AH0400 - DISCLOSURE OF ADVERSE EVENTS

1.0 PURPOSE

To assist physicians, managers and other healthcare providers in disclosing Adverse Events to Patients or their Representative(s).

2.0 DEFINITIONS

- **Adverse Event:** an unexpected and undesired incident which results in an unintended consequence and is directly associated with the care or services provided to the Patient rather than the Patient’s underlying medical condition.

- **Apology:** means an expression of sympathy or regret. An apology is not necessarily an admission of error.

- **Close Call:** an event with the potential for harm that did not result in harm because it did not reach the patient due to timely intervention or good fortune. (sometimes called a near miss or good catch)

- **Disclosure:** the imparting of information to a Patient pertaining to an Adverse Event and/or a Close Call affecting or liable to affect the Patient’s interest.

- **Most Responsible Practitioner (MRP):** the practitioner who has accepted the overall responsibility for the management and coordination of care of the patient at any given time.

- **Patient:** includes all clients, residents and persons in care in Interior Health facilities and programs.

- **Representative:** a Patient’s Committee, Representative appointed under the Representation Agreement Act, family member or significant other.

- **Senior Administrator:** a person in a senior management position within the facility, such as a senior risk manager, medical director or site administrator.

3.0 POLICY

3.1 Patient Right to Disclosure - Adverse Events

When a patient has experienced an Adverse Event the outcome of the initial Disclosure process is a critical opportunity to maintain trust and confidence, which if lost, is difficult to recover.

Patients and/or their Representatives are entitled to the facts about their care and treatment. Physicians, managers and health care providers have an ethical obligation to be honest with their Patients and/or their Representatives. Honestly discussing the difficult truth with a Patient and/or his/her Representative demonstrates respect for the Patient, professionalism, and a commitment
to improving care. It has been shown that Patients and families benefit from a genuine expression of regret and/or an Apology.¹

Any Adverse Event where there is harm, injury or complication due to healthcare service delivery must be disclosed to the Patient and/or his/her Representative. Disclosure must be made within a structured process and must involve more than one individual (e.g., the disclosure team).²

Physicians, managers, health care providers and administrators must work together to ensure timely and appropriate Disclosure as a routine part of the response to an Adverse Event. Only facts which are known at the time should be disclosed. Do not speculate.

Disclosure is a process that may involve an initial disclosure and follow-up discussion(s).

3.2 Disclosure Team

The Patient’s Most Responsible Practitioner and the Senior Administrator, in consultation with the healthcare team, will determine the appropriate person(s) to disclose the Adverse Event to the Patient.

3.3 Patient Right to Disclosure – Degree of Harm (Severity Rating)

There is no requirement to disclose Close Call/No Harm events. Generally a Close Call/No Harm event need not be communicated unless there is an ongoing safety risk for that patient or the patient is already aware. (see Appendix B for Degree of Harm table)

3.4 Documenting Disclosure

A complete, accurate and factual account of the Disclosure discussion must be recorded in the Patient’s health record including the following²:

a. time and place of meeting,
b. identity of all attendees,
c. the facts of the harm/event that are known at the time of the disclosure,
d. offer(s) of assistance and responses to the offer(s) of assistance,
e. questions raised and the answers given,
f. plans for follow-up, including key contact information from the appointed contact person.

The Most Responsible Practitioner or Senior Administrator (whoever does the disclosure) should be responsible for documentation. This is not a Patient Safety Learning System (PSLS) report, which is dealt with in policy (AK0400 - Incident Management).

Disclosure of Adverse Events and reporting Adverse Events or critical incidents are separate requirements. Critical incident reporting should continue to be done according to (AK0400 - Incident Management) and in a manner consistent with the requirements under Section 51 of the Evidence Act of British Columbia. While the facts of care may be disclosed, the contents of Section 51 documents and/or discussions must not be used as the source of information communicated to a Patient or their representative when disclosing an Adverse Event.
3.5 **Disclosures in the Public Interest**

When disclosing information to anyone including the Patient or the Patient’s Representative, physicians, managers and health care providers must also be mindful of their obligations to protect personal information as set out in the *Freedom of Information and Protection of Privacy Act*.

Occasionally, there may be a requirement for a broader notification of adverse events or risks to the public or a large number of Patients pursuant to the “public interest” as defined in Section 25 of that *Freedom of Information and Protection of Privacy Act* (e.g. SARS exposure, infected medical devices). It is important that there be a careful expert assessment (e.g. Chief Medical Health Officer etc.) of the risks and benefits to the public and that the appropriate contingency plans of the organization be in place (i.e., help-lines, testing information) before such public Disclosures are made, unless the emergency nature of the circumstances do not permit any delay.

3.6 **Sharing for the Purpose of Quality Improvement**

Information about Adverse Events or Close Calls may be shared between professional groups, Facilities and Health Authorities (on a strictly anonymized basis) in order to improve Patient safety throughout the health care system. Such sharing is intended to improve the quality of patient care while protecting personal privacy.

3.7 **Other Disclosures**

On rare occasions it may be necessary to disclose personal health care information regarding adverse events to comply with other legislation. In such instances, the regulations set out in the *Freedom of Information and Protection of Privacy* are enforced. Examples include; disclosure to the Minister of Health, the Attorney General or a Member of the Legislative Assembly of BC.

4.0 **PROCEDURES**

See attached flowchart (Appendix A)

**NOTE:** When Disclosure to 2 or more patients, resulting from a single Adverse Event, is required the Disclosure will follow the process set out in Appendix C.

5.0 **REFERENCES**

1. Institute for Healthcare Communication, DUMO training materials. 2008
2. CPSI Canadian Disclosure Guidelines, February 2008
APPENDIX A

DISCLOSURE OF ADVERSE EVENTS PROCEDURE

<table>
<thead>
<tr>
<th>PATIENT INVOLVED IN UNEXPECTED EVENT OR INCIDENT</th>
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<tr>
<td>PERSON IDENTIFYING UNEXPECTED EVENT OR INCIDENT</td>
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<tr>
<td>immediately notify Manager and Most Responsible Practitioner</td>
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<td>MANAGER MOST RESPONSIBLE PRACTITIONER</td>
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<td>MANAGER Notifies Local Administrator, Chief of Staff, Quality &amp; Patient Safety</td>
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<td>MRP OR MANAGER</td>
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<tr>
<td>• communicate Close Call (Near Miss) to healthcare team</td>
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<td>• do not disclose to Patient and/or Representative</td>
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<td>SR. ADMINISTRATOR</td>
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<tr>
<td>• advise Site Administrator, Senior Medical Director &amp; Risk Management of Adverse Event</td>
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<td>MRP/SR. ADMINISTRATOR</td>
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<tr>
<td>• ensure Incident Report is completed,</td>
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<td>• discuss with healthcare team to determine appropriate persons to disclose Adverse Event to Patient and/or Representative and timing of Disclosure</td>
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<tr>
<td>PERSONS CHOSEN TO LEAD DISCLOSURE MEETING</td>
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<tr>
<td>• refer to Canadian Patient Safety Institute Canadian Disclosure Guidelines</td>
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<td>• contact Disclosure Unanticipated Medical Outcomes coach</td>
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<tr>
<td>• as soon as practicable disclose Adverse Event to patient and/or Representative,</td>
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<td>• record conversation, and</td>
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<td>• document Disclosure procedure/discussion on Patient’s health record</td>
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<td>MOST RESPONSIBLE PRACTITIONER/SR. ADMINISTRATOR</td>
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<td>• debrief with healthcare team</td>
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Policy Sponsor: Vice President, Medicine and Quality
Policy Steward: Director of Patient and Systems Safety
Date Approved: January 2009
APPENDIX B

DEGREE OF HARM (Severity Rating)

The following table provides examples of incidents which fall under the corresponding rating and category. The lists do not contain all the incidents which may come under the specified category. Incidents which are not included in any of the following categories should be rated in consultation with the appropriate manager/designate. Degrees of Harm are based on World Health Organization Taxonomy, and examples are based on Calgary policy and developed internally by Interior Health.

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Degree of Harm</th>
<th>Description of Incident</th>
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</table>
| 0               | CLOSE CALL (Near Miss/Good Catch) | An event that could cause harm but is caught before it reaches the patient.  
Example: A nurse was about to give a medication to a patient but realized it was the wrong medication. |
| 1               | NO HARM | An unexpected, undesired event directly associated with care or services reaches the patient but no harm / injury occurs.  
Example:  
- Patient receiving codeine post op - physician discontinues order - order is not flagged for processing - nurse gives codeine instead of switching to tylenol - extra dose - no harm.  
- Oximeter malfunctioning - reading 65% - patient looks pink, in no distress - new machine applied - saturations 100% - no harm to patient.  
- Patient slipped on wet floor while ambulating without assistance - regained balance without falling but jarred back causing temporary increase in soreness. Recovered quickly without any additional pain medication or intervention. No harm to patient.  
- Blood ordered due to low counts. Delay in getting blood from lab due to no porters available. Delay in giving blood but no adverse effects noted. No harm to patient. |
| 2               | MINOR HARM | An unexpected, undesired event directly associated with care or services reaches the patient resulting in minor harm / injury.  
Example:  
- Patient's IV goes interstitial, red, swollen, sore. Requires warm compresses, acetaminophen. OK after a few hours, results in bruise.  
- Patient receives total enteral feed in 1 hour instead of 4 hours. Agitated, moaning, vomits. Needs extra bloodwork to check electrolytes.  
- Patient up to bathroom without assistance after epidural wears off. Falls, red area on knee, some bleeding from episiotomy incision. Physician examines, ice applied. |
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| 3               | MODERATE HARM  | An unexpected, undesired event directly associated with care or services reaches the patient resulting in moderate harm / injury. **Example:**  
|                 |                | • Patient's IV goes interstitial - on pump - limb is hard, site looks burned, plastic surgery consulted, ointment and dressings applied, some scarring occurs.  
|                 |                | • Patient receives 10-fold dose of IV morphine, has respiratory arrest, requires resuscitation, is transferred to ICU and ventilated once-a-day, recovers but spends extra 2 days in hospital, family very upset.  
|                 |                | • Patient falls out of bed, complains of pain in arm, x-rays reveal fracture, patient spends several additional days in hospital due to pain and mobility issues, needs home care set up before discharge can occur.  
|                 |                | • Injury or drug variance/reaction that has the potential to: a) significantly alter hospital stay or treatment plan or sure or b) result in admission to hospital or a higher level of care |
| 4               | SEVERE HARM    | An unexpected, undesired event directly associated with care or services reaches the patient resulting in severe harm / injury. **Example:**  
|                 |                | • Patient's IV goes interstitial during surgical procedure - on infusion pump - leg is grossly swollen, white, hard, pulseless - compartment syndrome diagnosed - requires emergency fasciotomy to release pressure - suffers severe pain, needs IV antibiotics, skin grafts - spends significant extra time in hospital - is left with limp and severe scarring.  
|                 |                | • Patient falls out of bed, fractures c-spine, requires surgery to fuse and repair, spends time in halo traction, in hospital for long period of time as a result, left with some permanent neurological deficits.  
|                 |                | • Wrong side surgery results in patient's healthy kidney being removed instead of cancerous one. Cancerous kidney subsequently removed, patient on dialysis awaiting transplant. |
| 5               | DEATH          | An unexpected, undesired event directly associated with care or services reaches the patient resulting in or significantly contributing to the patient’s death. **Example:**  
|                 |                | • Patient is inadvertently given HYDROmorphine instead of morphine resulting in a massive overdose, respiratory depression and death.  
|                 |                | • Patient's bowel is nicked during abdominal surgery, patient succumbs to massive infection.  
|                 |                | • Patient comes to ED seeking treatment for chest pain, but does not speak English. No interpreter is available and patient, who also has flu-like symptoms, is triaged as low priority by ED staff. Several hours later, while sitting in the waiting area, collapses and dies due to massive cardiac event. |
APPENDIX C

DISCLOSURE TO 2 OR MORE INDIVIDUALS FROM SINGLE ADVERSE EVENT

In some situations there may need to be disclosure to multiple patients about the same event. Privacy and confidentiality remain important. The disclosure should only be with one person (patient / client) at a time. If the disclosure cannot occur in person, it should be made first by telephone or but registered mail, with opportunities for follow up made available. In addition, disclosure should be timed to occur with all affected patients in the same time period (where possible) prior to any informing process, such as media coverage. In the case of multi jurisdictional disclosure, the Healthcare team from the jurisdiction in which the adverse event occurred, should lead the multi-jurisdictional disclosure discussion (CPSI May 2008 p.25)

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<thead>
<tr>
<th>Disclosure Team</th>
<th>Role on the disclosure team</th>
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<tbody>
<tr>
<td>1) Physician representative, (Chief of Medical Staff) from the facility / setting where the adverse events occurred.</td>
<td>Representing all affected physicians in the facility, leads the disclosure to the affected patient group by prompt, sequential; individual interviews, telephone call or letter in this order of preference.</td>
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<tr>
<td>2) Administrative leader from the facility / setting where the adverse events occurred.</td>
<td>Representing all affected staff in the facility, co-leads the disclosure, supporting the Physician lead (In some cases, the MD, Administrator roles may be reversed)</td>
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<tr>
<td>3) Medical Health Officer</td>
<td>Consulted promptly on all incidents affecting groups of 2 or more to determine whether his / her expertise is required</td>
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<tr>
<td>4) Communications Officer</td>
<td>Consulted promptly on all cases of group disclosure since his / her expertise is required</td>
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<tr>
<td>5) Content Expert (examples: Pathologist / Device reprocessing specialist)</td>
<td>Consulted promptly on all cases of group disclosure to determine whether his / her expertise is required</td>
</tr>
</tbody>
</table>

Disclosure Team Actions (as soon as possible)

1) As quickly as possible, identify affected patients and ongoing risks to affected patients
2) Develop group disclosure communication plan (to patients and their care providers) and medical treatment plan
3) Attempt to inform affected physicians of the situation, if this does not delay informing patients
4) Initiate disclosure, lead by a Physician / Administrator team
5) Consider having a 1-800 number for patient concerns and invite follow up / Consider offering to pay for transportation and minor expenses if follow up involves extra medical follow up