Safer Care Victoria

2023

Adverse Patient Safety Event guideline

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Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

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ISBN/ISSN

Available at the Safer Care Victoria website <https://www.safercare.vic.gov.au>

Overview

Safer Care Victoria is committed to co-creating a consistently safe and continuously improving healthcare system. To achieve this, we need to learn when things go wrong and put into place effective systems and processes to minimise future harm.

The Adverse Patient Safety Event policy and guideline have been developed to support health services to learn and improve from these harm events and improve the quality and safety of the Victorian health care system.

Safer Care Victoria respectfully acknowledges the lived experience of patients, families, carers and supporters who have been harmed when using health services. Our appreciation also extends to the clinical and non-clinical workforces that support people with lived experience. We are sorry for the distress, grief and harm these events cause.

The role of an adverse event management system is to improve patient care by learning from adverse events and near misses. A critical element of effective adverse event management is the thorough review of healthcare systems and processes when consumers have been harmed because of care delivery. This work supports a safety culture; without comprehensive effective adverse event review processes, we cannot understand what went wrong and, therefore, implement improvements to our systems of care.

Clinical governance is the central element of a system that supports the delivery of safe and high-quality healthcare, with adverse event management being one element of creating a safe system. Good governance is vital to safety culture, it drives best practice and ensures the creation of safe environments for healthcare workers and consumers. A focus on review without a robust clinical governance system to support the improvement and feedback loop from frontline staff to the Board will not lead to meaningful sustainable change.

It is also important to consider the leadership, culture and improvement processes within an organisation that impact on effective engagement and participation in adverse event review and response.

While learning from what has gone wrong when providing healthcare, consideration also needs to be given to what systems and processes were effective in avoiding harm, so these practices can be applied elsewhere. It is important to expand the review of individual adverse events to a review of broader safety themes occurring across the system. This will ensure that improvement opportunities will be applied widely across the system rather than in isolation.

Safer Care Victoria's Adverse Patient Safety Events policy and guideline provide health services with a comprehensive guide to manage adverse patient safety events and create safe systems. The policy and this supporting guideline align with the Victorian Clinical Governance Framework and National Safety and Quality Health Service (NSQHS) standards.

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Safer Care Victoria thanks members of the Adverse Patient Safety Event policy advisory committee and the Department of Health for their significant contribution to the development of the policy and this supporting guideline.

Professor Mike Roberts
Chief Executive Officer
Safer Care Victoria

Contents

Guideline purpose

The purpose of this guideline is to support health services to align their policies, procedures and guidelines with Safer Care Victoria's Adverse Patient Safety Event (APSE) policy. It contains information for health services and consumers on how to implement the **8 elements** of the adverse event review process when undertaking **formal reviews.** While this guideline specifically focuses on formal reviews, it can also be applied to other reviews such as aggregated or local reviews.

The **8 elements** of the adverse event review process described in this guideline apply to all formal adverse event reviews. Health services can determine the most appropriate analysis method (e.g. Root Cause Analysis and Action, AcciMap, London Protocol or in-depth case reviews) to apply to the analysis component (element 5) of the review process.

This guideline will also link to other published Safer Care Victoria guidance materials for this purpose.

APSE management principles

The first requirement of leaders in APSE management is that staff and patients feel safe to raise concerns. This creates a strong reporting culture, which is reinforced when those reporting events receive feedback on the actions taken as a result of their reporting.

There are two underpinning requirements when a person has experienced harm when in the care of a health service. These are that the event is appropriately reviewed and communicated to the affected individuals and that actions are taken to reduce the risk of the same event happening to someone else. To meet these requirements, health services should apply the below guiding principles to their policies, procedures and guidelines.

Compassionate consumer engagement

Involving the **impacted consumer** in the adverse event review process means engaging with the affected patient and/or their family or carer. Consumer insights into the identification of adverse events and their potential contributing factors inform the development of strategies to improve safety. By involving impacted consumers in adverse event reviews, a fuller understanding of contributing factors is gained, which leads to more accurate and robust findings, and better system improvements. This results in meaningful outcomes for the consumer. Impacted consumer involvement can also be healing and restorative for the consumer(s) involved and their family or carer.

Safer Care Victoria has developed a 9-step engagement process expanding on these points:
Resources for involving impacted consumers

A **consumer representative** is a consumer independent of the adverse event who participates as a full and equal member of the review team member to represent the patient, family, and carer voice. They also ensure that consumer perspectives and safety are at the centre of the review process.

More information: Guides to consumer representatives on adverse event reviews

An open and transparent review process

Services are required to provide open disclosure, which includes an apology, to patients and their families and carers after an adverse event. Communicate transparently with staff involved in adverse events, and assure patients, families, staff and the community that adverse events are reviewed and acted on to reduce the risk of a similar event happening to someone else.

Communicating with staff involved in an adverse event may include:

- Encouraging them to speak up for safety and positively reinforcing their actions
- prioritising their psychological safety and ensuring staff have access to support services such as employee assistance programs
- ensuring staff are provided with appropriately trained support to debrief about their experience
- ensuring staff are positively supported with any identified training or learning needs
- explaining the review process to staff and reinforcing that the process is not about assigning blame
- providing a feedback loop; keep staff informed about review outcomes and recommendations – seeing positive change and progress from reviews is a significant motivator for reporting adverse events
- involving staff in recommendation development if an adverse event has occurred in their unit or area.
- Ensuring that staff have appropriate resources to implement recommendations
- Involving staff in monitoring progress of implementing recommendations

Open disclosure and statutory duty of candour resources

- Australian Commission on Safety and Quality in Health Care's Open Disclosure Framework
- Statutory Duty of Candour and protections for SAPSE reviews
- Duty of Candour e-learning modules

Leadership engagement

Senior organisational leaders must model their tangible commitment to safety via their actions and decision-making, and by addressing patient safety issues through transparent, consistent and effective processes. Senior leaders, including executive staff and board members, are key to genuinely building, maintaining and promoting the principles of a safety culture across their organisation. A safety culture includes an organisational commitment to the importance of safety beliefs, values and attitudes being shared by staff within an organisation.

More information: Leadership and safety culture fact sheet

A consistent approach

Robust clinical governance systems ensure a consistent approach to adverse event management and organisational and health system-wide learning. Examples of actions that help a consistent approach include:

- maintaining up-to-date internal policies and procedures on adverse event management and aligning these with Safer Care Victoria's APSE policy
- ensuring policies and procedures are accessible and available to staff
- communicating policies and procedures to staff to promote understanding of their purpose
- training executive, staff and consumer representatives on adverse event management.

More information: Safer Care Victoria Clinical Governance Framework

Learning and improvement

Balancing resources between review and improvement to create a patient safety learning culture, as well as an environment that continuously improves from implementing review recommendations. Services should also systematically learn from safe, high-quality care and apply these lessons across the system. Where similar adverse events occur repeatedly in a system, services should reflect on whether there are adequate processes to support implementation of recommendations.

Where there is a strong reporting culture, services may need to risk-rate recommendations and take action to prioritise implementation of recommendations where there is a high risk of recurrence.

Just Culture and systems thinking

A just culture:

- is open, transparent and encourages staff reporting safety issues
- has a strong restorative focus by rebuilding trust between senior leadership, staff and consumers after an adverse event
- balances organisational and staff responsibility for safe, high-quality patient care
- appropriately considers the impact of systems issues on individual performance
- has leaders who model accountability to improve future systems and processes, rather than blaming staff for adverse events
- learns from adverse events and has systems and processes to improve the system accordingly.

More information: Just Culture toolkit for health services

Just Culture is closely linked to systems thinking and human factors. Systems thinking describes the process of applying a systems lens when looking at why a certain event occurred. The key principle of a systems-thinking perspective is that events in complex systems are the result of several contributing factors interacting within the health system.

Human factors:

- refers to the environmental, organisational, human and job factors that influence human performance
- recognises that making mistakes (human error) is a normal part of being human and is, therefore, inevitable
- attempt to understand human capabilities and limitations to improve the design of a workplace and care environments, equipment and processes and, thereby, making systems more resilient to error.

More information: Adverse event review and response

Patient safety culture

Patient safety culture is the extent to which an organisation's culture supports and promotes patient safety. It refers to the values, beliefs, and norms that are shared by healthcare practitioners and other staff throughout the organisation that influence their actions and behaviours. Establishing and maintaining a strong patient safety culture is the most effective leadership action to reduce the risk of adverse patient safety events occurring.

Psychological safety

Psychological safety is the belief that you won't be punished or humiliated for speaking up with ideas, questions, concerns, or mistakes. At work, it's a shared expectation held by members of a team that teammates will not embarrass, reject, or punish them for sharing ideas, taking risks, or soliciting feedback.

Cultural safety

Cultural safety is a fundamental human right. The workplace environment, services and settings for health, wellbeing and safety must be culturally safe for all people. Everyone has a responsibility for the cultural safety of all people in their organisation.

More information: Aboriginal and Torres Strait Islander cultural safety and Australian Charter of Healthcare Rights.

APSE management process

The 6 steps in this process are designed as a best practice guide for health services to manage adverse events. The order of the steps may happen concurrently rather than sequentially. The completion of all steps is necessary to support adverse event review, response and system wide learning and improvement. The 6 steps outlined below should be implemented with consideration of the APSE management principles and health service responsibilities.

APSE management process

1. Identify and immediate action
2. Adverse event reporting
3. Open disclosure and statutory duty of candour
4. External notification
5. Review and improvement (8 elements)
6. System-wide sharing and learning

1. Identification and immediate action

All staff are responsible for identifying adverse events, with most adverse events being identified at the time of occurrence.

Identification can also occur after the adverse event from various sources including:

- team discussions
- audits
- morbidity and mortality meetings
- safety committees
- coroner's findings
- consumer feedback.

After an adverse event has been identified, appropriate staff must act immediately to ensure everyone involved is safe and all necessary steps are taken to support and treat the people involved. Risks to safety are to be addressed immediately. This includes the physical and psychological safety of patients and staff. This occurs independently of commencement of the review. This remains an important consideration, even if there has been a prolonged period between the adverse event and the service becoming aware of it.

2. Adverse event reporting

Systems and processes for reporting need to be clearly documented in health service policies, procedures and guidelines. Health service staff must follow their local policies, procedures and guidelines to report the adverse event within the health service.

Health services and services under their governance structure are required to meet the Victorian Health Incident Management System Minimum Dataset reporting requirements.

Classification

An incident rating[1] classifies the severity of the adverse event. Once the classification is verified (see further information below), the incident rating is used to inform the type of review and external notification requirements. Health service policies, procedures and guidelines must document systems and processes for commissioning reviews and confirming the review type. See Set up and plan the review process for more information, including recommended and required review types.

Health services who submit the Victorian Health Incident Management System Minimum Dataset to the department use Incident Severity Rating (ISR) to classify adverse events. Health services who do not use ISR to classify adverse events must have an equivalent classification system and refer to local health service policy to classify SAPSEs, including the 11 reportable sentinel event categories in Victoria.

Incident Severity Rating (ISR)

ISR is the 4-tiered severity rating system for adverse events.

The ISR is derived from the response to 3 questions related to:

- level of harm (previously, ‘degree of impact’)
- required level of care (previously, ‘level of care’)
- level of treatment required (previously, ‘treatment required’).

ISR classification levels according to severity:

- ISR 1 – severe/death
- ISR 2 – moderate
- ISR 3 – mild
- ISR 4 – no harm / near miss

Verification

Verification of the adverse event report and classification is to be undertaken. This includes a review of the patient record and discussions with appropriate clinical staff, patient and family to confirm the details in the adverse event report. Note: Patient consent must be obtained prior to speaking with family or carers.

[1] While the APSE policy uses the term ‘adverse patient safety event’, ‘incident’ is continued to be used in the context of incident management systems and incident ratings, as this is a commonly used term in this context.

Health services must have in place a process to ensure incident severity ratings align with the level of harm that has occurred as a result of an adverse event. A process is required for **increasing** and **decreasing** an incident severity rating to ensure it is correct. The health service must provide a rationale for any reclassification and include it in the incident management system.

3. Open disclosure and statutory duty of candour

Open disclosure is to occur as per the Australian Open Disclosure Framework for all adverse events causing harm and near misses. Health services, excluding bush nursing centres, must complete the statutory duty of candour process with patients, their families or carers when they suffer a serious adverse patient safety event (SAPSE).[2]

4. External notification

Relevant external agencies are to be notified as required, depending on the nature of the adverse event. In addition to Safer Care Victoria's sentinel event program requirements, this may include but is not limited to the Coroner, Victorian Managed Insurance Authority, Office of Chief Psychiatrist, Aged Care Quality and Safety Commission, WorkSafe, Therapeutic Goods Administration.

On occasion, separate to the review process, Australian Health Practitioner Registration Agency and the Victorian Police may need to be contacted if notifiable activity is alleged.

5. Review and improvement

The review and improvement process focuses on understanding what happened, why it happened, and what system improvements can be made to prevent recurrence of similar adverse events or to minimise the harm if they do reoccur. Where similar adverse events occur repeatedly in a system, services should reflect on previous reviews and resulting recommendations, including considering the effectiveness of these as part of the review. In addition, services should reflect on how they can improve processes to strengthen recommendations.

A **formal review** is a structured systems-focused process following a predetermined methodology which includes a written report. The formal review process obtains input from relevant subject matter experts, with consumer representatives, a mandatory requirement for sentinel event reviews. All SAPSEs require a formal review; further detail regarding SAPSE review, notification and protection can be found in the Safer Care Victoria Adverse Patient Safety Event policy.

The 8 elements of the adverse event review process apply to all formal reviews regardless of the severity, review type and chosen review method. Depending on the severity of the adverse event, completion of all 8 elements may not be applicable (e.g. a low severity or near miss adverse event).

Adverse event review process

The 8 elements of the review and improvement process are:

A. Set up and plan the review process
B. Form review team
C. Gather the evidence
D. Develop timeline
E. Data analysis
F. Develop finding statements
G. Develop recommendations and action plan
H. Monitor recommendations

A. Set up and plan the review process

Commission the review

Health services should have a robust process to confirm governance arrangements. This includes:

- confirming the review method
- determining and allocating appropriate resources
- appointing an Executive Sponsor
- identifying how to include and inform the impacted consumer and staff involved in the adverse event.

Refer to Flowchart 1 to identify the appropriate review type, based on the severity of the adverse event.

More detailed information on the review methods is provided in the Analyse data section.

Review project planning – determining and allocating appropriate resources

Planning the review should follow well-executed project planning methodology and include key milestones and deliverables. Adequate time should be considered for the different stages of the review process. This plan should be endorsed by the Executive Sponsor.

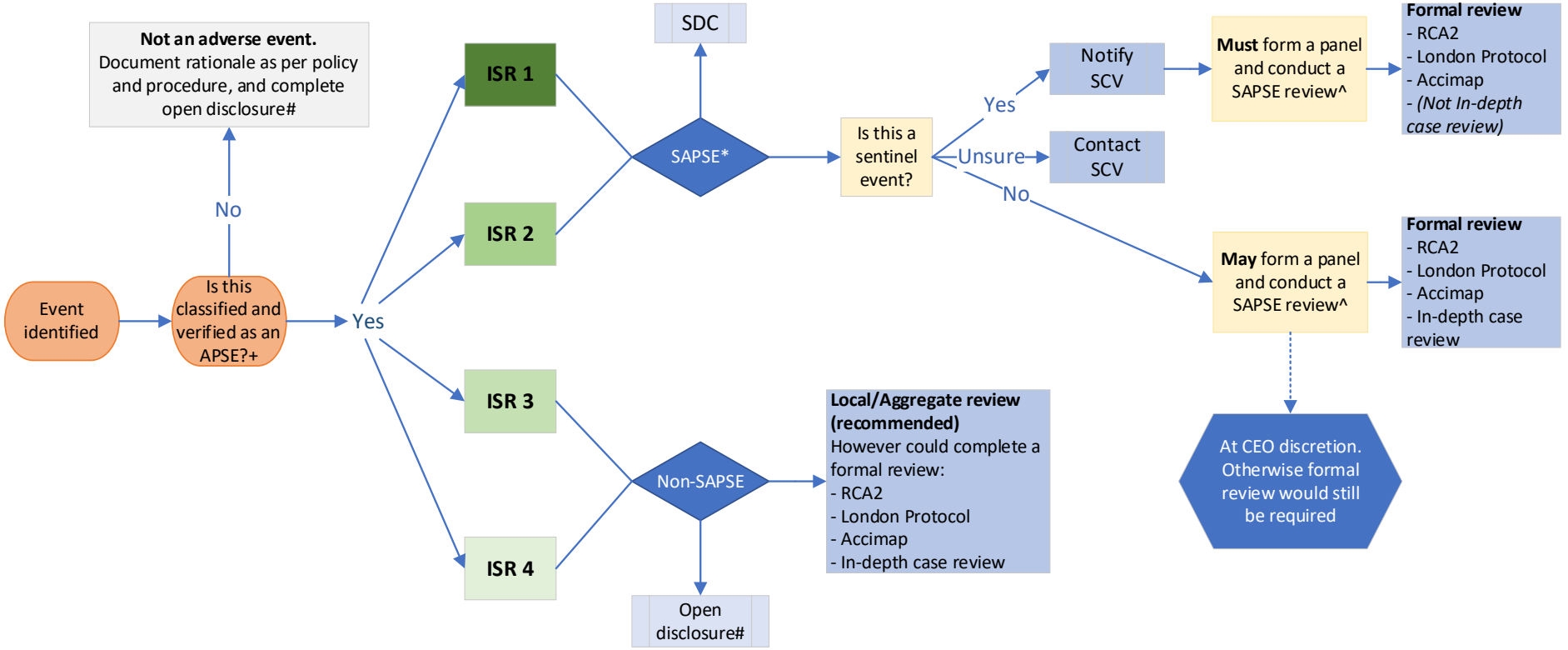
Table 1. Considerations for planning

Considerations for planning include:

Item	Review stage*
Administration of the review process. To meet tight timelines good administration processes is key. Having a clear role allocated to engaging review team members (including the external expert), coordinating diaries and scheduling in meeting times can be the difference between meeting deadlines or not. This may mean support from executive and senior hospital managers to ensure the review is prioritised.	1–7 days following confirmation of review type
Setting team expectations, time requirements and responsibility, so each member understands what is required of them for the duration of the review.	Before the first meeting
Event description – ensure team members understand the background to the adverse event review and why it is being reviewed at the determined review level. Send team members relevant information about being involved in a review; see Briefing review team members.	Before the first meeting
Determine how the review lead will prepare, distribute and protect the confidentiality of documentation. This includes having agreed responsibilities and pathway for document tracking and management for hard copy and electronic documents	Before the first meeting
Analysis and discussion of contributing factors	During a team meeting
Forming recommendations	During a team meeting
Report writing and preparation of documentation	Outside of review team meetings

*Planning and resources required may vary depending on the type of review and method chosen

Flowchart 1. Recommended and required review types



+ See definitions.
*Meets the SAPSE definition within the *Health Services (Quality and Safety) Regulations 2020*.
^Requirements within Division 8 of Part 5A of the *Health Services Act 1988*, as well as the regulations must be complied with for all **relevant protections to apply**.
As per the Australian Open Disclosure Framework: The Australian Open Disclosure Framework | Australian Commission on Safety and Quality in Health Care.

Involving the impacted consumer in formal reviews

Important elements of involving the impacted consumer include:

- informing them that an adverse event has occurred, in line with open disclosure and statutory duty of candour (outlined at Step 3 – Open disclosure and Statutory duty of candour)
- assigning a liaison to the consumer for the duration of the review process to be their key health service contact person
- explaining the review process to the consumer
- a plan for ongoing engagement based on the consumer's desired level of involvement (noting this may change over time)
- listening to the consumer's perspective of the event and the questions they hope the review will answer, and incorporating these into the review
- giving the consumer an opportunity to receive a copy of the final report, and to have its content explained to them, in line with open disclosure and statutory duty of candour requirements
- following up with the consumer on review outcomes and recommendation progress, as agreed with the consumer.

Resources

Resources for **engaging with consumers impacted by harm** (Resources for involving impacted consumers) include:

- a 9-step guide for health services in consumer involvement following a serious adverse patient safety event
- a consumer factsheet
- the Next Steps Pamphlet: a resource for consumer representatives
- Rachel's Story, a video example of close engagement between a health service and an impacted consumer.

Executive Sponsor

An Executive Sponsor should be appointed and briefed throughout the review process. The health service should have local governance arrangements for commissioning and appointing this role.

The Executive Sponsor is a senior executive who:

- holds financial, resource or program accountability
- holds accountability for an adverse event review
- deals with high-level barriers, and works closely with the team leader
- liaises with the executive team on review progress
- is usually not a member of the review team.

The role of the Executive Sponsor is important in undertaking, progressing and finalising recommendations. Executive sponsorship sends a strong message of support throughout an organisation.

B. Form the review team

Team-based reviews should be undertaken for all formal reviews. Most formal review teams should have no fewer than 4 members to ensure relevant expertise and experience is represented and to balance bias and perspectives. The expertise and experience of review team members should reflect that of staff who were directly involved in the adverse event.

In-depth case reviews[3] may have fewer people but should have oversight by a senior manager.

Consider limiting review team member numbers to ensure equitable, effective contribution to the review process and during review meetings – e.g. a maximum of 6 people – but this may vary depending on the event and number of services involved.

Key considerations when forming review teams

- They must represent the skills, knowledge and experience of staff involved in the event, or provide additional relevant subject matter expertise.
  - If you find this is resulting in a large review team, consider who can provide their experience and insight via well-constructed interviews instead.
- They must be independent of the event itself (i.e. must not include staff and consumers directly involved in or impacted by the adverse event).
- There should be diverse roles and experience on the review team relevant to the clinical context of the adverse event, including a consumer representative and external member.
- Each review team member should understand their role and responsibility as well as expectations and required timeframes for the end-to-end review (see Table 2). It is important not to assume that people understand the process or the detail around the adverse event. Setting clear expectations for the review team will avoid unnecessary confusion and delays.

Table 2. Overview of key review team members and their contribution

Review team members	Contribution/role
Review chair	• chairs team meetings and facilitate discussion • manages ground rules and behaviour; terminates blame discussions • ensuring involvement of the impacted patient/family • expertise in adverse event review process and method
Review team lead/ facilitator (typically a quality and safety staff member)	• expertise in review methodology and process • provide clear guidance and expectations • leads review process administration • ensures objectives of agenda are met • summarises meeting outcomes and next steps at end of meeting • responsible for the secure management (including distribution and storage) of review documentation
Review team members: representation from staff not involved in the adverse event	• relevant subject matter expertise in the clinical or non-clinical area where the adverse event occurred

[3] An in-depth case review is a structured systems-focused process, which may use AcciMap, RCA2, London protocol or similar methodology but is less resource-intensive than a sentinel event review**.** It can be undertaken by a team of two, but it should have oversight by a senior manager. An in-depth case review examines adverse events to identify process and system issues.

Review team members	Contribution/role
	• should represent the equivalent experience/seniority of staff involved in the adverse event to gain an accurate perspective of the event being reviewed
External independent subject matter expert*	• objective perspective outside the health service where the adverse event occurred • bring specific subject matter expertise relevant to the adverse event • for a SAPSE review/sentinel event, this person cannot be in current or recent employment of the service – including other sites of a multisite service (for example having worked in the service in the last two years)
Consumer representative^	• Are independent of the adverse event • can advocate for the patient to remain central to the review process • can challenge assumptions and identify gaps that may not be visible to staff • Their involvement can help address community expectations around public oversight and accountability

* For assistance in sourcing an external expert, or to register as an external expert, please visit Safer Care Victoria's **PEER Platform**.

^Consider allocating consumer representative team members a review team 'buddy' to support them during the review process with logistical requirements and to check in with them post-meeting to provide support and answer any questions. Consumer representatives should also be offered remuneration for their participation in the review process.

Note: Some health services may choose to combine the responsibilities of the review chair and team leader and allocate to one person.

Consider the biases and power imbalances within the review team and how these will be managed throughout the review process by the chair, lead or facilitator (see Cognitive bias factsheet for more information).

Involving consumers – resources

For resources about **consumer representatives on review teams**:

- A guide for health services, involving consumer representatives in reviews: Involve consumers in incident reviews
- A guide to consumer remuneration: Remuneration for Partners policy
- A guide for consumer representatives, undertaking adverse event reviews: Help review a serious incident

Briefing review team members

Review team members should be well informed of the review details ahead of the first meeting. Some team members may be unfamiliar with elements of the review process, so providing information prior to the review start date can help build a shared understanding.

Consider providing the following information:

- detail about the adverse event such as the incident report and de-identified copies of the medical record, provided in chronological order
  - More information about review documentation: Incident review documentation
- the rationale for undertaking a formal review
- a high-level overview of the review process
- their roles and responsibilities as a review team member (e.g. reviewing information, participating in team discussions, meeting attendance)
- information about the role of the consumer representative
- required timeframes for the review process
- contact details for the review chair and lead/facilitator

Consider providing the following fact sheets to review team members as part of their briefing:

- Just Culture Guide for health services
- Cognitive bias
- Leadership and Safety Culture
- Interviewing for adverse event reviews

Review team meetings

Organise meetings

Schedule team meetings with as much notice as possible and book meetings in advance. Usually, 3 to 5 review team meetings are held, depending on the complexity of the adverse event. Use calendar invitations to schedule the meeting time, length, and location (in person, online or hybrid).

Plan each meeting to ensure there is time to achieve the meeting's purpose. Time and responsibility must be allocated to complete each element out of session. For example, the first meeting may involve drafting the timeline, which may require further refinement after the meeting to include additional information. The timeline will be finalised by the team before analysis can occur.

In preparation, ensure roles and responsibilities of the chair and others involved are clear (e.g. note-taking). Refer to Table 2 for more information about roles and responsibilities.

Consider the following:

- access to a whiteboard, butcher's paper, pens and post-it notes for in-person meetings
- privacy, comfort and confidentiality when booking a venue
- that review team members know where to find the meeting venue (consider providing extra information for external team members and consumer representatives who may not be familiar with the venue)
- secure documentation management before, during and after each meeting.

For online meetings, consider:

- accessibility and usability of online meeting platforms (e.g. internet access and knowledge of applications such as MS Teams, Zoom)
- ensuring meeting attendees have access to the correct meeting links
- how to correctly identify meeting attendees (e.g. if joining via an unknown number)
- reminding participants about online meeting etiquette (e.g. 'raise hand' function)
- ensuring all participants are engaged and have a say in the discussions
- organising IT assistance if required.

Review team – ways of working

The team should agree to ways of working, which should be reiterated at the start of each meeting. The chair should refer to the ways of working to keep discussions on track and to maintain respectful behaviour.

Suggested ways of working include:

- discussing systems and processes, not people
- maintaining confidentiality
- welcoming questions – a necessary part of the review
- acknowledging there are no right or wrong answers
- noting all opinions and members of the review team are equal – everyone's ideas are valuable
- that everyone will listen to each other – no side conversations
- encouraging members to speak up if they do not understand something.

Each health service may have their own ways of working which can be adapted by review teams as appropriate.

Maintaining confidentiality

Staff and patient confidentiality is critical, and the following points should be considered to maintain this:

- Written agreements are required for external staff and consumer representatives if they are not employed by the health service conducting the review.
- If confidentiality agreements are required, organise documents before the interviews and make sure they are written in plain language, so everyone understands the content.
- Provide verbal reminders for internal staff of confidentiality agreements in line with contract of employment. Processes should be in place before review and reconfirmed at the first meeting.
- Apply watermark documentation 'confidential draft' to all working documents and draft reports.
- When documenting information about the review, be factual and evidence-based. Adverse event review documentation may be discoverable.

More information: Adverse event review and response fact sheet.

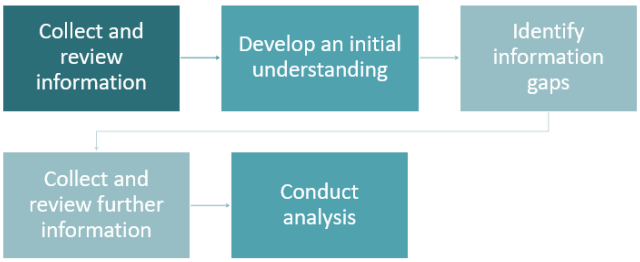
C. Gather the evidence

Before the first review team meeting, information should be collected to form an initial understanding of the adverse event. Thorough information collection will enable an efficient review process. As the team progresses through the review process, further information will be sourced to gather a full understanding of the event. The aim of information collection is to:

- ensure all review team members have a clear and factual understanding of what occurred leading up to and immediately after the event to:
  - develop an initial understanding of why the event occurred
  - support the review findings with sufficient evidence
  - develop robust recommendations to address the contributing factors identified.

The process in Figure 1 outlines the steps involved in gathering information.

Figure 1: Gathering evidence during the adverse event review process



Information sources

There are many information sources that should be considered to obtain an understanding of what happened and why. See Table 3 for example information sources (note these are examples only and the list is not exhaustive). It is important that information sought is systems-focused to obtain a comprehensive understanding of what happened.

Table 3. Example information sources to inform the adverse event review

Systems layer	Example information sources
Social and cultural factors	• Data on demographic and socioeconomic background of patients
Government, regulators and external influences	• State-wide policies, procedures and guidelines • Guidelines and training curriculums from colleges and universities • Relevant accreditation standards • National guidelines and frameworks (e.g. clinical care standards) • For equipment issues consider equipment recall notices (e.g. from Therapeutic Goods Administration)
Organisation and Management	• Internal health service policies and procedures • Safety Culture surveys (e.g. People Matter Surveys) • Established credentialing and competency processes • MET call systems and processes • Equipment maintenance records • Training records • Consumer feedback (e.g. complaints, Victorian Health Experience Survey) • Incident and consumer feedback data • Audit results
Work environment	• Interviews with staff to assess availability/accessibility of equipment • Layout of clinical area/ patient room/ transport vehicle (e.g. photos, videos or floor plan) • Decision-making aids/checklists • Rosters
Task and technology	• Photos of technology used to identify potential design inefficiencies • Workflow to achieve (complex) tasks • CCTV or swipe-card access records
Team	• Interviews with staff to assess team communication, coherence etc.
Staff	• Interviews with staff to understand what happened and made sense to them at the time • Training records
Consumer	• Interviews with consumers to understand what happened • Medical records (think broadly, GP referrals, imaging results, pathology results, observation chart trends)

Interviews are a key source of information

Interviews should be conducted with everyone involved in the adverse event. This includes staff and the impacted consumer, as well as family or carers (upon obtaining consent from the patient where possible). Speaking to all people directly involved in the event gathers evidence of first-hand experience and perspectives. The list of interviewees may increase as more information becomes available during the evidence-gathering process. Consider interviewing staff from the area where the adverse event occurred, even if they were not directly involved, to gain a more realistic perspective of how work is done in that area.

Key considerations for conducting interviews

Interviewing is a practised skill that requires active listening, with limited interruptions. Interviews should be planned with roles and responsibilities clear to interviewers. Some tips for conducting interviews include:

- keep to agreed timeframes
- explain the purpose of the interview to the interviewee
- one person should be interviewed at a time
- be mindful of the impact on interviewees and reassure them that interviewing is not a blame-focused exercise
- try to make the interviewee feel comfortable and at ease
- ask open-ended questions rather than making assumptions about what happened or should have happened (see Table 4)
- note down questions you may have while the interviewee is recalling events; this will allow you to ask them at the end and prevent you from interrupting their flow. It can be helpful to let them know you are doing this
- apply Just Culture principles such as systems thinking and mitigation of your own and review team members' biases to support a fair and objective interview process
- have a scribe at the interview to allow the interviewer to actively engage with the interviewee without the distraction of note-taking
- all interviewees (staff and consumers) can bring support person/s to an interview.

For more detailed guidance on interviewing impacted consumers: Resources for involving impacted consumers

Recording interviews

- verbal agreement is required for written notes to be taken
- written or taped consent is required if you record interviews. Recordings must be securely stored, as for any review documentation
- interviewees have the right to confirm that notes accurately reflect what was said. Refer to health service policies and procedures for local guidance

Table 4. Interview question types

Question	Description	Examples	Frequency of use
Unstructured free recall	Allow interviewee to go back to the day in their memory and talk through it in their own way and at their own pace	'Tell me everything you can remember about…' 'Tell me the sequence of events as you remember them…' 'Talk me through what happened on the day of the event. It can be helpful to start at the beginning of your shift…'	Use, predominantly, green unstructured and open questions. Listen openly to information you expect to hear and information that seems wrong or surprising to you to avoid confirmation bias.
Open questions	Allow for an unlimited response in the interviewees' own words; encourage lengthy responses	'Please describe your workload at the time.' 'What can you tell me about what staff said to you?' 'What else was happening at the time?'	
Closed questions	Limits the amount or scope of information the interviewee can provide	'How many people were in the room at the time?'	Use closed questions sparingly. Use them only to fill in gaps or confirm important details.
Leading questions	Suggesting an answer	'Was the patient still bleeding when he arrived?'	Avoid red leading questions to ensure the quality of information is not impacted by interviewer biases.

More information: Interviewing for adverse event reviews

Sourcing information from site visits

Walking through the area on site, with the review team, helps to see the design and layout of where the adverse event took place. This process can be undertaken as part of information-gathering:

- Visit the location
- Consider taking photographs or videos or walking through the process under review

Report-writing

Report-writing can commence at the evidence-gathering stage, for the event background or description. Ensure this is revisited as more information is collected, to maintain accuracy.

Event description

Describe the adverse event with sufficient detail. The description should:

- tell the story and set the scene with factual, evidence-based information only (no opinions)
- not provide a clinical summary of the patient journey, but should include relevant past medical and social history
- use de-identified information (e.g. de-identify the patient and staff)
- include the patient outcome
- spell out phrases the first time they are used, acronyms thereafter if commonly understood (e.g. deep vein thrombosis, thereafter DVT)
- identify processes and flows of the event
- be detailed but succinct.

The adverse event description will be drafted and refined over the duration of the review as more information becomes available and details are refined.

Documentation management

It is important to establish good document management processes at the beginning of review. This should be in accordance with your health service's local policies, procedures, guidelines and legal requirements including all information collected during the review (written, electronic recorded and digital media). Seek advice from your health service's legal counsel (on a case-by-case basis):

- Each health service is responsible for its own legislative compliance.
- All documentation and records created are discoverable and may be subject to Freedom of Information (FOI) and Request of information (ROI) applications (unless they are a SAPSE review, see Statutory duty of candour and protections for SAPSE reviews)
- Documents created should be factual and evidenced-based.

More information: Adverse Patient Safety Event Review documentation management 2022 guide

D. Develop timeline

A timeline is a visual, chronological representation of the sequence of events before, during and after the adverse event, and:

- are succinct and factual
- are not a clinical history and only include key contextual information
- provide a clear understanding of the events leading up to the adverse event.

Timelines should be developed for all formal reviews. See Appendix 1 for a timeline example.

Key considerations when developing a timeline

- Timelines should be developed in a team meeting. However, they can also be developed before the first meeting to ensure effective use of the meeting time.
- A draft can be circulated in advance of the meeting, with enough time for the review team members to consider what questions they may have. If a prepared draft is presented in a team meeting, ensure there is time and space provided for the team to review, query and edit the timeline as required.
- Timelines will likely be developed iteratively as more information is gathered but should be finalised before analysis commences.
- Use post-it notes and butchers' paper to create a timeline if meeting in person. For online meetings, MS Office has useful tools such as Visio for timeline development.
- The timeline does not need to be created sequentially in the first instance; rather, the group can start identifying events and then can be ordered appropriately. Post-it notes or e-tools allow you to move events around the draft timeline easily. Another useful planning tool is a Word document table with each row being an event. Once the sequence is confirmed, the table content can be copied into a timeline.
- Do not add arrows until the team has finalised the timeline, to prevent rework in reformatting the draft timeline.
- Begin by identifying the start and end points (anchor points). These points will vary depending on the event under review.
- The timeline should capture key points from the event summary and supporting evidence, with each event placed in one individual process box. The timeline is not a clinical history.
- Acronyms can be used in a timeline if a legend explaining the acronyms is provided.
- Each process box must contain the 'who, what, when and where' for an individual event in the sequence.
- Do not ask 'why' at this point as this is undertaken in element 5 – analysis. Commencing analysis at this time will distract from developing the end-to-end sequence and may lead the team to drill down on certain points too early.
- Each process box must have a timestamp, e.g. 'Day 1 and time', or date and time. Important contextual information can be provided via a 'context bubble' (a circle shape) to add clarity to an event in the patient's journey.
- Use a verb when writing the event statement to ensure the sentence makes sense.
- De-identify information, e.g. 'Nurse A', 'Junior Doctor'.
- It's best to include more information initially and refine this over time to prevent missing important detail – the timeline should be succinct and as complete as possible.
- It is important not to assume steps have been taken because they 'should be' taken – only include what actually happened.
- Avoid blame language such as 'failed to', 'despite', 'lacked', and present information factually:
- e.g. 'Nurse A failed to recognise the patient was in MET criteria' should be written as 'At 0900. the patient's observations were in MET criteria. A MET was not called.' This doesn't assign the blame to an individual and presents the information factually and as it occurred.
- Clustering timeframes may capture a longer period of time within one box. Prior to clustering a group of events, ensure each event is considered to confirm that a single event has not been missed.

E. Analyse data

Data analysis occurs once the timeline has been finalised. Different review methods can be applied at this stage.

All SAPSEs require a formal review; some examples of formal review methods are:

- Root Cause Analysis and Action (RCA2)
- London Protocol
- AcciMap
- In-depth case review (IDCR) – although IDCR is listed as a formal review, it is not an accepted review method for sentinel events.

In addition, there are **2 more specific approved review tools** that have been developed for **falls**[4] and **COVID-19**-related events[5].

Adverse event review approach

It is important to follow a structured review method to ensure adverse events are reviewed in a consistent, objective way with an approach that is validated or proven to be effective to identify contributing systems factors. The outcomes of applying a review methodology are then used by the review team to develop finding statements and recommendations.

This approach also ensures that adverse event reviews are approached with a Just Culture rather than trying to find 'who was at fault'.

All review methods are:

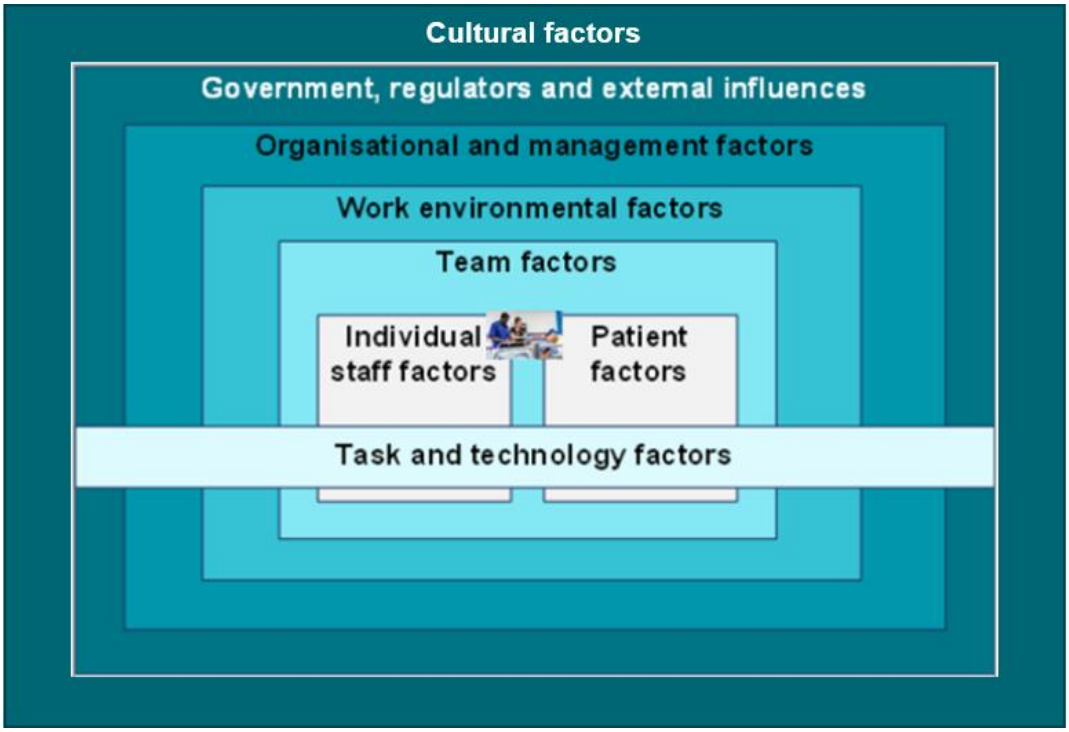
- **Team-based,** assuring that multidisciplinary (including consumer) subject matter expertise drives the identification of findings and recommendations
- **Systems-focused,** using a system-focused contributing-factors framework which Safer Care Victoria has adapted from the London Protocol[6] (see Figure 2). Please see Human factors fact sheet for more information
- **Solution-driven**, all aiming to identify sustainable system-based improvements that will prevent the recurrence of the adverse event or minimise the harm if a similar event occurs

[4] Safer Care Victoria Falls review tool

[5] https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/covid-19-deaths-in-hospitals-review-tool

[6] https://www.imperial.ac.uk/media/imperial-college/medicine/surgery-cancer/pstrc/londonprotocol_e.pdf, retrieved from https://www.imperial.ac.uk/patient-safety-translational-research-centre/education/training-materials-for-use-in-research-and-clinical-practice/the-london-protocol/

Figure 2. Systems-focused contributing factors framework



Social and cultural factors	Race, cultural background, gender, disability, age, sexuality, socioeconomic status, etc.
Government, regulators and external influences	Regulations, funding, links with external health services and colleges
Organisational and management factors	Financial resources and constraints, organisational structure, policies and standards, safety culture
Work environmental factors	Staffing, workload and shift patterns, design of equipment and environment
Team factors	Communications, supervision, team structure, leadership
Task and technology factors	Task design and clarity, availability and use of protocols, decision-making aids
Individual staff factors	Knowledge and skills, competence, physical and mental health
Patient factors	Condition (complexity and seriousness), language and communication and social factors

Root Cause Analysis and Action (RCA^2)

RCA^2 is a systems-focused review methodology that aims to determine *root causes* through a linear cause-and-effect analysis. RCA^2 starts with identifying critical events where (the point/s on a timeline where an intervention would have prevented the event occurring or altered the outcome). RCA^2 analysis may identify multiple root causes involved in an adverse event, rather than a singular root cause.

It then analyses the identified critical events using cause-and-effect analysis, focusing on systems and processes. Safer Care Victoria recommends using the London Protocol Contributing Factors framework in Figure 2 as a guide to identify contributing systems factors during the cause-and-effect analysis process – distribute this to the review team or print it out and display during the review meetings to prompt systems thinking.

RCA^2 emphasises the importance of 'taking action' following the analysis[7], focusing on identifying system-based recommendations that are implemented to improve quality and safety in the future. Engagement of senior leadership is key to ensure recommendations are signed off and approved for implementation.

Templates for the cause-and-effect analysis can be found in the sentinel event portal: Victorian Health Incident Management System – Manage Sentinel Events.

AcciMap

AcciMap is a systems-focused review methodology used to analyse how contributing factors at different levels of the systems interact with one another to cause the occurrence of an adverse event[1]. AcciMap is a contemporary human factors method used in many high-risk industries and is particularly suitable for adverse events in complex systems such as healthcare.

The AcciMap methodology guides reviewers to identify systems factors that contributed to an adverse event. AcciMap then analyses how the contributing factors interact with one another across systems layers. This will result in a visual map of contributing factors with connections. This does not have to be linear, and connections can occur across or within all layers of the system.

AcciMap is less linear than RCA^2 and, therefore, may provide a suitable alternative for adverse events that are complex and do not lend themselves to a linear analysis. AcciMap may also be more suitable for adverse events with unclear critical events as determined by RCA methodology or adverse events involving multiple health services.

London Protocol

The London Protocol is a systems-focused review methodology that focuses on identifying the '*care delivery problems'* that occurred during an adverse event. Care delivery problems are those where the care that has been delivered to patients that went beyond the accepted safety margin of clinical practice and had a (potential) direct or indirect effect on the outcome of the adverse event. Using an established contributing factors framework, the London Protocol then identifies systems factors that contributed to each of the care delivery problems.[8]

The London Protocol does not need to identify a root cause in a linear fashion as RCA^2, but by focusing on analysing contributing factors structured around care delivery problems, it provides a more structured process than AcciMap.

While methodologies such as RCA^2, AcciMap and the London Protocol are required for sentinel events, they can still be used for the other adverse event types.

[7] National Patient Safety Foundation. *RCA^2: Improving Root Cause Analyses and Actions to Prevent Harm*. Boston, MA: National Patient Safety Foundation; 2015.

[8] https://www.imperial.ac.uk/patient-safety-translational-research-centre/education/training-materials-for-use-in-research-and-clinical-practice/the-london-protocol/

In-depth case review

An in-depth case review is a structured process to identify what happened during an adverse event and why it happened. It is less resource intensive compared to RCA[2], London Protocol and AcciMap, but should still follow the same overarching review approach. It can possibly be undertaken with a smaller team, but still needs appropriate oversight and senior leadership involvement for endorsing recommendations.

An in-depth case review can be used for SAPSEs that are not classified as a sentinel event.

Key considerations for the data analysis

- Good facilitation is key to a structured and thorough analysis process. Ensure team members stay on task by guiding the conversation and noting other potential conversations for a later discussion.
- Allocate enough time to undertake data analysis to ensure review team members have sufficient time and do not cut corners (which can lead to biases).
- Actively manage cognitive bias throughout the process. More information and mitigation strategies: Cognitive bias
- Ensure team members are familiar with the analysis process being used.
- Start the analysis meeting by highlighting key principles.
- Pause and take a moment to step back and look at the bigger picture as you are progressing. This can help to identify areas or points that may not fit.

F. Develop findings

Findings should identify **what happened** and **why it happened**.

Finding statements describe the links between the contributing factors identified during data analysis, and the outcome of the adverse event. The output of the data analysis determines the content of the findings statement.

Finding statements should:

- focus on the process and the system, not individual performance
- not attribute the outcome solely or largely to the patient's clinical condition or behaviour without due consideration of other contributing systems factors
- logically flow from the data analysis output and not introduce new information
- be clear, concise, and de-identified – every word needs to earn its place
- avoid generic motherhood statements – needs to be able to be addressed with a recommendation
- identify preceding conditions for human error – human error cannot be identified as the cause.

Table 5 provides an example of 2 finding statements, one focusing on human error and the other focusing on systems. The comparison illustrates that the finding statement focusing on human error did not provide sufficient information on the systems that failed and contributed to the errors occurring. This will not support the development of effective recommendations. Instead, finding statements should focus on systems to identify effective system-based recommendations that support human performance, in line with systems-thinking and just-culture principles.

Table 5. Finding statement examples – human error versus systems-thinking focus

Finding statement focusing on human error	Medical staff did not appropriately observe a child presenting with medical emergency team (MET) call criteria.
Finding statement focusing on systems	The incomplete process for the rollout of new procedures contributed to medical staff being unaware of the updated paediatric/neonatal clinical deterioration procedure and resulted in incomplete observation of a child presenting with medical emergency team (MET) call criteria.

A **lesson learnt** is a finding or information identified during the review process that did not have an impact on the outcome under review (the adverse event) but is, nonetheless, a risk that should be addressed to prevent harm. It can also identify good practice and what went well. Lessons learnt should be documented in formal reviews, and recommendations should be developed as required (e.g. if a risk is identified).

Additional contextual information

Review teams may include an additional section outlining contextual information that is not included in the event description or analysis, e.g. a rationale for how care was being delivered that was considered by the team but did not contribute to the event and, therefore, excluded from the analysis. This may be beneficial for documentation purposes and audiences outside of the review team who read the review report (e.g. the impacted consumer/s, health service executive or coronial investigations). It can also assist with capturing what the review found went well in the patient's delivery of care if this has not been pointed out in other areas of the report.

G. Develop recommendations and action plan

Recommendations are the outcome of the review and aim to prevent or mitigate harm by addressing vulnerabilities in systems to reduce the likelihood of a similar adverse event recurring, or minimising harm in the event of recurrence. In line with systems thinking and Just Culture, recommendations should focus on addressing systems issues rather than individuals. Each finding should be addressed by a recommendation. Some recommendations may address multiple findings; i.e. there may be more findings than recommendations in a review report.

When writing recommendations, consider work already in progress that could be strengthened or complemented, planned projects and external bodies you may be able to engage with.

SMART principles

Recommendations should be written and developed in accordance with SMART principles:

- **S**pecific: recommendations are specific and contain detailed actions
- **M**easurable: recommendations are measurable (i.e. implementation and outcome can be measured)
- **A**ssignable: responsibility is assigned to the recommendation
- **R**ealistic: recommendations are achievable with the skills, knowledge and resources available
- **T**ime-bound: recommendations are implemented according to the agreed timelines

Strength of recommendations

Different types of recommendations have different levels of impact when it comes to making sustainable systems change. Recommendations are commonly categorised into 'weak, moderate and strong' to indicate their strength in addressing systems issues and improving quality and safety [9]

Weak recommendations tend to focus on changing people in the system by introducing more training, policies or introducing more warnings or double checks.

Moderate and **strong recommendations** are more effective because we know human behaviour is shaped by systems context. If we attempt to change human behaviour through more education and policies but don't address deficiently designed systems, similar adverse events will keep occurring. Moderate and strong recommendations focus on changing the design of systems to support human performance more effectively.

Ideally, recommendations developed as part of a review should be strong or, at least, moderate to affect change and improve quality and safety. This does not mean that weak recommendations should not be considered. For example, they may be required while developing and implementing moderate or stronger recommendations or, if the review identified a gap in a training program or policy, this gap also will need to be addressed.

Weak recommendations need to be complemented by stronger recommendations.

While requiring at least one recommendation per finding, strive for fewer high-quality strong recommendations rather than multiple weaker recommendations

Examples of strong, moderate and weak recommendations are provided in Table 6.

[9] Adapted from US Department of Veterans Affairs – VA National Center for Patient Safety (2015). Root Cause Analysis Tools, see https://www.patientsafety.va.gov/media/rca.asp, p. 22

Table 6. Example recommendations according to strength

Recommendation strength	Recommendation category	Example
Strong actions	Architectural/physical changes in surroundings	Replace revolving doors at the main entrance into the building with powered sliding or swinging doors to reduce patient falls.
Strong actions	New devices with usability testing	Perform pre-purchase testing of blood glucose monitors and test strips to select the most appropriate for the patient population.
Strong actions	Engineering control (forcing functions which force the user to complete the action)	Eliminate the use of universal adapters and peripheral devices for medical equipment; use tubing/fittings that can only be connected the correct way.
Strong actions	Simplify process and remove unnecessary steps	Remove unnecessary steps in a process; standardise the make and model of medication pumps used throughout the organisation; use barcoding for medication administration.
Strong actions	Tangible involvement by leadership	Participate in unit patient safety evaluations and interact with staff, purchase needed equipment, ensure staffing and workload is balanced.
Moderate actions	Redundancy	Use two RNs to independently calculate high-risk medication dosages.
Moderate actions	Increase in staffing/decrease in workload	Make float staff available to assist when workloads peak during the day.
Moderate actions	Software enhancements or modifications	Use computer alerts for drug–drug interactions.
Moderate actions	Eliminate/reduce distractions	Provide quiet rooms for programming PCA pumps; remove distractions for nurses when programming medication pumps.
Moderate actions	Education using simulation-based training with periodic refresher sessions/observations	Conduct patient handover in a simulation lab environment, with after-action critiques and debriefing.
Moderate actions	Checklist/cognitive aids	Use pre-induction and pre-incision checklists in operating rooms; use a checklist when reprocessing flexible fibre optic endoscopes.
Moderate actions	Eliminate look- and sound-alikes	Do not store look-alikes next to one another in the medication room.
Moderate actions	Standardised communication tools	Use read-back for all critical lab values; use read-back or repeat-back for all

Recommendation strength	Recommendation category	Example
		verbal medication orders, use a standardised patient handover format.
Moderate actions	Standardise process	Implementing a new standardised process for handover.
Weak actions	Double checks	One person calculates dosage, another person reviews their calculation.
Weak actions	Warnings	Add audible alarms or caution labels.
Weak actions	New procedure/memorandum/policy	Remember to check IV sites every two hours.
Weak actions	Training	Demonstrate the defibrillator during an in-service training.
Weak actions	Share outcomes/educational reference	Present at M&M as educational example. Share in newsletters. Add to orientation guides
Weak actions	Further review/develop action plan	Present at M&M as educational example. Share in newsletters. Add to orientation guides

Setting achievable timeframes and risk-rating recommendations

As health services progress in their review structures, they may find they have many recommendations to action. If timeframes to complete recommendations are set (e.g. all due in 3 months), the health service may find they are overwhelmed with recommendations and struggling to prioritise their completion.

One way to manage this is to develop an internally approved risk matrix for the timeframes applied to recommendations. The risk assessment should be, first, based on the risk to patients if the finding is not addressed and, second, the effort and time required to successfully implement the recommendation. Applying too short a timeframe to a complex recommendation can mean it is abandoned or not completed as intended. Applying a short timeframe to high-risk recommendations can help with assigning the appropriate resource to get it actioned quickly.

Recommendation prioritisation strategies need to be integrated into existing governance structures.

Health service examples

Table 7 is an example of a risk prioritisation matrix that has been developed and used by Monash Health for several years to guide the timeframes applied to recommendations and help manage workload. An example of an extreme risk may be a fault in the paging system for medical emergencies resulting in key staff not attending a MET/CODE.

Table 7. Health service example – recommendation prioritisation matrix

Risk based implementation timeframes (added by health service for internal purposes only)			
Rating	**Definition**	**Action required**	**Timeframe for completion**
Extreme	The review panel found a clinical process weakness that has no or minimal mitigation strategies in place and presents an extreme on-going clinical risk.	Immediate action required Delays to be escalated to executive Closure of recommendation to be approved by Clinical Council.	≤ 1 month *
High	The review panel found a clinical process weakness that has insufficient mitigation strategies in place and presents a high on-going clinical risk.	Prompt intervention required Closure of recommendation to be approved by Clinical Council.	≤ 3 months *
Medium	The review panel found a clinical process weakness that has insufficient mitigation strategies in place and presents a moderate on-going clinical risk.	Intervention required An update on the action plan to be provided to Clinical Council at 3 months. Closure of recommendation to be approved by Clinical Council.	≤ 6 months *
Low	The review panel found a clinical process weakness that has insufficient mitigation strategies in place and presents a minimal on-going clinical risk	Intervention required An update on the action plan to be provided to Clinical Council at 3 and 6 months. Closure of recommendation to be approved by Clinical Council.	≤ 9 months *

*Some actions may require a capital project, preparation and approval of a business case, service redesign, and model of care redesign and/or involvement of multiple services, programs or disciplines. These actions may require longer than the above timeframes. When the report is presented at Clinical Council an alternative timeframe can be proposed for approval by Clinical Council.

Consultation with key stakeholders

It is critical to develop recommendations in consultation with a range of key stakeholders and, most importantly, those who are affected by their implementation (i.e. frontline staff and consumers). Appropriate consultation ensures recommendations are feasible, increases the likelihood of successful implementation, and identifies unintended consequences. Other key stakeholders at managerial and executive levels also need to be consulted to determine whether the recommendations are feasible from their perspective.

Appropriate consultation with relevant stakeholders may require some time – this needs to be appropriately considered in the planning and agreed timeframes. It is important to determine unintended consequences on other systems areas when developing recommendations. Healthcare is a complex and interlinked system, making change in one area likely affects other areas in the health service. Appropriate consultation will increase the likelihood that these unintended consequences are recognised and suitably managed.

Key considerations for engaging stakeholders when developing recommendations

For a recommendation to be successful it must be endorsed and accepted by those who will be actioning it. One of the most common issues with recommendations that have failed to be implemented is a lack of engagement with the area or person implementing the recommendation. Steps can be taken to mitigate this risk.

- Identify the areas or executive who will be responsible for implementing the recommendations.
  - From this list, identify who you may need to meet with and whom you can engage 'offline'; this usually depends on how many recommendations there are or how complex or high-risk the finding.
- Provide this group the review findings to date, clearly stating that the findings are finalised and not part of the discussion.
- Go through each finding and work with those present to develop the recommendations, to ensure efficiency with this process. It can help to write the recommendation on a shared screen as you go.

Recommendation checks

- Have key stakeholders been actively consulted in the development?
- Have potential unintended consequences of implementation been assessed?
- Is there at least one recommendation for each finding?
- Are the majority of recommendations rated as moderate or strong?
- Are recommendations SMART (specific, measurable, assignable, relevant and time-bound)?

Governance and action plan

On completion, the report is escalated through the health service's internal governance processes. Governance processes differ between health services, but should all include:

- presenting the final report to the Executive Sponsor and providing rationale for how the recommendations were developed
- the Executive Sponsor prioritising the implementation of recommendations
- the Executive Sponsor confirming and signing off allocation of resources for the recommendations
- the CEO and Board endorsing and signing off the report and ensuring support for investment of resources.

Sharing the final report with the impacted patient, family or carer

The final report must be offered to the patient, family or carer (upon obtaining the patient's consent prior, where possible) directly impacted by the adverse event, along with the opportunity to have it explained to them or to discuss it with a staff member if they wish, in line with open disclosure and statutory duty of candour requirements.

H. Monitor recommendations

Recommendations should be monitored internally within the health service via the relevant clinical governance processes. This includes tabling recommendations at relevant committees and acting if items are stalled.

Part of monitoring includes informing relevant staff of updates and communicating with the impacted consumer about improvements, if they have requested this.

Key considerations for monitoring include:

- What has worked?
- What did not work?
- What improvements have been made?
- What can be applied elsewhere (internal and external)?

To help build a health service's capability in recommendation development and implementation, note if the recommendations were implemented as intended, abandoned or amended, and the reasons for this. Doing this can help the health service understand what may need to be improved in the recommendation development phase.

6. System-wide sharing and learning

Sharing of the review outcomes that have been learnt during the adverse event review process is key to achieving system-wide improvement of the safety of care. Sharing of review outcomes should occur within the health service as well as across the health sector.

Health services review adverse event management data and related data sets for action at an organisational level. Review outcomes should also be shared within and across speciality departments and sites to support learning and improvement in other areas of the health services where similar adverse events may occur.

Safer Care Victoria analyses sentinel event data to identify system trends and emerging risks. This information is shared in the Safer Care Victoria annual sentinel event report to facilitate health-sector-wide sharing and improvement. Safer Care Victoria also works with the Victorian Agency for Health Information, as the Victorian Health Incident Management System data owner, to share report data across the broader health sector to support learning and improvement in quality and safety of care.

Things to consider when sharing review outcomes include the potential impact on staff who were involved in events. Review outcomes can be shared without sharing full details of cases and, in fact, key lessons can be overlooked when a complex case is presented.

Examples of ways to share review outcomes from adverse events reviews include:

- communities of practice
- regional quality meetings
- monthly newsletter with a de-identified case summary outlining one or 2 key findings staff should learn from
- internal podcast
- aggregated data on themes from findings and lessons learnt.

Links and resources

Legislation / Instruments / Regulations

Ambulance Services Act 1986

Health Legislation Amendment (Quality and Safety) Act 2022

Health Services Act 1988

Health Services (Quality and Safety) Regulations 2020

Mental Health Act 2014

Victorian Duty of Candour Guidelines

Further resources

Chief psychiatrist guidelines

Learning and education | Safer Care Victoria

Open disclosure | Australian Commission on Safety and Quality in Health Care

Open disclosure resources and tools

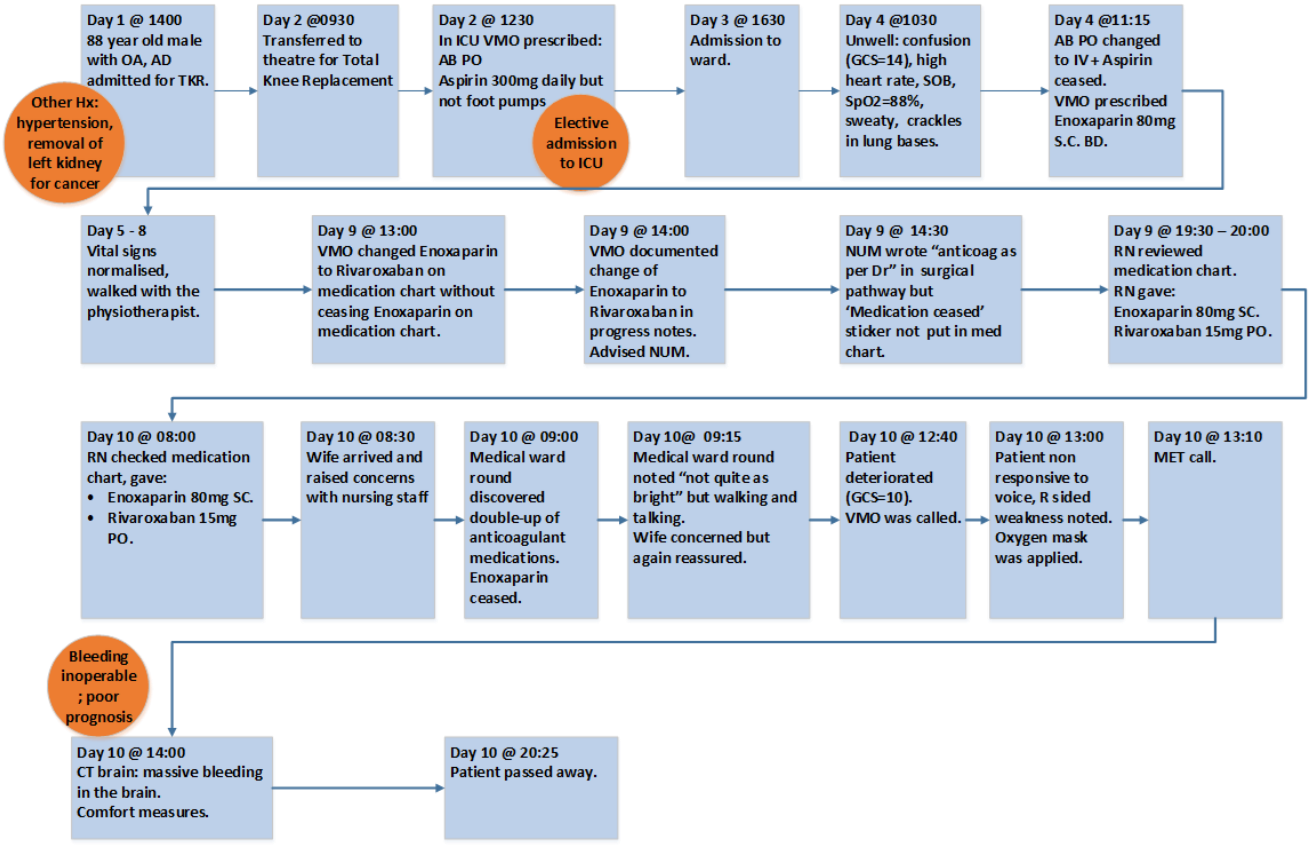
Victorian sentinel events guide

Statutory Duty of Candour and protections for SAPSE reviews

The Australian Open Disclosure Framework | Australian Commission on Safety and Quality in Health Care

Victorian Health Incident Management System – Minimum Dataset

Appendix 1: Timeline example



Legend
AB = antibiotics
AD = Alzheimer dementia
BD = twice a day
CT = computer tomography
ICU = intensive care unit
IV = intravenous
MET = medical emergency team
NUM = nurse unit manager
OA = osteoarthritis
PO = per os, literally, from Latin, 'through the mouth'
RN = registered nurse
SC = subcutaneous
SOB = shortness of breath
TKR = total knee replacement
VMO = visiting medical officer
VMO = surgeon
VTE = venous thromboembolism

[1] See the Victorian Duty of Candour Guidelines for more information

Version control

Version	Date	Changes made	Approved by
1.0		This guideline has been developed to support the Adverse Patient Safety Events policy published July 2023	Safer Care Victoria CEO

Safer Care Victoria