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Disclosing Adverse Clinical Events to Patients and Families

Fundamental Elements

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Cooper Corporate Policy/ Procedures Regarding Disclosure

The responsible licensed independent practitioner /designee shall disclose:

- Any serious adverse event that affects the patient and any adverse effect resulting from an allergic reaction not previously documented in the patient's medical history

- apologize as well as speak honestly and openly with the patient (and/or family)

- provide all information needed for current and future healthcare decisions

- answer the patient's questionS

Adverse Clinical Events Policy #1.216

Insert Link

What is a Serious Preventable Adverse Event?

- "Serious preventable adverse event" means an
  - adverse event – an event that is a negative consequence of care that results in unintended injury or illness
  - that is preventable, meaning it could have been anticipated and prepared against, but occurs because of an error or other system failure and
  - results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.
- May or may not be a result of "negligence" – meaning the care falls below the standard of care of a reasonable practitioner in the same or similar circumstances.

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Coopers Policy Follows the Dictates of NJ Law

- A health care facility shall ensure that a patient or resident or, in the case of a minor or incompetent adult, the patient's or resident's personal representative, guardian, parent, or other family member, as appropriate, and provided disclosure is permissible under applicable confidentiality law, is informed of the following:
  - Any serious preventable adverse event that affected the patient or resident; and
  - Any adverse event resulting from an allergic reaction that was not previously documented in the patient's or resident's medical history.
- The patient's or resident's attending physician, the facility administrator, the facility's medical director or another health care professional authorized in accordance with facility policies shall make the disclosure required pursuant to (a) above within 24 hours of the time the facility discovers the event
- N.J. Admin. Code § 8:43E-10.7

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Documentation of the Disclosure is Required

- In disclosing information the facility shall ensure that the following information is recorded in the patient or resident's medical record:
  - The time, date, and individuals present when the disclosure was made, and the person to whom the disclosure was made; and
  - A statement that the occurrence of a serious preventable adverse event or adverse event related to an allergic reaction, as applicable, was disclosed.
- N.J. Admin. Code § 8:43E-10.7

NJ Law Protects Practitioners Who Make this Disclosure

Disclosure and Documentation of the Disclosure are not Discoverable or Admissible

- "Any document or oral statement that constitutes the disclosure provided to a patient or resident or the patient or resident's family member or guardian, in accordance with N.J.A.C. 8:43E-10.7, as well as the entry in the medical record related to such disclosure, shall not be subject to discovery or admissible as evidence or otherwise disclosed in any civil, criminal or administrative action or proceeding"
- N.J. Admin. Code § 8:43E-10.9

Barriers to Disclosing

- Shame
- Lack of knowledge
- Fear of Liability
- Concern about Patient and family response
  - Fear, anxiety, depression
  - Anger
  - Humiliated, powerless, betrayed
- Fear and paralysis caused by lack of comfort in how to disclose the error to the patient or family

The Disclosure Discussion
Why, Who, When, Where?

Why Disclose Unanticipated Outcomes?

- Supports patient's right to know about their condition, make informed health care decisions, and regain control.
- May cause avoidable harm if further injury results from failure to disclose
- Improves Physician/ Patient Relationship
- Rebuilds trust-- Failing to disclose errors undermines public trust in medicine
- Ensures the quality of care – Performance improvement and prevention of future occurrences.
- It is a breach of professional ethics —lapse in commitment to act solely for the patient's best interests
- Ensures compliance with regulatory requirements and organizational policy/ procedures

Why?

Disclosure Important for Caregivers Too

- Feelings of guilt or fault impairs ability to deal effectively with patients
- Caregivers need care too
- Denial may be harmful both to ability to improve processes and performance in the future and to trust relationship with patients

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Plan Ahead

- Meeting before the patient meeting
  - Include: Care team members (physician and nursing), Patient Safety Officer, Department leadership
  - Discuss:
    - Who will be present and who will speak
    - When and Where the meeting will take place
  - Come to consensus so there is one message, one voice – avoid disagreement in front of the patient.

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The Disclosure Discussion Why, Who, When, Where?

Who will inform the Patient?

- Healthcare provider(s) involved in the unanticipated outcome
- Provider(s) with responsibility for ongoing care
- Person(s) with ability to answer questions
- Discuss with other caregivers who is best person to convey information to the patient and family.

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The Disclosure Discussion When?

When to Inform the Patient and Family?

- After immediate health care needs are addressed
- Within 24 hours of discovery of the event
- Consider patient’s physical and emotional readiness
- Obtain patient’s permission to discuss care with the family (if possible) – Consider which family members should be included.

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The Disclosure Discussion Where?

Where to Hold Discussion?

- Consider privacy and patient's current health needs
- Arrange for location with comfortable seating arrangement
- Do not block room exits
- Limit number of people participating

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What to Say?

- Treat conversation as an instance of ‘breaking bad news’
- State the nature of the mistake, consequences & corrective action
- Express personal regret and apologize
- Elicit questions or concerns and attempt to address them
- Plan the next step and next contact

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Things to Consider in Preparing for the Discussion

- Skills in Communication
- Current rapport with the Patient & Family
- Potential Language/ Cultural Barriers and Assess the patient and family's ability to understand the information.
- Review the facts

The Disclosure Discussion

- Express empathy with a sincere tone
- Convey compassion for the patient/ family’s pain and suffering
- “I’m sorry that you and your family have experienced this event”
- Focus on the patient’s and family’s needs
- Extend sympathy to family of a deceased patient
- Ask if they have any questions and attempt to answer
- Provide name of a contact person
- Ask if the patient or family need anything at this time
- Discuss follow-up care to be provided

Communicate Known Facts

- Provide objective information
- Provide a short, concise message, a simple description of what happened.
- Tell what is know of the outcome at that point and describe next steps in the patient's medical care and treatment options
- Acknowledge the patient and family's suffering
- Schedule follow-up meetings and/or establish that you will let them know further outcome/information.
- Ensure patient's understanding of the unanticipated outcome & prognosis

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Managing your own Emotions
What Not to Communicate

- Subjective information
- Conjectures, opinions or beliefs
- Confidential information
- Results of internal evaluations
- Speculation and blame
  - Unanticipated outcome not always due to negligence
  - May be result of disease process, risky life saving treatment or not preventable
  - Without investigation, the reasons for the event may not be known
- Finger pointing or defensiveness
- Making an admission of guilt

Discussion Tips

- Use no medical jargon
- Consider cultural/language barriers
- Speak slowly
- Be aware of body language and sit at their level - Do not stand
- Don’t overwhelm with information, but don’t oversimplify
- Allow ample time for questions—don’t monopolize the conversation
- Remind them that you will return to follow up
- Don’t avoid the patient or family, even if you don’t have all the answers yet

Sample Language

- Let me tell you what I know about what happened. Instead of receiving _______, we gave you _____. I want to discuss what this means for your health, but first I want to tell you how sorry I am that this happened to you.

- Right now I don’t know exactly what happened but the Hospital is committed to find out and make sure it doesn’t happen again.

- It may take time to get the answers, but I will share with you what we find out as soon as I know.

- Now, what does this mean for your health?............

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Medical Record Documentation

Record complete, accurate and factual record of the pertinent clinical information related to the event including:

- Date, time and location
- Patient's condition immediately before the event, if relevant
- Describe the event factually, without casting blame or speculating
- Medical interventions following the event i.e.
  studies ordered, therapies initiated, medications ordered
- Patient's response to medical intervention following the event
- Future treatment plans

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Medical Record Documentation

Record interaction following disclosure discussion with the patient /family including:

- Time, date and place of discussion
- What was communicated- the facts of the event- based on information available at the time of conversation
- Names and relationships of those present for the discussion
- Patient/ family understanding, any questions asked, responses given

Case Study 1

- 75 year old man has cataract surgery at a large teaching hospital. At a critical moment, the surgeon's hand slips & ruptures the lens capsule. The planned implantation of an intraocular lens has to be abandoned. Instead, the patient will have to use a contact lens.
- The physician wonders what he should tell the patient and his family about the surgery and what he should document in the operative note.

Case 1

- The surgeon should inform both patient and family about the intraoperative event and the inability to achieve the intended outcome.

- The incident may not have a bad visual outcome for the patient but the surgeon must warn them of the possibility. He should arrange for appropriate follow-up surveillance and tell them what, if anything, can be done should the bad outcome occur.

Case 1

- The surgeon should document the event in the medical record:
  - During procedure, instrument ruptured lens capsule . Implantation of an intraocular lens could not be completed.

- The surgeon must also document the disclosure to the patient:
  - Meeting on 9/1/2015 at 6 pm. Patient, spouse and resident, John Smith present. Discussed with patient and wife that lens capsule inadvertently lacerated during surgery. Implantation of an intraocular lens could not be completed. Patient will likely need to wear a contact lens.

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Case Study 2

- A 37-year-old woman, with an unremarkable medical history, visits her physician for a physical examination. As the physician enters the exam room, she is taken aside by her nurse. The nurse has just noticed that the patient's Pap smear results three years ago showed adenocarcinoma in situ.

  The report, although filed in the patient's chart, is a complete surprise to the physician as well. She cannot understand how it was missed because the patient had been seen several times in the clinic since the test was done.

  The physician considers what she should tell the patient.

Case 2

- The physician should ensure the report of the adenocarcinoma in situ is accurate and in the right chart.
- Disclose to the patient, before the examination, about the report and admit that it seems the report was not acted upon.
- The patient may ask what are the consequences now for her health. The physician may be unable to answer at this time. False reassurances, blame placed on the patient for failed follow-up or blame placed on office staff will not be helpful.
- The patient should be offered an immediate and thorough examination with prompt re-testing and, if needed, follow-up as soon as possible by an appropriate specialist.
- The physician should re-evaluate office procedures and inform the patient of what will be done to prevent similar errors in the future.

Case 2

- Document the disclosure in the chart:
  - Met with Patient on 9/1/2015 at 4:00 pm and advised that report dated 9/1/2012 regarding adenocarcinoma was discovered in file today. Discussed follow up testing to be completed. Discussed that I will review office procedures to ensure that this error does not occur again. Apologized that this occurred.

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Internal Support Resources

• Risk Management	342-2112 (on-call, after business hours)
• Patient Safety	342-2101
• Patient Relations	342-2539
• CIRT	342-2700
• EAP	342-2280