OPEN DISCLOSURE AND STATUTORY OF CANDOUR POLICY

Owner Title:	Approver Title:	Policy number:	Level:
Chief of Clinical Operations (or delegate)	Chief of Clinical Operations	CL.057	3
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BACKGROUND AND OBJECTIVES

In 2002 the Australian Council for Safety and Quality in Health Care (now the Australian Commission on Safety and Quality in Health Care) developed the National standard on Open Disclosure. This was endorsed by the Australian Health Ministers Conference in July 2003.

Open Disclosure facilitates an open and honest discussion with the young person and their support person(s), where appropriate, about an incident that resulted in harm to the young person while they were receiving care. Under the National Safety and Quality Health Service (NSQHS) Standards, Open Disclosure is mandated under Standard 1, Criterion 1.16.

As of 30 November 2022, the Health Legislation Amendment (Quality and Safety) Act 2022 (Vic) is enacted and the enforcement of the Statutory Duty of Candour (SDC) process is in effect. The process of SDC builds on the Open Disclosure process, with SDC being a legislative obligation in the event of a serious adverse patient safety event (SAPSE) and Open Disclosure being the process to follow in any other case of harm or near miss. If a patient suffers a SAPSE in the course of receiving health services, the health service entity responsible for providing those services owes an SDC to the patient.

The purpose of this policy is to support a just culture, transparency, accountability and the overall aim of improving safety and effectiveness of care, particularly in pursuit of ensuring that Orygen satisfactorily conducts the processes of Open Disclosure and SDC.

SCOPE AND EXCLUSIONS

This policy applies across clinical services including Orygen Recovery, Primary Services and MOST.

This policy applies to:

1. Staff of Orygen;
2. All other individuals engaged in activities reasonably connected with Orygen clinical service delivery. Typically, such individuals include (but are not limited to):
    a. contractors;
    b. students; and
    c. volunteers.

POLICY STATEMENTS

Clauses	Commitments
1	**The Guiding Principles of Open Disclosure**
1.1	The Statutory Duty of Candour (SDC) builds on the principles of Open Disclosure Framework. The reforms set out specific requirements to ensure a thorough response in the event of a serious adverse patient safety event (SAPSE).
1.2	Open and timely communication If things go wrong, the young person and/or their support person(s), where appropriate, should be provided with information about what happened in a timely, open and honest manner. The Open Disclosure and SDC processes are fluid and will often involve the provision of ongoing information.
1.3	Acknowledgement All adverse events should be acknowledged to the young person and/or their support person(s), where appropriate, as soon as practicable and initiate the Open Disclosure process.
2	**Medicolegal considerations and apology protections**
2.1	Open Disclosure A key barrier to Open Disclosure is the misconception that the acknowledgement of adverse events and an expression of regret constitutes an admission of liability or that it is implied. All Australian jurisdictions have enacted laws that protect expressions of regret or apology from use in legal settings.
2.2	Apology protections under Statutory Duty of Candour legislation Under the Victorian Statutory of Candour guidelines, an apology: • does not constitute an express or implied admission of liability for the death or injury; and • is not relevant to the determination of fault or liability in connection with that proceeding. The above applies whether the apology was made orally or in writing, and either before or after a civil proceeding. Apologies offered to young people will not constitute admissions of guild or liability, nor will they be admissible in civil proceedings. However, statements regarding a fact in issue, or tending to establish a fact in issue, are not protected under the legislation.
2.3	Apology or expression of regret The young person and/or their support person(s), where appropriate, must receive an apology or expression of regret for any harm that resulted from an adverse event. When the SDC applies, the young person and/or their support person(s) must receive an apology within 24 hours of Orygen becoming aware of a serious adverse patient safety event (SAPSE). An apology or expression of regret should include: • acknowledgment that harm or grievance has occurred; • an expression of sorrow or remorse; • a factual explanation of how the harm occurred; and • a commitment to the young person and their support person(s) that the underlying cause/s of the incident will be addressed. Suggested phrases to use: • ‘I am sorry’; ‘we are sorry’; • ’I/we am/are really sorry you had a reaction to drug X we prescribed you’; • ‘I/ we are sincerely sorry that this has occurred, we are investigating it now’; and/or • ‘I/we regret and apologise that this has occurred’. Both Open Disclosure and SDC apologies and/or statements should not contain speculative statements, an admission of liability or an apportioning of blame.

3	**Breaches**
3.1	There are current reporting obligations if a clinician has acted in a way that constitutes a 'prohibited act' or is notifiable under the Health Practitioner Regulation National Law. In these cases, the Australian Health Practitioner Regulation Agency (AHPRA) will be contacted as per usual procedure, and the apology protections do not prohibit this from occurring or from any disciplinary proceedings that follow in regard to the actual event.
3.2	Breaches of SDC obligations may be identified internally (e.g. internal audit, complaint made directly to Staff), externally (e.g. complaint to the Health Complaints Commissioner (HCC), Mental Health Complaints Commissioner (MHCC), Health Secretary or Minister's office, Department of Health, Safer Care Victoria) or as an outcome from an accreditation report. The relevant health legislation body may pursue legislative action or forward the report to the Secretary (in the case of reports made to either the HCC or MHCC).
4	**Recognition of the reasonable expectations of young person and their support person(s)**
4.1	The young person and their support person(s), where appropriate, can expect to be: • fully informed of the facts surrounding an adverse event and its consequences in an inclusive and accessible manner (e.g. language, mode, method of communication); • treated with empathy, respect and consideration; and • supported in a manner appropriate to their needs.
5	**Staff support**
5.1	Orygen will: • encourage individuals to recognise and report adverse events through all required internal and external channels; • prepare individuals through training and education to participate in Open Disclosure and SDC processes; and • support individuals through Open Disclosure and SDC processes.
6	**Integrated clinical risk management and systems improvement**
6.1	A thorough clinical review and investigation of adverse events and adverse outcomes should be conducted through processes that focus on the management of clinical risk. The information obtained about incidents from Open Disclosure and SDC processes should be incorporated into improvements related to quality of services.
7	**Governance**
7.1	Orygen has a Clinical Governance Framework, as well as Clinical Risk Policy and Procedures. Through these systems, adverse events are investigated and analysed to prevent them recurring.
8	**Confidentiality**
8.1	Orygen to conduct Open Disclosure and SDC with full consideration for the privacy and confidentiality of the young person, support person(s) and clinician, in compliance with relevant laws (including federal, state and territory privacy and health records legislation).

VALUES STATEMENT

Orygen was built on the foundations of accountability. Open Disclosure is integral to the delivery of safe and high-quality health care. It is crucial that Orygen adopts a consistent and young person-centred approach to information sharing that upholds young person rights, including accepting responsibility across our services.

DEFINITIONS

Term	Definition
Adverse event	is an incident that results, or could have resulted, in harm to a patient. A near miss is a type of adverse event.

	(as defined in Aust Commission on Safety and Quality in Health Care (2021) Incident Management Guide)
Harm	Impairment of structure or function of the body and/or any deleterious affect arising therefrom, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. Harm includes disease, suffering, impairment (disability) and death. • Disease – a psychological or physiological dysfunction; • Injury – damage to tissues caused by an agent or circumstance; • Suffering – experiencing anything subjectively unpleasant. This may include pain, malaise, nausea, vomiting, loss (any negative consequence, including financial) depression, agitation, alarm, fear or grief; or • 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.
Open Disclosure	An open discussion with a young person (and parents/guardian if under 18 as applicable or appointed due to the person living with a disability) about an incident(s) that resulted in harm to that young person while they were receiving 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.
SAPSE	A serious adverse patient safety event (SAPSE) is an event that: • occurred while the patient was receiving care 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 moderate or severe harm or prolonged psychological harm being sustained by the patient. For the avoidance of doubt, an event may be identified following discharge from the health service entity. A SAPSE is likely to be the equivalent of an Incident Severity Rating 1 or 2 event within RiskMan (Victorian Health Incident Management System – VHIMS) If a patient suffers a SAPSE in the course of receiving health services, the health service entity responsible for providing those services owes a SDC to the patient.
Staff	A person: • employed directly by Orygen; • provided to Orygen under an agreement with their employer (e.g. Melbourne Health or University of Melbourne); or • who is a visiting scholar or researcher (e.g. on sabbatical at Orygen).
Statutory Duty of Candour	The statutory duty of candour is a mandatory legal obligation, introduced in Victoria, to ensure that consumers of healthcare and their families are apologised to, and communicated with, openly and honestly, when things have gone wrong in their care. The communication should include the following: 1. a written account of the facts regarding the SAPSE; and 2. an apology for the harm suffered by the patient; and 3. a description of Orygen's response to the event; and 4. the steps that Orygen has taken to prevent re-occurrence of the event.
Support Person(s)	An individual who has a relationship with the young person, which can include: • parents/guardian (if under 18 or appointed due to the person living with a disability as applicable) • family members/next of kin • carers • nominated person

- friends, a partner or other person who cares for the young person
- guardians or substitute decision-makers
- social workers or religious representatives
- where available, trained client advocates

RELATED DOCUMENTS

This policy is to be read in conjunction with:

1. Open Disclosure Procedure
2. Orygen Recovery Clinical Incident Reporting and Investigation Procedure
3. Reportable Deaths Procedure
4. Primary Services Critical Incident Management Procedure
5. Protection of Children and Young People Policy
6. Protection of Children and Young People Procedure
7. Privacy Policy
8. Clinical Risk Policy
9. Clinical Risk Procedure
10. Clinical Governance Framework

REFERENCES

1. Charter of Human Rights and Responsibilities Act 2006 (Vic)
2. Freedom of Information Act 1982 (Vic)
3. Health Records Act 2001 (Vic)
4. Department of Human Services (2013) Open Disclosure for Victorian Health Services: A Guidebook
5. DHS, Melbourne.
6. Australian Commission on Safety and Quality in Healthcare (2013) Open Disclosure Framework
7. ACSQHC, Sydney
8. Department of Health Open Disclosure: General Principles for Open Disclosure
9. Deborah Glass OBE (2017) Apologies Victorian Ombudsman, Melbourne.
10. Wrongs Act 1958 (Vic)
11. Wrighton v Arnott [2005] NSWSC 637
12. Medical Board of Australia (2010) Good Medical Practice: A Code of Conduct for Doctors in Australia
13. Health Practitioner Regulation National Law 2009 (Cth)
14. Australian Standards requirements 3745-2010, 4083-2010
15. Department of Health (2010) Open Disclosure: General Principles for Open Disclosure DHS, Melbourne.
16. Victorian Duty of Candour Guidelines (legislative instrument)
17. Safer Care Victoria Statutory Duty of Candour (SDC) – Frequently asked question (FAQ) sheet
18. Health Services Act 1988 (Vic)
19. The Health Legislation Amendment (Quality and Safety) Act 2022 (Vic)

STAKEHOLDERS

Stakeholder (identified by Department or Title)	**Stakeholder category and description of involvement** (accountable, consulted, informed)
Chief of Clinical Practice	Consulted – for clinical expertise; has oversight of all clinical governance systems and is responsible to report to the relevant governing bodies

Chief of Clinical Operations	Consulted – for clinical expertise and oversight of safe and quality service delivery and operational governance
Director, Medical Services	Consulted – for medical and mental health care expertise and knowledge and oversight of safe and quality service delivery and clinical governance and oversight of medical workforce including students
Lived Experience Leads	Consulted – to ensure is young person centred, youth friendly and recovery orientated in language, steps and processes
General Counsel	Consulted – to ensure legislative compliance

REVISION AND APPROVAL HISTORY

Version	Revision Date	Summary
01	10.12.2021	First approved version
02	15.12.2022	Updated to reflect Statutory Duty of Candour legislation