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PURPOSE

Patients have the right to receive accurate, timely and easily understood information regarding all clinical events so that they can make informed decisions about their care. Patients and, when appropriate, their families are entitled to information about the outcomes of diagnostic tests, medical treatment and surgical intervention whether the results are expected or unanticipated. When an Unanticipated Outcome occurs, the patient is entitled to a timely explanation of the Unanticipated Outcome and its short and long-term effects. When an error contributed to the Unanticipated Outcome, the patient must be provided an honest and compassionate explanation of the error and the medical treatment available to the patient. The patient should also be informed that the factors involved in the Unanticipated Outcome will be reviewed so that corrective measures can be taken to reduce the possibility of similar outcomes in future patients.

DEFINITIONS

An **Unanticipated Outcome** is a result that differs significantly from what was anticipated to be the result of a diagnostic test, medical treatment, or surgical procedure. An Unanticipated Outcome includes a **Sentinel Event** or an **Occurrence**, as defined in Patient Care Corporate Policy #218 (Patient Safety and Quality Improvement Report), which results in actual injury or places the patient at risk for injury, for which monitoring and/or follow-up will be required. An Unanticipated Outcome may or may not be associated with an error. Errors discovered during retrospective peer review and/or quality assurance process are not subject to this policy. Contact the appropriate medical staff Chief of Service if there are any questions regarding application of this policy.

GUIDELINES FOR RESPONDING TO AN UNANTICIPATED OUTCOME

The order in which the following guidelines are implemented may vary depending on the individual situation. In every instance of an Unanticipated Outcome, however, caring for the patient's immediate needs should always come first. The Medical Chief of Service and Director of Nursing, in collaboration with the attending physician, nurse manager and/or department manager are responsible for implementing the following guidelines. If necessary, reference Patient Care - Corporate Policy #312, Chain of Command, to assure compliance with this policy.

1) **Care for the Patient:** Address the current health care needs of the patient. The patient's attending physician should be immediately notified of the Unanticipated Outcome and all necessary tests and/or consults ordered.

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GUIDELINES FOR RESPONDING TO AN UNANTICIPATED OUTCOME (Cont'd)

2) **Preserve the Evidence:** If the Unanticipated Outcome involves a medical device (pump, anesthesia machine, etc) or medical equipment (syringes, IV tubing, medication vials or packaging, etc), remove the device/equipment from service and immediately contact Biomedical Engineering at x16300 (RO & GP), x41070 (Troy). The medical device or equipment and related packaging materials should be preserved and turned over to Biomedical Engineering.

3) **Document in the Medical Record:** At the time of the Unanticipated Outcome, *objectively* document the facts known about the Unanticipated Outcome in the patient's medical record. Include the medical care provided in response and the plan of treatment.

4) **Complete a Patient Safety and Quality Improvement Report:** If the Unanticipated Outcome meets the definition of an Occurrence or Sentinel Event, an electronic **patient safety and quality improvement** (PSQI) report should be completed pursuant to Patient Care Corporate Policy #218. Contact the Quality & Patient Safety Department at Royal Oak, Troy or Grosse Pointe as appropriate immediately if the Unanticipated Outcome requires Sentinel Event or High Priority Review consideration.

5) **Initial Disclosure:**
   - An Unanticipated Outcome should be communicated to the patient, or appropriate guardian or representative, if there are clinical consequences or, if a reasonable person would want to know, regardless of whether any negative clinical consequences resulted.
   - The Medical Chief of Service and Director of Nursing are responsible to assure that the process of disclosure occurs in a timely and appropriate manner.
   - In rare instances, where it can clearly be demonstrated that the interests of the patient are harmed by disclosure, discussion of an Unanticipated Outcome may be withheld until the benefits of disclosure are greater than the harms. The reasons for this exception should be documented in the **Patient Safety and Quality Improvement** Report.
   - The initial disclosure should take place in a timely manner after the Unanticipated Outcome is identified and the immediate health care needs of the patient have been addressed.
   - The discussion of Unanticipated Outcomes is the responsibility of the patient's attending physician of record. A team approach may be necessary, however, as determined by the attending physician, nurse manager and, as necessary, the department manager. It is recommended at least one other individual from the hospital or medical staff be present to witness the discussion. The patient should be given the option of having another person with them as support during the discussion.
   - A nurse may discuss minor occurrences that do not result in morbidity, such as a patient fall without injury.

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GUIDELINES FOR RESPONDING TO AN UNANTICIPATED OUTCOME (Cont'd)

5) **Initial Disclosure:** (Cont'd)

- A meeting may be called with the attending physician and the disclosure team to discuss the presently known facts prior to the discussion with the patient and/or family. If the attending physician considers it appropriate, Legal Affairs, Corporate Communications and/or the Director of the Ethics Consult Service may be requested to assist in preparation for this meeting.
- The attending physician or, when appropriate, a designee and/or the disclosure team should discuss the situation with the patient and/or family. If necessary, consult pastoral care or social work to assist in the disclosure.
- The discussion should include:
  - An understandable, objective, factual explanation of the Unanticipated Outcome;
  - The follow-up treatment/monitoring plan for the patient;
  - Assurances that the Unanticipated Outcome is being investigated and information will be shared with the patient and/or family when this investigation is complete;
  - Immediate measures taken to prevent recurrence;
  - An opportunity for the patient/family to express his/her perception of the significance of the event.
  - An apology that an Unanticipated Outcome occurred. **NOTE: while expressions of sympathy, condolence and understanding may be appropriate, an admission of fault or responsibility should not be made until completion of the event review or Root Cause Analysis.**
  - The name and phone number of an individual in the hospital to whom the patient may address complaints or concerns about the Unanticipated Outcome.
- Verify the patient's/family's understanding of the unanticipated outcome and answer questions they might have.
- Make an appointment for follow-up phone call or visit with patient and/or family and encourage patient and/or family to call if they have questions. Provide patient and/or family with the name and number of a contact person.
- The discussion of the Unanticipated Outcome with the patient/family must be documented in the medical record. This documentation should include the time, date and place of the discussion, the names and relationships of those present, a summary of the information provided and questions answered, an offer of assistance and the response to it.

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GUIDELINES FOR RESPONDING TO AN UNANTICIPATED OUTCOME (Cont'd)

6) **Analyze Unanticipated Outcome:**
   - All Unanticipated Outcomes involving errors should be analyzed to prevent recurrence and improve future patient care. All Unanticipated Outcomes should be reported in a Patient Safety and Quality Improvement Report. Notification to the appropriate Quality and Patient Safety Department must be made for further assessment and, depending on severity, Sentinel Event or High Priority review (refer to Patient Safety and Quality Improvement Report Policy #218 and Sentinel Event Policy #219). This analysis is performed pursuant to Michigan's peer review statutes and is confidential and protected from discovery and subpoena pursuant to MCLA 333.20175, 333.21513, 333.21515 and 331.531-533.

7) **Follow Up Disclosure:**
   - This is when the attending physician and/or disclosure team should discuss the details of "how" and "why" the Unanticipated Outcome occurred.
   - The designated contact person should call back the patient and/or family as promised or as needed. Offer to meet with patient and/or family to discuss non-confidential information and findings regarding the analysis of the Unanticipated Outcome.
   - Providing an explanation of what occurred should not involve expressions of blame. However, if indicated by the investigative findings, an organizational apology and corporate admission of fault may be offered. The Chief of Service should determine the appropriateness of an admission of fault after his/her review of the investigative findings. The Director of the Ethics Consult Service and/or Department of Legal Affairs may also be asked to provide a review of the findings and to make a recommendation in this regard.
   - If the patient is still in the Hospital, document the discussion in the medical record. If the patient is discharged, document the discussion as determined appropriate by Legal Affairs.

8) **Employee Assistance Referral:** Acknowledge the effect an Unanticipated Outcome may have on members of the health care team and refer them to the Employee Assistance Program when necessary. Refer to Human Resource Manual Policy #269: Employees Involved in Clinical Errors.

RELATED POLICIES

Patient Safety and Quality Improvement Report Policy, 218
Sentinel Events Policy, 219.
Chain of Command Policy, 312.
Employees Involved in Clinical Errors Policy, 269 (Corporate Human Resources Manual).
Patient Information Confidentiality Policy, 314.