



Miami Valley Hospital
Sentinel Event Policy

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MVH Hospital Operations (PH) Sentinel Event Policy

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Submitted by: Ed Syron

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Scope:

PURPOSE:

The purpose of this policy is to guide in the identification and intensive assessment of sentinel events in order to improve patient care, treatment and services and to reduce their probability of recurrence.

DEFINITIONS:

Sentinel Event:

A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the 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

Reviewable Sentinel Event:

The subset of sentinel events that is subject to review by accrediting bodies includes any occurrence that meets any of the following criteria:

- The event has resulted in an unanticipated death or major permanent loss of function not related to the natural course of the individual's condition
- Or the event is one of the following (even if the outcome was not death or major permanent loss of function not related to the natural course of the individual's illness or underlying condition):
- Suicide of any individual served receiving care, treatment, or services in a staffed around-the-clock setting or within 72 hours of discharge from a 24-hour setting
- Abduction of any individual served receiving care, treatment, or services
- Rape, assault (leading to death or permanent loss of function), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the health care organization
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
- Invasive procedure, including surgery, on the wrong patient, wrong site, or wrong procedure
- Unintended retention of a foreign object in a patient after surgery or other invasive procedures
- Severe neonatal hyperbilirubinemia (bilirubin > 30 milligrams/deciliter)

- Prolonged fluoroscopy with cumulative dose > 1,500 rads to a single field or any delivery of radio therapy to the wrong body region or > 25% above the planned radiotherapy dose
- Oxygen fires (applicable to Home Health Care)

Not Reviewable Sentinel Event:

The subset of sentinel events that are outside the scope of review by accrediting bodies includes any occurrence that meets any of the following criteria:

- Any close call ("near miss")
- Full or expected return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function, whichever is the longer period
- Any sentinel event that has not affected a recipient of care (patient, individual, resident)
- Medication errors that do not result in death or major permanent loss of function
- Suicide other than in an around-the-clock care setting or following elopement from such a setting
- A death or loss of function following a discharge against medical advice (AMA)
- Unsuccessful suicide attempts unless resulting in major permanent loss of function
- Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical sequelae.

Close Call or Near Miss Event:

A "close call" or "near miss" includes any process variation that did not affect an outcome but for which a recurrence carries a significant chance of a serious adverse outcome

Root Cause Analysis:

A process for identifying the 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. The analysis progresses from special causes in clinical processes to common causes in organizational processes and systems and identifies potential improvements in these 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.

Procedure:

A. Response to a Reviewable Sentinel Event

System Quality and Risk Management will be consulted when determining whether the event meets a reviewable or not reviewable Sentinel Event.

1. A thorough and credible root cause analysis and action plan will be prepared within 45 calendar days of the event or of becoming aware of the event.
2. The Quality Innovation Department and/or Risk Management will facilitate assembling the team to conduct the root cause analysis. Team participation will include Operations from the area impacted, Quality Innovation and Risk Management representative(s), physicians including Chief Academic Officer for cases involving residents, and individuals most closely involved in the event and processes or systems under review
 - a. A root cause analysis will be considered acceptable if it has the following characteristics:
 - The analysis focuses primarily on systems and processes, not on individual performance
 - The analysis progresses from special causes in clinical processes to common causes in organizational processes
 - The analysis repeatedly digs deeper by asking “Why?” then, when answered, “Why?” again, and so on
 - The analysis identifies changes that could be made in systems and processes (either through redesign or development of new systems or processes) that would reduce the risk of such events occurring in the future
 - The analysis is thorough and credible
 - b. To be thorough, the root cause analysis must include:
 - A determination of the human and other factors most directly associated with the sentinel event, and the process(es) and systems related to its occurrence;
 - Analysis of the underlying systems and processes through a series of “Why?” questions to determine where redesign might reduce risk;
 - Inquiry into all areas appropriate to the specific type of event as described in the current edition of “Minimum Scope of Root Cause Analysis for specific types of Sentinel Events;” (Attachment #1)
 - Identification of risk points and their potential contributions to this type of event;
 - A 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.
 - c. To be credible, the root cause analysis must do the following:
 - Be internally consistent (that is, not contradict itself or leave obvious questions unanswered)
 - Provide an explanation for all findings of “not applicable” or “no problem”
 - Include consideration of any relevant literature
3. An action plan will be developed based on the root cause analysis. The action plan will identify changes to be made in systems and processes either through design or redesign of

new systems or processes that would reduce the risk of future events. The action plan will be implemented and then evaluated for effectiveness.

- d. An action plan will be considered acceptable if it does the following:
 - Identifies changes that can be implemented to reduce risk or formulates a rationale for not undertaking such changes
 - Identifies, in situations where improvement actions are planned, who is responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated
- e. A measure of success (MOS) is required for any action plan item identified as being a root cause to the event. A MOS is a numerical or quantifiable measure that determines if a planned action was effective or sustained. The following information outlines the required documentation for a MOS:
 - The method of measurement (i.e. chart audit, observations)
 - Definition of numerator and denominator
 - Frequency of measure
 - Sample size -The following sample sizes should be considered minimum requirements:
 - o For a population size of fewer than 30 cases, sample 100% of available cases.
 - o For a population size of 30 to 100 cases, sample 30 cases.
 - o For a population size of 101 to 500 cases, sample 50 cases.
 - o For a population size greater than 500 cases, sample 70 cases.
 - Sampling approach:
 - o The sampling approach should involve either systematic random sampling (for example, auditing process selects every second or third case for review) or simple random sampling (for example, process uses a series of random numbers generated by a computer to identify the cases to be reviewed).
 - Level of compliance (based on Joint Commission requirements)
 - o If the action is equivalent to an Evidence of Performance (EP) that is identified as a Category A, the level of compliance expectation for the MOS for that action will be 100%.
 - o If the action is equivalent to an EP that is identified as a Category C, the minimum required level of compliance for the MOS for that action will be 90%.
 - o If the action cannot be associated with an existing standard or National Patient Safety Goal requirement, the level of compliance expectation, which must be at least 85%
 - Level of compliance
 - o Data must be collected for a period of 4 months or until level of compliance has been achieved.

B. Response to a Not Reviewable Sentinel Event

1. A thorough intense assessment and action plan will be prepared within 45 calendar days of the event or of becoming aware of the event.
2. The Quality Innovation Department and/or Risk Management will facilitate assembling the appropriate individual(s) knowledgeable on the process or system under review.
3. The intense assessment will include inquiry into all areas appropriate to the specific type of event as described in the current edition of "Minimum Scope of Root Cause Analysis for specific types of Sentinel Events" (Attachment A)
4. An action plan will be implemented and then evaluated for effectiveness.

C. Support of Staff Involved in a Sentinel Event

This organization's policy and governing principles are to support our staff and provide them with the tools and training to fulfill the responsibilities of their role in caring for our patients. To further support our staff members, if they have been involved in an adverse or sentinel event, it is our responsibility as leadership to provide the resources to address their concerns and provide emotional support as well. If staff members feel that they need to discuss the incident and the circumstances involved with a counselor, we will provide every opportunity to do so and take the appropriate measures to see that the staff member's needs are addressed.

D. Medical Staff Quality Improvement Process

1. Potential issues relating to individual practitioner(s) performance will be referred to the Medical Staff's Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) process for evaluation and follow up as warranted.
2. Results of the FPPE will remain confidential under the hospital's peer review process and will not be included in the root cause analysis or action plans
3. Action plans should only state that the issue was referred to peer review and that the review had been completed.

E. Protection of Information

For protection of the information, all investigations will be conducted under the hospital's peer review and quality management functions.

1. The Risk Manager, in collaboration with a representative from the Quality Innovation Department, will conduct any interviews under the direction of Legal Counsel for purposes of maintaining privilege, and will obtain, sequester or preserve appropriate evidence.
2. The RCA and action plan will be maintained by the Quality Innovation Department.
3. Confidential information is prepared at the direction of and is intended to be made available only to the Medical Staff quality Improvement Subcommittees, Nursing Quality Improvement Committees, Quality Improvement Council and Board Quality Committee members of Premier Health, and is intended to be used by such committees and their members only in the

exercise of the proper functions of such committee. Any other use of this information is against Premier Health's policy and may subject you to civil liability per O.R.C. Section 2305.251 et seq.

4. The discussions, conclusions and recommendations of peer review are not disclosed as a part of the root cause analysis.
5. The responsible department/teams will maintain cycle rosters and reports to the Quality Innovation Department.

F. External Reporting

1. Disclosure of an event to patient or family will follow the process outlined in Disclosure of Unanticipated Outcome policy.
2. The decision to externally report an event to an accrediting body or agency will be based on recommendation from Risk Management and Legal Counsel in conjunction with the Quality Innovation and Executive Leadership

G. Quality Improvement

- A. The organization's design of new or modified services or processes incorporates information gained through adverse or sentinel event investigations.
- B. Lessons learned from root cause analyses, system or process failures and the results of proactive risk assessments are communicated to all staff that provide services specific to the event or situation.
- C. All sentinel events are reported to the Board Quality Committee in approved format. (Attachment B)

1 A distinction is made between an adverse outcome that is primarily related to the natural course of the patient's illness or underlying condition (not reviewed under the Sentinel Event Policy) and a death or major permanent loss of function that is associated with the treatment (including "recognized complications") or lack of treatment of that condition, or otherwise not clearly and primarily related to the natural course of the patient's illness or underlying condition (reviewable under the Sentinel Event Policy). In indeterminate cases, the event will be presumed reviewable and the hospital's response will be reviewed under the Sentinel Event Policy according to the prescribed procedures and timeframes without delay for additional information such as autopsy results.

2 *Major permanent loss of function* means sensory, motor, physiologic, or intellectual impairment not present on admission requiring continued treatment or lifestyle change. When major permanent loss of function cannot be immediately determined, applicability of the policy is not established until either the patient is discharged with continued major loss of function or two weeks have elapsed with persistent major loss of function, whichever is the longer period.

3 *Sexual abuse/assault (including rape)*, as a reviewable sentinel event is defined as unconsented sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal or anal penetration or fondling of the patient's sex organ(s) by another individual's hand, sex organ, or object. One or more of the following must be present to determine reviewability:

- Any staff- witnessed sexual contact as described above
- Admission by the perpetrator that sexual contact, as described above, occurred on the premises
- Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact

4 All events of invasive procedure, including surgery, on the wrong patient, wrong site, or wrong procedure are reviewable under the policy, regardless of the magnitude of the procedure or the outcome