Statutory Duty of Candour

**Hospital Acquired Complications**

**This document outlines considerations and common hospital acquired complications (HACs), and examples of when they could be considered a serious adverse patient safety event (SAPSE), triggering the Statutory Duty of Candour[[1]](#footnote-2) (SDC). These examples were developed by the Victorian Perioperative Consultative Council (VPCC) and Safer Care Victoria (SCV).**

The Australian HAC list can be found at <https://www.safetyandquality.gov.au/our-work/indicators/hospital-acquired-complications>.

### What is a SAPSE?

In Regulation 3B of the *Health Services (Quality and Safety) Regulations 2020* (the Regulations), a SAPSE is defined 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:

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 being suffered by the patient.

To avoid doubt, this includes an event that is identified following discharge from the health service entity.[[2]](#footnote-3)

A sentinel event is a subset of SAPSE. Please visit <https://www.safercare.vic.gov.au/notify-us/sentinel-events> for more information.

### What is the SDC?

The SDC refers to 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*.

If a patient suffers a SAPSE in the course of receiving care, the health service entity responsible owes a SDC to the patient and must do the following unless the patient opts out:

1. provide the patient with:
2. a written account of the facts regarding the SAPSE;
3. an apology for the harm suffered by the patient;
4. a description of the health service entity's response to the event;
5. the steps that the health service entity has taken to prevent re-occurrence of the event;
6. any prescribed information; and
7. comply with any steps set out in the [*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-10/Victorian%20Duty%20of%20Candour%20Guidelines%20-%20FINAL.docx).

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| **Key messages*** A patient-centred approach should always be taken when deciding if an event is a SAPSE, and whether the SDC should be completed.
* Open disclosure must occur for all cases of harm and near miss, and the [Australian Open Disclosure Framework](https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework) should otherwise be followed for events that do not meet the definition of a SAPSE.
* The intent of the SDC is for health services to review adverse events or outcomes, and openly communicate with patients and their next-of-kin when things go wrong.
* It is important to note that apologies provided under the SDC are protected from use within a civil or disciplinary proceeding[[3]](#footnote-4), and do not imply fault or liability. For the option of completing a SAPSE review (i.e. a protected review), the event must be deemed a SAPSE.
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## Considerations when determining if an event is a SAPSE

When assessing a HAC to determine if it fits the definition of a SAPSE, there must be a linkage to an adverse event. Consider the following when determining an event meets the SAPSE definition.

#### Consent

* As part of the consent process, all patients need to be provided a clear indication of the risks, benefits and alternatives for any procedure.
* A HAC would not be considered a SAPSE when it is a recognised complication of the procedure, or where procedural risks are high due to surgical or patient factors and the patient has been informed and has consented appropriately.

#### Risk mitigation

Appropriate preventative strategies for risks must be in place. Missed strategies that may have contributed to the HAC should be reviewed to determine if the event meets the definition of a SAPSE.

An event resulting in moderate-severe harm would meet the definition of a SAPSE if:

* nil appropriate policies, procedures or Clinical Guidelines were in place to manage the complication
* appropriate policies, procedures and Clinical Guidelines were in place, but not followed
* there was delayed or missed recognition and response of patient deterioration that led to the HAC or adverse event
* a complication was poorly managed that led to the HAC
* appropriate preventative strategies were missed that led to the HAC
* a health practitioner was not credentialed or qualified to perform the procedure
* the patient died due to missed identification of deterioration post-operatively
* a health service could not manage a surgical complication, as the level of response was outside of the health service scope, leading to further deterioration.

#### Common HACs

* A proportion of infections are deemed as a recognised complication of surgery and the risk is discussed as part of the consent process pre-operatively. Therefore, to be a SAPSE, an infection must be linked with an adverse event.
* An unplanned ICU admission may be appropriate to monitor a patient post-operatively, but it should be reviewed if it was the result of an appropriate escalation of care and clinical management of a complication, or if it was secondary to a preventable event.
* Health services should have robust processes to facilitate reviews of uncommon or higher than expected complication rates when compared to benchmark and peers. Such instances should have robust review processes, including cluster review of events where applicable. Identification of individual SAPSE should be managed as required.

Further resources and training are available at <https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour>.

## Common examples

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| Example | Considerations  |
| **3rd or 4th degree perineal laceration** | Perineal laceration is considered a known possible complication of pregnancy and labour and therefore, it is usually not a SAPSE. However, health services may opt to do a cluster review for these cases to ensure good review practice. If appropriate policy and Clinical Guidelines were not followed as they should have been (or nil guidelines available), and the patient suffered moderate-severe harm as a result, e.g. the tear was missed or repair delayed, or there was mismanagement in the labour and delivery, then it would be deemed a SAPSE. |
| **Anaphylaxis, e.g. to anaesthetic, medication, antibiotic, or food** | If a patient suffered anaphylaxis due to the prescription and administration of a medication, or consumption of a food allergen, there are some considerations as to whether this would meet the criteria of a SAPSE:* delay or mismanagement during the response to anaphylaxis that led to further harm or death
* known allergy, but lack of documentation, process or handover that led to incorrect administration or consumption.
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| **Anastomotic leak** | Whilst anastomotic leak following bowel resection is a known risk of the procedure, it should be appropriately discussed as part of the consent process. Due to the known complication, these cases would not be a SAPSE unless there was a delayed/inappropriate response to deterioration or a significant technical failure in performing the procedure. |
| **Bleed following an epidural injection or lumbar puncture** | Damage to a vessel following epidural with minor bleeding is a known complication in this setting, and therefore would generally not be a SAPSE. Any other instances of moderate-severe harm, e.g. neurological injury or need for spinal surgery, especially associated with anticoagulation management or procedure error, would likely be a SAPSE. |
| **Cardiac complication – STEMI/NSTEMI** | If the patient had an unknown cardiac issue and suffered a cardiac complication, it should be reviewed whether there were missed signs or symptoms or interventions that led to the STEMI/ NSTEMI. This will assist in determining if the event is a SAPSE.Note that some cardiovascular risk factors may have been discussed as part of informed consent and shared decision making, and the increased risk/potential risk was accepted. In this case, the complication would not be a SAPSE unless the risk factors were excessive, and/or those a reasonable practitioner would have chosen (and had the opportunity) to optimise the patient in the time available. |
| **Death** | Health services should have robust procedures in place for the monitoring and review of all deaths that occur, including consideration as to whether the circumstances leading up to the patient’s death would meet the definition of a SAPSE. Some examples of where a death may not be a SAPSE could be: * death as a result of natural progression of disease or natural causes
* death following a high-risk surgical procedure, such as in the instance of an elderly patient with hip fracture requiring repair. If the patient (or their delegate) consented to the surgical risks, including the possibility of death/palliative procedure, and died following the procedure, it may not be deemed a SAPSE if protocol was followed to ensure the safest treatment.
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| **Deep sternal wound infection** | Deep sternal wound infection is a rare but recognised complication of a median sternotomy that causes the patient significant morbidity. Although it can result in moderate-severe harm, it may not meet the criteria of a SAPSE if the risk was consented and all reasonable steps were taken to prevent and appropriately manage. Health services should review their aggregate rates benchmarked against other hospitals that provide cardiac surgery. Hospitals that are outliers should be prompted to review their practices and risk-adjusted rates.If the post-operative management of a sternal wound infection led to moderate-severe harm, then this event would likely meet the definition of a SAPSE. |
| **Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)** | Relevant Venous Thromboembolism (VTE) prophylaxis guidance or protocol should be followed and decisions about prophylaxis documented. It is important that there is a thorough history, which includes:* a VTE risk assessment, with consideration given to the patient’s medication list
* alerts for previous DVT/PE
* any contraindications to pharmacological prophylaxis.

In the instance of a patient sustaining moderate-severe harm or death due to DVT and/or PE as a result of care delivery which was not aligned to policy/guidelines, the event would likely fulfil the criteria of a SAPSE.  |
| **Delirium** | Delirium may not always be preventable, however risk mitigation requires adequate assessments on admission and policy/Clinical Guidelines to be followed. Additionally, there should be strategies in place to ensure that the patient is kept safe if they have delirium.There are a number of factors known to increase delirium risk and result in secondary harm, and where these things are not managed appropriately and the patient suffers moderate-severe harm as a result, this should be considered a SAPSE. |
| **Enterotomy**  | Whilst enterotomy is a known risk of some abdominal procedures, it should be discussed during the consent process. Additionally, a thorough assessment should be completed prior to concluding a surgical procedure to check for enterotomy. Noting that enterotomies may not always be visible on completion of a surgical procedure, some considerations as to whether this complication is a SAPSE may include:* if there is lack of identification intraoperatively due to incomplete review at the end of the procedure
* delayed recognition and response post-operatively.
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| **Fall** | Falls in health services are known to occur frequently, however there are a number of polices and guidelines in place to protect patients from falling, and they can be prevented in many cases.Due to the complexity of possible causes of falls, if a fall results in moderate-severe harm, e.g. a return to theatre for repair of a fracture or long-term disability, it will meet the definition of a SAPSE.There are multiple tools available for review of falls, including the Safer Care Victoria tool available at <https://www.safercare.vic.gov.au/improvement/projects/older-people-and-palliative-care/falls-review-tool-pilot-project>.  |
| **Implantable device infection** | Although implantable device infection is considered a known risk of surgery, the health service must ensure they are following appropriate policy and procedure in relation to the intraoperative and post-operative care to reduce the risk of infection. Where an implantable device should be changed or removed after a known period, failure to do so could result in moderate-severe patient harm and therefore be a SAPSE. For example:* sepsis and its complications from a ureteric or biliary stent not removed or changed at an appropriate interval)
* Inferior Vena Cava filter inadvertently remaining in situ and requiring major abdominal vascular surgery for removal.
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| **Loss of airway intraoperatively** | At times during anaesthesia or during critical care, there may be an unexpected loss of airway. If there was inability to oxygenate the patient with significant and prolonged desaturation, although there may be appropriate management when recognised, even if the patient did not suffer subsequent moderate-severe harm as a result, it will still require a review to understand why the loss of airway occurred and the completion of appropriate documentation, e.g. <https://www.safercare.vic.gov.au/news/difficult-airway-alert>.A lack of escalation of care resulting in deterioration, or an issue with recognition and response of the event leading to moderate-severe harm, or the event itself resulting in moderate-severe harm would determine the event as a SAPSE. |
| **Neonatal birth trauma** | Although neonatal birth trauma is an undesired outcome of labour, and attempts are made to avoid it, episodes of neonatal trauma may occur to preserve life. Health services must ensure they are following appropriate policy and Clinical Guidelines, and that pre-natal, labour, and post-natal management is appropriate. In the instance of care delivery, not following appropriate policy and/or guideline resulting in neonatal birth trauma, may mean the event fulfils the criteria of a SAPSE. |
| **Perforation – endoscope or colonoscope** | Although perforation during endoscopy and colonoscopy is a known complication of these procedures, it should be adequately discussed during the consent process and appropriate pre-operative assessment completed to avoid it as best as possible.Oesophageal perforation during a transoesophageal echocardiogram is likely to result in moderate-severe harm or even death and should be deemed a SAPSE. A conservatively treated rupture that has a good outcome may be an exception to this but where there is a need for surgery and/or stenting and/or subsequent oesophageal dilatation, the event would be deemed a SAPSE.A perforation of the colon, complicating colonoscopy and/or polypectomy, is a rare event however risk should be part of the documented informed consent. Its occurrence would not normally be considered a SAPSE if management was appropriate.Where there is failure to recognise, respond appropriately and/or delayed intervention for the complication, and additional patient suffering and/or harm, the event would constitute a SAPSE and would sometimes be a sentinel event. A cluster of perforations should result in a cluster review including the aggregate rate of post colonoscopy perforations.A splenic bleed necessitating splenectomy is also a rare but recognised complication of colonoscopy and whether or not the injury was appropriately managed would determine whether it was a SAPSE or sentinel event. |
| **Peripheral intravenous catheter (PIVC)/Central venous catheter (CVC)/Parenteral site infection** | There are a number of polices and guidelines in place to protect patients from developing a PIVC or CVC line infection, and they can be prevented in many cases. Where policy and procedure has been followed for infection prevention, it may not be a SAPSE.PIVC and CVC line infection rates should be known to a health service and compared with benchmarks. Where moderate-severe harm is sustained (such as septicaemia or endocarditis), then the event should be regarded as a SAPSE. |
| **Post-operative haematoma** | If a patient suffered a haematoma post-operatively to the surgical site, and all post-operative observations and management appear to be in line with policy, this may not be deemed a SAPSE as it is a complication of surgery which may not be unexpected.Mismanagement post-operatively and delay to response and recognition resulting in a moderate increase in treatment and moderate-severe harm would need to be considered when determining if this event is a SAPSE.  |
| **Postpartum haemorrhage** | Postpartum haemorrhage is considered a known complication of pregnancy and labour. Therefore, it is usually not a SAPSE. If appropriate policy and Clinical Guidelines were not followed as they should be or no guidelines were available and the patient suffered further harm as a result, then it could be deemed a SAPSE as it is likely to lead to moderate-severe harm and increased treatment. |
| **Pressure injury** | There are a number of polices and guidelines in place to protect patients from developing a pressure injury and they can be prevented in many cases. If the patient had a lack of pressure area care prevention strategies in place and irregular assessments that led to a pressure injury under the HAC category, then it is likely to be deemed a SAPSE. There may be a couple of exceptions, but these cases should be reviewed on a case by case basis.  |
| **Renal failure (acute kidney injury)** | Appropriate measures should be in place to reduce the risk of patients developing renal failure (or acute kidney injury), particularly if they have a history of kidney issues or higher risk factors for renal failure. If the mismanagement of a patient and/or lack of safe care or treatment has led to them developing renal failure and either moderate or severe harm, then this could fit the criteria of a SAPSE. |
| **Retained surgical product** | Retaining surgical products has a few different categories: 1. Surgical products being intentionally retained and planned return to theatre = Not a SAPSE
2. Items being retained and left in situ (risk of removal > risk posed) = Potentially not a SAPSE if no long-term consequence beyond index surgical procedure, and not fulfilling moderate-severe harm
3. Items retained inadvertently, resulting in a return to theatre, meeting moderate harm but not long-term harm = SAPSE, not a sentinel event
4. Items retained and fulfilling severe harm (i.e. needing lifesaving medical/surgical criteria or posing long-term harm) = SAPSE and sentinel event
5. An unplanned return to the operating theatre would be deemed a SAPSE, as the patient will have undergone a second anaesthetic and a potentially complicated procedure.
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| **Return to theatre** | An unplanned return to theatre, may not constitute a SAPSE if the event is well managed, and if all appropriate care and recognition of deterioration was sufficient. However, these events should be reviewed appropriately to ensure that all necessary care and safe treatment was provided, and that the likelihood of a return to theatre for a complication was discussed as part of the consent process pre-operatively. |
| **Surgical site infection**  | Infection is a known complication of surgery and the risk is likely discussed during the consent process pre-operatively in most cases. There are some considerations that may lead these events to being categorised as SAPSEs. For example:* delayed recognition (including missed identification) and response to signs of infection
* incomplete post-operative assessment/treatment leading to the development of necrotising fasciitis or septicaemia
* uncommon pathogens in the wound that were not treated appropriately due to a lack of microbiological assessment, leading to increased treatment and length of stay
* delay to commence IV antibiotics, leading to further harm.

Where there is a recall of a surgical product, e.g. a joint replacement, due to late recognition of a contaminated batch, this would constitute at least a SAPSE but would require notification and escalation to SCV and the Therapeutic Goods Administration (TGA).Open disclosure is appropriate for unplanned returns to theatre and where the infection results in the joint or implant having to be removed and replaced, and this may occur some months after the procedure. |
| **Unplanned ICU admission** | Where appropriate management of an event, e.g. unknown anaphylaxis or unexpected major haemorrhage, includes unplanned admission to ICU, it is not the unplanned admission to ICU that would trigger a SAPSE. The adverse event that has led to the unplanned ICU admission must be reviewed for level of harm sustained. If the event that led to the unplanned ICU admission is categorised as moderate-severe harm, then it would meet the criteria of a SAPSE, e.g. delayed recognition and deterioration in response to an event. |

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1. [↑](#footnote-ref-2)
2. Regulation 3B of the *Health Services (Quality and Safety) Regulations 2020*. See further definitions of moderate harm, severe harm and prolonged psychological harm in these Regulations also. [↑](#footnote-ref-3)
3. See section 128ZD of the *Health Services Act 1988*. [↑](#footnote-ref-4)