VARIANCE REPORTING/SENTINEL EVENT POLICY

Purpose:
To establish clear systems for hospital-wide online reporting of information related to medical/health care errors. To provide a confidential mechanism of identification, tracking, trending, and follow-up of all incidences that poses an actual or potential safety risk to patients, families, visitors and staff. Variances include events ranging from “falls” to near misses or sentinel events with serious adverse outcomes, occurring in the hospital setting.

Definitions:
- **Variance**: defined as any event or circumstance not consistent with the standard routine operations of the hospital and its staff or the routine care of a patient/visitor.
- **Near Miss**: any process variation which did not affect the 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.
- **Sentinel Event**: an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof to a patient, visitor, or an employee. 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.

Policy:
1. A Variance Report shall be submitted via on-line or on paper. A Variance Report form is located on the LSUHSC homepage, [http://www.sh.lsuhsc.edu](http://www.sh.lsuhsc.edu). Scroll to the bottom and select My HSC Portal, select Variance then select Variance Reporting form. Many units have this site saved under their favorites on their computer.

   Note: For on the job injuries refer to Administrative Directive 7.2.

2. The attending physician shall be notified immediately when the variance involves a patient.

3. If a patient or visitor is injured in a common area (i.e. sidewalks, stairwell, elevator, waiting area, etc.) the University Police Department shall be responsible for completing a Variance/Sentinel Event Report.

4. The employee identifying the Variance/Sentinel Event, or the employee to whom the Variance/Sentinel Event is first reported, shall be responsible for initiating the completion of the Variance Report Form prior to the end of their scheduled shift of duty.
Note: If the Variance/Sentinel Event occurrence is a potential Sentinel Event or Near Miss the individual responsible for reporting the variance shall notify their Supervisor immediately. The Supervisor shall then notify the Administrator on-call during normal business hours (Monday-Friday, 8:00am to 5:00pm). If the event occurs after hours, on weekends or holidays, the individual reporting the variance is responsible for printing a copy of the variance and delivering it to the House Manager, in addition to submitting the on-line form to Quality Management. If the House Manager determines the occurrence to be a potential Sentinel Event or Near Miss, the House Manager shall notify the Hospital Administrator on-call immediately.

The Administrator shall, after review and discussion with the Sr. Associate Dean/Chief Medical Officer, determine if involved employee(s) shall be drug screened; if so, the screen shall occur prior to the employee leaving the facility. The Institutions drug screen procedure shall be followed (See Employee Health policy manual for drug screening procedure)

5. Upon completion of the online Variance/Sentinel Event Report form:
   - The on-line form shall be simultaneously e-mailed to the manager for the unit on which the event occurred. (Enter the manager’s email address in the space located above the “submit” box at the end of the Variance Report.)
   - If the hospital Internet service or Microsoft Outlook is non-functional, a paper copy of the variance shall be submitted to the Quality Management Department prior to the end of the scheduled shift of duty.

6. The individual generating the report shall receive immediate notification via e-mail receipt that the Variance/Sentinel Event Report was received.

7. The Quality Management staff screens all variances and assigns a Harm Score Distribution based on a six-point classification scale (Attachment A). The Quality Management Department also summarizes each variance and refers them to the department(s) involved for investigation and resolution as needed. A resolution / corrective action related to conducting proactive risk reduction activities and the patient outcome shall be forwarded to the Quality Management Department for reporting to the Quality Leadership Team within fourteen (14) days.

8. A Sentinel Event Root-Cause Analysis shall be considered when an occurrence meets any of the following criteria:
   - The occurrence involves an unanticipated death or major permanent loss of function.
   - The occurrence is associated with significant deviation from the usual process(es) for providing health care services or managing the organization.
   - The event has undermined or has significant potential for undermining the public’s confidence in the organization.
Occurrences that potentially meet the above criteria shall be forwarded to the Hospital Administrator and the Vice Chancellor for Clinical Affairs for advisement and approval for a Root-Cause Analysis to be completed. The Hospital Administrator and the Vice Chancellor for Clinical Affairs shall direct the reporting of this occurrence to The Joint Commission and/or Centers for Medicare and Medicaid (CMS).

9. Quality Management shall coordinate the completion of a credible Root-Cause Analysis in conjunction with the assistance of the Assistant Hospital Administrator(s), Department Directors(s) and staff of the involved area(s). The Department Directors will also provide support, as appropriate, for staff who are directly involved in a sentinel event.

10. A thorough written summary of the Root-Cause Analysis of a Sentinel Event shall focus primarily on organizational systems and processes. The Root-Cause Analysis must include:

- Determination of the direct or “proximate” cause of the Sentinel Event and the processes and systems related to its occurrence.
- Analysis of the related systems and processes.
- Analysis of special causes in clinical processes and common causes in organization processes.
- Determination of appropriate risk reduction activities in order to minimize the likelihood of such risks in the future, or a determination that no such improvement opportunities exist.
- Establishment of a plan to address identified opportunities for improvement or formulation of a rationale for not undertaking such changes.
- Identification of who is responsible for implementation and how the effectiveness of the actions shall be evaluated.
- The completed RCA shall be presented to Hospital Administration.

11. When monitoring performance of specific clinical processes, certain events always elicit intense analysis. Based on the scope of services provided, intense analysis is performed on the following:

- Confirmed transfusion reactions
- Significant adverse drug reactions
- Significant medication errors and hazardous conditions

Hazardous conditions refer to any set of circumstances (exclusive of disease or condition for which the patient is being treated), which significantly increases the likelihood of a serious adverse outcome.
12. An intense analysis may also be performed when the following events occur:

- Major discrepancies, or patterns of discrepancies, between preoperative and postoperative (including pathologic diagnoses, including those identified during the pathologic review of specimens removed during surgical and invasive procedures; and

- Significant adverse events associated with anesthesia use.

- 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

13. The Hospital Administrator and the Vice Chancellor for Clinical Affairs choose performance improvement priorities and are responsible for overseeing the delegation and empowerment of staff to implement priorities for proactive reduction in patient risk.

14. Quality Management shall coordinate monitoring the effectiveness of the implemented improvements and reporting of the progress to the Hospital Administrator and Vice-Chancellor for Clinical Affairs as requested.

15. Quality Management shall forward Variance/Sentinel Reports received to the appropriate areas by Variance type:

- Environmental Variances involving falls or injuries, material safety handling or damaged/lost patient property shall be forwarded to the Safety Department, equipment malfunctions shall be forwarded to BioMed, utility outages and pest control issues shall be forwarded to Physical Plant, bed/rooms not ready shall be forwarded to Environmental Services for investigation.

- The Safety Department shall investigate patient falls/injuries and assign a Harm Score Distribution Classification Number, and provide identification of changes that will lead to improved patient safety, or tracking and trending. A description of Environmental Variances shall be forwarded to the Quality Leadership Team monthly.

- A Clinical Quality Performance Report shall also be compiled by the Quality Management Department for the Quality Leadership Team on a quarterly basis. The report shall identify the occurrence of medical/health care errors and actions taken to improve patient safety in response to actual occurrences and proactively.

- Medication Usage Variances (Adverse Drug Reactions, Medication Errors, and Controlled Substance/Narcotic Discrepancy) shall be forwarded to the appropriate department manager for investigation. Cases shall be referred to the Pharmacy and Therapeutics (P&T) Committee as appropriate. Results shall be tracked and trended by the Pharmacy Department and reported to the P&T Committee at least quarterly. The P&T Committee shall proactively review how errors occur and make recommendations to reduce patient risk. In addition, a Medication Variance Report is forwarded by Quality Management to the Quality Leadership Team monthly and quarterly.
• Clinical and Department Specific Variances shall be reviewed and investigated by Quality Management for possible input into the Medical Staff and Resident Peer Review Profiles and/or other areas as appropriate to proactively identify how errors occur and reduce risks relevant to the management of the patient’s condition. The data is utilized to generate a monthly and quarterly Patient Safety Report for the Quality Leadership Team and the Clinical Board.

• Disruptive Behavior Variances shall be investigated and action taken when indicated by the appropriate department manager and Hospital Administrator’ variances involving members of the medical staff, residents or fellows shall be forwarded to the appropriate Department Chairman and the Vice-Chancellor of Clinical Affairs for review and action.

16. The Quality Management Department shall maintain the information of all Variance/Sentinel Event Reports received in the department’s database management program. In addition to the above reports, ad hoc reports for other appropriate departments, committees or management are generated as needed.

Administrator

1/16/13
Date

Approved by Clinical Board: 1/12/01, 1/20/04, 6/15/04, 3/15/05, 2/21/06, 4/21/09, 3/16/10, 1/15/13
Written: 8/95
Revised: 10/97, 2/98, 12/00, 12/02, 11/03, 5/04, 2/05, 1/06, 3/09, 3/10, 1/13
Reviewed: 3/09, 3/10, 1/13
Harm Score Distribution
For Variances

A classification will be applied to each variance report by the Assistant Director of Quality Management. All safety variances will be classified by the Safety Office.

0. No Harm
1. Potential Harm/Injury
2. Injury
3. Near Miss
4. Harmful Event/Sentinel Event
5. Unknown

Definitions:

No Harm – an event occurring in which the patient is not injured, or otherwise harmed.

Potential Harm/Injury – an event in which a physician order was not followed or a medication was not administered.

Injury – physical harm, damage, or pain not otherwise classified as a Near Miss or Harmful Event/Sentinel Event.

Near Miss – an occurrence which did not affect the outcome, but for which the recurrence carries a significant chance of a serious adverse outcome.

Harmful Event/Sentinel Event – an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.

Unknown – an event occurring in which the actual or potential risk of harm is unidentified.

Developed by QM: 8/6/03
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