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| **Title** | **Open Disclosure** | | | | |
| **Code** | ANZ-FKC-PL-RM&Q-005 v3 | | | | |
| **Scope** | All ANZ Fresenius Kidney Care staff | | | | |
| **Purpose** | This policy describes the management of the open disclosure process to ensure it is conducted in a timely, supportive and effective manner for the patient, their support person and staff. | | | | |
| **Creation / Review Date** | 21-6-2021 | **Review Date** | 22-6-2021 | **Date of next review** | June 2024 |
| **Related Documents** | Clinical Quality & Risk Management SOP AP PT ref 887<br>Customer/Stakeholder Feedback Management AP PT ref 963<br>ANZ-FKC-PL-RM&Q-007 Root Cause Analysis & Clinical Investigations | | | | |
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| **Approved By** | Lisa Cresswell, Project Coordinator Clinical IT Systems<br><br>Signature Date:<br>Carolyn Chenoweth, Quality & IPC Manager<br><br>Signature Date: | | **Approved By** | Louisa Moloney, Regional Manager QLD & NT<br><br>Signature Date: | |
| **Change History** | Date and summary of changes to the document<br>21-6-2021 Policy reviewed and updated<br>30-06-2017 Policy reviewed, addition to training information, no approval required<br>27-03-2013 Policy created by Carolyn Chenoweth, Quality & IPC Manager | | | | |

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| **Abbreviations** | DCM – Dialysis Clinic Manager<br>FKC – Fresenius Kidney Care Clinics<br>HR – Human resources<br>ISR – Incident Severity Rating<br>RiskMan – electronic risk management system<br>WHS – Work Health & Safety |

| **Policy** | |
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| Definition of Open Disclosure | Open disclosure is the open discussion of adverse events that result in harm to a patient while receiving health care with the patient, their family and carers. |
| Principles for open disclosure | All FKC clinics follow the principles of Open Disclosure in accordance with the Australian Open Disclosure Framework:<br>1. Open and timely communication<br>2. Acknowledgement<br>3. Apology or expression of regret<br>4. Supporting and meeting the needs and expectations of patients, their family and carers<br>5. Supporting and meeting the needs and expectations of those providing health care<br>6. Integrated clinical risk management and systems improvement<br>7. Good governance<br>8. Confidentiality |
| Admission of liability | When discussing an incident with a patient and their support person, under the open disclosure process FKC staff should take care not to: |

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| | 1. state or agree that they are liable for the harm caused to the patient;<br>2. state or agree that another healthcare professional is liable for the harm caused to the patient;<br>3. state or agree that the healthcare organisation is liable for the harm caused to the patient. |

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| | When discussing an incident with a patient and their support person, under the open disclosure process FKC Clinic staff may:<br>a. acknowledge that an adverse event has occurred;<br>b. acknowledge that the patient is unhappy with the outcome;<br>c. express regret for what has occurred;<br>d. provide known clinical facts and discuss ongoing care (including any side effects to look out for);<br>e. indicate that an investigation is being, or will be undertaken to determine what happened and prevent such an adverse event happening again;<br>f. agree to provide feedback information from the investigation when available;<br>g. provide contact details of a person or persons within the health care organisation whom the patient can contact to discuss on-going care. |
| Process | Open Disclosure Process commences when a patient suffers unintended harm during their treatment.<br>Key considerations and actions during the open disclosure process are:<br>1. Detecting and assessing incidents<br>2. Signalling the need for open disclosure<br>3. Preparing for open disclosure<br>4. Engaging in open disclosure discussions<br>5. Providing follow-up<br>6. Completing the process<br>7. Maintaining documentation |
| Detecting and assessing incidents | 1. Identifying adverse events<br>1.1. Adverse events (incidents) are identified, recorded and reported in accordance with the FKC Clinic Incident Management System.<br>1.2. A patient or carer expresses concern or dissatisfaction with the patient's health care.<br>2. Level of response is determined by the Dialysis Clinic Manager.<br>Low level response – an adverse event (incident) where there is no permanent injury or increased level of care.<br>High level response – an adverse event (incident) where the impact or consequence is:<br>- death or major permanent loss of function<br>- permanent lessening of body function<br>- need for surgical intervention, transfer to higher level of care<br>3. Management is initiated appropriate to the level of the incident. |
| Management of low-level incident<br>For example, See Figure 1 & 2 in appendix | FKC Clinic staff may discuss incidents with patients and their support people, under the guidance of their Dialysis Clinic Manager and in accordance with the Australian Open Disclosure Framework<br>Aspects discussed are:<br>• acknowledgement of the incident and the patient's response to the incident<br>• details of the incident and ongoing clinical care of the patient (including any possible clinical outcomes of the incident)<br>• explanation of the corrective action being taken to prevent the incident from occurring again<br>• contact details of the Dialysis Clinic Manager if further discussion is necessary<br>• document the Open Disclosure actions taken in the patients' health care records<br>• document on the Electronic incident management system, open disclosure actions and outcomes. |
| Management of high-level incident | The Dialysis Clinic Manager will contact the relevant Regional Manager and Director of Clinical Services & Education to initiate the high-level incident management process.<br>The FKC Clinic Open Disclosure Team will<br>1. establish the basic clinical and other facts;<br>2. assess the event to determine the level of response; |

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| For example, See Figure 1 & 2 in Appendix | 3. identify who will take responsibility for discussion with the patient and their support person;<br>4. consider the appropriateness of engaging patient support including the use of a facilitator or a patient advocate;<br>5. identify immediate support needs for staff involved;<br>6. ensure that all team members maintain a consistent approach in any discussions with the patient and their support person;<br>7. consider legal and insurance issues, both for the organisation and health care professionals, and notification to relevant people. |

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| Team | The Director FKC or Director of Clinical Services & Education will determine members of the Open Disclosure Team |
| Communication | Communication with the patient and their support person will include;<br>• an expression of regret that the incident occurred<br>• a factual explanation of what happened, without drawing any conclusions<br>• an explanation of the current or potential consequences<br>• the steps being taken to manage the event, including the patient's ongoing care and support<br>• the actions being taken to prevent recurrence<br>• the opportunity for the patient and their support person to raise questions and obtain answers<br>• assistance to manage the open disclosure process<br>• contact person to discuss any issues. |
| Staff training | • The Dialysis Clinic Managers and FKC Clinics Care Open Disclosure team will receive necessary training to manage the open disclosure process.<br>• Dialysis Clinic Managers will educate their clinic staff in the management of low level incidents.<br>• Open disclosure training is located on the Fresenius Learning Centre for DCMs<br>• Open disclosure principle training is provided via Fresenius Clinic induction program |
| Reporting | Outcomes of Open Disclosure management of high level incidents will be reported to the Director FKC |
| **Performance Measurements** | When the high-level incident management process is activated the process will be reviewed by the Fresenius Kidney Care Leadership Team |
| **Evaluation** | The Open Disclosure Policy will be reviewed in accordance with the Documentation Framework policy. |
| **References** | • Australian Commission on Safety and Quality in Health Care<br>Australian Open Disclosure Framework, 2014<br>https://www.safetyandquality.gov.au/sites/default/files/migrated/Australian-Open-Disclosure-Framework-Feb-2014.pdf<br><br>• Australian Commission on Safety and Quality in Health Care. National Model Clinical Governance Framework.<br>Sydney: ACSQHC; 2017.<br><br>• AZ/NZS ISO 31000:2018 Risk management – Principles and guidelines<br><br>• SA Health Patient Incident Management and Open Disclosure<br>http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/safety+and+quality/governance+for+safety+and+quality/patient+incident+management+and+open+disclosure |

## APPENDIX

| Incident type | Response |
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| 1. Harm from natural progression of condition or disease process<br>*e.g. a treatment for cancer was unsuccessful* | Discuss and explain<br>*(lower-level)* |
| 2. Complication or natural disease progression<br>a. Anticipated by patient/family via education and consent process<br>b. Not anticipated by patient/family via education and consent process (go to 3)<br>*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)*<br>b. Open disclosure *(higher or lower-level depending on severity)* |
| 3. Patient harm/adverse event<br>*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<br>*e.g. medication error (no/minimal effect on patient)* | Generally disclose *(lower-level)* |
| 5. Clinical ('near miss') incident: does not reach patient<br>*e.g. an intercepted wrong-patient biopsy* | Team decision based on:<br>• context<br>• circumstances<br>• potential ramifications<br>*(lower-level)* |
| 6. Patient perception or report of harm<br>*e.g. patient perception of delay in diagnosis resulting in poor patient outcome* | Discuss and agree on appropriate form of disclosure<br>*(higher or lower-level)* |

Figure 1 Lower and Higher Level Responses

| Incident type | Crieria |
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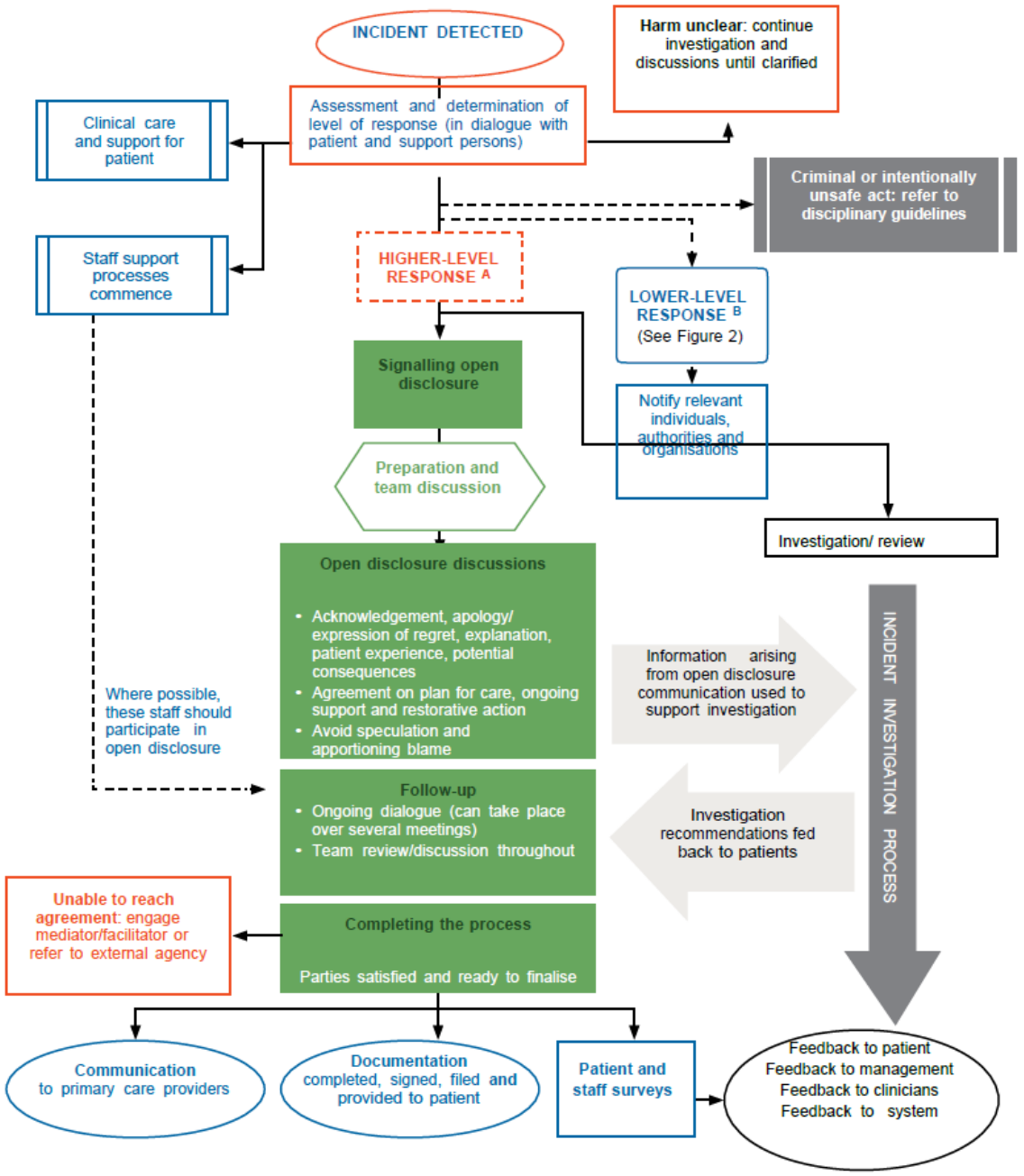
| Lower-level response | 1. Near misses and no-harm incidents<br>2. No permanent injury<br>3. No increased level of care (e.g. transfer to operating theatre or intensive care unit) required<br>4. No, or minor, psychological or emotional distress |
| Higher-level response | 1. Death or major permanent loss of function<br>2. Permanent or considerable lessening of body function<br>3. 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)<br>4. Major psychological or emotional distress<br>5. At the request of the patient |

**Figure 2 Flow Chart outlining the key steps of open disclosure**




**A General indications — higher-level response:**

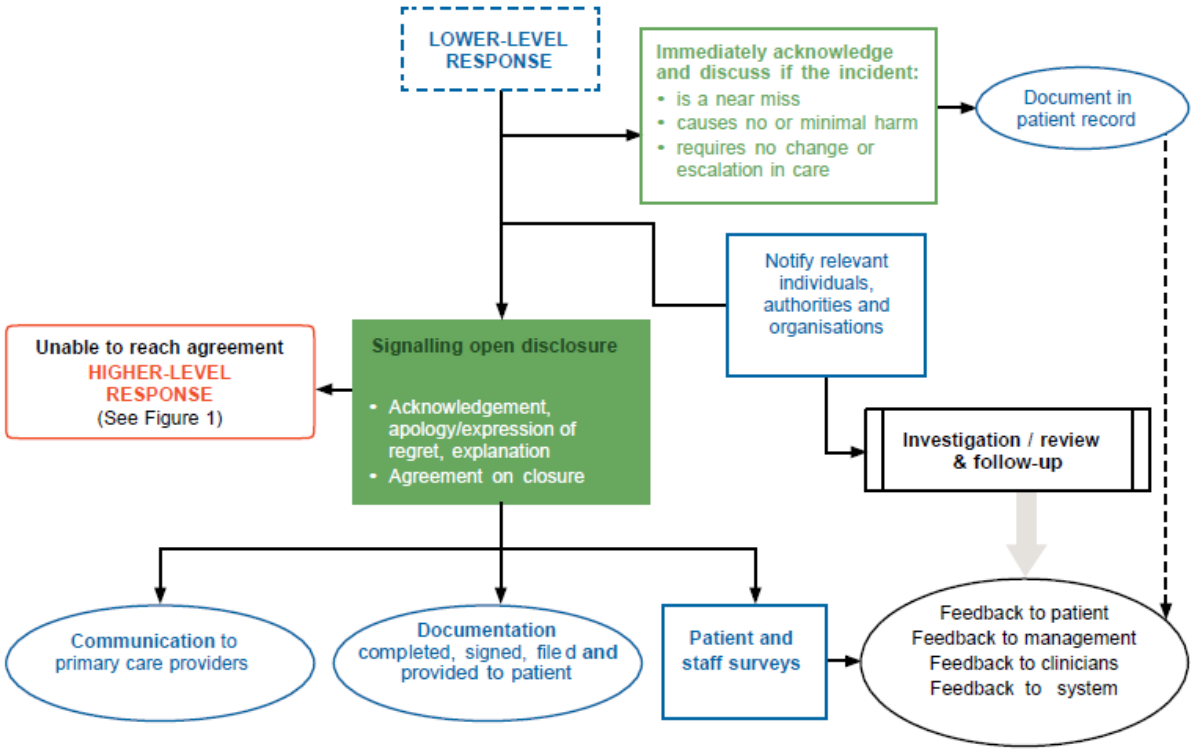
1. Death or major permanent loss of function
2. Permanent or considerable lessening of body function
3. Significant escalation of care / change in clinical management
4. Major psychological or emotional distress
5. At the request of the patient

**B General indications — lower-level response:**

1. Near miss / no-harm incident
2. No permanent injury
3. No increased level of care required
4. No, or minor, psychological or emotional distress

Adapted from Australian Open Disclosure Framework 2014, Australian Commission on Safety and Quality in Healthcare

**Figure 3 Lower level response**




Adapted from Australian Open Disclosure Framework 2014, Australian Commission on Safety and Quality in Healthcare