Disclosure Policy: Adverse Patient Events, Errors and/or Unanticipated Outcomes – SAMPLE

I. Statement of Policy:
   It is the policy of [insert name of facility] to maintain transparency and integrity in all of the organization’s functions. Consistent with this policy, it is appropriate to disclose adverse events, errors and/or unanticipated outcomes that could affect a patient’s emotional or physical health. Our framework for discussing unanticipated outcomes is premised on strong communication processes, both before and after treatment or procedures.

II. Definitions:
   A. **Adverse Event** – an unintended or negative result or complication stemming from a diagnostic test or medical/surgical treatment or a medical error
   
   B. **Errors** – preventable adverse events
   
   C. **Disclosure** – communication of information regarding the results of a diagnostic test, medical treatment, surgical intervention or unanticipated outcome
   
   D. **Unanticipated Outcome** – a result that differs significantly from what was anticipated to be the result of a treatment or procedure
      
      **Note:** An outcome may be negative and/or unanticipated, but not be the result of an error. The informed consent process should address possible risks, complications and adverse outcomes. A discussion about an unanticipated outcome that was addressed as part of the informed consent process is a much different discussion than disclosing an error.

III. General Principles:
   A. **Events to be disclosed** – Disclose adverse events, unanticipated outcomes and occurrences in which patients are significantly harmed or have the potential to be significantly harmed.
   
   B. **To whom disclosure will be made** – Make disclosure to the patient and, only when appropriate, to the patient’s family, significant other or patient advocate.
C. **Timing of disclosure** – Disclose adverse events as soon as possible after the identification that an adverse event has occurred. If event analysis is incomplete within the first 24 hours, then sharing only partial factual information is more important than waiting longer until all details of the event have been factually ascertained. If the patient is not able to comprehend the information, disclose to the patient advocate, depending on the severity of the occurrence and his/her need to know the information.

D. **Honest disclosure** – Tell the patient the facts as known, and assure him/her that you are committed to obtaining and providing all relevant information, if not already known at the time of initial disclosure. Consider using support services (e.g., social worker, chaplain, patient relations personnel, mental health therapist), as may be needed.

E. **Cultural sensitivity** – Ensure that respect is shown for the patient’s culture and provide interpreters for non-English speaking or cognitively impaired patients.

F. **Who should disclose events** – Disclosing adverse events is primarily the attending physician’s responsibility. When it is impractical or unreasonable for the physician to do so, a designee may conduct the disclosure. If the physician is uncertain regarding the event and/or the obligation to disclose, or finds it difficult to disclose the event to the patient, the physician should discuss the event with the chief medical officer (CMO) and the risk management professional. The CMO and the risk management professional will be responsible for ensuring that disclosure of an adverse event takes place if the physician cannot or does not inform the patient in a timely manner.

G. **Events for which disclosure may be discretionary** – Disclosure of events is a matter of clinical judgment. Errors that do not harm a patient and do not have the potential to do so may not require disclosure to patients.

H. **Mechanism to assist with the disclosure process** – The CMO and the risk management professional may provide assistance to physicians and hospital staff members regarding disclosure. They have the authority to help clinicians make decisions about which adverse events need to be reported and disclosed, and to help make decisions about disclosure when the most responsible clinician fails to do so or is unable.

I. **Beneficial consequences of disclosures** –
   1. Patients receive prompt care for injuries suffered and are fully informed to assist in further decision-making and treatment planning.
   2. Errors are opportunities to learn how to improve patient safety.
   3. Lessons learned from error reporting will serve to correct system problems.
   4. Generally, patient satisfaction increases and professional liability risk, claims and lawsuits decrease.¹
IV. Procedures

A. Staff Member and Physician Actions
   1. Take immediate actions to safeguard the patient, as applicable.
   2. If the adverse event is of a serious nature, notify the unit manager, the risk
      management professional and the physician as soon as possible. Complete an event
      report and inform the patient’s attending physician.
   3. Document the event in an objective and factual manner in the patient’s medical
      record as soon as possible after the event (see Item IV. E.).
   4. In consultation with the risk management professional, discuss the factual details
      and sequence of what occurred with the healthcare team and attempt to reconcile
      any differing perceptions of what occurred.
   5. Determine how the details of the event, the outcome and the treatment plan will be
      explained to the patient and family. Decide which member of the healthcare team will
      discuss the event and with whom (patient and/or family member). Designate a family
      contact person.
   6. Be accessible for questions. Repeated requests for an explanation of the event is a
      common reaction when patients and family members are informed of an adverse
      event or medical error.
   7. If the event involved a medical device or piece of equipment, preserve these
      materials for investigation. Do not clean or alter them in any way and contact the risk
      management professional immediately. Do not return defective devices to a
      manufacturer. Refer to the Safe Medical Devices Act Reporting Requirements policy
      and procedures for additional details.
   8. Notify the professional liability insurance carrier of the event in a timely manner and
      obtain guidance, as applicable.
   9. The risk management professional will determine when and if patient billing should
      occur.

B. Communication Framework for Disclosure
   1. Have the attending physician and/or leadership staff meet with the patient (and
      family as applicable) promptly following the event. Delays should be avoided.
   2. Present the nature, severity and contributing cause (if known) of the adverse event in
      a straightforward and non-judgmental manner.
   3. Avoid attributing fault or blame to the patient, patient’s family, yourself or to specific
      individuals or to the organization as a whole. Serious adverse events are rarely due
      to the sole action or inaction of one person. Do not criticize the care or response of
      another provider.
   4. Disclosure is a process; be sure the disclosing medical providers avoid speculation
      and focus on what is known at the time of the discussion, what happened, what led
      to the event, and the recommended course of action.
5. To avoid the appearance of contradicting information, provide a caveat that as information becomes available, further discussions will take place.

6. If further treatment is necessary as a result of the adverse event, describe what can be done, if anything, to correct the consequences of the adverse event.

7. Identify someone (staff member or physician) to have on-going communications with the patient and/or family.

8. Convey empathy and use language that is understandable to the patient. Make eye contact and concentrate on presenting your body language in an open and caring manner.2

9. It is appropriate to apologize for the occurrence of the adverse event. This aspect of communication is separate from discussing ascertained causes of the event. Sincere concern can increase the rapport between the patient and provider.

C. Withholding of Information

1. The disclosure of outcome information can sometimes put a patient at risk of psychological trauma or other difficulties. Accordingly, clinical judgment should be exercised when deciding on the nature and extent of the disclosure to make.

2. If information is withheld, document the reasons for such. It may be appropriate to have a mental health provider conduct an assessment.

D. Reporting and Accountability

Prompt and thorough reporting and disclosure of adverse events by the physician and staff members will be managed from the perspective of the organization’s systems as well as individual provider accountability. The hospital will address patient safety concerns through the medical staff peer review process and/or human resource procedures if the investigation reveals a serious lack of provider knowledge, skill deficit, unawareness of the hazard of oversight and negligence, and/or reckless disregard for patient safety.

E. Documentation

1. Document facts objectively, completely and contemporaneously, including that a discussion of the unanticipated event took place with the patient and/or family.

2. Ensure that the documentation is dated, timed and signed at the time of the entry.

3. Avoid writing any information unrelated to the care of the patient in the record (e.g., “event report filed” or “legal office notified”).

4. Do not alter any prior documentation or insert backdated information.

5. Record the names and relationships of those present.

6. Include documentation of any questions posed by the patient/family and indicate that answers were provided by the caregiver.
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7. While an addendum to the record may be made, consider carefully whether this information is relevant to the patient’s clinical management. Accepted rationales for making an addendum are to correct mistaken information (e.g., persons involved, time of event, sequence of events), add facts and clarify information. If you participated in the care, but were unable to access the record until a later date, you may provide added information. Do not use an addendum to state your opinions, perceptions or defenses.

8. Assign the most involved and knowledgeable staff member(s) to record the factual statement of the event in the patient’s record and any follow-up needed or done as a result of the event.

Reference: