



Relevant Audience:

All Board Members, AMPs, Management and Staff

Objective: VPH Governing Body/Board of Directors, Staff and Accredited Medical Practitioners (AMPs) support the practice and principles of Open Disclosure.

Rationale:

“Open Disclosure” is the open discussion of incidents that result in harm to a patient while receiving health care.

The underlying principles of Open Disclosure are:

1. Openness and timeliness of communication
2. Acknowledgement
3. Expression of Regret
4. Recognition of the reasonable expectations of patients and their support person
5. Staff support
6. Integrated risk management systems and system improvements
7. Good governance
8. Confidentiality

Outcome:

VPH has a clear and consistent approach to open communication and disclosure with consumers, patients and their carers following an Adverse Event with a view to fairness, accountability and transparency.

This governance policy/ statement will set out when and how Open Disclosure should occur.

Compliance with the Australian Commission on Safety and Quality in Health Care Standard 1 Governance for Safety and Quality in Health Care Organisations. In particular, standard 1.16, through implementing an Open Disclosure process based on the national open disclosure standard, including:

- An Open Disclosure program is in place and is consistent with the national Open Disclosure standard; and
- The clinical workforce are trained in Open Disclosure processes.

Method / Implementation:

Open Disclosure will be mandatory for an Adverse Event.

The CEO/DON or delegate is responsible for identifying and activating low level and high level responses and will oversee the Open Disclosure process.

Open Disclosure should be commenced as soon as practicable after the Adverse Event.

Initial assessment is required to determine the level of response

The individual who detected the incident should make an initial assessment of the incident. This may be in consultation with a colleague. The consideration will include the severity of harm and the level of response required.

In small practices, the causation of most adverse events will be able to be determined immediately, or soon after detection. For some, a review and investigation will need to be conducted before all the facts are known. In the latter scenario the initiation of open disclosure, acknowledgement and open disclosure should not be delayed.



All relevant organisations and authorities, such as indemnity insurance providers, should be notified immediately following detection of an adverse event.

The level of response required will be guided by the effect, severity and consequence of the incident. Table 1 below provides potential responses to incidents in which patients have, or may have been harmed.

Table 1: Potential responses to incidents of patient harm or potential patient harm

Incident type	Response
1. Harm from natural progression of condition or disease process <i>e.g. management of diabetes was unsuccessful</i>	Discuss and explain <i>(lower-level)</i>
2. Complication or natural disease progression a. Anticipated by patient/family via education and consent process b. Not anticipated by patient/family via education and consent process (go to 3) <i>e.g. patient not adequately informed of the possibility of side effects from beta blockers and feels that this would have altered their decision to proceed with treatment</i>	a. Discuss and explain (lower-level) b. Open disclosure <i>(higher or lower-level depending on severity)</i>
3. Patient harm/adverse event <i>e.g. adverse drug event (wrong vaccination given)</i> <i>e.g. patient fall during rehabilitation exercises</i>	Open disclosure (higher or lower-level depending on severity and impact on patient)
4. Clinical ('no harm') incident: reaches patient but no harm <i>e.g. medication error (no/minimal effect on patient)</i>	Generally disclose (lower-level)
5. Clinical ('near miss') incident: does not reach patient <i>e.g. an intercepted failure to follow up test results</i>	Decision based on: <ul style="list-style-type: none"> • context • circumstances • potential ramifications (lower-level)
6. Patient perception or report of harm <i>e.g. patient perception of delay in diagnosis resulting in poor patient outcome</i>	Discuss and agree on appropriate form of disclosure (higher or lower-level)



Table 2 describes lower-level and higher-level responses linked to criteria for harm that may be used to delineate lower-level and higher-level responses.

Table 2: Criteria for determining the appropriate level of response to an incident

	Criteria
Lower-level response	<ol style="list-style-type: none"> 1. Near misses and no-harm incidents 2. No permanent injury 3. No increased level of care (e.g. need for domiciliary care) required 4. No, or minor, psychological or emotional distress
Higher-level response	<ol style="list-style-type: none"> 1. Death or major permanent loss of function 2. Permanent or considerable lessening of body function 3. Significant escalation of care or major change in clinical management (e.g. present to emergency department, surgical intervention, other higher level of care) 4. Major psychological or emotional distress 5. At the request of the patient

Low level responses will be handled internally at the discretion of the CEO/DON as per the Risk Management Framework Governance Statement and Risk Management Policy at VPH, including the implementation of the VPH IIIR reporting process

High level responses will occur with assistance from the Board of Directors, Moores Legal and MDA National.

An offer to meet in person with the patient or family will occur for an Adverse Event. Such an offer may be declined by the patient or family.

Honesty and trust are central to the healthcare professional/patient and healthcare institution/patient relationships. VPH healthcare care professionals “want to do the right thing” by their patients.

The elements of Open Disclosure are an expression of regret, a factual explanation of what happened, the potential consequences and the steps being taken to manage the event and prevention of reoccurrence

VPH endeavours to work to a policy of no blame and focuses on the organisations systems and responsibilities. We strive to maintain professional accountability, and foster an environment where people feel supported and are encouraged to identify and report Adverse Events so that opportunities for systems improvements can be identified and acted on.

Communication should be open and honest, and immediate.

VPH endeavours to facilitate consistent and effective communication following Adverse Events. This includes communication between the following:

- a) Health care professionals.
- b) Health care professionals and patients and their support person.
- c) Health care professionals, health care managers and all staff.



Effective communication for patients commences from the beginning of an episode of health care and continues throughout the entire episode. We have an ethical responsibility to maintain honest communication with patients and their support person, even when things go wrong. With good communication when an Adverse Event occurs, we look at ways to prevent them from recurring.

VPH is committed to –

- a) provide an environment where patients and their support person receive the information they need to understand what happened;
- b) create an environment where patients, their support person, health care professionals and managers all feel supported when things go wrong;
- c) investigative processes to identify why Adverse Events occur;
- d) bring about any necessary changes in systems of clinical care, based on the lessons learned.

In implementing Open Disclosure, Management and Staff operate within VPH's;

- a) policies, procedures and processes;
 - b) within an integrated risk management framework and quality improvement processes;
 - c) in accordance with applicable Commonwealth State/Territory laws and regulatory regimes;
- and
- d) within particular requirements of insurance and employment contracts.

The **Principles** we have adopted and that form part of the VPH Open Disclosure process will include:

1. Openness and timeliness of communication

When things go wrong, the patient and their support person should be provided with information about what happened, in an open and honest manner at all times. The Open Disclosure process is fluid and may involve the provision of ongoing information.

2. Acknowledgment

All Adverse Events should be acknowledged to the patient and their support person as soon as practicable.

3. Expression of regret

As early as possible, the patient and their support person should receive an Expression of Regret for any harm that resulted from an Adverse Event. The *Wrongs Act 1958 (Victoria)* allows for an Expression of Regret.

4. Recognition of the reasonable expectations of patients and their support person

The patient and their support person may reasonably expect to be fully informed of the facts surrounding an Adverse Event and its consequence, treated with empathy, respect and consideration and provided with support in a manner that is appropriate to their needs. Support may include an offer of assistance or ex gratia payment, depending on the circumstances.

5. Staff support

VPH fosters an environment in which all staff are able and encouraged to recognise and report Adverse Events and are supported through the Open Disclosure process.

6. Integrated risk management and systems quality improvement

Investigation of Adverse Events and outcomes are to be conducted in accordance with VPH's Risk Management policies and procedures which are referenced to (AS/NZS 43601). This includes the documentation of incidents via the VPH IIIR reporting process.



7. Good governance

The Governing Body of VPH have endorsed the risk and quality improvement processes. The system of accountability is driven by management to ensure that changes are implemented and their effectiveness reviewed.

8. Confidentiality

Policies and procedures have been developed with full consideration of the patient's, carer's and staff's privacy and confidentiality, in compliance with relevant law, including Commonwealth and State/Territory Privacy and medical records legislation.

The **Key Steps** for the conduct of Open Disclosure – High Level Response will be:

1. Open Disclosure Team Meeting

Initial Open Disclosure Team Meeting and the completion of an Open Disclosure Plan.

2. Offer of Meeting

Offer to the patient/family/carer to meet to discuss the matter.

3. Open Disclosure Team Meeting

Discussion of approach for representatives at the Open Disclosure meeting.

4. Open Disclosure Meeting

Meeting between patient/family/carer and VPH's representatives.

5. Open Disclosure Documentation

Completion of the Open Disclosure documentation.

6. Report to Open Disclosure Team

Report back to Open Disclosure Team including a summary of the commitments given and how these will be followed up.

7. Lessons Learned

Ensure that lessons learned are communicated to the patient/family/carer, staff and AMPs.

Documentation:

The Open Disclosure process and meetings will be documented and kept securely.

Training:

The CEO/DON will oversee orientation and ongoing training resources about the Open Disclosure processes, which will include staff and AMPs. Records of education/training will be kept.

Reporting:

The CEO/DON will report information and data on Open Disclosure to the VPH Governing Body and Medical Advisory Committee.



Definitions:

Adverse event – An incident in which unintended harm resulted to a person receiving health care.

Expression of regret – An expression of sorrow for the harm experienced by the patient that will occur in accordance with the *Civil Liability Act*.

Higher level response - A comprehensive open disclosure process usually in response to an incident resulting in death or major permanent loss of function, permanent or considerable lessening of body function, significant escalation of care or major change in clinical management (e.g. admission to hospital, surgical intervention, a higher level of care or transfer to intensive care unit), or major psychological or emotional distress. These criteria should be determined in consultation with patients, their family and carers.

A higher level response may also be instigated at the request of the patient even if the outcome of the adverse event is not as severe.

Lower level response - A briefer open disclosure process usually in response to incidents resulting in no permanent injury, requiring no increased level of care (e.g. transfer to operating theatre or intensive care unit), and resulting in no, or minor, psychological or emotional distress (e.g. near misses and no-harm incidents). These criteria should be determined in consultation with patients, their family and carers.

VPH Governing Body – VPH Board of Directors

Open Disclosure - the open discussion of incidents that result in harm to a patient while receiving health care.

Team – CEO/DON and/or delegate representing the Board of Directors, Clinical Services Manager, admitting AMP and/or related Anaesthetist and key staff.

References and Supporting Documents:

S 01 F01	Std 1 Governance Management Plan
A 01 P04	Complaints Policy
A 01 P03	Control of Records & Documents Policy
TH 01 P02	Day Surgery Clinical Pathway Policy
TH 01 P03	Pre Admission Policy
TH 01 P04	Admission Policy
TH 01 F01	Clinical Handover & Risk/Alert Form
QMS 01	Quality Management System Manual
CF1 P02	Partnering with Consumers Policy
I1 P01	IIIR Policy
I1 WI01	IIIR Work Instruction
I1 F03	IIIR Form

Australian Commission on Safety and Quality in Healthcare (ACSQHC). Open Disclosure Program and supporting Resources. <https://www.safetyandquality.gov.au/our-work/clinical-governance/open-disclosure#open-disclosure-program>



Australian Commission on Safety and Quality in Healthcare (ACSQHC) 2013. Australian Open Disclosure Framework 2014. <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/australian-open-disclosure-framework-better-communication-better-way-care>

Australian Commission on Safety and Quality in Healthcare (ACSQHC). Implementing the Open Disclosure Framework Resources. <https://www.safetyandquality.gov.au/our-work/open-disclosure/implementing-the-open-disclosure-framework>

Australian Commission on Safety and Quality in Healthcare (ACSQHC), NSQHS Standards Guide for multi-purpose services and small hospitals 2017. [https://www.safetyandquality.gov.au/standards/nsqhs-standards/resources-nsqhs-standards#user-guides-for-the-nsqhs-standards-\(second-edition\)](https://www.safetyandquality.gov.au/standards/nsqhs-standards/resources-nsqhs-standards#user-guides-for-the-nsqhs-standards-(second-edition))

Australian Commission on Safety and Quality in Healthcare (ACSQHC). Open Disclosure – A Guide for Patients Booklet. <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/open-disclosure-guide-patients-booklet>

AS/NZS ISO 3100:2009 Risk Management – Principles and Guidelines

AS/NZS ISO 9001:2016 –Quality Management Systems – requirements

Australian Commission on Safety and Quality in Healthcare (ACSQHC). Standards Accreditation Workbook. <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/nsqhs-standards-accreditation-workbook>

Office of the Australian Information Commissioner. Australian Privacy Principles. <https://www.oaic.gov.au/privacy/australian-privacy-principles/read-the-australian-privacy-principles>

Private Patients Hospital Charter (PPHC)

Australian Charter of Healthcare Rights (Second Edition)

Privacy Act 1988

Privacy amendment Act 2004

Privacy Act Amendment (Private Sector 2000)

Privacy Amendment (Enhancing Privacy Protection) Act 2012

State Health Records Information & Privacy Act 2002

Victorian Health Records Act 2001

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