Serious Adverse Event Management Guideline

1. Guiding Principles

This document provides guidance on how WA Country Health Service (WACHS) will respond to serious adverse events. It guides an immediate and ongoing respectful response that demonstrates an organisation committed to learn, improve safety and demonstrates our values of integrity and compassion.

The principles are applicable to all serious adverse events. Most of these will be clinical incidents, but similar principles should apply to non-clinical situations and to events with less severe outcomes.

2. Guideline

It is an unfortunate reality that adverse events occur in our health systems. The outcome of such events can have devastating impacts on patients and families as well as staff members, the organisation and the community.

While we need to ensure that we take every effort to prevent them occurring, we also need to ensure that when they do occur, we respond in a timely and effective manner within a strong culture of safety.

2.1 Threshold for activation of a serious adverse event

A serious adverse event in this context is one that is an extraordinary event that could have or did have serious consequences, including immediate or delayed emotional reactions, physical or psychological harm for patients, public, staff or the organisation.[1]

Occasionally, there will be no actual harm, but is deemed significant because there is either a potential for serious harm or reputational risk.

Many adverse events are clinical incidents and will in addition be managed via existing policies and procedures such as:

- WA Health Clinical Incident Management Policy 2019 – MP 0122/19
- WACHS Open Disclosure Procedure
- Australian Commission on Safety and Quality in Health Care (ACSQHC) Australian Open Disclosure Framework – Better communication, a better way to care.

A small number of the most serious events require a more comprehensive response.

The WACHS Chief Executive (CE) determines whether an event meets the threshold for this plan to be enacted.

When a serious adverse event is thought to have occurred, the relevant accountable Executive should be contacted immediately (Regional Director, Chief Operating Officer or relevant Executive Director) should be contacted immediately. They will then initiate the organisational response through the WACHS Chief Executive and WACHS Executive Director Clinical Excellence (for clinical matters) or WACHS Chief Operating Officer (for non-clinical matters).

2.2 Organisational response

Serious adverse events can occur 24 hours a day, 7 days a week in any location and the organisational response needs to reflect this. Respectful management demands time and attention over long periods of time.

The hallmarks of a strong organisational response are:

- **Immediacy.** Acknowledging that not all information is available, it is extremely important that the initial response is prompt with open communication with what is known at the time.
- **Transparency.** It is important to acknowledge to patient / family / staff member that the systems in place may have failed and to assure all involved that a thorough inquiry will be undertaken to determine cause.
- **Apology.** An expression of regret and sincere apology which is empathetic and respectful.
- **Accountability.** The organisation is responsible for system failures that allowed an event to occur and the outcomes, and for the steps taken to minimise the likelihood of a similar event happening again and this should be clear to the patient / family / staff member.
- **Learning.** WACHS should investigate all such events with integrity and rigor to ensure that key learnings are sound and can be used to make the organisation a safer one.

Elements of Organisational Response

- The CE will notify the Board, Minister for Health and others as relevant.
- The CE will ensure that relevant regulatory agencies are notified, and that careful and rapid preparations of internal and external communications are underway immediately.
- For serious adverse events of a clinical nature Table 1 outlines key elements of the WACHS response:
  - the WACHS Executive Director Clinical Excellence will be accountable for the management of the clinical incident investigation
  - the WACHS Chief Operating Officer will be accountable for forming and conducting a Reference Group that will brief the CE and that will have membership to ensure of oversight all matters outside of the clinical incident investigation:
    - patient, family support including open disclosure process
    - frontline staff involvement
    - media and communications
    - record keeping
    - other notification processes that may arise including professional practice issues, coronial liaison, medico-legal etc.
  - The WACHS Director Safety and Quality will ensure coordination and communication occurs with the relevant Safety and Quality Manager.
- For serious adverse events of a non-clinical nature, the CE will determine the appropriate response, utilising similar principles of initiating a CMT of appropriate senior staff to coordinate the response.

Table 1: WACHS response for serious adverse events of a clinical nature

Immediate response	First 24 Hours	Subsequent
1. Ensure safety of patient / family / staff		
○ Meet immediate safety / care needs ○ Ensure that emotional and psychological care needs are met		
2. CE to convene Crisis Management Team (CMT) – see Section 2.4		
3. Implement the Organisational Response		
Priority 1: **Patient / family** ○ Communicate what happened, why it happened, and what's being done to prevent it from happening again. ○ Commence Open Disclosure using WACHS Open Disclosure Procedure ○ Acknowledge pain and express regret – apologise ○ Consider if just in time coaching required for staff involved	**Priority 1**: **Patient / family** ○ Establish a plan for ongoing support and communication ○ Address immediate concerns ○ Consider needs if transferred to another service ○ Consider needs for CALD and Aboriginal people ○ Invite participation in investigation process ○ Consider reimbursement for out of pocket expenses	**Priority 1: Patient / family** ○ Proactively check in and support ○ Continue to provide information ○ Feedback results of investigation, recommendations and evaluation ○ Provide information on where to access legal advice ○ Schedule ongoing discussion if required up to the point of conclusion as agreed with family
Priority 2: Frontline staff involved ○ Determine who will speak to staff involved and provide support ○ Appoint primary contact / support	**Priority 2: Frontline staff involved** ○ Establish plan for ongoing support and communication ○ Engage them in investigation ○ Engage with patient's extended care team and GP ○ Provide clear message of support and just culture	**Priority 2: Frontline staff involved** ○ Provide support via EAP ○ Debrief and evaluate support ○ Feedback results of investigation, recommendations and evaluation

Immediate response	First 24 Hours	Subsequent
4. Implement the Organisational Response cont.		
Priority 3: **Organisation** ○ Consider notifications required ○ Determine who will do this and how	**Priority 3: Organisation** ○ CE to inform organisation of incident ○ Consider other notifications – Risk Cover, medico-legal	**Priority 3: Organisation** ○ Feedback results of investigation, recommendations and evaluation ○ Including feedback to medico-legal, coronial liaison etc as required
5. Managing Media / Comms		
○ Establish contact for comms team re content ○ Establish who will speak on behalf of the organisation	○ Develop a media plan ○ Consider proactively providing with updates ○ Suppress all normal communications to the patient / family that may inflict further pain (e.g. surveys, billing notices)	○ Clarify what the patient / family want said to others and invite them to provide input into communications.
6. Clinical incident investigation		
○ Determine lead of panel ○ Determine lead facilitator ○ Determine open disclosure lead	○ Confirm team and begin investigation ○ Involve patient / family and staff in investigation	○ Finalise report and recommendations ○ Table at AvERT and Board. Monitor via AvERT. ○ Share with other Health Service Providers

2.3 Long term follow-up

- After the initial response phase, the organisation will review the organisation's response and consider:
  - What worked?
  - What didn't work?
  - What was learned?
- Systems, policies, procedures and guidelines should be revised based on learnings.
- This applies to the process of serious adverse event management as well as the systems involved in the actual event itself.
- Sharing learnings with other organisations is encouraged.

2.4 Crisis Management Team

The Crisis Management Team (CMT) operates under the direction of the WACHS CE and continues for as long as required by the CE. Depending on the type of event, in addition to the CE, the membership may include any / all of below as appropriate for the type of incident:

Table 2: WACHS Crisis Management Team

Clinical Adverse Event	Occupational Safety and Health	Ethics / Integrity / Misconduct
Executive Director Clinical Excellence	Executive Director People, Capability and Culture	Executive Director People, Capability and Culture
Chief Operating Officer	Chief Operating Officer	Chief Operating Officer
Executive Director Nursing and Midwifery	Director Staff Health and Wellbeing	Executive Director Medical Services
Executive Director Medical Services	General Counsel	Executive Director Nursing and Midwifery
General Counsel	Manager Strategic Communication	Relevant Regional Director
Manager Strategic Communication	Relevant Regional Director	Relevant Operations Manager
Relevant Regional Director	Relevant Operations Manager	General Counsel
Relevant Regional Director of Medical Services	Relevant Human Resources Manager	Manager Investigations, Integrity Unit
Relevant Regional Director of Nursing and Midwifery	Director Aboriginal Health	Relevant Human Resources Manager
Relevant Operations Manager		Director Aboriginal Health
Executive Director Mental Health		
Director Aboriginal Health		

The Crisis Management Team is likely to be time limited. It has a key role in initial assessment of the event and issues, and to advise the CE and lead the organisation's initial response. Depending on the circumstances, it may continue for a duration as determined by the CE.

In a clinical incident where the WACHS Enhanced Clinical Incident Investigation process is being utilised, the Crisis Management Team is likely to be time limited and transition into the Reference Group.

3. Definitions

Serious Adverse Event	An extraordinary event that could have or did result in serious psychological and/or physical harm, or death, to a patient, staff member, the community or the organisation.[1]

4. Roles and Responsibilities

The roles and responsibilities are outlined in Section 2.2 Organisational response.

All Staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place to be.

5. Compliance

Guidelines are designed to provide staff with evidence-based recommendations to support appropriate actions in specific settings and circumstances. As such, WACHS guidelines should be followed in the first instance. In the clinical context, where a patient's management should vary from an endorsed WACHS guideline, this variation and the clinical opinion as to reasons for variation must be documented in accordance with the Documentation Clinical Practice Standard.

WACHS staff are reminded that compliance with all policies is mandatory.

6. Records Management

All WACHS corporate records must be stored in the approved Electronic Documents and Records Management System in accordance with the WACHS Records Management Policy.

All clinical records must be managed in accordance with Health Record Management Policy.

7. Evaluation

Monitoring of compliance with this document is facilitated by the Chief Operating Officer.

8. Standards

National Safety and Quality Health Service Standards

Clinical Governance Standard: 1.10, 1.11 and 1.12.

9. Legislation

State Records Act 2000 (WA)

10. References

1. Government of Western Australia. Department of Health: South Metropolitan Health Service. Management of Serious Adverse Events Guideline [HealthPoint]. Perth: SMHS: 2017. 6 [Accessed 19 September 2022] Available from:

https://healthpoint.hdwa.health.wa.gov.au/policies/_layouts/DocIdRedir.aspx?ID=TS4KSNFPVEZQ-210-21772

2. Australian Commission on Safety and Quality in Health Care. Australian Open Disclosure Framework – Better communication, a better way to care [Internet]. Sydney: ACSQHC: 2013. 72 [Accessed 19 September 2022] Available from: https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework#australian-open-disclosure-nbsp-framework

11. Related Forms

Nil

12. Related Policy Documents

WACHS Open Disclosure Procedure

13. Related WA Health System Mandatory Policies

Clinical Incident Management Policy 2019 – MP 0122/19
WA Health Clinical Incident Management Guideline 2019
WA Health Clinical Incident Management Toolkit 2019

14. Policy Framework

Clinical Governance, Safety and Quality

This document can be made available in alternative formats on request for a person with a disability

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