

## **Sunnybrook Policy: Disclosure of Adverse Medical Events and Unanticipated Outcomes of Care**

### **POLICY STATEMENT:**

It is Sunnybrook & Women's Policy, in keeping with our Mission, Vision, Values and philosophy of care, to ensure that patients and/or their substitute decision maker, and/or their family are properly informed about their health care. This includes an obligation on the part of all physicians and health care practitioners to inform patients about significant adverse medical events and unanticipated negative outcomes of care that may affect their well-being.

### **DEFINITIONS:**

#### **Adverse Medical Events (significant):**

Adverse medical events are negative patient outcomes that can occur as the result of health care treatment and not due to the patient's illness. They are often unanticipated and unexpected outcomes of health care that do, or have the potential to, negatively impact a patient's health and quality of life. They include complications and side effects of treatment as well as errors in the performance of medical duties. Adverse medical events are not necessarily markers of substandard care.

#### **Non-Significant Events:**

Non-significant medical events are minor incidents that do not have a negative impact on patient outcomes, now or in the foreseeable future. No extra procedures affecting the patient are required to prevent negative patient outcomes. These events are not significant from the patient's perspective and disclosure to the patient and /or substitute decision maker or family is discretionary.

### **PROCEDURE:**

#### **Disclosure Process**

Disclosure of significant adverse medical events is required as part of the general professional duty to inform patients about events that have

affected or may affect their health in the future. It is the timely and open response to such difficult incidents by trusted and responsible medical personnel that can prevent dissatisfaction with care and improve the quality of care provided to patients in the future. Health care practitioners are encouraged to seek out the available hospital resources to help them inform patients about an adverse medical event. [See Appendix I: Frequently Asked Questions (FAQ's) which offers guidelines for disclosure and resources to enable practitioners to be open with patients about difficult incidents]

## APPENDIX I

### Frequently Asked Questions (FAQs)

#### About Disclosing Adverse Medical Events & Unanticipated Outcomes of Care

##### 1. What events ought to be disclosed?

- \* Incidents causing patients harm or, in some cases, having the potential to do so or

- \* Incidents requiring additional non-trivial interventions to prevent harm

##### Examples:

This might include events such as an unexpected admission to intensive care due to a drug reaction, a prolonged hospital stay on account of complications arising from treatment, or an intra-operative event, such as rupturing an organ or major blood vessel, that required unexpected and significant interventions to correct.

##### 2. To whom should disclosure be made?

- \* Disclosure of the event should be made to the patient or in certain circumstances the patient's substitute decision maker and/or family.

- \* ii. If the patient is deemed incapable of understanding a discussion of this nature, then in accordance with the Health Care Consent Act (1996), the patient's substitute decision maker should be informed.

### 3. When should disclosure take place?

\* Disclosure of the event should take place as soon as practically possible after it has occurred or has been identified.

\* Disclosure to the patient should occur when the patient's condition is stable and/or the patient is able to comprehend the information. Disclosure to the patient's substitute decision maker may occur prior to this and will depend on the severity of the event.

### 4. Who ought to disclose events to patients?

\* If the event is most associated with physician staff, the patient's attending physician, whether or not this physician was involved in the event, would usually initiate the discussion with the patient. There may be situations where another staff physician would take the lead, for example where the event occurred in one of the diagnostic units.

\* If the event is most associated with non-physician staff/employees of the hospital, such as nursing or other health care professionals, the manager or director of the area would usually initiate the disclosure in consultation with the Director of Quality and Risk Management or delegate. The patient's attending physician will always be informed of the event and will be given the option of being part of the discussion with the patient.

### 5. Are there events where disclosure is not required?

\* Disclosure of non-significant events, (ones that do not harm a patient), should be a matter for clinical judgement by the skilled practitioner. Such incidents do not require disclosure to the patient because they do not affect the patient's well-being. Disclosure is a matter of 'proportionality': the greater the harm or risk of harm caused by an event, the greater is the duty of the health practitioner to disclose this event to the patient and/or to the patient's substitute decision maker.

#### Examples:

A minor delay in giving a patient a medication may be an unwanted event but if there was no harm to the patient as a result, disclosure would not be required. The disclosure of certain intra-operative events, such as bleeding or hypotension that are promptly treated with no consequence to the patient, would also be discretionary.

6. What mechanism will be in place to help with disclosure?

\* During business hours, staff involved in an event who are employees of the hospital will immediately contact the Director of Quality and Risk Management or delegate to review an adverse event. The role of Quality and Risk Management is to facilitate the staff's discussion about the event and to help plan the conversation with the patient or substitute.

\* After hours the on-site Manager or Administrator-on-Call is contacted immediately.

\* The Director of Quality and Risk Management or delegate is available upon request to support physicians in the disclosure of adverse events.

7. What are the beneficial consequences of disclosure?

\* Patients will receive prompt and thorough interventions for any harm suffered or anticipated.

\* Patients and/or their families will have their concerns and fears openly addressed and respected.

\* Patients will receive important information about their care in a timely manner.

\* Errors and adverse events, while unwanted, are opportunities for practitioners and institutions to learn how to improve the quality of care and improve patient safety.

8. What is the difference between an error and an adverse event?

\* Errors and adverse events overlap but are also different.

\* Adverse events and errors are alike in that they are unwanted and often unanticipated events or processes of care. They occur to even the most careful practitioner and are not markers of negligent care.

\* Some adverse events are unexpected, such as an allergic reaction to a first-time treatment with penicillin.

\* An error is sometimes considered to be a "preventable adverse event," such as prescribing penicillin to a patient with a history of penicillin allergy. It is unlikely, however, that all errors are 'preventable.'

\* What may seem like an 'error' after the fact may simply be due differences in professional judgement. Professional judgement tolerates a wide variety of approaches to patient situations. Less than optimal patient outcomes and even adverse outcomes may be due to legitimate differences in approach rather than any 'error' per se.

\* Adverse events are 'adverse' because they cause, or threaten to do so, some harm to patients. Not all errors are harmful to patients if caught in time, such as a pharmacist, who, noting the patient has a penicillin allergy, alerts the prescribing doctor. Such 'harmless' errors are "near-misses" that should not require disclosure to the patient.

9. What actions are recommended for staff to take when a significant event occurs or is identified?

These actions apply to those most immediately responsible for the care of the patient.

\* The event should be documented in the patient's chart in an objective, factual and narrative way. This should be done as soon as possible after the event has occurred or has been recognized.

\* Staff who are employees of the hospital will involve their manager and the Director of Quality and Risk Management or delegate immediately. Quality and Risk Management is available upon request to support physicians with disclosure on request

\* Disclosure of the event to the patient, substitute decision-maker, and / or family should take place in a timely way. The adverse outcome may be obvious; what may require special attention is disclosure of the circumstances leading up to / surrounding the event. [See #2, "When should disclosure take place?"; #6, "What mechanism will be in place to help with disclosure?"; #7, "What are the beneficial consequences of disclosure?"]

\* Discuss the event with members of the patient's care team and, where appropriate, the manager or department/division head

10. What Hospital actions will be taken when a significant event occurs or is identified?

\* The hospital encourages reporting of adverse events and errors and will support staff in this initiative. Patient safety is the primary concern of the organization, not disciplining the individuals involved in events. The hospital will focus on correcting the factors that allow events

to occur and work with staff affected to prevent the recurrence of such events.

\* Secondary records made about the event, e.g., incident reports, interview notes, will be factual and objective. They will be stored in a secure area and will be destroyed in keeping with Retention Guidelines. Summary reports used for quality improvement or to meet the requirements of S&W's Accountability System. Secondary records will not contain information that would identify the patient or staff.

#### 11. What are the recommendations for disclosure?

\* The attending physician or manager (see #4 above) should meet with the patient / substitute decision maker as promptly as other duties permit and as appropriate given the patient's clinical condition. The assumption is that most patients / families would want to know what has happened. However, patients have the right to decline disclosure. If in doubt, ask before you tell. Waivers of information should be recorded in the patient's chart.

\* Disclosure is a process. Practitioners should avoid speculation, focus on what is known about the event at the time of the discussion, and answer questions from the patient or substitute decision maker to the best of their ability. Unanswered questions ought to be noted and prompt and thorough responses sought.

\* Avoid attributing blame to specific individuals or simple explanations as to 'cause'. Most serious events have multiple contributing factors that may not always be apparent at the time of the first meeting with the patient/family.

\* A timely and empathic expression of sorrow or regret and condolences may well be appropriate and should not be construed or taken to be an admission of liability or fault. ("This must be very difficult for you. I wish things had turned out differently.") Doing so soon after an adverse outcome can help promote confidence in hospital staff and prevent unnecessary feelings of distrust.