I. DEFINITION OF SENTINEL EVENT:

A. The Joint Commission (TJC) defines “sentinel event” as an event that has resulted in an unexpected death or major permanent loss of function, not related to the natural course of the patient’s illness or underlying condition.

B. An 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):

1. Suicide of any patient in a setting where the patient receives around-the-clock care or suicide of a patient within 72 hours of discharge.
2. Unanticipated death of full-term infant.
3. Abduction of any patient receiving care.
4. Infant abduction or discharge to the wrong family.
5. Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the hospital.

a) Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual 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 that it is a sentinel event:

(1) Any staff-witnessed sexual contact as described above
(2) Admission by the perpetrator that sexual contact, as described above, occurred on the premises
(3) Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact
6. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.
7. Surgery of invasive procedure performed on the incorrect patient or incorrect body part.
8. Patient death or permanent injury/loss of function as a result of a nosocomial infection.
9. Unintended retention of a foreign object in an individual after surgery or other procedure.
10. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
11. 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.

C. “Or risk thereof” is further clarified to include those situations where, in the collective determination of the Administrative Review Team (see below), there is evidence that, if left unresolved, there is a significant chance that a negative impact on patient safety or care could potentially occur. Examples of situations where the ART should consider the “risk thereof” include, but are not limited to findings of:

1. Identification of significant system or process design gaps
2. Identification of significant issues involving process consistency
3. Multiple departments or disciplines are involved
4. Potential frequency of occurrence (high volume)
5. Potential for severe outcomes (high risk)

II. POLICY:

A. St. Joseph Hospital is committed to providing quality health care to our patients. An integral part of any risk/quality management program is the establishment of a sentinel event plan.

B. An event is called “sentinel” because it sends a signal or sounds a warning that requires immediate attention. Accordingly, this policy is designed to ensure maximum risk-prevention and loss-reduction activities on the part of the organization in response to a sentinel event.

C. Appropriate response includes a thorough and credible root cause analysis, implementation of improvements to reduce risk, and the monitoring of the effectiveness of those improvements. The results of this approach will help maintain the confidence of the public in our organization, and have a positive impact on improving patient care.
III. PROCEDURE:

A. Notification:

1. All St. Joseph Hospital and medical staff personnel are responsible for reporting any suspected sentinel event or significant adverse event immediately by contacting the Risk Management Department or House Supervisor, in addition to completing an Incident Reporting System form.

2. During business hours the Chief Operating Officer (COO) and Chief Medical Officer (CMO), or after hours the COO or the Administrator on call, will be notified of any suspected sentinel event.

3. The Quality and Risk Management Department will also screen for potential sentinel events via the Incident Reporting System system and the quality monitoring processes of the organization.

4. On an annual basis, staff will be educated regarding their role in the event reporting process as well as their role in promoting patient safety (cross-reference to Patient Safety Program and Plan).

5. If the event involves a CHOC patient (shared service area), SJH Risk Management will be responsible for notification of CHOC Risk/Administration.

B. Determination of a Sentinel Event and Initial Response:

1. The Quality and Risk Management Department, in collaboration with appropriate supervisors and staff, shall conduct the initial investigation into a potential sentinel event. They shall, in concert with the CMO, identify those incidents, which need further analysis in accordance with this policy.

2. An Administrative Review Team (ART) will be convened to make the determination of a sentinel event when needed.

a) The Administrative Review Team will be composed of the Department Heads of Risk Management and Quality Management, the Medical Staff Chief of Staff or designee, CMO or his designee, and operational VP, COO and/or others as representative of the event.

(1) The Chair(s) of any Medical Staff Departments with oversight for the patient locations, in which the event...
occurred and/or for a Department involved in the event, will be contacted with the initial findings to determine if the Chair wishes representation on either the ART or any Root Cause Analysis Team.

(2) For events involving CHOC patients, a review team will be convened consisting of the SJH ART composition (as above) and a designated CHOC team.

b) The Administrative Review Team shall be convened as soon as possible to:

(1) Review the initial findings
(2) Determine if the event meets the definition of a sentinel event
(3) The ART may determine on occasion that it needs more information to make the determination (e.g. pending autopsy results), in which case the ART will extend the timeline and re-convene upon the availability of such information to make the determination decision
(4) If so, then select and charter a Root Cause Analysis Team (RCAT).

(a) The members of the RCAT shall be representative of the process/services to be examined.
(b) The RCA team will include representation from medical staff leadership, administration, staff and physicians, and others as appropriate to the event, with facilitation by the Quality and Risk Departments.
(c) If the Sentinel event is a physician-specific performance issue, the review team composition shall be determined by the Chief of Staff or designee per the Medical Staff Peer Review Plan.

(5) The Administrative Review Team will also make recommendations for any initial sentinel event intervention plan for immediate follow-up care and services, risk reduction and any appropriate reporting requirements. Immediate response may include:

(a) Ensuring everything possible is being done to provide follow-up care and services to ensure the best possible outcomes for any involved patients or parties.
(b) Ensuring all parties receive appropriate information. If necessary, a hospital spokesperson will be appointed.
(c) Following any immediate regulatory reporting requirements.
(d) Obtaining, sequestering or preserving any appropriate evidence and or medical equipment related to the event.
(e) Reminding all staff of the confidentiality surrounding the event and the patient.

(3) In the circumstance that an event is deemed to be non-sentinel but still presenting an opportunity for performance improvement and/or risk reduction, the Administrative Review Team will recommend an intensive assessment process be conducted, and/or decide on specific actions to be implemented.

(4) Oversight of the initiation of the initial sentinel event intervention plan is the responsibility of the Quality and Risk Management Departments.

(5) If the ART is unable to meet within 5 days or immediate actions need to take place, a representative from RM, the CMO and or designee and an EMT member may meet and designate the event as sentinel. This group will identify any immediate actions that need to take place and the Root Cause Analysis Team will be scheduled.

C. Root Cause Analysis Team Process:

1. The Root Cause Analysis Team (RCAT) will be convened as soon as possible by the Quality and Risk Management Departments. The RCAT shall be constituted as an Ad Hoc Committee of the Medical Staff and shall report to the Medical Staff Quality Enhancement Committee through the Chief of Staff or designee. The Team will be facilitated by a member of the Quality / Risk Department.

2. The RCAT is responsible for following this Policy and Procedure, and for submitting a thorough and credible Root Cause Analysis, with reporting to the Quality Safety Committee of the Medical Staff. The review and recommendations of the RCAT will be completed within 45 Business days of discovery of the event.
3. In the rare circumstance that the RCAT requires greater than 45 days to complete its work in order to do a thorough and credible root cause analysis (e.g. highly and multiple complex processes under investigation), the facilitator from Quality / Risk Management will notify the CMO and COO of the status of the Team and expected date of completion. All efforts will be made to complete the RCA and recommendations in a timely manner.

4. The RCAT will primarily focus on the systems and processes that were responsible for the event. The Team will complete a root cause analysis using the "Framework for Conducting a Root Cause Analysis" (Attachment B).

   a) Utilizing the Framework, the RCAT will determine the potential improvements in processes or systems that would tend to decrease the likelihood of such an event occurring in the future.

   b) The RCAT will ensure a thorough analysis by:

      (1) 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.

      (2) Analysis of the underlying systems and processes through a series of “Why” questions to determine where redesign might reduce risk.

      (3) Inquiry into all areas appropriate to the specific type of event as described in the current edition of “Minimum Scope of Review of Root Cause Analysis”. (Attachment C). A copy of the Minimum Scope will be attached to the RCA report.

      (4) Identification of risk points and their potential contributions to this type of event.

      (5) 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 improvements exist.

   c) The RCAT will ensure a credible analysis by:

      (1) Ensuring the Minimum Scope of Review areas of the TJC are addressed

      (2) Including participation by the leadership of the organization and by the individuals most closely involved in the processes and systems under review

      (3) Being internally consistent, not contradicting itself or leaving obvious questions unanswered

      (4) Providing an explanation for all findings of “not applicable”
(5) Including consideration of any relevant literature

d) The RCAT will generate an acceptable action plan that:

(1) Identifies changes that can be implemented to reduce risk, or formulate a rationale for not undertaking such changes, and

(2) Where improvement actions are planned, identifying 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) An Executive Summary of the RCA will be prepared by the Quality / Risk Department to include a high-level summary of the issue, team membership by discipline, relevant literature searches, Minimum Scope of Review, primary root causes identified and summary of the Action Plan to include risk reduction strategies and status.

D. Approval and Oversight of Action of Plan:

1. The RCAT shall receive and act upon the report and recommended action plan and timeline submitted by the RCAT within 45 days of the initial notification of the event.

2. Physician specific performance issues, if any, will be referred to the Chief of Staff or designee.

3. A report of the RCAT findings, action plan and Medical Staff Quality Enhancement Committee approvals will be made to the Medical Staff Executive Committee and the Medical Affairs Committee of the Board. The Summary report will also be presented for informational purposes to selected Quality Committee of the Board of Trustees

4. The Risk and Quality Management Departments, in collaboration with Departments and Medical Staff Leadership.

5. Record will include any and all documentation related to the event, the subsequent root cause analysis, any corrective actions taken in response to identified opportunities for improvement or risk reduction strategies, and documentation that actions taken have demonstrated effective resolution to concerns identified.

E. Reporting:

1. Department of Public Health (DPH) shall be notified for unusual occurrences and all reportable never events.
2. TJC may be notified for significant sentinel event. In the event, the Administrative Review Team (ART) determines to voluntarily report a sentinel event; notification to TJC should be made within 5 working days of the event. The ART will select, in collaboration with Administration, which methodology should be selected for TJC review of the RCA.

3. Any employee death due to a sentinel event will be reported to OSHA.

4. In the event of a medical device related sentinel event, reporting to the FDA will occur and the “lock-out tag-out” policy will be followed.

5. Other reporting shall be completed as appropriate for the type of event.

6. The Quality Management Department shall keep a complete and confidential record of the sentinel event. The record will include any and all documentation related to the event, the subsequent root cause analysis, any corrective actions taken in response to identified opportunities for improvement or risk reduction strategies, and documentation that actions taken have demonstrated effective resolution to concerns identified.

IV. RELATED POLICIES:

Disclosure of Unanticipated Outcomes, Clinical Manual
Incident Reporting System, Administrative Manual

V. AUTHORITY/REFERENCES:

California Hospital Association Consent Manual
Joint Commission Hospital Accreditation Standards
St. Joseph Hospital Patient Safety Program and Plan