Safer Care Victoria

2023

Adverse Patient Safety Event policy

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Introduction

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 in place effective systems and processes to minimise future harm.

The role of an adverse event management system is to improve patient care by learning from adverse events and near misses that occur in health services with the aim of improving the safety and quality of the system of health care provided. This work supports a just culture and progresses in parallel with learning from what has gone right in delivering safe care.

Policy purpose

The Adverse Patient Safety Events (APSE) policy supports in-scope Victorian health services to improve systems for delivering care in response to adverse events. APSEs will be referred to as 'adverse events' throughout this policy.

This policy describes adverse event management requirements, accountabilities and definitions. Aligning this policy with health service policies, procedures and guidelines helps to develop systems that support effective reporting, review and learning across Victoria, with the goal of reducing preventable harm and continuously improving the quality and safety of patient care.

Refer to Helpful resources for a list of legislation and guidelines supporting this policy.

Refer to Definitions for key terminology used throughout this policy.

Alignment with this policy supports the implementation of actions 1.11 and 1.12 of the National Safety and Quality Health Service (NSQHS) standards from the Australian Commission on Safety and Quality in Healthcare.

Policy scope

Public health services

This policy applies to the following Victorian health services and all services under their governance structures:

- public health services
- public hospitals
- multi-purpose services
- denominational hospitals
- Ambulance Victoria
- Victorian Institute of Forensic Mental Health (Forensicare)
- bush nursing centres (publicly funded).[1]

[1] Bush nursing services are in scope of this policy except for requirements to comply with the statutory duty of candour.

Examples of services managed within the governance structures of the above health services may include (but is not limited to) Hospital in the Home, residential aged-care services and community health services.

This policy relates to adverse events that directly impact or involve a person to whom care is being provided. The policy does not:

- cover adverse events unrelated to the delivery of care
- focus on investigating personnel-related performance issues such as staff misconduct.

Private health providers

This policy is recommended best practice for the following private health providers:

- private hospitals
- day procedure centres
- non-emergency patient transport (NEPT) service
- first aid services.

Alignment with this policy is recommended to meet review requirements for statutory duty of candour and the Sentinel Event Program. The Serious Adverse Patient Safety Event (SAPSE) and Adverse event management process sections provide further information.

The Victorian Duty of Candour Guidelines require private hospitals, day procedure centres and NEPT to complete a review of a SAPSE (which includes sentinel events) to meet the requirements for statutory duty of candour. First Aid services are not in scope of the Victorian Duty of Candour Guidelines.

In relation to sentinel events, private hospitals, day procedure centres, NEPT and First Aid services are legally required to report sentinel events as per relevant regulations.

Private hospitals, day procedure centres, NEPT and First Aid services are not in scope for reporting the Victorian Health Incident Management System Minimum Dataset.

Adverse Patient Safety Event (APSE) management principles

Health services should apply the following principles when managing and reviewing adverse events.

Compassionate consumer engagement

Ensuring consumers participate in the review process and development of recommendations.

An open and transparent review process

Provide open disclosure 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.

Leadership engagement

Engaged senior leaders, including executive staff and board members, who promote and model the principles of a safety culture across their organisation to enable a safe reporting environment as well as learning and improving from adverse events.

A consistent approach

Robust clinical governance systems to support a consistent approach to adverse event management and organisational and health-system-wide learning.

Learning and improvement

Balancing resources between review and improvement to create a patient safety learning culture and an environment where there is system improvement from implementing review recommendations. In addition to learning and improving from adverse events, services should learn from safe, high-quality care, and apply these lessons across the system.

Just Culture and systems thinking

Ensure there is a fair and balanced response to adverse events and the creation of a safe reporting environment. Just Culture is underpinned by systems thinking and human factors principles, and views safety as a balance between the design of the broader system and the actions of people working and receiving care within the system.

Patient safety culture

The 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.

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.

APSE management responsibilities

Health services

All health services are required to have systems and processes for **monitoring**, **identifying**, **notifying**, **reporting**, **reviewing** and **learning from** adverse events and subsequent improvements[2]. Key to this is for health services to:

- focus on delivering outcomes to share learning
- implement learning into practice
- monitor that implementation to ensure that there is a low risk of similar events recurring.

An important measure is for learning to be shared across the health service in which it has occurred and with other health services to reduce the risk of similar adverse events happening.

More information on adverse event management responsibilities: Adverse event management process[3] section.

All health services are required to incorporate the requirements of this policy into their policies, procedures and guidelines. This must be supported with a workforce communication and education strategy to support successful uptake and implementation of this policy.

At a minimum, health services are required to:

- have an organisational approach to learning from the robust review and management of adverse events, with roles, responsibilities and accountabilities clearly understood by everyone
- have established clinical governance processes to implement, monitor and evaluate the effectiveness of implementation of endorsed recommendations including clinical audit and reporting to the Board
- proactively identify and address patient safety risks across the health service and use this information to plan the health service's response to adverse events
- have systems to report and notify adverse events through an incident management system
- have a classification system that identifies the severity of adverse events, e.g. incident severity rating (ISR), for public health services, and an equivalent rating system for private health services
- document all adverse events in the patient's healthcare record. Care must be taken to ensure only clinically relevant and factual information is included
- undertake an appropriate level of open disclosure with the patient, their family, and carers as soon as practicable
- comply with the requirements of the Victorian Duty of Candour Guidelines when conducting statutory duty of candour. More information: Victorian Duty of Candour Guidelines[4,5]
- implement processes and systems to ensure executive, staff and consumer representatives receive appropriate training for managing adverse events, including:
    - skill to participate and chair or facilitate the review process, including knowledge of relevant review methodologies
    - expertise in monitoring the effectiveness of recommendations
    - open disclosure

[2] See APSE management process for more information

[3] Note: The adverse event management responsibilities outlined in this policy do not replace other agencies' requirements for review and notification of adverse events.

[4] The Victorian Duty of Candour Guidelines are made by the Minister for Health as permitted by section 128ZF of the *Health Services Act 1988.* They are a legislative instrument for the purposes of the *Subordinate Legislation Act 1994.*

[5] Bush nursing centres are not in scope of the Victorian Duty of Candour Guidelines.

- partner with the impacted consumer, their family and carers to learn from the adverse event at a level appropriate to the severity of the event
- have processes to ensure the wellbeing of teams or individual staff involved in an adverse event
- ensure all adverse event reviews (including near misses) consider what worked well in the system and, in the case of a near miss, identify what prevented the adverse event from eventuating
- across the health service, implement lessons learnt from this good practice.

Notification and reporting

At a minimum, health services are required:

- meet the notification, reporting and review requirements of Victoria's sentinel event program. More information: Sentinel Event Program[6]
- report Victorian Health Incident Management System Minimum Dataset to the Victorian Agency for Health Information. More information: Victorian Health Incident Management System Minimum Dataset manual[6]
- comply with relevant legislation and notify relevant agencies.

Safer Care Victoria

Safer Care Victoria is an Administrative Office of the Department of Health under Section 11 of the *Public Administration Act 2004*. Safer Care Victoria works with and supports health service leaders, clinicians and consumers to manage and respond to adverse events by:

- supporting health services to review adverse events by providing guidelines, tools and training
- providing advice on sentinel event reviews
- collaborating with the Department of Health and the health sector to identify and respond to safety risks and issues
- engaging with Victorian Agency for Health Information to disseminate lessons learnt from state-wide adverse event reporting
- publishing the annual sentinel event report to share lessons learnt and assist health services in preventing similar events from occurring
- supporting in scope health services with guidance to implement the legislative reforms for the statutory duty of candour and SAPSE reviews
- delivering education and training in line with this policy to strengthen capability in adverse event review processes across the Victorian health sector
- monitoring implementation of the recommendations and providing feedback to Department of Health performance meetings.

Chief Quality and Safety Officer

The Chief Quality and Safety Officer functions are set out in the *Health Services Act 1988*, and a key function is the ability to conduct quality and safety (Q&S) reviews of services provided in or by health service entities. A trigger for a quality and safety review may include a single or cluster of adverse events where there has been risk to patient safety.

[6] As outlined in the Policy and funding guidelinesPolicy and funding guidelines for health services

APSE management process

The 6 steps in the APSE management 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. Timeframe requirements for the Sentinel Event Program, protected SAPSE reviews and statutory duty of candour are located in the SAPSE section. Health services determine timeframes for any other review type and should be outlined in their policies, procedures and guidelines.

APSE management process

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, including 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[7] 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 Flowchart 1 for recommended and required review types.

Health services who submit the Victorian Health Incident Management System Minimum Dataset to the department use 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, including 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.

Health services must have 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).[8]

[7] While this 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.

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

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 Victoria 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.

The 8 elements of the adverse event review process can be applied to all adverse events, regardless of the severity and chosen review methodology. 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), see 'Review types'.

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

More detailed information regarding the 8 elements can be found in the APSE guideline.

6. System-wide sharing and learning

Sharing of the review outcomes is key to achieving system-wide improvement of the safety of care. Sharing of lessons learnt should occur within the health service as well as across the health sector.

Health services must review adverse event management data and related data sets for action at an organisational level. Lessons learnt should also be shared to support learning and improvement in other areas of the health service 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 SCV 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 owner of the Victorian Health Incident Management System Minimum Dataset, to share data in reports across the broader health sector to support learning and improvement in quality and safety of care.

Review types

The ISR (or equivalent classification) of the adverse event informs the decision to undertake a formal, local or aggregate review. See Flowchart 1See Flowchart 1 for more information on choosing a review type.

Formal review

A formal review is a structured systems-focused process following a predetermined methodology which includes a written report. The formal review process sources 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 SAPSE section.

Some examples of formal review methods are:

- root cause analysis and action (RCA2)
- London Protocol
- AcciMap
- in-depth case review (IDCR).

Local review and aggregate review

Health services are responsible for developing governance processes for the review of all adverse events with an ISR of 3 or 4, or equivalent.

The initial review of ISR 3 and 4 adverse events can be undertaken at the local level with management responsibility for the review process and level of review being assigned.

Monitoring of trended aggregate adverse event data may also identify common contributing factors, detect clinical risks, and prioritise issues requiring a quality improvement response. This should be discussed at the appropriate quality committee or equivalent. In addition, analysis and review of aggregate ISR 3 and 4 adverse events should be discussed locally to increase staff's awareness of the importance of reporting and involve staff in the identification and implementation of improvement opportunities. Data from these reviews should inform the health service's quality and safety performance indicators to highlight risks and areas for improvement.

When reviewing ISR 3 or 4 events (or equivalent), consider if:

- the adverse event requires an individual adverse event review
- the adverse events can be classified into themes
- an aggregated review can be commissioned for similar events
- there are actions that prevented the adverse event from causing harm (near miss) or reduced harm, and whether the lessons learnt can be implemented elsewhere in the health service.

Serious adverse patient safety event (SAPSE)

SAPSE requirements

SAPSEs are classified as an ISR 1 or 2 event (refer to SAPSE definition[9]) and sentinel events are a subset of a SAPSE. Health services must have procedures to verify the adverse event against the SAPSE definition[9].

When classifying and verifying adverse events (see Adverse event reporting and Flowchart 1),Flowchart 1), health services need procedures to identify ISR 1 and 2 events that do not meet the definition of an adverse event. The rationale should be documented as per health service policy. An example of this may be when the incident management system is used for data collection or where an event is classified as an ISR 2 due to 'external transfer' unrelated to an adverse event.

All adverse events that meet the SAPSE definition:

- require statutory duty of candour and review of the SAPSE as outlined in the Victorian Duty of Candour Guidelines
- require a formal review using one of the following review methods
  - RCA2
  - London Protocol
  - AcciMap
  - IDCR – although IDCR is listed as a formal review, it is not an accepted review method for sentinel events.

Protected reviews (SAPSE review)

The *Health Legislation Amendment (Quality and Safety) Act 2022* introduced protections for adverse event reviews. These protected reviews must be completed in accordance with Division 8 of Part 5A of the Act and will be called a 'SAPSE review'. It will be at the discretion of a health service whether a 'SAPSE review' will be conducted for a SAPSE. If a 'SAPSE review' is conducted, this requires the formation of a 'SAPSE review panel' to conduct the SAPSE review.

When undertaking a review of a sentinel event, if the requirements of a 'SAPSE review' are met, then relevant protections will apply to the panel members, participants and documents created as part of a review process.

For more detailed information on the requirements of a 'SAPSE review', including the panel and protections offered as well as which entities can undertake these reviews, see Protections for serious adverse patient safety event (SAPSE) reviews.

Note: A formal review of all SAPSE is required. However, a protected review (SAPSE review) is not mandatory for all SAPSEs. A **SAPSE review** refers to a **protected review process**.

Note: A CEO of a bush nursing centre cannot appoint a SAPSE review panel because a bush nursing centre is not a health service entity as defined by section 3(1) of the *Health Services Act 1988*. Bush nursing centres are still required to undertake a formal review of all SAPSEs as outlined in this policy, but they will not be provided with the protections of SAPSE reviews.

[9] Definitions

Sentinel events

In Victoria, sentinel events are a subset of SAPSEs, which include all adverse events that result in serious harm to, or death of a patient and fit into the sentinel event categories 1 to 11. Health services are required to report sentinel events to Safer Care Victoria.

Categories 1–10 are the nationally reportable sentinel events. These are defined as a particular type of serious adverse event that is regarded as wholly preventable and has caused serious harm to, or the death of, a patient (Australian Sentinel event list – Version 2).

Category 11 includes all adverse patient safety events resulting in serious harm or death that are not included in the 10 national categories.

All adverse patient safety events at a health service that meet sentinel event criteria must:

- be notified to Safer Care Victoria's sentinel event program within 3 business days of the health service becoming aware that the adverse event has occurred
- have an open disclosure process with affected consumers and/or their families, in line with statutory duty of candour and the Australian Open Disclosure Framework
- be reviewed using a just-culture approach
- be timely, appropriately resourced and high-quality (using human factors and systems thinking), meeting the minimum standard outlined in the Victorian sentinel events guide
- have a review team that is led by suitably qualified staff and:
    - must consist of no less than 3 members
    - must include a person not employed or engaged by the health service
    - must not include any person who was directly involved in the SAPSE
    - must include a consumer representative[10]
    - may include independent experts
- have a review report that includes at least one recommendation for improvement
- be reviewed using an SCV approved methodology (e.g. RCA2, AcciMap or London Protocol) submitting:
    - a review report (part a and b) within 30 business days of notification
    - recommendations arising from the review (part c) within 50 business days of notification (75 business days for a SCV approved Multiagency review)
    - a recommendation monitoring report (part d) at 6 months and 12 months of the sentinel event notification.

Private hospitals and day procedure centres are required to notify in writing a sentinel event that occurred at the health service establishment to the Secretary within 3 days of the health service becoming aware that the adverse event has occurred.

NEPT and First Aid license holders are required to report sentinel events to the Secretary within 24 hours after the event occurring in line with relevant regulations.

More detailed information can be found in the Victorian Sentinel Event guide and the Australian Sentinel Events List (version 2) Specifications | Australian Commission on Safety and Quality in Health Care.

Contact the program via email sentinel.events@safercare.vic.gov.au or phone 1300 543 916.

[10] As per Regulation 3D of the *Health Services (Quality and Safety) Regulations 2020.*

Further considerations

Multi-agency reviews

Engaging with other health services

If a SAPSE (including a sentinel event) involves 2 or more health services, the CEOs of those services may agree to appoint a multi-agency SAPSE review panel. If the event is a sentinel event, all services involved in the care of the patient are expected to participate in a multi-agency review of the adverse event.

Collaboration across health services can further strengthen the review process by:

- obtaining a more complete picture of the care delivered to the patient
- considering subject matter expertise from different health service perspectives
- applying systems improvements across health services.

A successful multi-agency review agrees:

- on terms of reference for the review
- all services will maintain deadlines
- on a plan of approach for each of the required report submissions
- on a 'responsible person' at each service to act as the service's key contact.

Notification

In the case of a sentinel event, it is the responsibility of all services to ensure a sentinel event notification is made when applicable. Safer Care Victoria recommends the health service that provided the final period of care related to the sentinel event takes responsibility for notifying the event, initiating the review, and engaging the other health services. This can be negotiated on a case-by-case basis. Safer Care Victoria can provide advice if required.

Safer Care Victoria recommends that the notifying service informs all other listed agencies prior to or at the time of notification, but this should not delay notification.

Protections for the review

In the case of multi-agency reviews and forming a joint SAPSE review panel, the health services must follow the requirements set out in section 128P(2) and section 128P(3) of the Act, as well as the *Health Services (Quality and Safety) Regulations 2020.* If all requirements are met, the same SAPSE review protections apply as for a single-entity review.

Sharing of information between health services

Health services can share confidential information gathered as part of the multi-agency review, as outlined within the 'Ministerial Authorisation for the collection, use and disclosure of confidential information for Adverse Patient Safety Event Reviews'[11]. This instrument of authorisation is made under section 134ZB of the Act and applies to the conduct of reviews of adverse events (as defined in this policy), where patient care has been provided by multiple health service entities.

SAPSEs that occur at other health services

Where a health service becomes aware of an actual or likely SAPSE or sentinel event at another service (e.g. the patient was transferred for treatment to another health service after the SAPSE occurred), they are expected to

[11] Office of the Victorian Information Commissioner (2020). Information Sharing by Health Service Entities for Quality and Safety Purposes. OVIC, Melbourne.

alert the affected health service quality and safety unit and Safer Care Victoria's sentinel event program (in the case of a sentinel event only). In these cases, Safer Care Victoria encourages collaboration across services, including participation on review panels where appropriate.

Where a service is unsure of the best way to contact the affected health service, they should reach out to the sentinel event program for assistance. It is recommended that the health service in which the SAPSE occurred leads the review process. Contact the program via email sentinel.events@safercare.vic.gov.au or phone 1300 543 916.

Cluster reviews

Cluster reviews are required when multiple (~3 or more) events of a similar nature result in actual harm or may result in harm to a patient. Cluster events can occur within or across health services and in various ways, for example:

- One thing that went wrong and harmed a number of people (e.g. broken equipment or IT system resulting in multiple patients experiencing or being exposed to harm).
- Multiple occurrences of similar outcomes (harm) within one area or across different areas.

Identification of clusters of events:

- **Health services** – must have processes to identify and manage clusters of events when they occur. If a health service identifies a cluster of events resulting in actual or potential harm, they should notify Safer Care Victoria for advice on next steps.
- **Safer Care Victoria** – may identify or be notified of clusters of events. If not already notified by the health service involved, Safer Care Victoria will contact the health service and provide advice on next steps.

Partnering with consumers in undertaking patient safety reviews

Consumers are significant contributors to patient safety. Because of their experiences, consumers bring a different perspective to patient safety initiatives. Consumer self-reported estimates of adverse events are similar to medical record review which reflects that consumers are capable of identifying adverse events and factors that may have contributed to them.

The involvement of consumers in how systems and practices of care can be changed to improve safety is a significant addition to improving patient safety. Consumer insights into the identification of adverse events can be used to inform the development of potential strategies to improve safety. Interviews with consumers to elicit barriers and enablers of safe, high-quality care, as identified and viewed as important to them, should be considered in the development of safety initiatives targeting adverse events. This will result in meaningful outcomes from the perspective of consumers.

Definitions

The following definitions apply to this policy:

Term	Description
Adverse patient safety event (APSE)	An incident that results, or could have resulted, in harm to a patient or consumer. A near miss is a type of adverse event.[12] (SAPSE and sentinel event are a subset of APSE.)
Clinical governance	The integrated systems, processes, leadership and culture that are at the core of providing safe, effective, accountable and person-centred healthcare underpinned by continuous improvement.[13]
Clinical incident	An event or circumstance that resulted or could have resulted, in unintended or unnecessary harm to a person receiving clinical care. Clinical incidents include adverse patient safety events, including near misses, in an environment that pose a clinical risk.
Cultural safety	Identifies that health consumers are safest when health professionals have considered power relations, cultural differences and patients' rights. Part of this process requires health professionals to examine their own realities, beliefs and attitudes. Cultural safety is defined not by the health professional but, rather, by the health consumer's experience – their experience of care given and their ability to access services and to raise concerns. The essential features of cultural safety are: • an understanding of one's culture • an acknowledgment of difference, and a requirement that caregivers are actively mindful and respectful of difference(s) • that it is informed by the theory of power relations; any attempt to depoliticise cultural safety is to miss the point • an appreciation of the historical context of colonisation, the practices of racism at individual and institutional levels, and their impact on First Nations people's living and wellbeing, in the present and the past • that its presence or absence is determined by the experience of the recipient of care and not defined by the caregiver.[14]
Formal review	A structured systems-focused review process following a predetermined methodology which includes a written report. The review sources input from relevant subject matter experts. Consumer representatives are a mandatory requirement for sentinel event reviews.
Harm	Is defined in regulation 3A of the *Health Services (Quality and Safety) Regulations 2020* to include moderate harm, severe harm and prolonged psychological harm. • *Moderate harm* means harm that requires a moderate increase in treatment to a patient, such as an unplanned or unexpected return to surgery, but does not include harm that causes permanent damage or injury to an individual. • *Severe harm* means harm that causes a permanent lessening in the functioning of an individual that is unrelated to the natural course of a person's illness or underlying condition, including harm that can lead to a person experiencing a permanent impairment or disability, or death. • *Prolonged psychological harm* means psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days.

[12] Australian Commission on Safety and Quality in Health Care (2021). Incident Management Guide. ACSQHC, Sydney.

[13] Safer Care Victoria (2018). Clinical Governance Framework

[14] Australian Commission on Safety and Quality in Health Care (2020). Cultural safety definition. Resources for the NSQHS standards.

Term	Description
Health service	For the purpose of this policy, 'health service' is defined as: • public health services • public hospitals • multi-purpose services • denominational hospitals • Ambulance Victoria • Victorian Institute of Forensic Mental Health (Forensicare) • bush nursing centres (publicly funded). Note: The term 'health service entity' is defined in the *Health Services Act 1988*, and is relevant for serious adverse patient safety events, SAPSE reviews, and the Statutory Duty of Candour.
Just Culture	Just culture is part of safety culture with the key features including: • Restoring trust with those involved in an adverse event (consumers and staff) • a systems-thinking mindset to adverse event review • provision of a psychologically safe workplace where employees feel safe to report adverse events and near misses • managing the innate cognitive biases we all have as part of being human • the concept of shared accountability between the organisation and an individual when adverse events occur.[15]
Near miss	An incident or potential incident that was averted and did not cause harm, but had the potential to do so.[16]
Open disclosure	An open discussion with a patient and/or their family or carers about an adverse event(s) that resulted in harm to that patient while they were receiving health care. The elements of open disclosure are an apology or expression of regret (including the word 'sorry'), a factual explanation of what happened, an opportunity for the patient to relate their experience, and an explanation of the steps being taken to manage the event and prevent recurrence. Open disclosure is a discussion and an exchange of information that may take place over several meetings.[17]
Patient/resident/client/consumer	Children, adults or young people who receive services delivered by Victorian public health services that are funded by the department. Note: Patient/Resident/Client/Consumer can be used interchangeably depending on the healthcare setting. For the purpose of this policy, 'patient' is used except where 'consumer' is used for a specific role title.
Private health provider	For the purpose of this policy, 'private health provider' is defined as: • private hospitals • day procedure centres • NEPT and First Aid services.

[15] SCV Just culture guide for health services

[16] Australian Commission on Safety and Quality in Healthcare. Glossary. ACSQHC, Sydney.

[17] Australian Commission on Safety and Quality in Healthcare (2013) Australian Open Disclosure Framework. [17] Australian Commission on Safety and Quality in Healthcare (2013) Australian Open Disclosure Framework.gov.au). ACSQHC, Sydney.

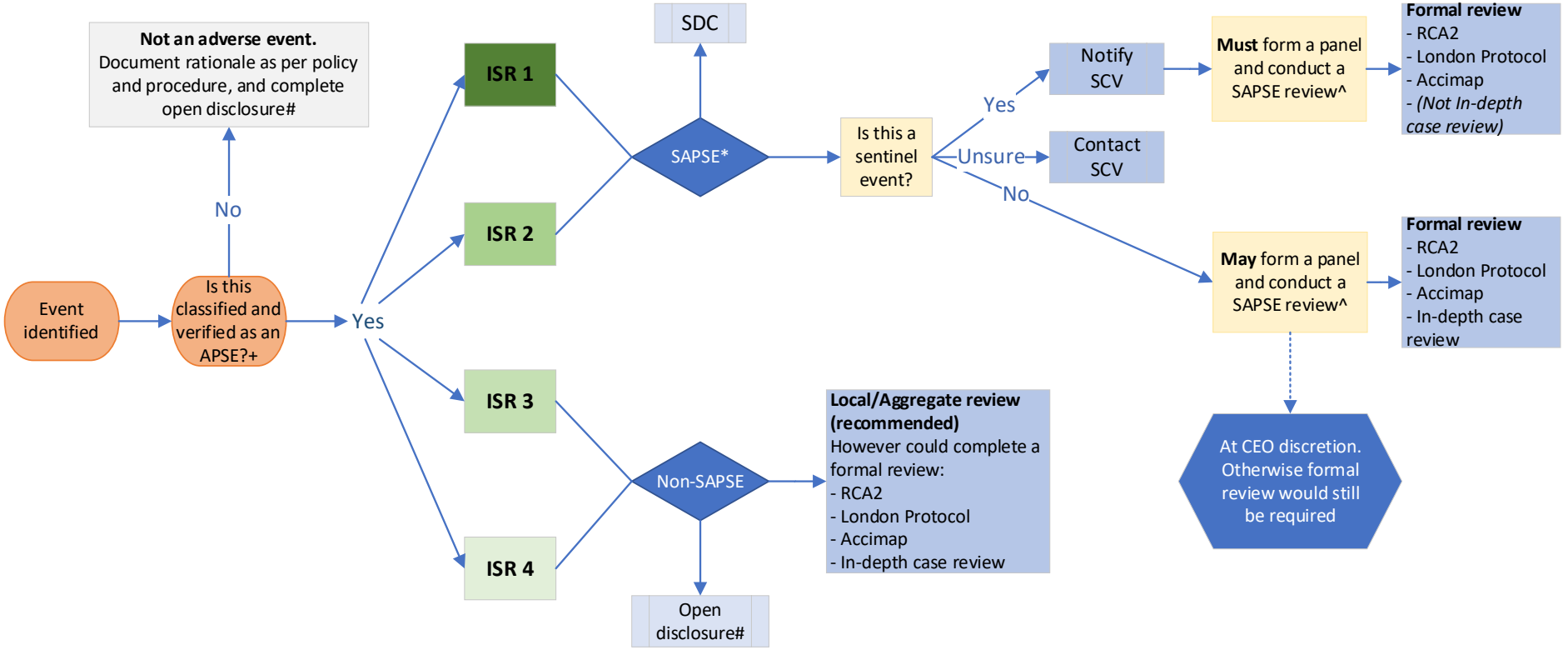
Term	Description
SAPSE review	A review of a serious adverse patient safety event conducted in accordance with Division 8 of Part 5A of the *Health Services Act 1988*. (It refers to a protected review process).
Sentinel event	Is defined in the *Health Services (Quality and Safety) Regulations 2020* as an unexpected and adverse event that occurs infrequently in a health service and results in the death of, or serious physical or psychological injury to, a patient as a result of system and process deficiencies at the health service entity.[18]
Serious adverse patient safety event (SAPSE)	A serious adverse patient safety event is defined, in section 3(1) of the *Health Services Act 1988*, as an event of a prescribed class or category that results in harm to one or more individuals. A prescribed class or category is an event that: • occurred while the patient was receiving health services from a health service entity; and • in the reasonable opinion of a registered health practitioner, has resulted in, or is likely to result in, unintended or unexpected harm (which includes moderate harm, severe harm or prolonged psychological harm) being suffered by the patient.[19] To avoid doubt, this includes an event that is identified following discharge from the health service entity.
Statutory duty of candour (SDC)	A legal obligation for Victorian health service entities to apologise to and communicate openly and honestly with patients, their families or carers when a SAPSE has occurred. It builds on the Australian Open Disclosure Framework currently used for all cases of harm and near miss. Statutory duty of candour is set out in section 128ZC of the *Health Services Act 1988*, section 22I of the *Ambulance Services Act 1986* and section 345B of the *Mental Health Act 2014*. Note: Bush nursing centres and first aid services are not in scope for statutory duty of candour.
Victorian Health Incident Management System Minimum Dataset	A standardised dataset for the collection and classification of clinical, occupational health and safety (OHS) incidents, near misses, hazards and consumer feedback.[20]

[18] Regulation 3A of the *Health Services (Quality and Safety) Regulations 2020.*

[19] For full definition, see Regulation 3B of the *Health Services (Quality and Safety) Regulations 2020*

[20] Victorian Agency for Health Information (2022). VHIMS Minimum Dataset Manual 2021–22 (edition 1). Victorian Department of Health, Melbourne.

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.

Helpful resources

Legislation, Instruments and Regulations

Health Services Act 1988
Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013
Ambulance Services Act 1986
Health Services (Quality and Safety) Regulations 2020
Non-Emergency Patient Transport and First Aid Services (First Aid Services) Regulations 2021
Non-Emergency Patient Transport Regulations 2016

Guidelines and Frameworks

Policy and funding guidelines
Australian Commission on Safety and Quality in Health Care (ACSQHC)
Australian Open Disclosure Framework
Open disclosure | Australian Commission on Safety and Quality in Health Care
Victorian Health Incident Management System – Minimum Dataset
Safer Care Victoria Clinical Governance Framework
Protections for serious adverse patient safety event (SAPSE) reviews
Victorian Duty of Candour Framework
Victorian Duty of Candour Guidelines

Other

Aboriginal and Torres Strait Islander cultural safety
Australian Charter of Healthcare Rights
Guides to consumer representatives on adverse event reviews
Just culture fact sheet
Resources for involving impacted consumers
Statutory Duty of Candour and protections for SAPSE reviews

Safer Care Victoria