

PENNSYLVANIA HOSPITAL & Surgery Center



ADMINISTRATIVE POLICY MANUAL

SUBJECT: OCCURRENCE ASSESSMENT AND INTERVENTION

POLICY NUMBER: IOP2 – 1207

Issued

- April, 1996

Committee Approval

- Medical Executive – May, 1999
- Safety - May, 1999
- Performance Improvement - May, 1999
- March, 2003
- Patient Safety, 2005, 2006, 2007

Administrative Policy Review Committee

- April, 2001
- April, 2003
- April, 2004
- February, 2005
- August, 2005
- December, 2005, 2006, 2007

Attachment(s)

Related Policies

- [Product Recall, EC21](#)
- [Participation in Incident/ Occurrence Reporting, IOP3](#)

POLICY STATEMENT:

The purpose of this policy is to outline the process that will enable the organization to:

- Triage occurrences and facilitate disposition through the appropriate channels; and,
- Have a positive impact on improving patient care by focusing the organization's attention on identification of underlying causes and implementing changes to reduce the risk of such events occurring in the future.

DEFINITION:

An occurrence is a hospital-related event not consistent with the desired routine operations of the hospital or the care of the patient. For the purposes of management, occurrences are classified from level I to level III as follows:

1. **Level I** - no additional action required beyond that taken at the time of the occurrence. Example: patient fall, incorrect count in OR, patient or family complaints. This is reported through the Occurrence Reporting process for tracking and trending. Analysis is initiated when comparisons show that levels of performance, patterns, or trends vary significantly and undesirably from those expected.
2. **Level II** - requires further information and/or investigation. Additional concurrent intervention may be required to improve outcome and process or minimize risk. Example: confirmed transfusion reactions, significant adverse drug reactions, and significant medication errors.
3. **Level III** - critical/sentinel event that requires immediate action and in-depth analysis. A sentinel event is an unexpected occurrence involving death or serious or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Sentinel events include any occurrence that meets any of the following criteria:
 - a) The event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or
 - b) The event is one of the following (even if the outcome was not death or major permanent loss of function):

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- i) suicide of any individual receiving care, treatment or services in a staffed around-the-clock care setting or within 72 hours of discharge (i.e. hospital, residential treatment center, crisis stabilization center)
- ii) abduction of any individual receiving care, treatment or services
- iii) infant discharge to the wrong family
- iv) unanticipated death of a full-term infant
- v) rape
- vi) hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
- vii) surgery on the wrong patient or wrong body part
- viii) unintended retention of a foreign object in an individual after surgery or other procedure
- ix) severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- x) prolonged fluoroscopy with cumulative dose >1500 rads to a single field, or any delivery of radiotherapy to the wrong body regions or >25% above the planned radiotherapy dose

PROCEDURE:

1. All Occurrences

- a) It is the policy of Pennsylvania Hospital to ensure timely reporting of incidents/occurrences through implementation of a system that appropriately considers timely reporting by a staff member of an incident/occurrence in which he/she is involved in making any determination as to whether disciplinary action will be taken and/or corrective action initiated. The Participation in Incident/Occurrence Reporting Process policy (IOP3) ensures that staff members who timely report incidents/occurrences that they witness or of which they are aware but in which they are not involved are protected from retaliatory action in the workplace.
- b) Internal Reporting and Analysis – Pennsylvania Hospital has established a system for reporting of serious events and incidents, which is accessible 24 hours a day, 7 days a week. Members of the medical staff and hospital employees are required to report serious events and incidents within 24 hours of the event or discovery of the event via electronic occurrence report or a telephone call. Telephone and pager numbers are available for use by members of the medical staff and hospital employees during business hours as well as at night and on weekends. As part of its performance improvement process, Pennsylvania Hospital has adopted a procedure to triage occurrences and facilitate disposition through the appropriate channels. This process, which focuses the hospital's attention on identification of underlying causes and implementing changes to reduce the risk of such events occurring in the future, is designed to enhance patient safety.
- c) Occurrences are reported via PORTS, which is the Penn Occurrence Reporting and Tracking System and is accessed via any computer with the hospital intranet. Staff may report anonymously via PORTS. When PORTS is not available occurrences can also be called in to the

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- University of Pennsylvania Health System (UPHS) Risk Management's voice mail (215-746-5303) that is available 24 hours a day for reporting.
- d) The supervisor reviews the occurrence and documents any additional information or follow-up in PORTS.
 - e) All occurrences entered in PORTS or received by any other means are reviewed by the Director of Patient Safety or designee to identify opportunities for process improvement and make appropriate referral and follow up to ensure compliance with regulatory and insurance reporting requirements. All occurrences entered in PORTS or received by any other means also will be promptly transmitted to UPHS Risk Management.
 - f) For any occurrence with a potential of being a Level II or III, in addition to entering in PORTS, notification should be given by contacting the Director of Patient Safety (215-829-5161) during regular business hours or the Patient Care Coordinator and Administrator-on-Call during non-business hours who will notify the attorney-on-call if indicated to ensure timely notification of a critical/sentinel event.
 - g) Patient-related occurrences are to be documented appropriately in the medical record only when the event directly involves the patient's care, treatment, clinical course, or clinical outcome. All documentation must be objective and factual and should not include subjective comments, opinions, or conclusions. Guidance for proper documentation of the occurrence can be obtained from UPHS Risk Management, if needed. **Since the Occurrence Report is not part of the medical record, neither a copy of the form nor any reference to the form or notification of UPHS Risk Management is to appear in the medical record.**
 - h) Incidents related to Controlled Substances should be reported on the Controlled Substance Investigative Report by the employee discovering the error in addition to reporting via PORTS and forwarded to his/her supervisor for follow-up. The final report should be sent to Pharmacy.
 - i) Product or equipment failure/defect should be reported by the employee who identifies the failure/defect by notifying his/her supervisor and notifying biomedical engineering in addition to reporting via PORTS. Any pharmaceutical, blood product, medical device or equipment that may have malfunctioned or contributed to the occurrence should be retained. This includes disposable devices and equipment. The device or piece of equipment should have no changes made to any controls or settings, and should not be sent for repairs, cleaning or processing without approval from UPHS Risk Management.
 - j) UPHS Risk Management will be consulted to ensure compliance with all insurance reporting requirements and with all regulatory requirements for disclosure, reporting and notification, including, but not limited to, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Pennsylvania Department of Health and the Patient Safety Authority. UPHS Risk Management will handle all insurance reporting requirements as well as any reporting required under Act 13 to the Pennsylvania Department of Health and the Patient Safety Authority. UPHS Risk Management also will perform all manufacturer and FDA reporting occurrences meeting the criteria of the Safe Medical Device Act.

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2. **Level I**
 - a) Occurrence Reports are reviewed by the Director of Patient Safety, or designee, with additional information requested if needed and referred for follow-up to area/person as appropriate.
 - b) Reports are generated for trending and analysis and provided to appropriate committees and/or departments for action and education.

3. **Potential Level II and III**
 - a) Notification of any occurrence with a potential for Level II or III should be given by contacting the Director of Patient Safety (215-829-5161) during regular business hours or the Patient Care Coordinator and Administrator-on-Call during non-business hours who will notify the attorney-on-call if indicated as outlined in 1f above.
 - b) The information related to any occurrence that has the potential to be considered a critical/sentinel event will be evaluated by the Director of Patient Safety in conjunction with the Patient Safety Officer, appropriate Department Chairman and/or Administrator and UPHS Risk Management to determine if the occurrence meets the definition of a critical/sentinel event.
 - c) If the determination is made that the event meets the criteria of a critical/sentinel event, notification will be made by UPHS Risk Management to the Executive Director, Chief Operating Officer, Chief Nursing Officer, Chief Medical Officer and Department Chair, if indicated.
 - d) Based on this review and evaluation, the occurrence will be routed as outlined in the following #4 and #5.

4. **Level II**
 - a) Additional information may be obtained from involved parties individually or together. A team may be formed to evaluate the information and assist with the appropriate disposition for analysis and coordination of action plan and follow-up based on the specific nature of the event. Staff at all levels closest to the issue(s) and additional members of Administration may be included.
 - b) The occurrence can be channeled through the appropriate committee and/or department for peer review and follow-up. Performance Improvement initiatives taken as a result of the review should be forwarded to the Director of Patient Safety.

5. **Level III** - immediate action will be taken and in-depth analysis including assignment of a team, root cause analysis, establishment of a plan and timeline to address identified opportunities for improvement will be implemented.
 - a) Notification will be made as outlined in 3c above
 - b) Support for the Patient, Family and Caregiver – Immediate interventions will be instituted for all incidents and occurrences, as indicated, based on established policies and protocols of the pertinent departments including but not limited to Patient and Guest Services, Clinical Services, Security, Public Affairs, Administration and UPHS Risk Management, to provide communication to the patient, family,

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- healthcare team and UPHS as appropriate and to facilitate all additional initiatives and interventions indicated.
- c) Assignment of a team to assess the critical/sentinel event
 - i) With guidance from Risk Management and the Patient Safety Officer, the Director of Patient Safety will appoint members to the team.
 - a) This team will include representation from Clinical Services, Administration, Professional Staff, Director of Patient Safety, Patient Safety Officer, UPHS Risk Management.
 - b) Based on the nature of the event, staff at all levels closest to the issue(s) and additional members of Administration as indicated.
 - c) Confidentiality by team members is expected.
 - d) If an occurrence meets the requirements of a sentinel event, a root cause analysis will be conducted as part of the hospital's quality improvement process, within the required timeframe, and include the following:
 - i) Determination of the proximate cause of the critical/sentinel event and the process(es) and systems related to its occurrence
 - ii) Utilization of Performance Improvement tools including but not limited to Failure Mode Effects Analysis (FMEA) as appropriate
 - iii) Analysis of the related systems and processes
 - iv) Identification of possible common causes and their relative potential contributions to the event
 - v) Consideration of any relevant literature
 - vi) Determination of potential improvement in processes or systems that would tend to decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist
 - vii) Establishment of an action plan to address identified opportunities for improvement or formulation of a rationale for not undertaking such changes
 - viii) Implementation of incremental change rather than waiting until the analysis is done if injury can be prevented
 - e) The Director of Patient Safety will document the results of the root cause analysis. Patient and staff identifiers will be removed from this document.
 - f) Where improvement actions are planned, the Director of Patient Safety will document the actions, who is responsible for implementation (including any pilot testing) and the timeline for completion. The effectiveness of the actions will be evaluated utilizing the PDCA method.
 - g) Outcomes will be monitored, trended, analyzed and reported within the parameters of confidential peer review and Performance Improvement to appropriate person(s), committees and/or departments.
6. Action to Ensure Patient Safety – When there is an incident or occurrence, the employee(s), professional Staff and manager(s) involved in an incident or occurrence will take immediate action to ensure the safety of the patient, staff and others in the environment. Preservation of all items involved in the

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incident will be undertaken. If an immediate procedural change is determined to be necessary, the involved manager(s) and professional staff members will work with the appropriate administrator to communicate safety alert and immediate changes that might be required.

7. Disclosure to Patient/Family – It is the policy of Pennsylvania Hospital to ensure that patients and, when appropriate, their families are informed about unanticipated outcomes of care. To that end, Pennsylvania Hospital has provided guidance to its professional/medical staff on the making of such disclosures consistent with the guidelines promulgated by JCAHO. Also, UPHS Risk Management will notify the Executive Director of any serious event (as defined by Act 13) reported and the Executive Director will provide written notification as required by law to the patient, or where appropriate, a family member within seven (7) days of the event or the discovery of the event.
8. The Incidents and Occurrence Committee, which is part of the hospital's quality improvement process, reviews Level II and III incidents and selected Level I incidents showing unfavorable trends or potential for negative patient outcomes.

/s/Kathleen Kinslow

12/31/07

Kathleen Kinslow
Executive Director

Date

/s/R. Michael Buckley

12/31/07

R. Michael Buckley
Chief Medical Officer

Date

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