



Policy and Procedure

Title Sentinel Events Policy No. I.29

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Revised by: R. Chapin

POLICY:

It is the policy of Lemuel Shattuck Hospital to continuously improve safety and quality of care provided for patients by implementing and maintaining a process for the identification, reporting, analysis and presentation of sentinel events. Any time a sentinel event occurs, LSH will complete a thorough and credible root cause analysis, implementing improvements to reduce risk and monitor the effectiveness of those improvements.

GENERAL DEFINITION - SENTINEL EVENTS:

- A sentinel event is defined by the Joint Commission as 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.
- Such events are called "sentinel" because they signal the need for immediate investigation and response.

The subset of sentinel events that may occur at Lemuel Shattuck Hospital is subject to voluntary submission for review by the Joint Commission includes any occurrence that meets 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 patient's illness or underlying condition,^{1,2} or
- The event is one of the following (even if the outcome was not death or major permanent loss of function, unrelated to the natural course of the patient's illness or underlying condition):
 - Suicide of any individual receiving care, treatment or services in a staffed around-the-clock care setting or within 72 hours of discharge.

- Abduction of any individual receiving care, treatment or services
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities³
- Rape⁴
- Surgical and non surgical invasive procedure on the wrong patient or wrong site, or wrong procedureUnintended retention of a foreign object in an individual after surgery or other procedure.
- Prolonged fluoroscopy with cumulative dose >1500 rads to a single field, or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.

GOALS:

The goals of the policy are four-fold:

- To have a positive impact in improving patient care.
- To focus the attention of the facility, which has experienced a sentinel event, to understand the underlying causes of the event, and to improve systems and processes to reduce the probability of such an event reoccurring in the future.
- To increase the general knowledge about sentinel events, their causes, and strategies for prevention.
- To maintain the confidence of the public in the facility's systems and processes related to patient/resident care.

PROCEDURE FOR REPORTING:

The employee involved in or discovering a Sentinel Event is responsible for initiating an Incident/Occurrence Report within that work shift.

- The Sentinel Event will be reported verbally to an immediate supervisor. Supervisors will oversee the completion of the initial Incident/Occurrence Report and will communicate Sentinel Event occurrences to the Director of Risk Management (off hours: after 5:00 pm, holidays, weekends – contact the Administrator-On-Call and the Risk Management hotline X 3498)
- Director of Risk Management will convene a meeting to establish facts regarding the event.

- The facts will then be presented to the EVP of Quality Management, Medical Director, and the Chief Executive Officer, to decide the need to convene a peer review committee to complete a root cause analysis.
- Peer Review Committee includes the CEO, EVP for Patient Care Services, Medical Director, EVP for Quality Management, Director of Risk Management, affected area Director or Manager and other personnel as necessary.
- Upon completion of the Root Cause Analysis and Action Plan (within 30 days of the Sentinel Event), a decision to volunteer information to accreditation organizations will be determined by the Chief Executive Officer or designee.

COMPONENTS OF SENTINEL EVENT RESPONSES:

The facility will identify and respond appropriately to all sentinel events occurring in the organization or associated with services that the organization provides, or provides for. Appropriate response includes a thorough and credible root cause analysis, implementation of improvements to reduce risk, and monitoring of the effectiveness of those improvements.

Root Cause Analysis

- Root cause analysis is a 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 individual performance. It progresses from special causes in clinical processes to common causes in organizational processes. A root cause analysis also 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.

A root cause analysis is considered **acceptable** if it has the following characteristics:

- The analysis focuses primarily on systems and processes, not 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 which 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.

To be thorough, the root cause analysis will 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;
- an analysis of the underlying systems and processes through a series of "Why?" questions to determine where redesign might reduce risk;
- an inquiry into all areas appropriate to the specific type of event as described in the Minimum Scope of Review of Root Cause Analysis attached.
- an 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.

To be credible, the root cause analysis will:

- include participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review;
- be internally consistent, i.e., not contradict itself or leave obvious questions unanswered; and
- provide an explanation for all findings of “not applicable” or “no problem”
- include consideration of any relevant literature

Action Plan

- The product of the root cause analysis is an action plan that identifies the strategies that the hospital intends to implement to reduce the risk of similar events occurring in the future. The plan will address responsibility for implementation, oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

An action plan is considered **acceptable** if

- it identifies changes that can be implemented to reduce risk, or formulates a rationale for not undertaking such changes
- in situations where improvement actions are planned, identifies 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.

The facility will prepare a thorough and credible root cause analysis and action plan within 30 calendar days of the event or of becoming aware of the event

ATTACHMENTS:

Attachment A, *Root Cause Analysis Framework*

Attachment B, *Root Cause Analysis Form and Action Plan*

Footnotes

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). In indeterminate cases, the event will be presumed reviewable and the organization'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 life-style 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 occurs first.
3. For laboratories, as required by standard QC.5.280, a confirmed fatal transfusion reaction must be reported to the FDA Center for Biologics and the Joint Commission within seven days.
4. The determination of "rape" is to be based on the health care organization's definition, consistent with applicable law and regulation. An allegation of rape is not reviewable under the policy. Applicability of the policy is established when a determination is made that a rape has occurred.

ASSOCIATED POLICIES:

LSH Policy I.6: *Patient Rights*

LSH Policy I.7: *Incident Reporting System*

LSH Policy I.8: *Management of Patient Complaints/Reporting Instruction*

LSH Policy I.13: *Release of Information to Media or Press*

LSH Policy I.26: *Serious Incident Reporting*

LSH Policy I.32: *Patient Safety Program*

LSH Policy III.79: *Reporting Disclosure of Medical Events, Including Sentinel Events*

LSH Policy IV.5: *Medical Equipment Management Plan*

A Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event

This template is provided as an aid in organizing the steps in a root cause analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest for “root cause” and risk reduction.

As an aid to avoiding “loose ends,” the three columns on the right are provided to be checked off for later reference:

- “Root cause?” should be answered “yes” or “No” for each finding. A root cause is typically a finding related to a process or system that has a potential for redesign to reduce risk. If a particular finding that is relevant to the event is not a root cause, be sure that it is addressed later in the analysis with a “Why?” question. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan.
- “Ask Why?” should be checked off whenever it is reasonable to ask why the particular finding occurred (or didn’t occur when it should have) – In other words, to drill down further. Each item checked in this column should be addressed later in the analysis with a “Why?” question. It is expected that any significant findings that are not identified as root causes themselves have “roots”.
- “Take Action?” should be checked for any finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan. It will be helpful to write the number of the associated Action Item in the “Take Action?” column for each of the findings that requires an action.
- Attach all policies and/or procedures related to the event.

Root Cause Analysis

(Include type of Incident and date analysis completed)

Level of Analysis Possibilities	Questions	Findings	Root Cause Y/N/NA	Take Action Y/N/NA
Participants in the Root Cause Analysis	<ul style="list-style-type: none"> List by job title only, no names. 		NA	NA
What happened	<ul style="list-style-type: none"> Date of Occurrence? What are the details of the event? 	(Give a narrative description of the event)	NA	NA
Patient Assessment Process	<ul style="list-style-type: none"> Process Deficiencies? What was the missing/weak step? What factors directly affected outcome? 			
Patient Identification Process	<ul style="list-style-type: none"> What are the steps in the process? What steps contributed to the event? What is used currently to prevent failure at this step? 			
Continuum of Care	<ul style="list-style-type: none"> What are steps in the process? What steps contributed to the event? 			
Staffing Levels	<ul style="list-style-type: none"> What was patient census/schedule? What was acuity level on the unit? Was Agency/Float staff used? 			
Competency assessment/credentialing cont	<ul style="list-style-type: none"> Mention physician board certifications and any other certifications held. Were there any physician performance issues? 			
Staff Performance	<ul style="list-style-type: none"> Did staff performance during the event meet expectations? Did staff perform as expected? In other words, did they follow policy and procedure during the event? 			
Communication with patient/family	<ul style="list-style-type: none"> Was the event disclosed to the patient/family/guardian/proxy? Indicate when and by who? 			

Root Cause Analysis

(Include type of Incident and date analysis completed)

Level of Analysis Possibilities	Questions	Findings	Root Cause Y/N/NA	Take Action Y/N/NA
Communication among staff members	<ul style="list-style-type: none"> Address communication issues between all participants (MD to RN, MD to MD, RN to RN, RN to tech, tech to tech. Pharmacist to RN, etc.) Any lack of verbal or written communication? Was information timely, effective and adequate? Any misunderstandings due to language barriers, abbreviations? 			
Human factors	<ul style="list-style-type: none"> Evaluate the role of human performance factors that may have contributed to the event such as fatigue of staff, personal problems, inability to focus on task, complex critical thinking skills needed, failure to follow established policies/procedures, substance abuse, boredom rushing to complete task, etc. 			
Availability of information	<ul style="list-style-type: none"> Was all the necessary information available when needed? Was patient related information (assessments, medication lists, orders, etc.) available, accurate, complete and unambiguous? Was the level of automation appropriate? Did staff have access to policies and procedures? 			
Environmental Factors	<ul style="list-style-type: none"> Consider level of care, space, privacy, safety, ease of access, etc. Was work performed under adverse conditions (i.e. heat, humidity, improper lighting, construction, cramped space, noise, etc)? Was the environment appropriate to support the function it was being used for? Identify environmental risk assessments performed. Does the current environment meet codes, specifications, regulations? Does staff know how to report environmental risks? Was there an environmental risk involved in event 			

Root Cause Analysis

(Include type of Incident and date analysis completed)

Level of Analysis Possibilities	Questions	Findings	Root Cause Y/N/NA	Take Action Y/N/NA
	<p><i>that was not previously identified?</i></p> <ul style="list-style-type: none"> • <i>Have safety evaluations and disaster drills been conducted?</i> • <i>How frequently?</i> • <i>Have provisions been planned and available to support a breakdown in operations, i.e. back-up generators?</i> • <i>Are mock codes conducted? How often?</i> • <i>Did any emergency or failure-mode response play a role in the outcome of the event?</i> • <i>Are mock codes conducted?</i> • <i>How often?</i> • <i>Were there any environmental factors within the organization's control that affected the outcome? For example, site marker washed off during prep, overhead paging cannot be heard in physician offices, safety risks, risks including activities of visitors etc. For Mental/Behavioral health, consider if there were safety risks and or security risks involved.</i> 			
Medication Management	<ul style="list-style-type: none"> • <i>Includes selection and procurement ,storage, ordering, transcribing, preparing, dispensing, administration and monitoring</i> 			
Other factors that directly influenced the outcome	<ul style="list-style-type: none"> • <i>Were there any other factors that the HCO has the ability to change by making process changes? For example making a change to a form; adding additional site verification</i> 			
Uncontrollable environmental factors	<ul style="list-style-type: none"> • <i>Identify any factors the HCO cannot change that contribute to a breakdown in the internal process, for example natural disasters.</i> 			
Future Planning	<ul style="list-style-type: none"> • <i>Describe how education/orientation/training can be revised or implemented to reduce risk in relation to this event</i> 			

Root Cause Analysis

(Include type of Incident and date analysis completed)

Level of Analysis Possibilities	Questions	Findings	Root Cause Y/N/NA	Take Action Y/N/NA
	<ul style="list-style-type: none"> • <i>Was available technology used as intended?. For example, CT scanning equipment, Pyxis system, Nighthawk services, electronic charting, etc.</i> • <i>How might technology be introduced or redesigned to reduce risks in the future?</i> • <i>Describe future plans for implementation or redesign</i> 			
<p>The Root Cause Analysis includes an analysis of the Preventability Determination Analysis requires response to all <u>three</u> of these questions:</p>	<ol style="list-style-type: none"> 1. Was this event preventable? <ul style="list-style-type: none"> • <i>Indicate response of yes or no and include justification of determination</i> 2. Could this event have been avoided by proper adherence to applicable patient safety guidelines, best practices, and hospital policies and procedures? <ul style="list-style-type: none"> • <i>Indicate response as yes or no. If the response is yes, identify non adherence with the:</i> <ul style="list-style-type: none"> - Applicable patient safety guidelines - Best practices - Hospital policies and procedure 3. Did this event result from result from a failure to follow the hospital's policies and procedures; or inadequate or non-existent hospital policies and procedures, or inadequate system design? <ul style="list-style-type: none"> • <i>Indicate response as yes or no. If the response is yes, identify as a failure of:</i> <ul style="list-style-type: none"> - Following hospital policies and procedures - Inadequate or non-existent hospital policies and procedures - Inadequate system design 			

Root Cause Analysis

(Include type of Incident and date analysis completed)

INSTRUCTIONS:

Action Plan Item	Description
Issue	For each of the findings identified in the analysis as needing an action, indicate the planned action expected, implementation date and associated measure of effectiveness. OR If after consideration of such a finding, a decision is made not to implement an associated risk reduction strategy, indicate the rationale for not taking action at this time.
Action Item	<p>Risk Reduction Strategy:</p> <ul style="list-style-type: none"> - Identify Measure of Success/indicator - What is being measured and how? - Where will monitoring results be reported? - How long will this be monitored? <p>Check to be sure that the selected measure will provide data that will permit assessment of the effectiveness of the action.</p>
Responsible Party	Who is assigned to do the monitoring?
Date of Implementation	<p>When and where</p> <ul style="list-style-type: none"> - Consider whether pilot testing of a planned improvement should be conducted. - Improvements to reduce risk should ultimately be implemented in all areas where applicable. - Identify where the improvements will be implemented.
Findings/Results of Monitoring	The results of the monitoring, and where the findings will be presented.

ACTION PLAN

#	Issue	Action Item:	Responsible Party (ies)	Date of Implementation	Findings/Results of Monitoring