Sentinel Events/Patient Safety Events

Purpose & Scope

This policy defines the process to be undertaken when an incident defined as a sentinel event has occurred. It also governs the reporting of sentinel events to the Behavioral Health Administration and, as required, to The Joint Commission and the Office of Health Care Quality. The policy also provides definitions for sentinel event and for other types of patient safety events. The essential goals of this policy are:

1. To improve patient care.
2. To determine the underlying causes of a sentinel or other adverse event and make those changes which will reduce the likelihood of such an event from reoccurring in the future.

Policy

A comprehensive systematic analysis of all sentinel events will be completed in a timely, thorough and credible manner. It will yield an action plan with specific strategies for risk reduction, evaluation of effectiveness, and sustainment of changes made.

Definitions

Patient Safety Event: An event, incident, or condition that could have resulted or did result in harm to a patient. Patient safety events include sentinel events, no-harm events, close calls, and hazardous condition.

Sentinel Event: For purposes of this policy and procedure, a sentinel event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches the patient and results in any of the following: death, permanent harm, or severe temporary harm. Severe temporary harm is defined as critical, potentially life-threatening harm lasting for a limited time with no permanent residual. It requires transfer to a higher level of care with medical monitoring for a prolonged period of time, transfer to a higher level of care for treatment of a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition.

The following events are potentially considered sentinel events at Spring Grove Hospital Center:

1. Suicide of a patient in the hospital, or while on a therapeutic leave of absence, or while on elopement status, or within 72 hours of discharge.*
2. Elopement (i.e. unauthorized departure of a patient from the hospital leading to death, permanent harm, or severe temporary harm).*
3. Rape, assault (resulting in death, permanent harm, or severe temporary harm), or homicide of a patient receiving care, services, or treatment while on site at the hospital.*
4. Rape, assault (resulting in death, permanent harm, or severe temporary harm), or homicide of a staff member, visitor, or vendor while on site at the hospital.*
5. Death, permanent harm, or severe temporary harm directly related to a patient fall, medication error, hospital care associated infection, delay in treatment, or use of seclusion or restraint.
6. Major fires.
7. Riots and hostage taking.
8. Abduction of a patient receiving care, treatment, or services at the hospital.*
9. Other events as determined by hospital leadership.

*These events are specifically listed under The Joint Commission's definition of sentinel event.

Response to a Sentinel Event: All events identified as sentinel in nature by the hospital leadership will be responded to with investigation, systematic review, and appropriate follow-up. Key elements will include: patient and family care and support, disclosure of the event to the patient and family (per the patient's preferences), involvement of members of the patient's care team and hospital leadership, comprehensive systematic (root cause) analysis, corrective actions (action plan) with defined time lines and responsibility yielding measurable system based improvements.

Adverse Event: The Joint Commission defines an adverse event as a patient safety event that results in harm to a patient. COMAR 10.07.06 defines an adverse event as, "an unexpected occurrence related to an individual's medical treatment and not related to the natural course of the patient's illness or underlying condition." Both of these adverse event definitions are taken into consideration when the hospital identifies and responds to patient safety events.

Three levels are identified in COMAR:

Level 1 - An adverse event results in death, or serious disability, defined as a physical or mental impairment that substantially limits one or more of the major life activities of an individual lasting more than 7 days or still present at time of discharge. A Level I Adverse Event is typically a **"Sentinel"** event.

Level 2 - An adverse event that requires a medical intervention to prevent death or serious disability.

Level 3 – An adverse event that does not result in death or serious disability and does not require any medical intervention to prevent death or serious disability.

No Harm Event: A patient safety event that reaches the patient but does not cause harm. Example: a missed or wrong dose of medication that does not cause any harm to a patient.

Near Miss/Close Call: A patient safety event that does not reach the patient. It typically involves a situation that could have led to harm if it reached the patient, but did not, either by chance or through timely intervention. Medication ordered, transcribed, and/or dispensed for which a patient has a known allergy recognized prior to the patient receiving the medication is an example.

Hazardous/Unsafe Condition: A circumstance (other than a patient's own disease process or underlying condition) that increases the probability of an adverse event.

Root Cause Analysis: A process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. Focus is primarily on systems and processes, not on individual performance. It progresses from special causes to common causes in organizational processes and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future. Analysis identifies changes which should be made in systems and processes through design, redesign or development of systems or processes. The primary goal of a root cause analysis is to reduce the risk of such events occurring in the future. Root Cause Analysis is conducted on Level 1 and Level 2 events and if warranted, other patient safety events. Root cause analysis is not considered complete until the system and process improvements identified through the root cause analysis are implemented and evaluated for effectiveness.

Comprehensive Systematic Analysis: A process for identifying basic or causal factors underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis is one type of comprehensive systematic analysis.

Procedure

A. Any occurrence which is thought to be a sentinel event shall be immediately reported to the department's supervisor or department head, and a Management Variance Report (MVR) shall be promptly initiated, and submitted the same shift to Quality Assurance and Performance Improvement (QAPI). Upon the completion the MVR will be placed in the MVR in the locked drop box in Smith Building or delivered directly to the Quality Assessment & Performance Improvement Department.

B. The department supervisor, or department head shall be responsible for immediately notifying the hospital management as follows:

   1. The Chief Medical Officer for events that are primarily related to clinical care and treatment of patients.

   or

   2. The Chief Operating Officer for events related to support services or physical plant.

C. The Chief Medical Officer or Chief Operating Officer will promptly report the event to the Chief Executive Officer.

D. In the event that the Chief Medical Officer or Chief Operating Officer cannot be reached, the supervisor and/or department head should contact the Chief Executive Officer directly.

E. When notified, by the Chief Executive Officer, Clinical Risk Manager/Safety Coordinator (RM/PSC) will initiate a preliminary investigation of all the possible sentinel/adverse and near-miss events for the purpose of fact finding. The investigation will be in conjunction with the offices of the Chief Medical Officer, Chief Operating Officer, Chief Nursing Officer and others as appropriate. This process will not be in lieu of conducting a review of such incidents by the Patient Care Committee or performing a root cause analysis as indicated. The RM/PSC will monitor follow-up resulting from the RM/PSC investigation.

F. The Chief Executive Officer is responsible for notification to Behavioral Health Administration (BHA), Office of Healthcare Quality (OHCQ), and/or The Joint Commission. OHCQ requires notification of Level 1 adverse events within five days of the hospital's knowledge that an event occurred.

G. Once the Chief Executive Officer determines that an occurrence is a sentinel/Level 1 adverse event, a root cause analysis must begin as soon as possible. The Joint Commission requires that a thorough and credible systematic analysis and action plan be received within 45 business days of the occurrence or awareness of the event. The analysis must be completed with time for review, approval, and transmittal by the Chief Executive Officer. [For Level 1 adverse events, the root cause analysis and action plan must be received by OHCQ within 60 days.] As appropriate, the Chief Medical Officer as chair of the Patient Care Committee/or designee shall convene a group of staff with pertinent expertise or knowledge of the event, necessary to

conduct a root cause analysis. The group should be comprised of a broad base of individuals with expertise and knowledge specific to the specific sentinel/adverse event. The Chief Operating Officer shall convene the group for non-clinical sentinel/adverse events.

H. The Joint Commission provides detailed definitions and expectations for comprehensive systematic analyses and action plans in the "Sentinel Events" chapter of the Consolidated Accreditation Manual for Hospitals. A downloadable document, *Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event*, is available at http://www.jointcommission.org/sentinelevent.aspx. A thorough and credible analysis must be done to all the questions in the Framework. Required activities also include:

- Review of policies, procedures and protocols which may pertain to or govern the processes involved in the event.
- Literature review specific to the nature of the event.
- Review of relevant statistical data.
- Use of quality of improvement tools and techniques (e.g. flowchart, cause and effect diagram, timeline).
- Consideration of the adequacy of staffing, including nursing staffing, in the analysis of possible causes. Adequacy at a minimum looks at number, skill mix, and competency.

The *Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events* table contained in the "Sentinel Events" chapter identifies areas for inquiry when conducting a root cause analysis.

I. In order to reduce the risk of reoccurrence of the sentinel/adverse event, conferees shall design an **action plan**, and shall identify responsibility for execution of the action plan. In addition, the conferees shall set deadlines for the completion of the action plan, and shall make additional recommendations for system or hospital-wide changes, as required, to the Management Committee.

J. The chairperson of the comprehensive systematic analysis group shall prepare a written report that meets the expectation of The Joint Commission for a thorough and credible comprehensive systematic analysis and action plan. Attached to the report should be copies of any performance improvement tools which were used in the analysis and a bibliography of relevant literature.

Copies of the report should be sent to the following individuals:

1. Chief Executive Officer
2. Chief Medical Officer
3. Chief Operating Officer (for events pertaining to support services and plant management)
4. Director of Performance Improvement and Risk Management
5. Risk Manager/Patient Safety Coordinator
6. Chief Nursing Officer

The report, as a medical review activity, must be marked **"Confidential: Not For Redistribution."** Individual identifying information for patients, staff, and any others is not to be included in the written analysis.

K. The Chief Executive Officer shall approve the written analysis and action plan and assure that appropriate action and follow up occurs in response to the findings and recommendations of the sentinel/adverse event conferees.

Primary responsibility for implementation and monitoring of the risk reduction and improvement strategies in the action plan will reside with the analysis group chairperson and staff assigned responsibility in the approved action plan. Action plan progress updates will be provided in writing to the Performance Improvement Steering Committee with a copy to those identified in the preceding Section J. Additional review of the action plan will take place in committees and other hospital entities as appropriate. Action plan strategies may be shared internally with SGHC staff for education purposes.

L. The Maryland Behavioral Health Administration, as the hospital's governing body, shall be notified by the Chief Executive Officer or designee of all sentinel/adverse events, and shall also be notified of all actions planned and taken to resolve the issue(s) identified during the comprehensive systematic analysis.

M. Hospitals are strongly encouraged, but not required to report to The Joint Commission any patient safety event that meets The Joint Commission's definition of a sentinel event. In the event that the Chief Executive Officer determines that the sentinel/adverse event should be reported to The Joint Commission, the Chief Executive Committee shall notify The Joint Commission. In all cases the comprehensive systematic analysis and action plan must be provided to The Joint Commission within 45 business days of the event or of the hospital becoming aware of the event.

Level 1 sentinel/adverse events are required to be reported to the Office of Healthcare Quality within 5 days of the hospital's knowledge that the event occurred. The resulting comprehensive systematic analysis and action plan must be completed and submitted to OHCQ within 45 days of our knowledge of the event. This reporting and documentation will be submitted by the Chief Executive's Office.

N. Prior to notification of a sentinel/adverse event to The Joint Commission on Accreditation of Health Care Organizations, the Chief Executive Officer shall confer with a representative of the Governing Body.

Approved by

2/22/19
Marie Rose Alam, M.D., Chief Medical Officer Date

2/22/19
Dwain Shaw, M.P.H., J.D., Chief Executive Officer Date

DSH/jw

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