October 2022

Victorian Duty of Candour Framework

An implementation guide

OFFICIAL

 Our office is based on the land of the Traditional Owners, the Wurundjeri people of the Kulin Nation. We acknowledge and pay respect to their history, culture, and Elders past and present. We acknowledge Aboriginal people as Australia’s first peoples and as the Traditional Owners and custodians of the land and water on which we rely. We recognise and value the ongoing contribution of Aboriginal people and communities to Victorian life and how this enriches us. We embrace the spirit of reconciliation, working towards the equality of outcomes and ensuring an equal voice. For this land always was, and always will be, Aboriginal Land.

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| **A note on terminology**Adverse event is an incident that results, or could have resulted, in harm to a patient or consumer. A near miss is a type of adverse event.[[1]](#footnote-2)Apology an expression of compassion, regret or sympathy in connection with any matter, whether the apology admits or implies an admission of fault in connection with the matter.[[2]](#footnote-3) Chief Quality and Safety Officer (CQSO) means the person appointed as Chief Quality and Safety Officer under section 116 of the *Health Services Act 1988*.Cultural safety is defined as an environment that is safe for Aboriginal people and Torres Strait Islanders, where there is no assault, challenge or denial of their identity and experience.Harm is physical or psychological damage or injury to a person. Examples of harm are disease, suffering, impairment (disability), and death.* Disease: a psychological or physiological dysfunction.
* Suffering: experiencing anything subjectively unpleasant. This may include pain, malaise, nausea, vomiting, loss (any negative consequence, including financial) depression, agitation, alarm, fear, or grief.
* Impairment (disability): any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with a past or present harm.[[3]](#footnote-4)

Incidents are events or circumstances that resulted, or could have resulted, in unintended and/or unnecessary harm to a person and/or a complaint, loss or damage.[[4]](#footnote-5)Incident Severity Rating (ISR) is the four-tiered severity rating system for clinical incidents recorded in VHIMS. ISR ratings are determined by the level of harm, the required level of care, and the level of treatment required.ISR 1 is the highest incident severity rating category. These incidents result in severe adverse outcomes or death.ISR 2 is the second highest incident severity rating category. These incidents result in moderate adverse outcomes.Just Culture A part of safety culture with the major features being: * a systems-thinking mindset to adverse event review and improvement
* provision of a psychologically safe workplace where employees feel safe to report adverse events and near misses
* acknowledging and managing the innate cognitive biases that we all have as part of being human
* the concept of shared accountability between the organisation and an individual when adverse events occur.[[5]](#footnote-6)

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.[[6]](#footnote-7)Near miss is an incident that did not cause harm. A near miss is also an incident that had the potential to cause harm but didn't, due to timely intervention and/or luck and/or chance.[[7]](#footnote-8)Next of kin (NOK) is the patient’s next of kin which may be any partner, parent, legal guardian, child or sibling of 18 years or older, or executor when a harm event causes death. Parent is an adult in a significant primary caring role, whether they are a biological, adoptive, foster or step-parent, or the legal guardian of a child.Patient refers to any patient including inpatients, consumers, clients or residents who have suffered a SAPSE in the course of receiving health services. In circumstances where the patient lacks capacity or dies, the term patient also includes others who may be involved in the SDC process including the patient’s immediate family, carer, NOK, or any person nominated by the patient.[[8]](#footnote-9)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.[[9]](#footnote-10)Racism is that which maintains or exacerbates inequality of opportunity among ethnoracial groups.[[10]](#footnote-11)Registered health practitioner means an individual who:1. is registered under the Health Practitioner Regulation National Law to practise a health profession, other than as a student; or
2. holds non-practising registration under this Law in a health profession.[[11]](#footnote-12)

Secretary means the Department Head (within the meaning of the *Public Administration Act 2004*) of the Department of Health.[[12]](#footnote-13) Self-reported harm refers to if a patient identifies that they have experienced harm that has not yet been recorded by the health service entity.Sentinel event means an unexpected and adverse event that occurs infrequently in a health service entity 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.[[13]](#footnote-14)Serious adverse patient safety event (SAPSE) is an event of a prescribed class or category that: 1. occurred while the patient was receiving health services from a health service entity; and
2. 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.[[14]](#footnote-15)

This includes an event that is identified following discharge from the health service entity. 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.[[15]](#footnote-16)Sexual safety has been defined as a state in which physical and psychological boundaries of individuals are maintained and respected.[[16]](#footnote-17)Statutory Duty of Candour (SDC) must be performed if a patient suffers a SAPSE in the course of receiving health services. The health service entity responsible for providing those services must provide them with:* a written account of the facts
* an apology for the harm suffered
* a description of the health service entity’s response to the event, and
* the steps that the health service entity has taken to prevent re-occurrence of the event.

They must also comply with the steps set out in the *Victorian Duty of Candour Guidelines*.Victorian Health Incident Management System (VHIMS) is a standardised dataset for the collection and classification of clinical, occupational health and safety incidents, near misses, hazards and consumer feedback. |

# About this framework

This framework will assist your health service entity to provide patient-centred care, create a just and transparent culture, and comply with mandatory and legislated requirements to undertake SDC. It provides a framework, guidance and considerations on the SDC and should be read together with the relevant legislation and [*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx).

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| In this Framework ‘support person(s)’ refers to the patient’s NOK, family, carer, or any other person nominated by the patient. |

## Why use this framework?

This framework supports health service entities to understand what a SAPSE is, and the considerations when undertaking the SDC process. It includes guidance on:

* the principles and benefits of SDC
* what is a SAPSE with examples
* escalation process for disagreements
* patient considerations
* the governance of SDC.

### Please read this framework in conjunction with:

* Relevant legislations and underpinning regulations (see resources page)
* *Victorian Duty of Candour Guidelines*
* Australian Open Disclosure Framework
* Policy: Adverse Patient Safety Events, and
* Victorian sentinel events guide.

## Why Safer Care Victoria developed this framework

SDC was a key recommendation from the *Expert Working Group: A statutory duty of candour* report. The expert working group was established to advise on legislative reforms arising from *Targeting Zero:* *Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care*. The Targeting Zero report found that there was a lack of open disclosure with patients, and that almost half of hospital board members were not familiar with the Australian Open Disclosure Framework.

The *Health Legislation Amendment (Quality and Safety) Act 2022* and associated resources are the result of five years of significant consultation, and were developed with input from expert healthcare workers, leaders and consumers. This resource should also be referred to alongside relevant legislation and the *Victorian Duty of Candour Guidelines*, which stipulate what SDC is, and the key requirements and timelines.

* In 2017, an expert working group was appointed, led by Michael Gorton AM, to develop a consultation paper on the scope, processes, compliance measures and protections for adverse event reviews.
* This group received 61 submissions from stakeholders across the state.[[17]](#footnote-18)
* Safer Care Victoria (SCV) consulted publicly on 27 recommendations in 2020–21, receiving 60 submissions from individuals, public/private health services, professional associations, colleges and insurers.
* SCV established an advisory group in 2021 to develop this resource and support the implementation of SDC in health service entities.

### Open disclosure

The Australian Commission on Safety and Quality in Healthcare (ACSQHC), through the National Safety and Quality Health Service Standards (NSQHS), mandates open disclosure as part of health service accreditation[[18]](#footnote-19). The Australian Open Disclosure framework highlights the importance of open disclosure, and the role it plays in learning from errors[[19]](#footnote-20). It acknowledges open disclosure as:

* a patient right
* anchored in professional ethics
* good clinical practice
* part of the care continuum.

SDC is legislated under the *Health Services Act 1988* and it is now a legal requirement to conduct open disclosure in relation to SAPSE. If an adverse event does not meet the definition of a SAPSE, and trigger the legal obligations required of the SDC process, a process of open disclosure should still be undertaken.

Please read this framework in conjunction with the[**Australian Open Disclosure Framework**](https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf) **(2014).**

## Audience

This framework is for clinicians and health service representatives responsible for carrying out SDC. The relevant health service entities (and **any services under their governance**) that must undertake SDC include:

* a public health service
* a public hospital
* a multi-purpose service
* a denominational hospital
* a private hospital
* a day procedure centre
* an ambulance service within the meaning of the *Ambulance Services Act 1986*
* a non-emergency patient transport service within the meaning of the *Non-Emergency Patient Transport and First Aid Services Act 2003* that is licensed under that Act
* the Victorian Institute of Forensic Mental Health established by section 328 of the *Mental Health Act 2014*.[[20]](#footnote-21)

# What is Statutory Duty of Candour?

SDC is a legal obligation for Victorian health service entities, to ensure that patients or their support person, receive an apology and are communicated with openly and honestly, when a SAPSE has occurred.

## Principles of SDC

The following principles underpin SDC:

* patient-centred care
* respect
* transparency
* communication
* advocacy/partnership
* accountability
* leadership
* creating a just culture.

## Benefits of SDC

Undertaking SDC has many benefits for patients, carers and families, healthcare workers and the broader health system.

### Benefits for patients

SDC can help a patient

* understand what has happened and why
* make informed decisions about their future
* rebuild their trust in the healthcare system
* avoid secondary harm through improved management and communication of SAPSE
* be involved in system improvements through SAPSE reviews.

Where the harm has resulted in death, SDC requires the patient's nominated support person to be fully informed about what occurred and provided with clear pathways to obtain answers. This includes acknowledging that the situation may be difficult and offering support where appropriate.

### Benefits for healthcare workers

Clarifying that a health service entity is responsible for SDC requirements rather than an individual clinician helps to:

* encourage staff to raise safety concerns without fear of reprisal
* alleviate feelings of stress or guilt for healthcare staff involved in the SAPSE
* provide an opportunity for learning to prevent similar events in future.

### Benefits for the health sector

SDC will help to create a just culture in the Victorian healthcare sector. Within Victorian health service entities, SDC will:

* ensure accountability
* drive cultural change
* enable greater transparency.

Transparency in healthcare helps to recognise, value and learn from the experiences of patients and their support persons.

## The importance of a just culture for successful SDC implementation

Leadership must support their trained staff to practice open disclosure and implement SDC when required. This means staff know the processes in place and are comfortable using them when something has gone wrong.

A positive safety culture is consistently associated with a range of patient outcomes including reduced mortality rates, falls, hospital acquired infections and improved patient satisfaction. The Executive/Directors of the health service entity must implement systems and processes to support the staff that will be involved in open disclosure or SDC conversations, to implement SDC when required.

A just culture is established by senior leadership actively modelling just culture principles.

A just culture:

* is open, transparent and encourages staff reporting safety issues
* balances organisational and staff responsibility for high quality and safe patient care
* appropriately considers the impact of systems issues on individual performance
* is not accountability free – it has leaders who model accountability to improve future systems and processes, rather than blaming staff for adverse events that occurred[[21]](#footnote-22)
* has a strong restorative focus by restoring trust between senior leadership, staff and consumers after an adverse event occurred, by identifying their short term and long-term needs
* learns from adverse events and has systems and processes in place to improve the system accordingly.

A just culture is underpinned by a systems-thinking mindset which recognises that human behaviour is affected by the systems context it takes place in. Systems thinking recognises that human error is normal, given the natural limitations of our physical and cognitive capacities, and that systems need to be designed to support humans in doing their work as effective as possible. When an adverse event occurs, a just culture acknowledges who is harmed, identifies their needs and identifies whose responsibility it is to meet these needs.

Please see SCV Just Culture Guide for more information: [SCV-Just-Culture-Guide-for-Health-Services.pdf (safercare.vic.gov.au)](https://www.safercare.vic.gov.au/sites/default/files/2022-08/SCV-Just-Culture-Guide-for-Health-Services.pdf). Also see the Just Culture factsheet: [Just-Culture-in-adverse-event-reviews-factsheet.pdf (safercare.vic.gov.au)](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Just-Culture-in-adverse-event-reviews-factsheet.pdf).

# When to undertake SDC

SDC needs to be undertaken when a SAPSE has occurred to a patient in a relevant health service entity. The SDC process should occur with the patient and/or their support person(s), except when the patient has opted out.

SDC will need to be undertaken when a SAPSE has occurred and has been identified:

* by a registered health practitioner, or
* by a patient as self-reported harm which, in the opinion of a registered health practitioner, meets the definition of a SAPSE.

The above applies except when the patient or their support person (in circumstances when the patient lacks capacity or has died) opts out. See the[*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx) for more information.

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| **When determining a SAPSE**If the harm experienced was not unintended or unexpected, then the adverse event may not fulfill the definition of a SAPSE. Health service entities should interpret ‘unintended or unexpected’ in relation to the harm resulting from an adverse event that arises in the course of a patient receiving health services. Therefore, if the treatment or care provided went as intended and as expected, an incident may not qualify as a SAPSE, even if harm occurred.Note: This does not mean that known complications or side effects of treatment will never be a SAPSE. In every case, the health service entity must use their judgement to assess whether treatment or care provided went as intended and as expected, and therefore whether the adverse event fulfils the criteria of a SAPSE.[[22]](#footnote-23) |

While most SAPSE will be identified through health service entity incident management and patient/consumer feedback systems, the SDC must also be undertaken when SAPSE are identified through other avenues (e.g. Coronial processes, Serious Incident Response Scheme (SIRS), and SAPSE that occur during a research trial). In such instances, health service entities must comply with any other reporting expectations in addition to their SDC obligations.

The full extent of the SAPSE may still be unknown in the initial stages and the health service entity will need to undertake a thorough review and formulate a clear plan, including risk assessment, timelines, communication strategy and protocols. Clearly document the timeline and processes in these cases.

If an event does not meet the definition of a SAPSE, and therefore does not trigger the legal obligations required of the SDC process, open disclosure should still be followed as outlined within the [Australian Open Disclosure Framework](https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf).

## Harm categories

### Moderate harm

The *Health Services (Quality and Safety) Regulations 2020* defines ‘moderate’ harm as requiring a moderate increase in treatment to a patient, such as unplanned or unexpected return to surgery, but that does not cause permanent damage or injury to an individual. For health service entities that use the Victorian Health Incident Management System (VHIMS), this type of harm corresponds with an Incident Severity Rating (ISR) 2. More information on the VHIMS rating system is available in the [VHIMS Minimum Dataset Manual](https://www.health.vic.gov.au/publications/victorian-health-incident-management-system-minimum-dataset).

Some health service entities may use their clinical incident management system to collect all data, not just adverse events. In this instance, some events that currently trigger an ISR 2 rating would not represent an unexpected adverse outcome, and therefore not be a SAPSE (see case example 2). For an adverse event to be deemed a SAPSE, it must be unplanned or unexpected and fulfil the SAPSE definition.

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| **Case example 1 – Moderate harm**Jaime is 46 years old and has been suffering symptoms of Multiple Sclerosis for 10 years. Over the past 12 months Jaime has become wheelchair bound. Jaime is admitted to hospital for a large lower leg skin tear, which requires a skin graft and bed rest for 5 days. During this period, the nursing staff did not provide Jaime with the appropriate pressure area care required. On day 5 whilst conducting a skin graft check, staff found an ulcer on Jaime’s heel. The nurse-in-charge explains to Jaime that a Stage 3 pressure injury has developed and sincerely apologises for this occurring. The nurse-in-charge outlines that additional equipment and monitoring will be instigated to manage the pressure injury and that a review will be conducted to improve future systems and processes. They enter the event into the clinical incident management system. Jaime required an extra 2 days in hospital and was then discharged to the health service entity’s Hospital in the Home service, for nurses to provide regular dressing changes to the pressure injury. The pressure injury healed within 3 weeks. This event is a SAPSE, and therefore requires SDC, because Jaime required a moderate increase in treatment, therefore sustaining ‘moderate’ harm.See the [*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx) for more information. |

Case example 2 – Moderate harm

In the below examples, two scenarios are presented to demonstrate the circumstance where an adverse event does, and does not, fulfil SAPSE criteria.

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| Terry is 74 years old presents to hospital for a radical neck dissection (surgery to remove cancerous tissue in neck). Terry completes the consent process for this operation with the surgeon, acknowledging the risk of post-surgery bleeding. Terry has the surgery without complication and returns to the ward for recovery.  |
| **Scenario A:**As part of routine post-surgical monitoring the nursing staff identify evidence of bleeding and the development of a haematoma. The surgeon is notified and reviews Terry immediately. Given the risk of the haematoma to Terry’s airway, the surgeon recommends a return to surgery to decompress the haematoma and manage bleeding. This progresses without complication and Terry’s recovery is otherwise uneventful. Terry makes a full recovery. This event is not considered a SAPSE, and **therefore does not trigger the SDC**, as post-operative bleeding is an acknowledged risk of this procedure, and monitoring, escalation and management was appropriate post identification of the developing haematoma. Although the health service should complete open disclosure in this circumstance, the SDC requirements are not mandated. | **Scenario B:**There is an emergency on the ward and nursing staff fail to complete Terry’s post-surgical wound monitoring and clinical post-operative observations. Several hours later Terry presses the call bell to inform staff of breathing difficulty. Nursing staff recognise that the wound drain is not functioning, and a large haematoma has developed, compromising Terry’s breathing. Terry is reviewed by the surgeon who immediately transfers Terry to surgery. The haematoma is successfully decompressed, bleeding controlled and drain re-sited. Terry requires admission to the intensive care unit for monitoring of his airway, but recovery progresses otherwise without complication. This event is a SAPSE, and **therefore requires SDC**, because Terry required a moderate increase in treatment, therefore sustaining ‘moderate’ harm. In this instance, the harm resulted from a process failure (post-surgical monitoring).See the [***Victorian Duty of Candour Guidelines***](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx)for more information. |

#### Restrictive interventions

Restrictive interventions (the use of bodily restraint and seclusion) may be used in designated health services if the requirements of the *Mental Health Act 2014* are met. Restrictive interventions can be used where it is necessary to prevent imminent and serious harm to the person or to another person or in the case of bodily restraint—to administer treatment or medical treatment to the person. There is broad agreement that the experience of being restrained and secluded can be profoundly distressing and traumatic for consumers, and steps are being taken in Victoria with the aim of eliminating these practices within 10 years as recommended by the Royal Commission into Victoria’s Mental Health System. See the Department of Health website on the Framework for reducing restrictive interventions: [Framework for reducing restrictive interventions (health.vic.gov.au)](https://www.health.vic.gov.au/practice-and-service-quality/framework-for-reducing-restrictive-interventions).

A restrictive intervention would be unlikely to constitute a SAPSE if a consumer experienced psychological harm as it is not an unexpected harm of the use of restrictive interventions. However, a restrictive intervention could constitute a SAPSE if the consumer experienced harm that was not expected to arise from these practices. Examples include if a consumer’s arm was broken during the use of restraint, or if a consumer was found unresponsive after a period of seclusion.

### Severe harm

The *Health Services (Quality and Safety) Regulations 2020* defines ‘severe’ harm as harm that causes a permanent lessening in functioning of an individual that is unrelated to the natural course of a person’s illness or underlying condition. Severe harm can lead to a person experiencing a permanent impairment or disability, or death.

In VHIMS, this level of harm corresponds to an ISR 1 rating. Severe harm is considered to have occurred if the patient has experienced, or is likely to experience:

* an *unexpected* duration of pain (beyond 3 months), that impairs the patient’s ability to return to pre-event level of function (persistent pain)
* a need for life-saving surgical or medical intervention
* a shortened life expectancy
* permanent or long-term loss of function or disability
* death directly related to the adverse event and not due to a natural cause or an underlying condition.

#### Sentinel events

Sentinel events are a subset of a SAPSE that result in serious harm to, or death of, a patient. Sentinel events must be reported via the Safer Care Victoria sentinel events portal, along with the required review and reporting processes, and the SDC process must occur for these patients.

See the Victorian Sentinel event guide for further information on the 11 subcategories, and what to report: [Victorian sentinel events guide\_0.pdf (safercare.vic.gov.au)](https://www.safercare.vic.gov.au/sites/default/files/2019-06/Victorian%20sentinel%20events%20guide_0.pdf).

#### Reportable deaths to the Office of the Chief Psychiatrist (OCP)

There may be some instances where a reportable death to the OCP may also trigger the SDC. This may include but is not limited to:

* death of an inpatient in a public mental health inpatient unit
* death of an inpatient on approved leave, or an inpatient who has absconded from the inpatient unit
* death of a mental health consumer on a non-psychiatric ward during a mental health admission.

For such an event to meet the SAPSE definition, it must have occurred whilst the patient was receiving health services from a health service entity and be unintended or unexpected harm.

Please see the Reportable Deaths: Chief Psychiatrist’s Guideline, regarding reportable deaths to the OCP: [reportable-deaths-chief-psychiatrist-summary.pdf (health.vic.gov.au)](https://www.health.vic.gov.au/sites/default/files/migrated/files/collections/policies-and-guidelines/r/reportable-deaths-chief-psychiatrist-summary.pdf).

#### Serious Incident Response Scheme (SIRS)

The Serious Incident Response Scheme (SIRS) is an initiative that helps prevent and reduce incidents of abuse and neglect in residential aged care services. A health service entity that is also an approved provider for the purposes of the Commonwealth *Aged Care Act 1997* will have to comply with both regulatory regimes of SIRS and SDC. See the Australian Government site on SIRS: [Serious Incident Response Scheme (SIRS) | Australian Government Department of Health and Aged Care](https://www.health.gov.au/initiatives-and-programs/serious-incident-response-scheme-sirs).

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| **Case example 3 – Severe harm**Sam is a 23-year-old football player with a leg bone deformity that causes pain when walking or running. Sam sees an orthopaedic surgeon who explains that surgery, involving an overnight stay in hospital, is required. Sam agrees and signs consent and the procedure is completed the following month. The surgery finishes at 8:30pm and Sam is taken back to the ward with patient-controlled analgesia (PCA). The only post-surgical clinical note states “neurovascular observations”. During the night, Sam complains of increasing leg pain, however the nurse does not escalate Sam’s concerns. The overnight staff do not review Sam’s foot or perform neurovascular observations. In the morning, the surgeon arrives to review the patient. Sam is distressed and explains the nursing staff did not believe the reported pain overnight. The surgeon reviews Sam’s leg and makes a preliminary diagnosis of compartment syndrome, noting there is foot drop present. The surgeon immediately prepares Sam for urgent surgery and the SDC process is commenced. The nurse-in-charge apologises for the interaction with the nurse overnight, and for the complication requiring a return to surgery. The event is entered into the clinical incident management system. Sam requires 4 further surgeries, a large skin graft and a hospital admission of more than 5 weeks.Sam is informed that full foot movement may not be regained, a splint will likely be required for ongoing use and that a return to football will not be possible. The hospital offers Sam access to a social worker to help with the application process to the National Disability Insurance Scheme (NDIS) and Centrelink.This event is considered a sentinel event and a SAPSE, and thereby triggers SDC provisions, because Sam has suffered permanent or long-term loss of function or disability, therefore sustaining ‘severe’ harm.See the [*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx) for more information. |

### Prolonged psychological harm

The *Health Services (Quality and Safety) Regulations 2020* defines ‘prolonged psychological’ harm as psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days. This type of harm results from an adverse event and causes, or is likely to cause, mental or emotional trauma, behavioural changes, loss of enjoyment in life, or psychological symptoms that require psychological or psychiatric care.

**Health service entities should adopt a patient-centred approach when determining whether prolonged psychological harm has occurred.**

Prolonged psychological harm may result from an experience that, in the opinion of a registered health practitioner:

* likely requires counselling or psychiatric treatment lasting more than 28 days after a SAPSE and/or
* renders a patient unable to resume all their normal activities for at least 28 days after a SAPSE.

Psychological harm may result from adverse events, including trauma, violence and abuse, which occur while a patient is receiving services or care from a health service entity.

Abuse can be verbal or psychological, and can include, but is not limited to sexual abuse, psychological ill-treatment, acts of omission which constitute neglect, exploitation, defamation, discriminative and organisational abuse (including racism) where:

* the health service entity did not take appropriate action to safeguard against such abuse occurring

or

* where abuse occurred during the provision of a health service within a health service entity[[23]](#footnote-24).

Sexual safety incidents and racism are two examples of SAPSE resulting from abuse that require SDC compliance.

#### Sexual safety incidents

Sexual safety incidents in bed-based mental health services must currently be rated a minimum ISR 2 (to ensure escalation to senior management for timely review and response, as well as oversight and monitoring). If appropriate, these incidents can be classified as ISR 1. The classification of sexual safety incidents, including mandated ISR, is currently the focus of review and updated guidance will be provided when this is completed. Please refer to the Chief Psychiatrist guidelines for more information regarding promoting sexual safety: [Promoting sexual safety (health.vic.gov.au)](https://www.health.vic.gov.au/mental-health/promoting-sexual-safety).

**Racism**

Racism may be considered a SAPSE if the event fulfils the criteria of prolonged psychological harm. [Victoria’s Charter of Human Rights and Responsibilities](https://www.humanrights.vic.gov.au/for-individuals/human-rights/) contains 20 basic rights that promote and protect the values of freedom, respect, equality, and dignity, supporting the right to access safe healthcare that is void of discrimination. If the patient suffers psychological harm for a continuous period of at least 28 days post a discriminative or racial event, then the SDC process must be followed. Aboriginal and Torres Straight Island patients are over 40 per cent more likely to experience racism in a health setting than any other group in Victoria.[[24]](#footnote-25)

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| **Case example 4 – Prolonged psychological harm**Lee is preparing for abdominal surgery to repair a large hernia that has been symptomatic for a few years. The surgeon has discussed the procedure, and later the anaesthetist comes to review Lee’s history. Lee recalls difficulty waking up post a previous anaesthetic and the anaesthetist notes this. Later that day Lee is taken to theatre. 30 minutes into the procedure, Lee’s heart rate increases and blood pressure rises. The anaesthetist decides to give more anaesthetic. When in recovery, Lee describes being awake during the surgery and feeling the surgeon operating. Lee describes how traumatic this was and begins to cry. The staff console Lee and the anaesthetist comes to speak with Lee. The anaesthetist explains that this is a rare occurrence and apologises. The anaesthetist then calls the on-call psychiatrist for assessment. The event is entered into the clinical incident management system. The clinical team feel this event is likely to cause Lee prolonged psychological harm, therefore meeting the definition of a SAPSE and triggering SDC requirements. See the [*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx) for more information.Lee is reviewed by the psychiatrist at the hospital who diagnoses the surgical complication as a traumatic event. They prescribe diazepam and continue to monitor Lee for the next 4 days. Over the next month, Lee suffers flashbacks and nightmares almost daily and cannot attend to normal daily activities. Lee’s mood becomes very low, dietary intake declines and Lee withdraws from family and friends. Lee is subsequently diagnosed with post-traumatic stress disorder (PTSD) and depression a month after the event. Three months post the event, Lee still suffers flashbacks and remains on medication for PTSD and depression. |

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| **Case example 5– Prolonged psychological harm**Cameron presents to an emergency department (ED) accompanied by several family members. Cameron has some chest pain, dizziness and slurred speech and is eventually seen by a physician who completes the admission, noting Cameron identifies as Aboriginal. The physician records Cameron’s medical history including poorly managed diabetes and that Cameron is a current smoker and consumes alcohol. Cameron explained that they had not been drinking prior to the ED presentation although to the physician, Cameron appears intoxicated. The physician concludes that Cameron had a minor fall due to being intoxicated and tells Cameron and family they “shouldn't have come to ED for such minor issues and to go to their general practitioner”. Cameron and family are distressed by this, concerned that a more serious health issue is being missed. Cameron states they are being discriminated against because of their Aboriginality. Cameron then visits the local Aboriginal community-controlled health organisation (ACCHO) to see a GP and remains distressed from the ED incident. The GP refers Cameron to the social and emotional wellbeing service to see a counsellor/psychologist. Cameron receives treatment over the next five weeks to address the psychological distress resulting from the ED experience. Cameron later calls the hospital’s Aboriginal Hospital Liaison Officer (AHLO) and explains the events that led to the psychological distress. The AHLO then contacts the ED clinical services director (a registered health practitioner) who records the event in the health service clinical incident management system. Cameron’s physical health issue has been addressed, however in the ED clinical services director’s opinion, this event has caused Cameron ‘prolonged psychological’ harm, therefore meeting the definition of a SAPSE and triggering SDC requirements.See the [*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx) for more information. |

### Self-reported harm

If a patient identifies they have experienced harm that was not recorded by the health service entity, the entity must report this within their clinical incident management system. If the event is considered a SAPSE as per a registered health practitioner, usual SDC processes should occur. If it falls outside this criteria, open disclosure should still occur, and a meeting be offered to the patient if appropriate.

The SDC process starts at the time the SAPSE is identified, whether that be through notification via a clinical incident management system, or via a patient self-reporting the harm event. If there was delayed identification of the SAPSE, health service entities should clearly explain and document the rationale for the delay and the steps undertaken to reduce the risk of the event recurrence and to improve timely identification of future events.

## Cases involving more than one health service entity or patient

### SAPSE occurs at another health service entity:

Where a SAPSE has occurred at another health service entity (e.g. the patient was transferred for treatment at another entity after the SAPSE occurred), collaboration is strongly recommended with the other health service entity.

* It is recommended that the health service entity in which the SAPSE occurred should lead the SDC process.
* If this is not practicable, both parties are to agree who will lead the SDC process.

### SAPSE occurs across more than one health service entity:

In the case of a SAPSE that involves two or more health service entities (i.e. events at each entity likely contributed to the harm), the health service entities should discuss how to conduct the SDC process, but all entities should participate.

If the harm has occurred in two or more health services entities, one of which is in another state, the Victorian service must still meet SDC requirements.

### Cases involving multiple patients

There may be instances where multiple people are harmed from a single event. The health service entity should initiate the SDC once the SAPSE has been identified and follow up individually with each patient harmed by the event. Where multiple people are harmed from a single event and the health service entities are unsure how to conduct this process, SCV may offer guidance to the health service entities.

Where the SAPSE affects multiple patients, it may be appropriate to conduct a joint meeting with those involved. However, consent is necessary and must be obtained by the health service entity from each party involved.

## Escalation process for disagreements

### Escalation within a health service entity

Health service entities should have an agreed process to manage the scenario where an adverse event occurs, and two or more registered health practitioners disagree as to whether an event constitutes a SAPSE (which then triggers the SDC). This process should be approved and endorsed by the Chief Executive Officer (CEO) or their delegate(s).

### Escalation when SAPSE occurs at another health service entity

If a SAPSE occurs at another health service entity and there is a refusal to conduct SDC or the parties cannot agree on the process, this must be escalated to the Secretary. The Secretary may defer these concerns to other bodies such as the Chief Quality and Safety Officer (CQSO).

### Escalation when SAPSE occurs across multiple health service entities

If two or more health service entities involved in an event disagree as to whether the event constitutes a SAPSE, or there is a disagreement about how to conduct the SDC process, these matters should be escalated to the Secretary. The Secretary may defer these concerns to other bodies such as the Chief Quality and Safety Officer (CQSO).

### Escalation for disputed self-reported harm

If a patient self-reports a harm that they believe constitutes a SAPSE, and this is disputed by a registered health practitioner the health service entity should provide the patient with a means of escalation to mediate the disagreement. This point of escalation may be:

* the internal consumer liaison officer (or equivalent)
* the [Health Complaints Commissioner](https://hcc.vic.gov.au/) (HCC), or
* the [Mental Health Complaints Commissioner](https://www.mhcc.vic.gov.au/) (MHCC).
* The [Chief Aboriginal Health Advisor](https://www.health.vic.gov.au/health-strategies/aboriginal-health) (for Aboriginal and Torres Strait Islander patients).

## Non-compliance with SDC

Non-compliance with SDC can be identified through:

* data provided to the Victorian Agency for Health Information (VAHI)
* internal audits of the health service entity or a direct complaint to the health service entity
* information provided to the Department of Health (DH), SCV, or the Minister for Health, the Minister for Ambulance Services or the Minister for Mental Health
* a complaint to the Health Complaints Commissioner (HCC) or the Mental Health Complaints Commissioner (MHCC).

Where minor incidents of non-compliance (i.e. not all stages followed, or timelines altered) or self-reported non-compliance of SDC are identified, SCV may work with health service entities to assist them to improve practice.

Where major incidents or repeated non-compliance occurs, there are a number of informal and formal options that may be pursued including the Minister for Health publishing a statement setting out the name of a relevant health service entity. See the [*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx) for more details.

# Patient considerations

Patient consideration is pivotal when undertaking SDC. Although this section of the Framework highlights some vulnerable groups, clinicians should acknowledge that when harm has occurred, every patient is vulnerable and may have lower capacity for self-advocacy than usual. The support persons of patients who have suffered harm will also require support throughout the process. There may also be intersectionality between the groups highlighted below.

## Patients with learning difficulties or cognitive impairment

For patients with learning difficulties or cognitive impairment, ensure:

* communication is in a format that is accessible
* necessary supports, including the patient’s usual carer or representative, are available
* Health service liaison officers are made available.

## Patients with mental illness

The *Mental Health Act 2014* outlines the rights of people receiving compulsory mental health treatment and aims to protect and support the rights of people living with mental illness. This includes the right to nominate support people, who can receive information and support decision-making. Clinicians should ensure they have considered the appropriate communication approach for these cases.

**Note**: Patients under the *Mental Health Act 2014* may have lower capacity for self-advocacy and be less able to protect themselves from harm.[[25]](#footnote-26)

See the DH site on presumption of capacity for guidance on informed consent: [Presumption of capacity (health.vic.gov.au)](https://www.health.vic.gov.au/practice-and-service-quality/presumption-of-capacity).

## Paediatric and Young People cases

Together with family members/carers, assess whether a child should be informed of the SAPSE. Consider the child’s maturity, their wishes about their treatment and their parents’/family members/carers wishes. Where the SAPSE occurs in relation to a child or young person, the health service entity should consider the best way to incorporate all family members/carers who have responsibility for the child. In the case of separated families this may be via one or more meeting(s) depending on the situation.

Where the child is considered to have capacity to provide medical consent, parents’ involvement would be comparable to that of parents’ involvement in consent to treatment for the child. The team should decide capacity on a case-by-case basis.

See the Office of the Public Advocate site for information on medical treatment for people aged under 18 years, in relation to decision making capacity: [Children under 18 years - Office of the Public Advocate](https://www.publicadvocate.vic.gov.au/medical-treatment/children-under-18-years).

## Language considerations

Qualified health interpreters should be considered, and utilised where indicated, throughout the SDC process. Using family members or friends as interpreters is not adequate for the SDC process.

Health service entities may also consider translating materials into the preferred language for the patient, however this may not be available for every case.

## Patients with visual, hearing, or other impairment

Arrange appropriate supports based on the patients’ specific needs to ensure effective communication. This could include organising a qualified health interpreter, such as an Auslan Certified Specialist Health Interpreter. The patient’s usual carer or representatives are important to the process and may provide valuable insights, but they should not be used in place of professionally trained interpreters.

## Cultural considerations

Health service entities should incorporate cultural considerations into the SDC process ensuring appropriate resources, liaison and support are made available for the patient and family where indicated. The SDC process must prioritise the needs of the patient and support persons and be conducted in a way that is culturally safe and meaningful to them.

### Aboriginal and Torres Strait Islander peoples

Cultural safety is an important consideration when implementing SDC for Aboriginal and Torres Strait Islander peoples. This means the environment is safe for Aboriginal and Torres Strait Islander peoples, where there is no assault, challenge or denial of their identity and experience[[26]](#footnote-27).

Culturally unsafe practice comprises any action which diminishes, demeans, or disempowers the cultural identity and wellbeing of an individual, whereas culturally safe practice is where there is a positive recognition of Aboriginal culture enabling individuals and communities to feel respected and safe.

It is important to understand that historically, hospitals were places of trauma where babies were removed or where family were sick and died. In addition to this, many Aboriginal people have a fear of hospitals due to concerns about racism and unconscious bias.

Health service entities and their staff who are carrying out SDC with Aboriginal and Torres Strait Islander peoples, and their support persons, must be proficient in cultural safety and respect Aboriginal ways of being, knowing and doing. All health service entities and staff have a role in providing culturally safe services. The cultural expertise of Aboriginal hospital liaison officers (AHLO) also plays an important role in supporting Aboriginal patients. All Aboriginal patients and their support persons should be asked if they would like to see the AHLO in those health service entities that have this program.

Health service entities may consider notifying the Chief Aboriginal Health Advisor of any potential, agreed or disputed SAPSE involving Aboriginal and Torres Strait Islander carers or family.

See the Aboriginal and Torres Strait Islander cultural safety framework for more information: [Aboriginal and Torres Strait Islander cultural safety (health.vic.gov.au)](https://www.health.vic.gov.au/health-strategies/aboriginal-and-torres-strait-islander-cultural-safety?utm_medium=email&utm_campaign=HeadsUp---Consultation-open-to-all-staff&utm_content=health.vic.gov.au%2Fhealth-strategies%2Faboriginal-and-torres-strait-islander-cultural-safety&utm_source=comms.health.vic.gov.au).

# Governance, training and support

## Local policy and procedure recommendations

Health service policies must embed SDC as a key element of healthcare. For example:

* Explicitly outline the requirements of the SDC process in employee contracts (including casual and sessional) and policies. Consider including a question on SDC when interviewing candidates.
* Add SDC as a standing agenda item to all quality and safety committee meetings to enhance visibility of the process.
* Identify how SDC is embedded in risk management and clinical governance processes, including adverse events and complaints management.

The health service entity's policy around open disclosure and SDC should align with other related governance and operational processes, such as incident reporting and reviews, complaints management and confidentiality requirements.

## Roles and Responsibilities

### Board chair and members

* Ensure the necessary governance structures for the SDC process are in place in their health service entities.
* Ensure adherence to relevant reporting requirements, including SDC requirements in the annual report.
* Ensure action is taken to address gaps in compliance with SDC.

### Chief executive officer (CEO)

* Ensure they are displaying the principles of a just culture.
* Consider appointing a SDC expert to educate, advocate and mentor on SDC. This expert can build relationships and navigate between professions, units and organisational levels.
* Ensure staff can access training and information on SDC.
* Ensure the necessary processes are in place when a SAPSE occurs.

### Quality and safety staff

This may be an appointed SDC representative. After a SAPSE, the health service entity SDC representative:

* ensures SDC requirements are followed
* ensures staff are appropriately trained in the SDC process
* supports training, debriefing and planning the SDC meeting
* considers alerting insurers and legal representatives if needed
* ensures the SDC process has been completed through VHIMS or an equivalent system
* advises the board when the SDC process has not been implemented fully.

### Health service staff

Health service entities will identify staff involved in each stage of the SDC process.

Specific staff will:

* be required to have completed training for SDC and understand the process and local policies for SDC
* need to know how to use their clinical incident management system and input all cases of harm to patients as soon as practicable
* immediately inform a line manager when a SAPSE occurs to trigger the local SDC procedure
* clearly document all conversations with patients and/or support persons throughout the SDC process.

## Education and training

Health service leadership must ensure that all staff, especially casual or sessional staff, are aware of the SDC and aware that it builds on the open disclosure principles.

SCV has developed training modules on the SDC process that are available for clinicians and health service staff, but it will be at the health service entity’s discretion who should complete this training. It is suggested that any clinician involved within the SDC process should be adequately trained.

Health service entities may consider implementing the following measures to support the education of staff in SDC:

* appoint current employee(s) as SDC expert(s)
* include clear information in onboarding documents, internal policies and contracts
* mandate staff training, including:
* SCV e-learning modules on the SDC process and introduction to open disclosure, available on the SCV website: [Learning and education | Safer Care Victoria](https://www.safercare.vic.gov.au/e-learning)
* Aboriginal and Torres Strait Islanders’ cultural safety training
* Give staff the opportunity to observe SDC meetings to enhance their capabilities.

### Open disclosure training

Literature shows clinicians have little in-depth knowledge of how to conduct an open disclosure process highlighting that the process and communication skills required are difficult to approach without adequate training[[27]](#footnote-28).

Clinicians who have had open disclosure training feel more prepared, confident and comfortable with disclosing errors to patients[[28]](#footnote-29) [[29]](#footnote-30).

In addition to the e-learning outlined above, health service entities may consider providing staff with additional resources in open disclosure available from:

* the [Australian Commission on Safety and Quality in Health Care](https://www.safetyandquality.gov.au/our-work/clinical-governance/open-disclosure)
* the [Victorian Department of Health](https://www.health.vic.gov.au/quality-safety-service/open-disclosure-resources-and-tools)

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## Supporting staff after a SAPSE

Healthcare staff involved in a SAPSE may experience feelings of stress, anxiety or guilt.

Through the SDC process the emotional health of staff members is important. Health service entities should consider:

* providing practical and social support for the staff member, such as transport home or contacting next of kin
* providing peer support and directing staff to the Employee Assistance Program, counselling services or equivalent
* conducting a planning meeting before the SDC meeting.
* Recognise vicarious trauma risk and ensure culturally appropriate employee assistance programs/supports are in place.

Research has shown that adequate preparation for the SDC meeting allows time for clinicians to deal with their emotions and provides a more successful and compassionate message to the patient[[30]](#footnote-31). Staff should also de-brief after the incident and after the SDC meeting.

# Consumer Awareness

Educational patient facing materials around a health service create early awareness that errors can occur. This can help decrease unrealistic patient expectations[[31]](#footnote-32).

Ensure information is available to patients and support persons when harm does occur. This may include information provided by:

* the DH
* the Australian Commission on Safety and Quality in Health Care (ACSQHC)
* locally adapted information about the SDC process.

This should also include information on how to make a complaint about the SDC process to the HCC or the MHCC, as well as professional complaints to the Australian Health Practitioner Regulation Agency (Ahpra).

Health service entities should also have this information available on their website.

**Note:** Online consumer information on the SDC and health service entity requirements will be available on the Better Health Channel website from late 2022.

# Helpful Resources

#### Legislation / Instruments / Regulations

[*Ambulance Services Act 1986 (legislation.vic.gov.au)*](https://content.legislation.vic.gov.au/sites/default/files/2021-09/86-114aa047%20authorised.pdf)

[*Health Legislation Amendment (Quality and Safety) Act 2022*](https://www.legislation.vic.gov.au/as-made/acts/health-legislation-amendment-quality-and-safety-act-2022)

[*Health Services Act 1988 (legislation.vic.gov.au)*](https://content.legislation.vic.gov.au/sites/default/files/2022-03/88-49aa175%20authorised.pdf)

[*Health Services (Quality and Safety) Regulations 2020*](https://www.legislation.vic.gov.au/as-made/statutory-rules/health-services-quality-and-safety-regulations-2020)

[*Mental Health Act 2014 (legislation.vic.gov.au)*](https://www.legislation.vic.gov.au/in-force/acts/mental-health-act-2014/023)

[*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Victorian%20Duty%20of%20Candour%20Guidelines%20.docx)

#### Further resources

[Aboriginal and Torres Strait Islander cultural safety (health.vic.gov.au)](https://www.health.vic.gov.au/health-strategies/aboriginal-and-torres-strait-islander-cultural-safety?utm_medium=email&utm_campaign=HeadsUp---Consultation-open-to-all-staff&utm_content=health.vic.gov.au%2Fhealth-strategies%2Faboriginal-and-torres-strait-islander-cultural-safety&utm_source=comms.health.vic.gov.au)

[Chief psychiatrist guidelines (health.vic.gov.au)](https://www.health.vic.gov.au/key-staff/chief-psychiatrist-guidelines)

[Framework for reducing restrictive interventions (health.vic.gov.au)](https://www.health.vic.gov.au/practice-and-service-quality/framework-for-reducing-restrictive-interventions)

[Just-Culture-in-adverse-event-reviews-factsheet.pdf (safercare.vic.gov.au)](https://www.safercare.vic.gov.au/sites/default/files/2022-08/Just-Culture-in-adverse-event-reviews-factsheet.pdf)

[Learning and education | Safer Care Victoria](https://www.safercare.vic.gov.au/e-learning)

[Mental Health Act 2014 handbook](https://www.health.vic.gov.au/practice-and-service-quality/mental-health-act-2014-handbook)

[Children under 18 years - Office of the Public Advocate](https://www.publicadvocate.vic.gov.au/medical-treatment/children-under-18-years)

[Open disclosure | Australian Commission on Safety and Quality in Health Care](https://www.safetyandquality.gov.au/our-work/clinical-governance/open-disclosure)

[Open disclosure resources and tools (health.vic.gov.au)](https://www.health.vic.gov.au/quality-safety-service/open-disclosure-resources-and-tools)

[Promoting sexual safety (health.vic.gov.au)](https://www.health.vic.gov.au/mental-health/promoting-sexual-safety)

[SCV-Just-Culture-Guide-for-Health-Services.pdf (safercare.vic.gov.au)](https://www.safercare.vic.gov.au/sites/default/files/2022-08/SCV-Just-Culture-Guide-for-Health-Services.pdf)

[SCV-Leadership-safety-culture-factsheet.pdf (safercare.vic.gov.au)](https://www.safercare.vic.gov.au/sites/default/files/2022-08/SCV-Leadership-safety-culture-factsheet.pdf)

[Victorian sentinel events guide\_0.pdf (safercare.vic.gov.au)](https://www.safercare.vic.gov.au/sites/default/files/2019-06/Victorian%20sentinel%20events%20guide_0.pdf)

[Statutory Duty of Candour and protections for SAPSE reviews | Safer Care Victoria](https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour)

[The Australian Open Disclosure Framework | Australian Commission on Safety and Quality in Health Care](https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework)

[Victoria’s Charter of Human Rights and Responsibilities](https://www.humanrights.vic.gov.au/for-individuals/human-rights/)

[Victorian health incident management policy. (nla.gov.au)](https://nla.gov.au/nla.obj-2803595290/view)

[Victorian Health Incident Management System Minimum Dataset | health.vic.gov.au](https://www.health.vic.gov.au/publications/victorian-health-incident-management-system-minimum-dataset)

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