

Disclosing Serious Unanticipated Adverse Events
Educational Guidelines for Washington University Physicians
Adopted: June 21, 2007
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Timely, honest and sustained communication with patients is an essential component of exceptional health care. Washington University School of Medicine (WUSM) recognizes that patients have the right to know the details of significant events that have the potential to impact their health status. The following guidelines have been designed to assist you in communicating with patients and/or their families in the event of a serious adverse outcome.

Terms

Adverse Event: An injury to a patient caused by their medical care rather than their underlying disease. Some examples of adverse events include:

- Pneumothorax from central venous catheter placement
- Anaphylactic reaction to a medication
- Unintended laceration/perforation

Identifying something as an adverse event does not imply "error," "negligence," or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process.

Medical Error: The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Some examples of medical errors include:

- Ordering a medication for a patient with a documented allergy to that medication (an act of commission)
- Failing to prescribe a proven medication with major benefits for an eligible patient, e.g. not administering low-dose unfractionated heparin as venous thromboembolism prophylaxis for a patient after hip replacement surgery (an error of omission)
- Patient scheduled for amputation of the right leg, but has the left leg removed (failure of a planned action)

Patient Harm: Temporary or permanent impairment of a body function or structure requiring medical intervention. Medical intervention may include monitoring the patient's condition, change in therapy or active medical or surgical treatment.

Sentinel Event: As defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), an event that results in unanticipated death or serious injury to a patient and is not related to the natural course of a patient's illness or underlying condition, or the risk thereof. In addition to unanticipated death, some examples of sentinel events include:

- Permanent loss of function unrelated to the course of illness
- Surgery on the wrong site or wrong patient

- Hemolytic reaction related to administration of blood or blood products having major blood group incompatibilities

Patient Disclosure: Providing information to patients and/or their families about unexpected harm that occurs as a result of their medical care, not directly because of a patient's illness or underlying disease.

Guidelines for Disclosure Process

1) Patient disclosure does not include:

- claiming liability by saying, “I caused this problem . . .”
- criticism of the care or response of other providers
- making excuses, being misleading, defensive or mysterious
- altering the medical record, or placing personal notes or comments in the record
- stating or implying causation or the reason why you believe the adverse outcome occurred unless causation is clear and unequivocal

2) Patient disclosure is appropriate in the following situations:

- All sentinel events
- Adverse events and medical errors that:
 - Result in temporary or permanent impairment of body function,
 - Require transfer to an ICU, additional surgery or other medical intervention

If there is any uncertainty about the appropriateness of disclosing an event to a patient and/or family or a faculty member has any questions regarding disclosure, they should contact the WUSM Department of Risk Management at **362-6956**. The WUSM Department of Risk Management will, as appropriate, coordinate communications with Children’s and Barnes-Jewish Hospitals’ patient safety/risk management personnel.

3) The attending physician or his/her designee should speak with the patient as soon as the patient is medically stable enough to absorb the information. If the patient has suffered permanent injury or death, information should be provided to the patient’s family. Initial disclosure should be made within 48 hours of the adverse event when practicable. Whenever possible, the members of the care team (e.g. attending physician, residents, fellows, nurses) should meet in advance to discuss the known facts and to prepare to advise the patient and, when authorized, the patient’s family (*See Appendix for guidance*). In the event that disclosure is made immediately, the care team should be informed of the information and details provided to the patient and/or the family as soon as possible.

4) When more than one attending physician is involved in an adverse event, they should confer and collaborate on the disclosure conversation to the fullest extent possible before speaking to the patient and/or family. Subsequent conversations with the patient and/or family should involve prior consultation with all attending physicians involved in the event, and team disclosure, if appropriate.

- 5) Every physician should be responsible for disclosing medical errors for which they feel personally responsible. Physicians should not disclose perceived errors made by other caregivers without involving those caregivers in the disclosure process.
- 6) If the WUSM Department of Risk Management was not involved or contacted regarding the disclosure of the adverse event, please report the event to the Department at 362-6956.

Guidelines for Communication

- 1) Acknowledge that an adverse event or medical error has occurred. Describe the nature of the event in a factual and compassionate manner, i.e.
 - What happened and what are the potential consequences to the patient
 - How and why it happened, to the best of your knowledge (do not speculate or hypothesize if the exact cause of the adverse event is unknown)
- 2) Express your personal concern regarding the adverse event:
 - Patients and their families appreciate a sincere expression of regret and sympathy.
 - If the adverse event is attributable to a medical error, an expression of apology is appropriate. Saying “I’m sorry” may help to strengthen, rather than undermine, the physician-patient relationship.
- 3) If the cause of the adverse event is uncertain, tell the patient and/or family that further investigation is necessary before the exact cause will be known and commit to follow-up with the patient/family once the investigation is completed. Ask the patient and/or family if they have any questions and answer them to the best of your ability based on what information is known at the time of the conversation – do not speculate or hypothesize.
- 4) Identify who will be involved in the ongoing care of the patient. If maintaining the physician-patient relationship appears difficult, it may be appropriate for the attending physician to offer to transfer the care of the patient to another provider.
- 5) Reach out to the family and emphasize your willingness to speak with them at any time. Follow-up with the family as to the results of any investigation undertaken and let them know what steps will be taken to prevent future similar events.
- 6) In some cases it may be appropriate to waive or adjust the patient’s bill. Please speak to the WUSM Department of Risk Management before making any such offers.

Guidelines for Documentation

- 1) The patient’s medical record should contain a complete, accurate and factual record of pertinent clinical information related to the event and should be completed in a timely manner. The documentation should include:

- Objective details of the event, including date, time and place (avoid hypothesizing, speculation or assignment of blame until a full investigation has been completed)
 - The patient's condition immediately before the time of the event
 - Medical intervention following the event including studies ordered, therapies initiated, medications ordered and requested consultations
 - Patients response to the medical intervention
 - Future treatment plans
- 2) Disclosure discussions with patients and/or their families should also be documented in the medical record. The medical record documentation regarding the disclosure discussion should include the following:
- Time, date and place of discussion
 - Names and relationships of those present at the discussion
 - Documentation of discussion of the event (be objective and state only the facts)
 - Patient/family response
- 3) Any follow-up conversations with the patient and/or family should also be factually documented in writing in the medical record.
- 4) Do not make reference in the medical record that the WUSM Department of Risk Management was contacted or that an incident report has been filed. When necessary a separate writing can be prepared to document the investigation of the adverse event, any peer review and/or process issues, or demands for payment. This separate documentation should be sent to WUSM's Department of Risk Management.

APPENDIX - A Physician's Guide: Basic Steps for Disclosure

- **Preparing**
 - **Initiating the conversation**
 - **Actively listening**
 - **Acknowledging what you have heard**
 - **Responding**
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Patient disclosure does not include:

- claiming liability by saying, "I caused this problem . . ."
- criticizing the care or response of other providers
- making excuses, being misleading, defensive or mysterious
- altering the medical record, or placing personal notes or comments in the record
- relying on an *ad hoc* process to determine what will be communicated or who will speak for the team
- communicating "off the record"
- stating or implying causation or the reason why you believe the adverse outcome occurred unless causation is clear and unequivocal

Preparing

- Review the facts
- Identify and involve the appropriate participants, if practicable
- Use an appropriate setting

Initiating the conversation

- Determine the patient/family readiness to participate as soon as possible
- Assess the patient and family's medical literacy and ability to understand what you are about to disclose
- Determine their level of medical understanding in general

Presenting the facts and actively listening

- Give a simple description of *what* happened
- Tell what is known of the outcome at that point
- Describe the next steps in the patient's medical care and treatment options
- Sincerely acknowledge the patient and family's suffering

Concluding the conversation by acknowledging what you heard

- Summarize what you have just told them
- Repeat key questions raised by the event
- Establish that *you will follow up* with them and that you will let them know what we are doing to prevent this from happening in the future - Do not make it *ad hoc*, but set a timeframe to follow-up/meet with them again

Documentation

- Describe the event and disclosure discussion in the medical record
- Refer any need for further investigation or demand from payment in writing to WUSM Risk Management

Other Considerations

- 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

Even after reviewing the guidelines above on disclosing adverse events to patients, you may find it helpful to consider some model language if this is new to you:

- *Let me tell you what I know about what happened. Instead of receiving _____, we gave you _____ instead. I want to discuss what this means for your health, but first I want to tell you how sorry I am that this happened..*
- *I'm sorry. This should not have happened...or...We made an error. I'm sorry.*
- *Right now I don't know exactly what happened but I promise you that we're going to find out and make sure it doesn't happen again. It may take time to get to the bottom of it, but I'll share with you what we find out as soon as I know. Again, let me tell you how sorry I am that this happened.*
- *Now, what does this mean for your health?.....*

Please Note: If you have any questions about what to disclose or need guidance as to how to do it, please contact WUSM Risk Management at 362-6956.