

UMHHC Policy 03-07-004

Sentinel and Serious Adverse Event Reviews

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I. POLICY STATEMENT

University of Michigan Hospitals and Health Centers are committed to identifying and correcting processes or variations in care/service that are conducive to error. A critical element of error prevention is the timely evaluation of untoward, undesirable and unanticipated events. The determination as to whether the adverse event situation meets the definition of a "sentinel event" as defined by the Joint Commission on Accreditation of Healthcare Organizations will be made by the Chief of Staff. A team including leadership and content experts will be formed to complete the root cause analysis (RCA) and action plan. In an effort to provide a systematic and timely response to all sentinel and serious adverse events, staff are to follow the process defined below.

II. POLICY PURPOSE

The purpose of this policy is to specify and disseminate the mechanism for a systematic and timely response to sentinel events and serious adverse events.

III. DEFINITIONS

Action Plan (AP): A written plan developed in response to the completion of a sentinel event or serious adverse event review, after a root cause analysis has been completed. The AP identifies the strategies that UMHHC intends to implement in order to reduce the risk of similar events occurring in the future. The plan should address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions. If no strategies are identified, the AP must indicate the rationale for not undertaking changes.

Adverse Event: An unexpected injury or potential for injury that occurs during the care of the patient, caused by care processes (rather than underlying condition) which can and frequently does, adversely affect the health of the patient. Adverse events may result from acts of commission or omission (e.g., administration of the wrong medication, failure to make a timely diagnosis or institute the appropriate therapeutic intervention, adverse reactions or negative outcomes of treatment, etc.). Some examples of more common adverse events include patient falls, medication errors, healthcare associated infections, and procedural errors/complications. When the event is determined to be preventable, it is reviewed.

Near miss: Used to describe any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome. Such a "near miss" falls within the scope of the definition of a sentinel event but outside the scope of those sentinel events that are subject to review by the Joint Commission under its Sentinel Event Policy.

Quality Improvement Department (QI): The Quality Improvement Department provides oversight for UMHHC Continuous Quality Improvement Program. The Continuous Quality Improvement Program exists to build organizational excellence in patient care, education, and research. The focus is on patients, customers and involvement of staff and faculty closest to the work. This is accomplished through a philosophy of continuous quality improvement and the application of quality improvement processes, tools, and techniques (PDCA: Plan-Do-Check-Act). Part of the Continuous Quality Improvement Program is the review of sentinel and serious adverse events and implementation of corrective actions to prevent recurrence of the events.

Risk thereof: involves system issues, near-misses, or errors whose re-occurrence poses a patient safety risk of permanent harm and/or death.

Root Cause Analysis (RCA): A systematic process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event. A root cause analysis focuses primarily on systems and processes, not on individual performance. It progresses from special causes in clinical processes to common causes in organizational processes and systems and identifies potential improvements in processes or systems that would tend to decrease the likelihood of such events in the future or determines, after analysis, that no such improvement opportunities exist. Root cause analyses will be completed within 45 calendar days for all sentinel events and within 90 days for all serious adverse events.

Sentinel Event: An unexpected occurrence involving death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition. The following are also considered Sentinel Events:

- Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge
- Unanticipated death of a full-term infant
- Abduction of any patient receiving care, treatment and services
- Infants discharged to wrong family
- Rape
- Hemolytic transfusion reaction involving the administration of blood or blood products having major blood group incompatibilities
- Surgery on the wrong patient or wrong body part
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any deliver of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose

Serious: significant injury such as loss of limb or function, cardiac or respiratory arrest

Serious Adverse Event: Serious adverse events are unexpected events that do not meet the TJC definition for Sentinel Events defined below, but may involve permanent injury to the patient that is not recognized as a complication or consequence of the patient's disease process. Serious adverse events can also reflect situations where the patient was not injured, but where the event has potential for serious patient injury. These events may result from known system or multi-disciplinary processes.

Unexpected: Unanticipated outcome due to omission or commission; Patient may experience permanent harm and/or death due to a threatening medical condition which is not unexpected, but a natural progression of their medical condition. This outcome differs significantly from what was anticipated to be the result of a treatment or procedure. An unanticipated outcome may or may not include error. A known complication or side effect is not an unanticipated outcome, but information about such outcomes should also be provided to the patient.

University of Michigan Health System Risk Management (UMHSRM): The UMHS Risk Management Department is responsible for identifying and attempting to contain, reduce, prevent, eliminate, or manage the risk of avoidable harm to patients, visitors, and employees, and the risk of financial loss to UMHC and its staff due to untoward events.

IV. POLICY STANDARDS

A. To provide a systematic and timely response to sentinel events by:

1. Reviewing all adverse events that occur within the Hospitals and Health Centers to determine which are "sentinel events"; and, institute root cause analysis and corrective action plans, as appropriate;

2. Conducting a thorough review/investigation of the events in a mutually supportive manner;
3. Identifying the related issues through root cause analysis;
4. Empowering clinical and administrative staff with authority to approve the resources necessary to implement corrective actions;
5. Assessing and measuring the effectiveness of the interventions.

B. The Chief of Staff shall determine if the event meets the criteria for a sentinel or serious adverse event review. If so, UMHSRM shall conduct an initial investigation of the facts of the event and identify discipline(s) to participate in the review. Specific staff participants will be recommended based on the facts known.

C. Established clinical practice in addition to literature review with benchmarking will be used to assess the quality of patient care.

D. Any records, data, and knowledge collected for or by individuals assigned to investigate and review adverse events are a part of a professional/peer review function and are confidential subject to MCLA 331.531, 331.532, 331.533, 333.20175, 333.21513, 333.21515, and other state and federal laws.

E. A fixed team of leaders consisting of the Chief of Staff, Chief of Nursing, Chief Operating Officer, or their designees will be formed with a representative from UMHSRM and QI to review the case along with additional content experts, as appropriate.

V. PROCEDURE ACTIONS	
PHASE I (Immediate Action)	SENTINEL or SERIOUS ADVERSE EVENT REVIEW
Responsibilities of Staff Involved in the Event	<p>The flowchart for the Sentinel and Serious Adverse Event Review Process is displayed in A</p> <ol style="list-style-type: none"> 1. Immediate stabilization of situation by clinical staff. 2. Responsible attending or resident physician should examine the patient and document the findings in the medical record for all sentinel events. 3. Immediate notification of attending physician, nurse manager/charge nurse, Nursing Services house manager, UMHSRM, and/or department manager about the event. This is the responsibility of the staff discovering the event. (see Exhibit B) <ul style="list-style-type: none"> • The attending physician will notify the Service Chief(s), Departmental Chair(s)/designee. In the event of death, the attending will follow the reporting process for the Medical Examiner. See Death Certificate and UMHHC Post Mortem Care Policy 02-03-002. • On weekends and after-hours, notify the Administrator-on-Call who will then determine the need for notifying UMHSRM

	<p>4. If the event is recognized as it is occurring or just after it has occurred, in addition to doing whatever is necessary for safety (including stopping any causative medications or treatments), leave everything else intact - i.e. leave pumps on but running into a receptacle, leave equipment in the room, etc.:</p> <ul style="list-style-type: none"> • Leave all monitors/pumps ON. Save ALL syringes/vials/ IV bags/ tubing or other equipment and packaging in a plastic bag labeled with the patient's name. • Documentation by staff with knowledge of the event must be: <ul style="list-style-type: none"> - In the medical record: factual, descriptive, accurate and legible. - Incident Report Form: in accordance with UMHHC Policy 03-07-001. (Staff should not write/keep any additional notes of the event). <p>5. For sentinel events involving patients enrolled in research, or research related equipment, the attending physician must inform the Internal Review Board (IRB) within seven working days of determining that a sentinel event has occurred.</p>
<p>Responsibilities of Nurse Manager/Administrative Leadership of Involved Area(s)</p>	<ol style="list-style-type: none"> 1. Immediately review information and data with the physician to determine the need for, and apply initial corrective action. 2. For an inpatient event, notify the Director of Nursing and Patient Care Services / designee. 3. For an outpatient event, notify the clinical and administrative leadership of the area(s) involved. 4. Review factual information with Risk Management within 24 hours of the event. 5. In consultation with Risk Management, oversee the immediate sequestering of equipment, ensure documentation in the medical record, and conduct further notifications, as needed. <ul style="list-style-type: none"> • Secure any evidence, i.e., mechanical devices, drugs, IV Lines, packaging, etc. (Exhibit B). 6. Managers of involved area(s) and physician consult with Risk Management to identify the appropriate contact person to maintain communication with the patient/family: <ul style="list-style-type: none"> • Support services should be offered to the patient/family • Conversations with the patient/family should be witnessed and documented in the medical record 7. In consultation with nursing/area leadership and Risk Management, initiates Initial Meeting for chronology of event

	<p>with the staff involved in the situation. (see exhibit A)</p> <ul style="list-style-type: none"> • Offer support through trained counselors, as needed • Ascertain the facts surrounding the event • Reinforce confidentiality and security • Inform staff that all media inquiries are to be referred to Public Relations Office, or designee
<p>Responsibilities of Risk Management</p>	<ol style="list-style-type: none"> 1. Begins fact-finding and immediate evaluation of the case upon notification. 2. Sends a memo describing the event to the Office of Clinical Affairs (see exhibit A). 3. Works with area managers(s) and staff to address communication issues, sequester equipment, etc. as previously described. 4. Notifies Biomedical Engineering when equipment is involved in an event. <ul style="list-style-type: none"> • Biomedical Engineering will communicate to the Safe Medical Device Committee who determines the need to report to regulatory agencies. 5. Assigns the event identification number
<p>Responsibilities of the Chief of Staff</p>	<ol style="list-style-type: none"> 1. The Chief of Staff and associate chiefs of staff determine if the event meets the criteria for Sentinel or Serious Adverse Event at the weekly Chiefs' meeting 2. The Chief of Staff/designee, within 24 hours of Chiefs' meeting, communicates determination of the review status of any event submitted for determination to the Quality Improvement Department and UMHSRM.
<p>Responsibilities of Risk Management</p>	<ol style="list-style-type: none"> 1. Notifies Senior Leadership in writing of the determination of a sentinel and/or serious adverse event 2. Convenes and staffs the Initial Meeting for chronology of the event.
<p>Responsibilities of the Director and Chief Executive Officer</p>	<ol style="list-style-type: none"> 1. Determines if the sentinel event will be reported to TJC within 30 calendar days of institutional discovery.
<p>Responsibilities of Quality Improvement</p>	<ol style="list-style-type: none"> 1. If the sentinel event is to be reported, submits the report form to TJC within 35 calendar of institutional discovery. 2. QI submits additional reports as requested by TJC.

PHASE II (Initial Meeting to Review Event Chronology)	SENTINEL or SERIOUS ADVERSE EVENT REVIEW
Responsibilities of Quality Improvement	<p>1. Schedule huddle with the assigned Office of Clinical Affairs lead, the UMHSRM consultant and the QI coordinator to plan review process. A determination of combined Debriefing/RCA versus separate debriefing and RCA will be made. Participant list will also be determined (see exhibit A).</p>
Responsibilities of Risk Management (MCRM)	<p>1. Conduct investigation process by completing the following:</p> <ol style="list-style-type: none"> a. Interview staff as soon as possible after notification of the event b. Offer support to staff through trained interventionists/counselors c. Reinforce confidentiality and security d. Inform staff that any media inquiries are to be referred to Public Relations, or designee <p>2. Schedule and convene a Sentinel or Serious Adverse Event - Initial Meeting for chronology of the event (see exhibit A).</p> <ol style="list-style-type: none"> a. Involved area(s) leadership in collaboration with Risk Management/Quality Improvement will conduct an Initial Meeting for chronology of the event, to complete the following: <ul style="list-style-type: none"> • Review event and determine the chronology of actions • Establish an attendance record that includes the confidentiality acknowledgment statement • Offer support to all staff members • Develop a flowchart of the event prepared by RM • Begin the literature review b. Meeting attendees include: Chief of Staff/designee (Chair); parties directly involved in the event, medical and Nursing leadership, content experts, Quality Improvement staff, Risk Management staff.
PHASE III (Root Cause Analysis Meetings)	SENTINEL or SERIOUS ADVERSE EVENT REVIEW
Responsibilities of Quality Improvement	<p>1. Identify the Sentinel or Serious Adverse Event Review Team (fixed) and Content Expert team. The Sentinel Event Review Team includes the Chief of Staff (Chair), Chief Operating Officer, Chief of Nursing Affairs, or their designees, QI staff, RM staff..</p> <p>2. Quality Improvement schedules and facilitates meeting(s) to:</p>

	<p>a. Review information and chronology completed during the initial meeting</p> <p>b. Begin brainstorming analysis on possible causes for at least all areas identified by JCAHO</p> <p>c. Begin root cause analysis to determine proximate and common causes</p> <p>d. Identify high level corrective action plan, including leads and timeframes</p> <p>e. Determine measures of effectiveness</p> <p>3. This team will continue to meet until proximate and common causes have been determined and a corrective action plan has been established within 45 days of notification of incident for Sentinel Events and 90 days of notification of incident for Serious Adverse Events.</p>
PHASE IV (Wrap-Up Meeting)	SENTINEL or SERIOUS ADVERSE EVENT REVIEW
Responsibilities of Quality Improvement	<p>1. Quality Improvement schedules and facilitates meeting to:</p> <p>a. Wrap up the review and root cause analysis</p> <p>b. Finalize the action plan</p> <p>c. Communicate the analysis and action plan to all participants</p> <p>d. Participants include: Chief of Staff/designee (Chair), Quality Improvement staff, Risk Management staff, members of Sentinel Event Review and Content Expert teams, and parties originally involved in the initial meeting (those involved in event).</p>
PHASE V	IMPROVEMENT MONITORING AND FOLLOW-UP
Responsibilities of Quality Improvement Staff, CQI Lead Team, and Chief of Staff	<p>1. Quality Improvement Coordinator reviews status of corrective actions & measurements monthly.</p> <p>2. Corporate Director, Quality Improvement, or designee reviews status of corrective actions with CQI Lead Team quarterly.</p> <p>3. CQI Lead Team facilitates the implementation of follow-up actions, as required</p> <p>4. Corporate Director, Quality Improvement and/or Chief of Staff provides a summary of sentinel events, related actions and measures of effectiveness to the Hospital Executive Board, at least annually.</p> <p>5. Chief of Staff updates the Executive Committee on Clinical Affairs (ECCA) and the Medical Liability Review Committee (MLRC) on progress, as needed.</p>

Responsibilities of Faculty, Staff and Leadership	<ol style="list-style-type: none"> 1. Attend and participate in the meetings. 2. Provide additional information as requested. 3. Complete corrective action plans, as assigned. 4. Monitor the effectiveness of actions, as appropriate. 5. Associate Director and/or Service Chiefs responsible for assigned area(s) are accountable to ensure corrective action plans are implemented.
Responsibilities of the Chief of Staff/Designee	<ol style="list-style-type: none"> 1. Chair the RCA process and insure that peer review issues are addressed in accordance with the current UMHHC Bylaws and policies and Medical Staff Bylaws.

VI. EXHIBITS

Exhibit A, page 1- [Flow Chart for Sentinel Events and Serious Adverse Events](#)

Exhibit B - **Staff Responsibilities When a Patient Incident Results in an Unexpected Outcome**

VII. REFERENCES

The Joint Commission 2009 Comprehensive Accreditation Manual for Hospitals.

Infection Control Related Sentinel/Adverse Events Infection Control Related Sentinel/Adverse Events (www.med.umich.edu/i/policies/ice/ICM_gen/sentinel.htm)

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