Institutional Ethics: Building a Policy and Procedure for Disclosure of Medical Errors to Patients

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Background & History

- Medical errors are the primary cause of patient injury
- A “shame & blame” culture contributes to the problem
- Most errors result from systems issues rather than individual failure
- Addressing the systems component of errors → quality improvement

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Background & History: AMA

- AMA Code of Ethics
  - Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situation, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care.

Background & History: AMA

- AMA Code of Ethics
  - When patient harm has been caused by an error, physicians should offer a general explanation regarding the nature of the error and the measures being take to prevent similar occurrences in the future. Such communication is fundamental to the trust that underlies the patient-physician relationship , and may help reduce the risk of liability.

Background & History: ACP

- American College of Physicians
  - …physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient's well-being. Errors do not necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may.

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Background & History: ACEP

- American College of Emergency Physicians
  – If, after careful review of all relevant information, an emergency physician determines that…an error has occurred in the care of a patient...he or she should provide information about the error and its consequences promptly…

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Background & History: JCAHO

The Joint Commission's accreditation standards require the disclosure of sentinel events and other unanticipated outcomes of care to patients and to their family members when appropriate. A recent study confirms that many hospitals – half of those surveyed – are reluctant to comply with this standard for fear of medical liability suits.

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Error Disclosure: Legislative Action

- States, such as Colorado and Oregon, have taken legislative actions that protect an apology from being used against a doctor in court.

Definitions

- Serious Event: An objective and definable consequence of patient care, that is unanticipated, may be preventable, and results in:
  - Life-threatening consequences or death;
  - Loss of a body part;
  - Hospitalization or prolonged hospitalization;
  - Disability or loss of bodily function that last for more than seven days;
  - Cancer;
  - Congenital anomaly; or
  - Other significant morbidity, including significant physical or psychological injury to the patient.

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Definitions

- Error: The failure to complete a planned action, use of a wrong plan of action, or failure to execute an action as planned or desired. Errors may or may not result in harm to the patient. Anticipated or common side effects or adverse outcomes from treatments are not errors. The four types of treatment errors are:
  - Major Permanent Error: A permanent injury that affects basic functions of daily living; these are Serious Events.
  - Major Temporary Error: A temporary injury that exceeds Minor Temporary or increases length of hospitalization by one to six days.
  - Minor Permanent Error: A permanent injury that does not compromise basic functions of daily living.
  - Minor Temporary Error: Minor patient injury, increased patient monitoring, or change in treatment plan.

Definitions

- Near Miss: An error that could have led to a Serious Event or Major Error but did not due to planned or unplanned actions.

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Definitions

- Disclosure: Communication of Serious Events, Errors, or Near Misses to a patient and/or the patient's LAR, into the hospital system, and, when appropriate, to licensing or regulatory agencies. Disclosure must be consistent with pertinent State laws.

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Disclosure to Patient

- Disclosures to Patient or Patient's Legally Authorized Representative:
  - All Serious Events: Disclosure required.
  - Major Errors: Disclosure required.
  - Minor Permanent Errors: Disclosure required.
  - Minor Temporary Errors: Use professional judgment in determining which of these should be disclosed.
  - Near Misses: There is no requirement to disclose; however, there is no prohibition on doing so.

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Disclosure to System

- Disclosures Within the Health Care System: The goals of internal disclosure are to address system issues and prevent future Serious Events and Major Errors. Health Care Systems should establish an Incident Reporting and Investigation Policy for reporting occurrences using a Confidential Incident/Quality Concern Report in reporting the following:
  - All Serious Events: Disclosure required
  - Major Errors: Disclosure required
  - Minor Errors: Disclosure required
  - Near Misses: Disclosure is required if the potential outcome could have been a Serious Event or Major Error

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External Disclosures

- Disclosures outside of the Health Care System:
  - External reporting should be managed by Risk Management and/or Legal Departments. External agencies may include:
    - Licensing boards
    - Peer review
    - Wellness committees

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Internal Dispute Resolution

- When there are interdepartmental disagreements as to the occurrence or definition of an error, these should be resolved by an internal Professional Board. The Professional Board may involve Risk Management or the Legal Department if such involvement will help inform the discussion. Additionally, internal compliance or ethics experts should be available to discuss any issues related to error disclosure.

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When to Disclose

- If *immediate disclosure* is appropriate: The HCP should use professional judgment regarding the timing of disclosure and follow departmental policy.
- An appropriate hospital administrator should then be advised.
- The HCP and administrator should develop an appropriate follow-up communication plan.

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When to Disclose

- If the situation is *<u>not urgent</u>*:
  - The HCP should use professional judgment regarding the timing of disclosure and follow departmental policy.
  - An appropriate hospital administrator and Risk Management should formulate a communication plan for disclosure to the patient and/or the patient's LAR.
  - Coordinate with the Patient Advocate's Office is highly desirable.

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What to Disclose

- Disclosures of Serious Events or Errors to patients should be verbal and must be honest and factual. Components should include:
  - A statement that an Serious Event or Error occurred and a description of the known or expected and likely consequences;
  - An apology regarding the Serious Event or Error on behalf of the health care team and the hospital/unit/school;
  - A brief discussion of how the Serious Event or Error occurred (only if known: do not speculate on proximate or contributing causes);
  - Information regarding any tests, procedures, therapies, change in level of monitoring, or change in level of care that will likely be necessary as a result of the Serious Event or Error;
  - Answers to the patient's questions;
  - An offer to obtain help and support from appropriate health care workers (e.g., social worker, Patient Advocate, clergy); and
  - Assurance that the institution will perform a thorough investigation and implement any changes if appropriate for improvement and/or in order to reduce the likelihood of similar Serious Events or Errors.

What Not to Disclose

- The HCP should not discuss:
  - The name(s) of any person(s) involved
  - Assignment of blame or responsibility
  - Criticism of the actions of any persons or teams
  - Any reference to the Serious Event or Error as a "sentinel event"
  - Any financial implications of the Serious Event or Error, including any plans to waive or refund a fee
  - Any promise of written reports or other documents generated during an investigation of the event
  - Any promise of information regarding specific outcomes arising from internal investigations.

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Special Issues

- The HCP should recognize any cultural, language, auditory, or visual challenges to effective communication and utilize available services, including interpreters, to support effective patient communication. Adequate time for questions and dialogue should be provided with an open invitation for further dialogue at a later time.

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Documentation

- The attending HCP must provide thorough and factual documentation of Serious Events or Errors. Elements of the documentation must include:
  - An objective description of the event, medical condition, and treatment required, written by the provider. This description must not include defensive or value-laden language, conjecture, blame, or any legal conclusions (such as “negligent,” “intentional,” “unlawful,” “non-compliant,” etc);
  - The steps taken to minimize or ameliorate the Serious Event or Error and/or the effects thereof;
  - An indication of when the information about the Serious Event or Error was given to the patient and who was present at the time;
  - Indication as to whether a medical interpreter was needed and present; and
  - Documentation of the plans for follow-up care as medically indicated and as desired and agreed to by the patient and/or his/her LAR.

HCP Support

- HCPs may suffer a heavy emotional burden when Serious Events or Errors occur. HCPs should be encouraged to discuss these events with any of the following resources:
  - Appropriate supervisors or managers;
  - An Employee Assistance Program; or
  - A Patient Advocate Office.

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HCP Support

- HCPs may have lingering concerns about the legal implications of errors. They should be encouraged to discuss these concerns with:
  - Risk Management,
  - The Legal Department
  - Compliance

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