Open Disclosure Process

Policy and procedure GCL 014

Policy and procedures are mandatory and caregivers must follow the content

1. Purpose

To provide guidance to caregivers on how to communicate openly with patients/clients and their carers/family when an incident results in harm to that patient/client, whilst receiving health care.

2. Scope

3.1 This document applies to Australian Divisions of St John of God Health Care (SJGHC).

3. Policy

3.2 This policy is to be read in conjunction with:

(a) SJGHC policy GCL 003 Clinical Incident Management, which describes the requirement for caregivers to report clinical incidents through the incident reporting system; and

(a) The Australian Commission on Safety and Quality in Health Care's Australian Open Disclosure Framework. Sydney, Australia (2013).

3.3 All Divisions must create an environment in which all relevant caregivers are:

(a) encouraged and enabled to recognise and report incidents and adverse events;

(b) prepared through education to participate in open disclosure; and

(c) supported through the open disclosure process.

3.4 The principles of confidentiality must be ensured and maintained throughout the process of incident investigation and open disclosure.

Determining the Level of Open Disclosure

3.5 Following an adverse event, the divisional departmental manager shall assess and determine the level of open disclosure response required. This process will:

(a) involve consultation with his/her manager, the treating medical practitioner, and where relevant, the divisional CEO (or delegate); and

(b) consider the severity of harm and the level of response required. The level of response required will be determined by the effect, severity or consequence of the incident. Examples of incident types and suggested responses are described in **Appendix C**.

3.6 A comprehensive open disclosure process (high-level response) is usually required in response to an incident resulting in:

(a) death or major permanent loss of function;

(b) permanent or considerable lessening of body function;

(c) significant escalation of care or major change in clinical management (e.g., admission to hospital, surgical intervention);

(d) a higher level of care or transfer to intensive care unit; or

(e) major psychological or emotional distress.

3.7 A high-level response may also be initiated at the request of the patient even if the outcome of the adverse event is not as severe. Please refer to **Appendix B** for high-level response flowchart which illustrates general principles and may be modified by Divisions according to local context.

3.8 A briefer open disclosure process (low-level response) is usually required in response to incidents resulting in:

(a) no permanent injury;

(b) no increased level of care (e.g., transfer to operating theatre or intensive care unit); or

(c) no or minor, psychological or emotional distress (e.g., near misses and no-harm incidents).

3.9 Please refer to **Appendix B** for low-level response flowchart which illustrates general principles and may be modified by Divisions according to local context.

Key Components of Open Disclosure

3.10 In undertaking any open disclosure:

(a) Divisions should refer to **Appendix D**, which provides an overview of key components of the open disclosure process.

(b) The patient/client will receive an apology or expression of regret for any harm that resulted from an adverse event. An apology or expression of regret may include the words 'I/we are sorry for the distress the situation has caused you', but must not contain speculative statements, admission of liability or apportionment of blame.

(c) The patient/client will be provided with information about what happened in a timely, open and honest manner.

(d) The patient/client can expect to be fully informed of the facts surrounding an adverse event and its consequences, treated with empathy, respect and consideration, and supported in a manner appropriate to their needs.

(e) During the open disclosure planning process, the open disclosure team should determine what the patient/client expects in regards to written feedback regarding the adverse event.

Documentation requirements

3.11 A written record must be maintained in relation to the open disclosure process in the patient's clinical record, which should include the following information:

(a) patient/client contact details

(b) all discussions – time, date, location and attendees

(c) all information provided – written and verbal

(d) agreements and commitments made

(e) progress notes of the clinical situation

(f) copies of letters sent to patient/client and their GP

3.12 A notation or brief summary that the open disclosure process has been completed shall be recorded in the incident management system.

Education Requirements

3.13 All Divisions must:

(a) support key caregivers to be expert leaders in the open disclosure process. e.g., Chief Executive Officer, Director of Nursing, Medical Director and the Clinical Risk and Quality Manager.

(b) ensure other relevant caregivers have access to and complete open disclosure education, as relevant to their roles.

Evaluation Requirements

3.14 All Divisions must undertake routine evaluation (at least annually, and more frequently where local risk assessments indicate the need) of open disclosure processes, to identify gaps and improvement opportunities.

4. Procedure

High-level Response

4.1 A senior appropriate caregiver must be identified (e.g., Divisional Medical Director, Director of Nursing, Department Head) to coordinate the open disclosure process with other key stakeholders. This individual should not be directly involved in the care of the patient who experienced the adverse event.

4.2 A suitable caregiver must be identified to lead the open disclosure meeting, and selection criteria for this role include:

(a) appropriate seniority to ensure credibility;

(b) experience in the open disclosure process;

(c) familiarity with the facts of the adverse event; and

(d) ability to provide feedback and reassurance to the patient/client in the medium to long term future.

4.3 The treating medical practitioner should be involved in the open disclosure planning process and/or meeting, where appropriate.

4.4 Group Legal is to be consulted for advice in planning the open disclosure meeting with the patient/client.

4.5 For high-level open disclosure response procedures, Divisions shall refer to **Appendix A**.

Low-level Response

4.6 For lower-level open disclosure response procedures an appropriate caregiver (e.g., Department/Unit Manager, Shift Coordinator, Clinician) may undertake the process. Please refer to **Appendix B**.

5. Dictionary

Term	**Meaning** for the purposes of this policy document
Adverse event	A clinical incident where an injury/harm results from healthcare or complication thereof, instead of the underlying disease. Ref 7.3(a)
Apology	An expression of sorrow, sympathy and (where applicable) remorse by an individual, group or organisation for a harm or grievance. It includes the words 'I am sorry' or 'we are sorry'. An apology may also include an acknowledgement of responsibility, which is not an admission of liability.
Harm	Impairment of structure or function of the body and/or any deleterious effect arising from disease, injury, suffering, disability and death. Harm may be physical, social or psychological.
Incident	An event or circumstance resulting from health care which could have, or did lead to unintended and/or unnecessary harm to a patient/consumer. Ref 7.3(a)
Patient/Client	Patient/client or carers/family provided that patient consent has been given.

Term	Meaning for the purposes of this policy document
Open disclosure	An open discussion with a patient/client about an adverse event. 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 describe their experience, and an explanation of the steps being taken to manage the event and prevent recurrence. Ref 7.3(b)

6. Accountabilities

Accountability	Responsible position
Communication	
Implementation	
Monitoring	
Review	

7. Related and supporting documents

7.1 Legislation

Nil

7.2 Related SJGHC policy or document

(a) GCL 003 Clinical Incident Management

7.3 Supporting documents

(a) Western Australia Department of Health. Clinical Incident Management Policy 2015.

(b) Australian Commission on Safety and Quality in Health Care 2013. Australian Open Disclosure Framework. Sydney, Australia. Available at: https://www.safetyandquality.gov.au/wp-content/uploads/2013/03/Australian-Open-Disclosure-Framework-Feb-2014.pdf

(c) The Department of Health Western Australia. Open Disclosure Policy Statement 2015.

(d) New South Wales Department of Health. Open Disclosure Policy 2014.

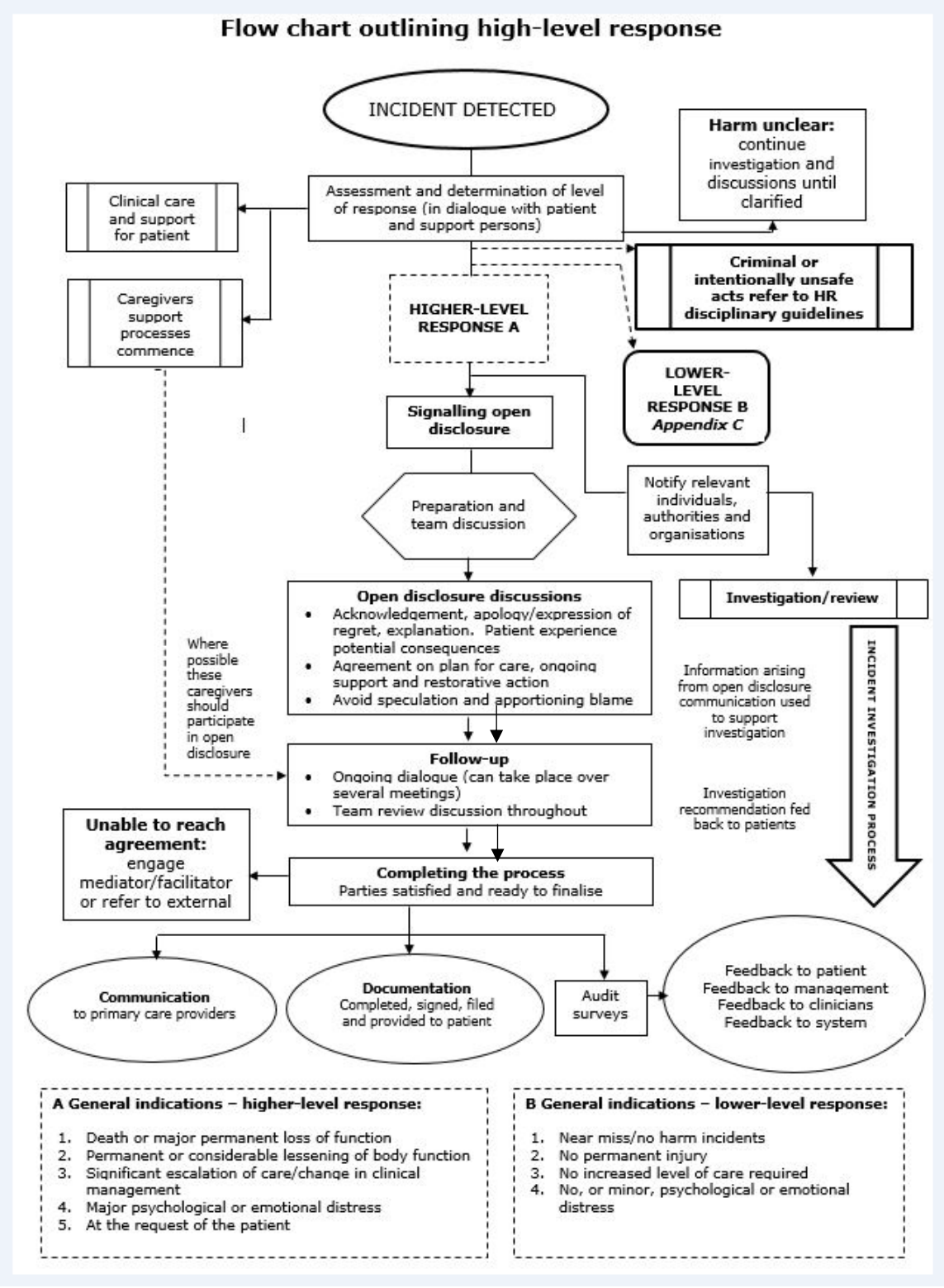
(e) The Victoria Department of Health. Open Disclosure and Management of Adverse Events 2014.

8. Current and previous versions

Version number	Policy Owner	Approver	Date approved
New*	Group Manager Clinical Risk	Group Director of Medical Services	08/2017

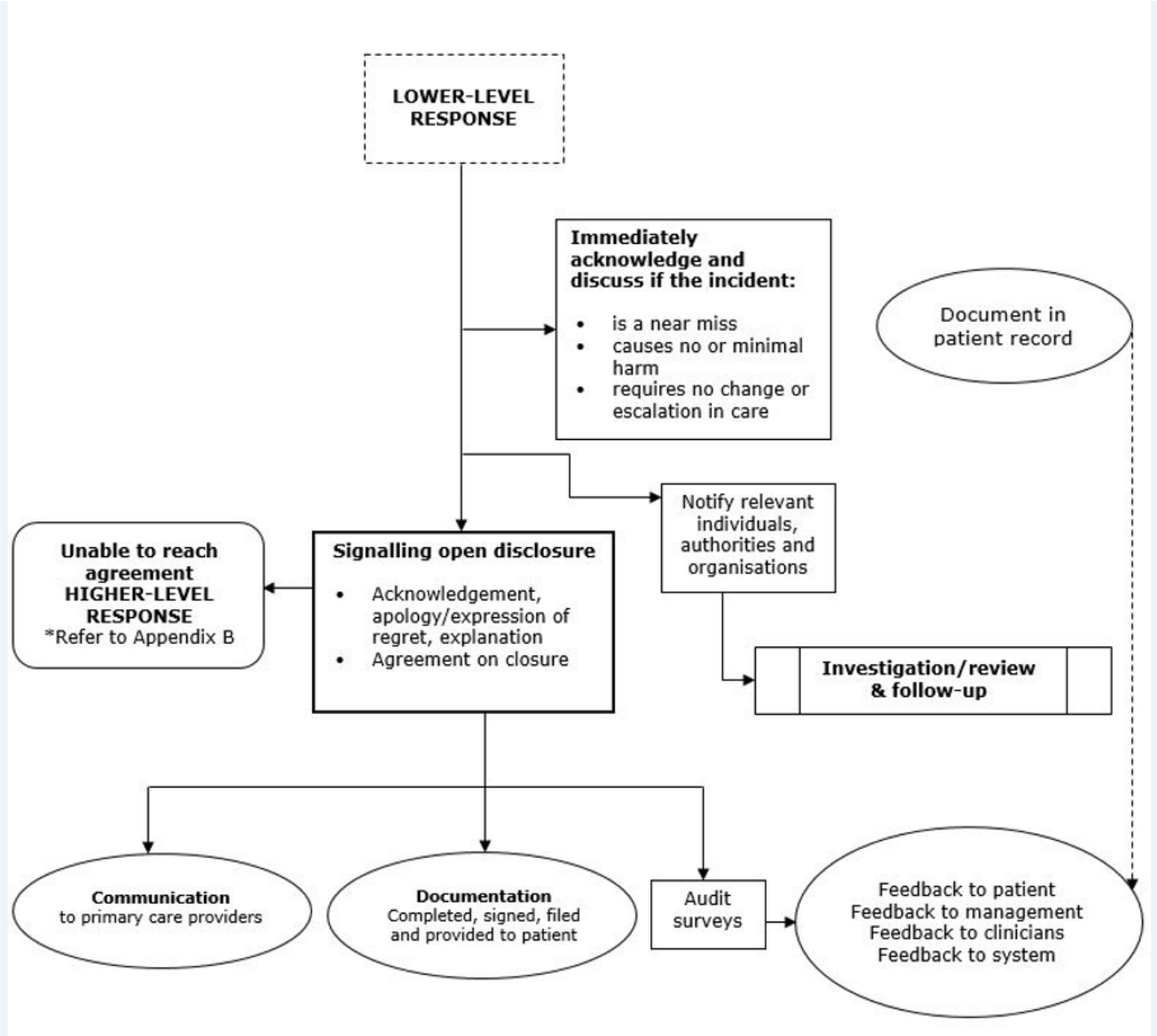
*Previously encompassed in clinical incident management

Appendix A - High-Level Open Disclosure Procedure



Reference: Australian Commission on Safety and Quality in Health Care 2013. Australian Open Disclosure Framework. Sydney, Australia

Appendix B - Lower-level Open Disclosure Procedure



Reference: Australian Commission on Safety and Quality in Health Care 2013. Australian Open Disclosure Framework. Sydney, Australia

Appendix C - Potential response to various situation and incidents

Incident type	Response
1. Harm from natural progression or condition or disease process *e.g., a treatment for cancer was unsuccessful*	Discuss and explain *(lower level)*
2. Complication or natural disease progression 2.1. Anticipated by patient/family via education and consent process 2.2. Not anticipated by patient/family via education and consent process (go to 3) *e.g., patient not adequately informed of the possibility of respiratory complications of general anaesthesia and feels that this would have altered their decision to proceed with treatment*	a. Discuss and explain *(lower-level)* b. Open disclosure *(higher or lower-level depending on severity)*
3. Patient harm/adverse event *e.g., adverse drug event (wrong dose medication)*	Open disclosure *(higher or lower-level depending on severity and impact on patient)*
4. Clinical ('no harm') incident: reaches patient but no harm *e.g., medication error (no/minimal effect on patient)*	Generally disclose *(lower-level)*
5. Clinical ('near-miss') incident: does not reach patient *e.g., an intercepted wrong-patient biopsy*	Team decision based on: • context • circumstances • potential ramifications *(lower-level)*
6. Patient perception or report of harm *e.g., patient perception of delay in diagnosis resulting in poor patient outcome*	Discuss and agree on appropriate form of disclosure *(higher or lower-level)*

Reference: Australian Commission on Safety and Quality in Health Care 2013. Australian Open Disclosure Framework. Sydney, Australia

Appendix D - Key Components of Open Disclosure Discussions

1. Introductions

The patient, their family and carers is told the name and role of everyone attending the meeting, and this information is also provided in writing.

2. Saying sorry

A sincere and unprompted apology or expression of regret is given on behalf of the healthcare service and clinicians, including the words 'I am' or 'we are sorry'. Examples of suitable and unsuitable phrasing of an apology are provided in the resource titled *Saying Sorry: a guide to apologising and expressing regret in open disclosure* available at www.safetyandquality.gov.au/opendisclosure

3. Factual explanation: providers

A factual explanation of the adverse event is provided, including the known facts and consequences of the adverse event, in a way that ensures the patient, their family and carer understand the information, and considers any relevant information related earlier by the patient, family and carers. Speculation should be avoided.

4. Factual explanation: patient, family and carer(s)

The patient, family and carers have the opportunity to explain their views on what happened, contribute their knowledge and ask questions (the patient's factual explanation of the adverse event). It will be important for the patient, their family and carers that their views and concerns are listened to, understood and considered.

5. Personal effect of the adverse event

The patient, family and carers is/are encouraged to talk about the personal effect of the adverse event on their life.

6. Plan agreed and recorded

An open disclosure plan is agreed on and recorded, in which the patient, their family and carer(s) outline what they hope to achieve from the process and any questions they would like answered. This is to be documented and filed in the appropriate place and a copy provided to the patient, their family and carers.

7. Pledge to feed back

The patient, their family and carers is assured that they will be informed of any further reviews or investigations to determine why the adverse event occurred, the nature of the proposed process and the expected time frame. The patient, their family and carers are given information about how feedback will be provided on the investigation findings, by whom and in what timeframe, including any changes made to minimise the risk of recurrence.

8. Offer of support

An offer of support to the patient, their family and carers should include:

a. ongoing support including reimbursement of out-of-pocket expenses incurred as a result of the adverse event

b. assurance that any necessary follow-up care or investigation will be provided promptly and efficiently

c. in the relevant settings, clarity on who will be responsible for providing ongoing care resulting from the adverse event

d. contact details for any relevant service they wish to access

e. information about how to take the matter further, including any complaint processes available to them

9. Support for patients and staff

The patient, their family and carers engages in open disclosure with staff. Staff are supported by their colleagues, managers and health service organisation, both personally (emotionally) and professionally, including through appropriate training, preparation and debrief.

10. Other health service organisations

In cases where the adverse event spans more than one location or service, relevant clinicians and staff will ensure, where possible, that all relevant staff from these additional institutions are involved in the open disclosure process.

If necessary, hold several meetings or discussions to achieve these components

Reference: Australian Commission on Safety and Quality in Health Care 2013. Australian Open Disclosure Framework. Sydney, Australia