



Event Reporting and Investigation Process -- SAHS

- I. Policy Statement:** This policy sets forth guidelines for the identification, reporting and investigation process for Events as defined in this policy.

The purpose of the policy is to facilitate the systematic collection of data, research and analysis to effect the review and/or appropriate revision of procedures and systems, to reduce morbidity and mortality and to enforce and improve the standards of health care practices in the State of Idaho, consistent with the purpose as stated in Idaho Code § 39-1392 et seq, and Oregon Code §41.675 et seq.

II. Definitions:

- A. An Event is an occurrence that is inconsistent with the normal or expected operation of the organization that either did, or could, adversely affect a visitor or patient, or a patient's planned care. Reportable Events include but are not limited to:
1. Patient behavior that may be harmful to themselves or others;
 2. Medical equipment or device malfunction;
 3. Visitor injury;
 4. Hazardous environmental conditions within the organization;
 5. Medication variances, including adverse drug reactions;
 6. Inappropriate provider behavior;
 7. Patient property loss/damage;
 8. Specimen variances;
 9. Unexpected variation during surgery or invasive procedures; or
 10. Variations or complications during labor and delivery.
- B. Adverse Event: Any unexpected clinical event that
1. Results in death or permanent disability
 2. Could reasonably be expected to lead to reputational harm
 3. Could reasonably be expected to result in a review by a licensing or accrediting agency
 4. Requires securing non-Trinity Health resources for advice, or consultation during the investigation or
 5. Could reasonable affect multiple patients
- C. Sentinel Event: A Sentinel Event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches the patients and results in any of the following: death, permanent harm or severe temporary harm [refer to Sentinel Events/Serious Reportable Events (SREs) and Root Cause Analysis (RCA) policy]

- D. Severe Temporary Harm: Critical potentially life-threatening harm that lasts for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition
- E. Serious Reportable Event: One of twenty nine (29) events as endorsed by the National Quality Forum (NQF) [refer to Sentinel Events/Serious Reportable Events (SREs) and Root Cause Analysis (RCA) policy]
- F. Significant Facility Event: An issue impacting the normal functioning of the building (flood, air handling system, air conditioning, heating, electrical supply) that could possibly negatively impact patient care, or require transferring patients to another unit or facility.

III. Procedure:

A. Reporting Procedures for an Event:

1. The employee or medical staff member involved in, observing, or discovering an Event is responsible for initiating an event report.
2. If this is an event involving an adverse event, severe temporary harm, or a significant facility event please report immediately to department leadership (lead, charge, supervisor, manager, or director) to initiate a Critical Event Response Team.
3. The event report will be completed online by accessing the SAHS intranet at any SAHS computer terminal and selecting the appropriate link.
4. Generally, Events should be reported within 24 hours of their occurrence. However, should the event rise to the level of a Sentinel Event, it must be reported as set forth in the Sentinel Event and Root Cause Analysis policy, located in the Administrative Policy and Procedure Manual.
5. Individuals required to complete the event report have the option of submitting the report anonymously; however, such individuals are encouraged to identify themselves to enable a more complete investigation of the event.
6. The completed Event Report form will be objective, comprehensive, and should not include personal opinion or speculation.
7. All patient events with a severity level 3 (reached patient, no harm) or higher shall be reported to the licensed independent practitioner in a timely manner.

B. Review of Events:

1. All Event Reports will be reviewed by Risk Management within one business day of receipt with the objective of:
 - a. Ensuring proper routing and distribution to appropriate managers/supervisors;
 - b. Confirming that reports are appropriately submitted and categorized;
 - c. Identifying issues that need immediate action; and

- d. Identifying recurring events that need further investigation and/or action.
 2. Event Reports will be routed, either automatically or manually to pre-defined managers/supervisors.
- C. Investigation and Follow-up:
1. All managers/supervisors who have received notification and routing of an Event Report are responsible for follow-up as needed and documenting the follow-up within 7 calendar days.
 2. The following events will be monitored for trends:
 - a. Severity Level 1: Event has the capacity to cause harm.
 - b. Severity Level 2: Did not reach the patient.
 - c. Severity Level 3: Reached patient, no harm.
 - d. Severity Level 4: Increased patient monitoring, but no harm.
 - e. Severity Level 5: Temporary harm to patient, requiring treatment or intervention. For example, patient fall and monitoring increased to prevent future falls; patient fall, hit head and CT Scan ordered; medication error, order for another medication to reverse effects of wrong medication given.
 3. The following events will be evaluated by risk management and the involved manager/supervisor to determine whether the medical condition or error contributed to the harm requiring a Root Cause Analysis and to determine next steps:
 - a. Severity Level 6: Temporary harm to patient and prolonged hospitalization. For example, temporary disability or loss of bodily function lasting more than 7 days or still present at time of discharge.
 - b. Severity Level 7: Contributed to permanent patient harm.
 - c. Severity Level 8: Temporary harm to patient lasting greater than 7 days and/or present at discharge and required intervention to sustain life of patient.
 - d. Severity Level 9: Contributed to patient death.
 4. Risk Management will electronically close the report not sooner than 60 days from date entered.
- D. Confidentiality:
1. It is the intent of Saint Alphonsus to preserve the confidentiality of all its peer review activities as defined in Idaho Code Section 39-1392 (a) (9), and Oregon Code §41.675 including specific event reports and investigations. All information, interviews, reports, statements, memoranda, notes, investigative graphs and compilations and contents thereof, or other data of any nature whatsoever generated in accordance with Peer Review statutes, as well as peer review information relating findings and conclusions, or recommendations resulting from the applications of this policy, are privileged and confidential information.
 2. Employees and medical staff will maintain the confidentiality of all information and documents generated pursuant to this policy and refrain from discussing any Event with, or in the presence of the medical staff or employees who are not involved in the investigation

process. Release of such information must be authorized by the Chief Quality Officer and/or the Vice President and General Counsel.

E. Documentation in the Medical Record:

1. All patient events shall be thoroughly documented in the patient's medical record including, but not limited to:
 - a. The facts of what occurred,
 - b. Patient assessment,
 - c. Steps taken and interventions in response,
 - d. All licensed independent practitioner contact and communications,
 - e. Under no circumstances shall documentation in patient's record include the opinions or speculation regarding the event.
2. Mention of the completion of an Event Report shall not be included in the patient's medical record.

F. Reporting:

1. Risk Management will provide Lessons Learned from Root Cause Analyses to the Quality and Safety Council and the Quality Care and Professional Practice Committee of the Board.
2. Risk Management will provide unit-specific data to patient care units. The managers of these units are tasked with reviewing the data, identifying any trends or areas of concern, and instituting appropriate corrective actions.

IV. Related Policies/Forms:

- A. Appendix A: File Manager Checklist
- B. Event Reporting and Investigation Severity Level Scoring -- SAHS
- C. Injury, Illness and Exposure Reporting - Colleague -- SAHS
- D. CERT-Critical Event Response Team -- SAHS
- E. Sentinel Events/Serious Reportable Events (SREs) and Root Cause Analysis (RCA) -- SAHS

V. References:

- A. Idaho Code § 39-1392 et seq.
- B. Oregon Code §41.675 et seq.

VI. Approval Committee(s): None.

Appendix A: File Manager Checklist

Turnaround time expectations for file investigation and documentation:

- Severity Level 0-3: 1 week
- Severity Level 4-9: 3 days or less

- Read the submitted file
 - This workflow should be scheduled into your daily routine
- Thoroughly investigate the event
 - May include chart review, employee interviews, patient interviews, policy review, etc.
 - Focus on systems and processes that contributed to the event
 - Methodology may include asking '5 Whys', utilizing a Learning From Defects model, etc.
 - Adhere to the principles of Just Culture
- Follow up on the event
 - Are there any immediate responses that are needed?
 - Example: defective products removed from stock, halting a dangerous practice/procedure, conversations with Risk Management when injury level is more severe than originally reported, service recovery with patient/family, support to employees who may be upset by event
- Validate that all information in the file is correct
 - Make any corrections
 - If 11other11 is used for any fields, change to a selection that is more accurate/descriptive
 - Update the Severity Level to reflect your investigative findings (this field may be updated multiple times as new information is made available to you)
- Create an action plan for prevention of a similar event from occurring in the future
 - Focus on systems and processes, the problem not the person
 - Utilize industry standards and best practices, tap into internal resources and experts
 - Share learnings with other staff, leaders, and departments
- Document within the file, including:
 - How you investigated the event
 - What you found
 - What you did to resolve this event
 - What you did to prevent a similar event from reoccurring in the future

File Manager Expectations:

- Commit to making safety a priority in your work area
- Promote a culture in which employees feel safe reporting and don't fear reprisal or blame
- Encourage employees to submit events AND near misses/Good Catches
- Don't submit events for your employees
- Promptly investigate and sign off on your files
- You must close the loop with employees about VOICE files. May do so individually and at staff meetings/huddles, while respecting anonymity.
- Know your trends, share your data, and celebrate your successes!