HAWKES BAY DISTRICT HEALTH BOARD	**Manual:**	Operational Policy Manual
	Doc No:	HBDHB/OPM/123
	Date Issued:	April 2019
	Date Reviewed:	
Event Management Guideline	**Approved:**	Executive Director – People & Quality
	Signature:	Kate Coley
	Page:	1 of 8

PURPOSE

This document provides step by step guidance for the use of Event Management Process for **Adverse Events** Flowchart *(see Appendix 1)*. This document must be read in conjunction with the Hawkes Bay DHB Event Management Policy (OPM002).

PROCEDURE

When an event occurs

1. Take immediate action to treat or protect the person directly involved with the event as well as protecting yourself, others and property from further harm.

2. Inform your manager immediately. If out of hours inform the Duty Manager.

3. If the event has serious consequences for the patient contact the lead senior medical officer (SMO) and inform them of the event.

4. Using the guidance in the Open Communication policy OPM/111 communicate with the consumer and/or family/whanau to explain what has occurred and what they can expect to happen next. This will may involve an apology for their experience and will involve asking the lead SMO to talk to the consumer and/or family within the first 24hours.

5. Notify the Health and Safety Advisor if the event meets the notification criteria for Worksafe NZ.

All staff

An event form is to be completed and submitted to the appropriate manager by:
- The employee who first becomes aware of the event; or
- The employee most involved in the event (this person must fill in the event submission form if they are the injured party, unless incapacitated); or
- The employee to whom an event is reported.

Are expected to report events, accidents and near misses in the electronic event management system known as RADAR as soon as possible (within 24 hours) and inform relevant people i.e. manager and/or duty manager or health and safety advisor.

Can complete an event form on behalf of patients, visitors, volunteers or other personnel working or providing services to HBDHB who do not have access to RADAR.

Documentation

The event form is to contain facts only. The information provided is to be objective and not subjective (Use - what, when, how, who and why).

Use the Severity Assessment Code to guide your selection of degree of *actual* harm (link provided within RADAR). **Note:** Harm is defined as the **ACTUAL** outcome for the patient or staff member.

Document the facts of the event, the event form ID number and actions taken in the Health Record. **Note:** A printed copy of the event form is not required to be placed into the paper Health Record.

STEP BY STEP GUIDANCE
(Aligns with the Event Management Process for Adverse Events Flowchart)

1. **Submission and Triage**

- Confirmation of SAC rating required **within 2 working days**.

- Clinical nurse/midwife manager/unit manager or delegate must review each newly submitted event form and advise and confirm this with the Directorate leadership team (DLT) **within 2 working days**.

- Using the Severity Assessment Code (SAC) criteria and (if required) advice from the Patient Safety Advisor (PSA) confirm the classification of the event in RADAR. This may include reclassification. If the event is to be reclassified make the changes to the field 'SAC score (actual)'. **Note:** The original version is saved within the event system and will not be lost.

- *For reclassification* of adverse events (AE) (SAC1 or 2) provide a rationale to the Directorate leadership team and the Patient safety advisor. Use the 'follow up' function in RADAR to document this including your rationale.

  ### *Reclassification to SAC 3 or 4:*
  - The area manager or delegate must complete the review within 30 working days.
  - Write the investigation directly into RADAR
  - The following process is not required.

2. **Confirmed Adverse Events (SAC1 or 2)** (*formally referred to as severe or major)*

  - The AE review and process is supported by the Patient Safety Advisor/s (PSA).

  - A lead reviewer and/or SWARM team will be appointed by the CMDO, CNMO and PDAH within 5 working days of confirmation of AE.

  - An Adverse Event Brief part A (AEB part A) to be completed and submitted to the HQSC with 15 days of notification of the event by the PSA.

  - A Terms of Reference is to be drafted and endorsed by CDMO, CNMO or PDAH and provided to the review SWARM team members.

  - Confirmation of 'Location' – the DLT responsible for the location identified will be responsible for undertaking the review and providing open communication.

  - Open communication should have been completed by the SMO at the time of the event. If this has not been done or additional information is required to be supplied then the DLT is responsible for this action.

- A phone call is usually the most appropriate method of communication and can be followed up with a written communication.

    Note: An apology and one point of contact for the consumer/whanau is to be provided.

3. Review

The Patient Safety Advisor will coordinate this process:

- Contact SWARM team
- Coordinate any meetings, this will include staff and the consumer and/or their representative.
- Provide a timeline of the event if SWARM team unable to do so.
- Provide advice and support regarding process and methodologies.
- Provide advice regarding content of review.
- Circulate draft versions of the review and provide editing.
- Once final draft review is complete send to the DLT for endorsement.

Lead Reviewer as part of SWARM Team:

- The PSA will contact this person ASAP
- Use a formal review methodology e.g. RCA or London protocol to complete the review.
- Follow the Terms of Reference
- Confirm final version with PSA within 60 days.

4. Directorate Leadership Team (DLT)

- Final draft provided to DLT by PSA/s
- Review final draft (preferably prior to submission to the Clinical Risk Event Advisory Group):

    a. Read the fact and analysis sections and consider the causes and contributory factors. Reviewers have been allocated due to their subject matter knowledge, however some service issues may have escaped their scrutiny.
    b. Review the recommendations. Make sure they are SMART (specific, measurable, achievable, realistic and timely).
    c. Consider approving several (1-3) SMART recommendations rather than many.

- If required - make changes to the review
- If changes are required discuss as a courtesy with the lead reviewer/s
- Approve the review and send a validated version to the PSA.
- Ensure open communication has been completed.

5. Clinical Risk Event Advisory Group (CREAG)

- DLT validated review submitted to CREAG by PSA/s.
- Review to be presented by representative of DLT and/or lead reviewer where possible.
- CREAG to consider approval of review by:
    a. Ensuring there is correlation between the analysis, the causes and contributory factors.

b. Ensure a robust methodology has been utilised including but not limited to RCA, London Protocol, The five Whys, Cause and Effect diagrams, Barrier analysis and Human factors.
c. Review must avoid blaming individuals and focuses on systems and processes.
d. Opportunity provided for all staff involved in event to provide information.
e. Ensure the recommendation/s address the causes only and are SMART.
f. If there are recommendations that need to be considered but do not relate directly to the cause/s of the event being reviewed they should be actioned in a separate pathway to the adverse event.

Approved Review

Review to be anonymised and executive summary (if required) to be drafted by PSA/s within 14 working days.

Non-approved Review

- Feedback to be provided to DLT representative and lead reviewer at CREAG.
- Support provided by PSA/s to amend review.
- Once amended and DLT have endorsed changes the review will be re-presented to the CREAG following the steps above (unless the CREAG Chair determines otherwise).

6. **Directorate Leadership Team – post endorsed review**

- DLT to contact consumer/whanau via a phone and provide update on review status and extend an offer to meet.
- If the consumer and/or whanau do not wish to meet deliver an anonymised copy of report, a cover letter which includes an executive summary to consumer and/or representative through consumer/whanau preferred method.
- Allocate recommendations to be actioned to appropriate staff to implement.
- Follow up and ensure recommendations are implemented to completion.
- Report progress of implementation to Patient safety administrator monthly.

7. **Patient Safety Advisor**

- For approved reviews complete AEB part B and send to HQSC within 15 days of approval.
- Update databases/RADAR.
- Support writing of open communication letters.
- Provide an anonymised copy of review and executive summary to DLT.
- Facilitate sending copies of the review to appropriate external bodies e.g. the Health and Disability Commissioner, Coronial Services Unit and ACC Treatment Injury Centre.

8. **Patient Safety Administrator**

- Email monthly reminders to DLT for updates of progress for recommendations.
- Update recommendations database monthly and as appropriate.
- Provide updated documentation to CREAG agenda for tabling by Patient Safety and Clinical Compliance Manger or delegate.

KEY ASPECTS OF EVENT REVIEW AND MANAGEMENT

Open Communication

- For adverse events the lead SMO or delegate must provide open communication with the consumer and/or their representative at the time of the event and within 24hours.
- The DLT that has overall responsibility for the event (determined initially by the 'Location' of the event on the submission form) must provide open communication with the consumer and/or their representative within 14 working days either verbally or written.
- Provide verbal communication if appropriate and also send a letter explaining what has happened, when it happened, what is being done and a contact name and number.
- If appropriate offer to meet with the consumer and/or representative.
- The DLT that has overall responsibility for the event (determined initially by the 'Location' of the event on the submission form) must provide open communication with the staff involved within 7 working days. This might include arranging for Critical Event Debrief.
- Following Terms of Reference the review team will engage with the consumer and/or their representative and offer to meet.
- A copy of the final review will be provided to the consumer and/or representative and staff involved in the event. The review will be anonymised and an accompanying summary will provide explanation of the review content in simple easy to understand language.
- An offer will be made to meet with the consumer, family and staff if appropriate to discuss the review and answer questions.
- National Adverse Event Annual Release report - Approximately 2 weeks before the expected release of this report contact will be made with all the consumers or their representative by the DLT in conjunction with the patient safety team, this maybe by telephone or by letter to advise them of the upcoming release of information.

How to Review an event?

For AE support will be provided by the Patient safety advisor/s following the process outlined above.

The review must focus on reviewing systems and processes and does not blame or punish individuals. The review seeks to determine the underlying system failure/s. Please refer to the Event Management Policy for more information.

In General

- Develop a timeline using information sourced from documentation, staff involved, and the patient and whanau.
- Once the timeline has been completed it will identify gaps in information. Attempt to resolve these gaps by expanding the source of information to seek the facts.
- Once you have established the facts begin your analysis (you will need to confirm with those involved if the facts are correct at this stage).
- It is not good practice to have a single reviewer.
- The review team should be made up of experts related to the specific event and an expert in a formal review process e.g. RCA or London Protocol etc e.g. a prescribing medication event should include a prescriber or a maternity event should include an obstetrician and a midwife. If your review team does not have the required subject matter expertise then seek it either from within the organisation or externally.
- Analyse the facts. The analysis is to include (but not limited to) best practice, policy, the situation at the time e.g. an emergency and does not blame the individuals.
- The analysis will determine any failings in the systems and processes.

- Determine the cause/s of the failure/s. A good tool to use is to ask why? Keep asking why until you can't ask it anymore. There is usually more than one cause and together they cause the harm (Swiss cheese model).
- Include a human factors approach.
- Against each cause develop a recommendation for change following the SMART criteria – Specific, Measureable, Achievable, Realistic and Timely.

REFERENCES

Health Quality and Safety Commission (HQSC). 2012. *Health and Disability Services' National Reportable Events Policy*. Wellington; Author

Frankel A, Haraden C, Federico F, Lenoci-Edwards J. *A framework for Safe, Reliable, and Effective Care.* White Paper. Cambridge, MA: Institute for Healthcare Improvement and Safe & Reliable Healthcare; 2017.

Reason J. *Managing the Risk of Organizational Accidents.* Aldershot, Hants, England: Ashgate 1997

Jing Li, Bernard Boulanger, Jeff Norton et al. *"SWARMing" to Improve Patient Care: A novel approach to Root Cause Analysis.* Vol 41, Number 11. The Joint Commission Journal on Quality and Patient Safety; 2015

Vincent C, Patient Safety. Second Edition. Wiley-Blackwell. BMJIBooks. 2010

DEFINITIONS

Adverse Event
An event with negative or unfavourable reactions or results that are unintended, unexpected or unplanned13 (also referred to as 'incident' or 'reportable event'). In practice this is most often understood as an event which results in harm or has the potential to result in harm to a consumer.

Consumer
For the purposes of this Policy a consumer can also be a client, patient or resident. It is the person who uses/receives health and disability services, or their representative.

Just Culture
Is one in which frontline personnel are comfortable disclosing errors, including their own, while maintaining professional accountability. It recognises individual practitioners should not be held accountable for system failings over which they have no control, yet does not tolerate conscious disregard of clear risks to patients or gross misconduct (Centre for Patient Safety, www.centerforpatientsafety.org/ patient-safety-glossary).

Near Miss
This is an event which, under different circumstances, could have caused harm to a consumer but did not, and which is indistinguishable from an adverse event in all but outcome.

Open Communication
Open communication, or open disclosure, refers to the timely and transparent approach to communicating with, engaging with and supporting consumers and their whānau when adverse events occur.

RADAR *(Report, Analyse, Determine, Act, Resolve)*
The electronic risk management system where events, complaints, complements and organisational risk is reported, managed and monitored.

Review
A review is another name for a formal process that is carried out by the health or disability service provider to analyse an adverse event or near miss and develop recommendations based on the findings. There are a variety of review methodologies.[17] Reviews can be undertaken at different levels, depending on the adverse event (e.g., comprehensive, concise, desk-review or single aggregated review of similar events).

Severity Assessment Code (SAC)
The SAC is a numerical rating which defines the severity of an adverse event and as a consequence the required level of reporting and review to be undertaken for the event.[18]

Whānau
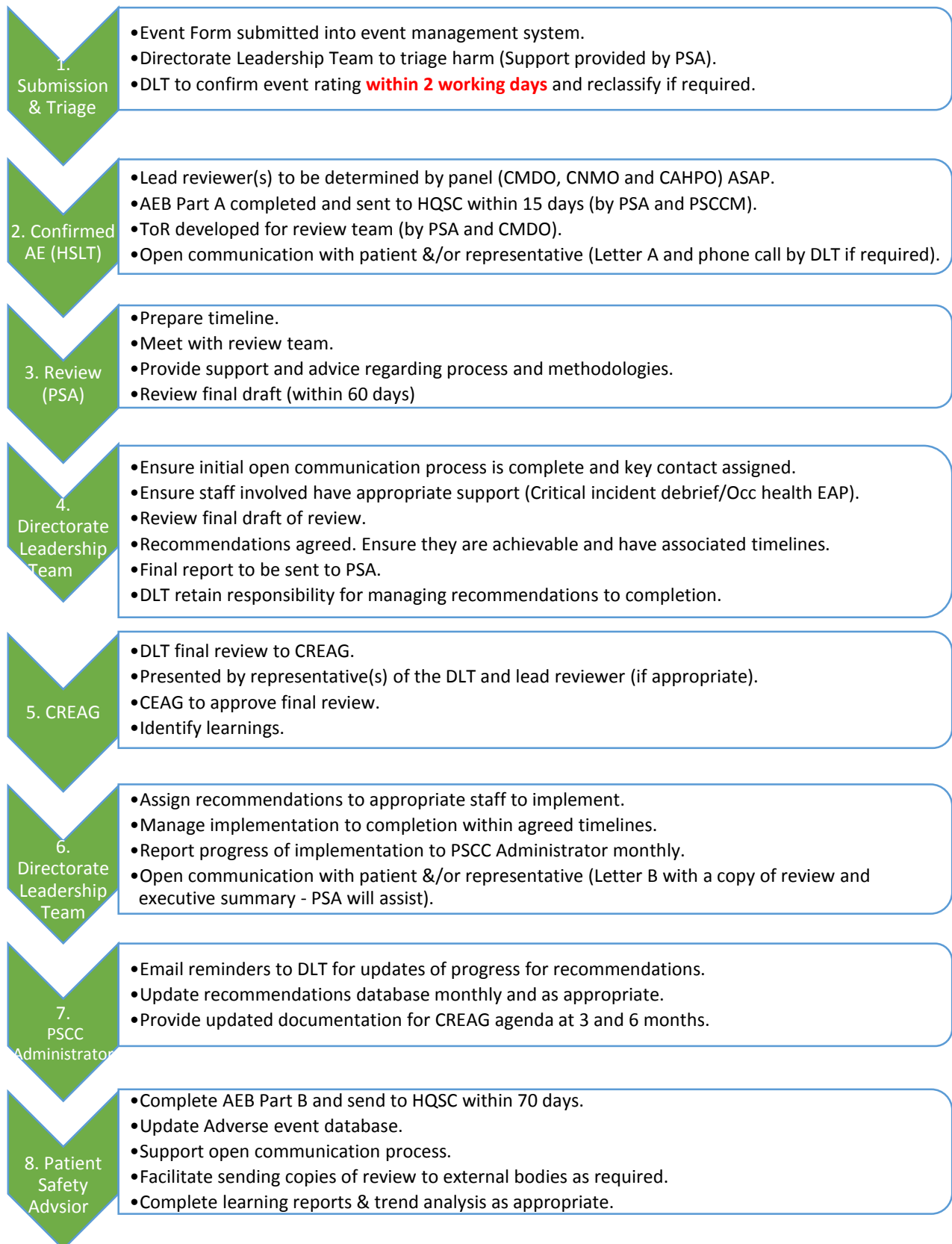The family or extended family/group of people who are important to the consumer.

KEY WORDS

Incident
Adverse
Event
SAC
WorkSafe
Classification
SWARM

For further information please contact the Patient Safety Advisor.

Appendix 1

Event Management Process for Adverse Events Flowchart

1. Submission & Triage
- Event Form submitted into event management system.
- Directorate Leadership Team to triage harm (Support provided by PSA).
- DLT to confirm event rating **within 2 working days** and reclassify if required.

2. Confirmed AE (HSLT)
- Lead reviewer(s) to be determined by panel (CMDO, CNMO and CAHPO) ASAP.
- AEB Part A completed and sent to HQSC within 15 days (by PSA and PSCCM).
- ToR developed for review team (by PSA and CMDO).
- Open communication with patient &/or representative (Letter A and phone call by DLT if required).

3. Review (PSA)
- Prepare timeline.
- Meet with review team.
- Provide support and advice regarding process and methodologies.
- Review final draft (within 60 days)

4. Directorate Leadership Team
- Ensure initial open communication process is complete and key contact assigned.
- Ensure staff involved have appropriate support (Critical incident debrief/Occ health EAP).
- Review final draft of review.
- Recommendations agreed. Ensure they are achievable and have associated timelines.
- Final report to be sent to PSA.
- DLT retain responsibility for managing recommendations to completion.

5. CREAG
- DLT final review to CREAG.
- Presented by representative(s) of the DLT and lead reviewer (if appropriate).
- CEAG to approve final review.
- Identify learnings.

6. Directorate Leadership Team
- Assign recommendations to appropriate staff to implement.
- Manage implementation to completion within agreed timelines.
- Report progress of implementation to PSCC Administrator monthly.
- Open communication with patient &/or representative (Letter B with a copy of review and executive summary - PSA will assist).

7. PSCC Administrator
- Email reminders to DLT for updates of progress for recommendations.
- Update recommendations database monthly and as appropriate.
- Provide updated documentation for CREAG agenda at 3 and 6 months.

8. Patient Safety Advsior
- Complete AEB Part B and send to HQSC within 70 days.
- Update Adverse event database.
- Support open communication process.
- Facilitate sending copies of review to external bodies as required.
- Complete learning reports & trend analysis as appropriate.

Key: AEB – Adverse Event Brief, **DLT** – Directorate Leadership Team, **PSA** – Patient Safety Advisor, **PSCCM** – Patient Safety & Clinical Compliance Manager
Relevant polices: Event Management OPM002, Open Communication OPM111, Employee Assistance Programme PPM028