harm may also be self-inflicted or as a result of violence and aggression.

- **Incident scope:** means the extent to which an incident affects patients or the organisation. This description should include the degree of patient harm, number of patients impacted by the incident, number of staff involved in the incident, complexity of the incident, locations and health services involved in the incident, and any equipment or systems external to the patient that are involved in the incident.
- **Key messages:** means the main points of information for the audience to receive. In the context of this guideline the audience is mostly likely to be the patient, staff, or the public. The information is usually simple to understand and easy to convey. These are best prepared and/or reviewed by the communications team.
- **Open disclosure:** means an apology or expression of regret (including the word 'sorry'), a factual explanation of what happened, an opportunity for the patient/family/carer to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence. Open disclosure is a discussion and an exchange of information that may take place over several meetings.
- **Open disclosure facilitators:** means those staff who have completed an education course about how to facilitate an open disclosure meeting.
- **Parent incident:** means incident to be entered in the SLS and titled 'cluster' and 'cluster' in the first name and surname fields for the overarching management of the cluster incident. Individual patient incidents can be linked to this parent incident.
- **Patient:** means a person receiving services from a SA Health service or a service funded by SA Health. For the purpose of this document, patients, consumers, clients and residents are equivalent terms.
- **Patient safety:** means a framework of organised activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce impact of harm when it does occur.
- **Root cause:** means the primary reason that an incident happened.
- **Serious harm:** means an outcome that involves a patient death, or where a patient requires life-saving surgical or medical intervention, has shortened life expectancy, experiences permanent or long-term physical harm, or permanent or long-term loss of function.
- **Significant incident:** means an incident that did not result in serious harm, but where significant safety implications are identified.
- **Simple cluster incident:** means a cluster incident where patients are impacted with minimal or no harm.
- **State-wide services:** means includes State-wide Clinical Support Services, Prison Health, SA Dental Service, BreastScreen SA and any other state-wide services that fall under the governance of the LHNs and DHW.

8. Document ownership

Guideline owner: Domain Custodian for the Clinical Governance, Safety, and Quality Policy Domain

Title: How to Conduct a Cluster Incident Review Guideline

Objective reference number: A5574335

Review date: 15/04/2029

Contact for enquiries: Health:DHWClinicalGovernance@sa.gov.au

9. Document history

Version	Date approved	Approved by	Amendment notes
1.0	15/04/2024	A/Chief Executive, DHW	Original Version

10. Appendices

1: The Cluster Incident Review Process

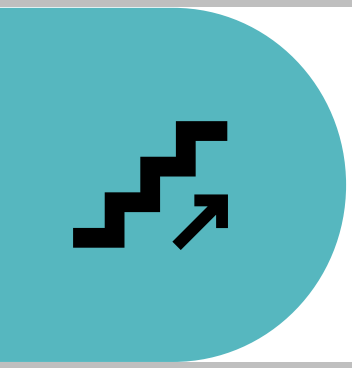
2: The Cluster Review Checklist

3: The Cluster Incident Response Plan Template

Appendix 1 The Complex Cluster Incident Review Process

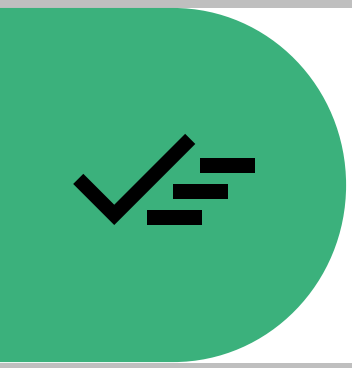
Step 1 Establish Leadership Team & Plan

- Cluster Response Team (CRT) formed within 1 business day of cluster identification.
- CRT meet either virtually or face to face.
- CRT establish the incident scope, contributing factors and risks based on initial information.
- CRT develop draft response plan to coordinate actions and address system issues and failures.
- Cluster Oversight Group formed where indicated and meets as soon as practical of cluster identification.



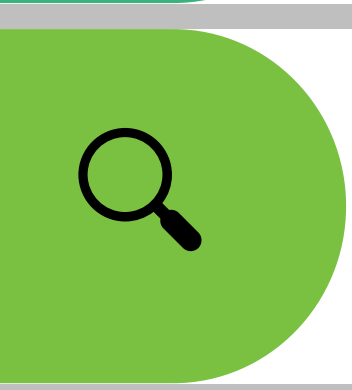
Step 2 Escalate and Implement

- CRT escalate incident to CEO and CE with a Clinical Incident Brief (CIB).
- Ongoing review of incident including issue/ system fix.
- Ongoing communication about review progress.
- Preparation of patient open disclosure documents (letters, FAQs).
- Development of other resources (hotlines, hot line flow charts, key messages, hotline webpages).



Step 3 Complete Implementation

- Distribute patient apology letters, activate webpages and hotline.
- Media release.
- Prepare close out CIB or report for CEO and CE with summary of incident facts, incident response/actions and open disclosure outcomes.
- Finalise review and document in the SLS.



Step 4 Evaluation

- Finalise SLS documentation and finally approve.
- Evaluate effectiveness of incident review coordination.

Appendix 2 The Complex Cluster Incident Review Checklist

SLS Cluster Title:

Cluster Incident Description: Date cluster identified: / /

Complex Cluster Review Checklist

STEPS	ACTION	OWNER	STATUS
STEP 1 ESTABLISH LEADERSHIP TEAM & PLAN	Immediate risks addressed by health service teams		
	Digital health incidents only – commence diagnostic to inform incident scope		
	Identify members for Cluster Review Team (CRT)		
	Send out initial huddle invites to CRT members within 1 business day of cluster identification date		
	Enter parent incident into SLS and request cluster title from DHW		
	CRT consider the incident facts and determine the scope of the incident		
	CRT identify risks and appropriate controls		
	CRT develop draft cluster incident response plan		
STEP 2 ESCALATE and IMPLEMENT	Digital health incidents only – commence technical fix		
	Escalate CIB and initial response plan to LHN or SAAS CEO and DHW CE		
	Response plan implementation commences		
	For incidents involves privacy breech refer to the *SA Health Privacy Policy Directive* and report to the Privacy Committee as required		
	Key messaging about incident developed		
	Draft media release prepared (if required)		
	Communication plan finalised		
	Communication with staff		

STEPS	ACTION	OWNER	STATUS
	Open disclosure resources developed		
	Regular updates from CRG to CAG informing stakeholders about response plan progress		
	Open disclosure with patients/families/carers		
	Communication with the general public (if required)		
STEP 3 COMPLETE IMPLEMENTATION	Response Plan implementation complete		
	Close out CIB or report to CEO and DHW CE		
STEP 4 EVALUATE	Finalise SLS documentation		
	Evaluate effectiveness of incident review coordination		

Appendix 3 The Complex Cluster Incident Response Plan Template

Date: XX/XX/20XX SLS Cluster Title:

Cluster Incident Description: *1-2 sentences*

Complex Response Plan Detail

Response	Plan	Owner
DETERMINE INCIDENT SCOPE	Sample text sample text	
IDENTIFY CLINICAL RISK		
ESCALATE		
COORDINATE		
COMMUNICATE		
OPEN DISCLOSURE		
EVALUATE		