Patient Safety Event Reporting Policy

Policy Owner: Clinical Quality Excellence

POLICY STATEMENT

AU Health System is committed to improve the quality and safety of patient care through the following:

- Identification and evaluation of errors, near misses or hazardous/unsafe conditions that are a threat to patient safety or have the potential to result in patient harm
- To improve systems and processes
- To foster a culture of safety and learning across the organization by openly discussing patient safety at all levels.

Within a culture of safety, there is continuous reporting of patient safety events, near misses and hazardous conditions so these occurrences can be analyzed and processes can be changed or systems improved.

Reporting is essential to the identification and evaluation of errors for the purpose of identifying root causes and trends which leads to improving processes which is essential to reduce risk and prevent patient harm. All team members are required to participate in the detection and reporting of any error, medication error, near miss, hazardous/unsafe condition, process failure, injuries involving patients, visitors and staff or a sentinel event.

This policy will be reviewed annually to ensure compliance with each element for regulatory compliance, Leapfrog compliance, and to Patient Safety Organization reporting compliance.

AFFECTED STAKEHOLDERS

Indicate all entities and persons within the Enterprise that are affected by this policy:

☒ Hired Staff
☒ House Staff/Residents & Clinical Fellows
☒ Leased staff
☒ Medical Staff (includes Physicians, PAs, APNs)
☒ Vendors/Contractors

☒ Other: Include any other stakeholders not listed above.

DEFINITIONS

Disclosure - for purposes of this policy, disclosure is the sharing of a patient's health information to individuals, or their personal representatives, specifically when they request access to, or an accounting of disclosures of, their protected health information; and to Health and Human Services when it is undertaking a compliance investigation or enforcement action.

Root Cause Analysis and Action (RCA^2) - a process for identifying basic or casual factor(s) underlying variation in performance, including the occurrence or possible occurrence of a sentinel event. The RCA^2 will include assessment of the problem, identification of an opportunity for improvement, planning and implementation of improvement strategies and long term effectiveness evaluation to sustained improvement.

Patient Safety Organization (PSO) for the purpose of this policy, the PSO is Vizient PSO, a federally listed PSO. A health care provider can only obtain the confidentiality and privilege protections of the Patient Safety Act by working with a Federally-listed PSO. PSO shall have the same meaning as defined at 42 CFR 3.20.

Patient Safety Event – An event, incident, or condition that could have resulted or did result in harm to the patient and can be but is not necessarily the result of a defective system or process design, a system breakdown, equipment failure, or human error. A patient safety event can be any of the following events:

Adverse Event – a patient safety event that resulted in harm to a patient.

No-harm event- a patient safety event that reaches the patient but does not cause harm.
Near miss event (or "Great Catch") – a patient safety event that did not touch the patient.

Hazardous condition (or unsafe condition)- a circumstance, other that the patient's own disease process or condition, that increases the probability of an adverse event.

Sentinel Event – Sentinel events are defined by The Joint Commission within the standards accreditation manual. 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 a patient and results in any of the following:

1) Death
2) Permanent harm
3) Severe temporary harm – A critical, potentially life-threatening harm lasting 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.

An event is also considered sentinel if it is one of the following:

1) Suicide of any patient receiving care, treatment, and services in a staffed around the clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED).
2) Unanticipated death of a full-term infant.

3) Discharge of an infant to the wrong family.
4) Abduction of any patient receiving care, treatment, and services.
5) Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient.
6) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups).
7) Rape or 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:
    - 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:
        - 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
8) Rape or assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital.
9) Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure.
    - Invasive procedures, including surgery, on the wrong patient, or at the wrong site, or that is the wrong procedure are reviewable under the policy, regardless of the type of the procedure or the magnitude of the outcome.
10) Unintended retention of a foreign object in a patient after an invasive procedure, including surgery.
    - "After surgery" is defined as any time after the completion of final skin closure, even if the patient is still in the procedural area or in the operating room under anesthesia. This definition is based on the premise that a failure to identify and correct the unintended retention of a foreign object prior to that point in the procedure represents a system failure, which requires analysis and redesign. It also places the patient at additional risk by extending the surgical procedure and time under anesthesia. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk of the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.
11) Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter).
12) Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body regions or >25% above the planned radiotherapy dose.
13) Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care.

- Fire is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in smoldering condition (no flames) is still classified as fire. Source: National Fire Protection Association. NFPA 901: Standard Classifications for Incident Reporting and Fire Protection Data. Quincy, MA: NFPA, 2011.

14) Any intrapartum (related to the birth process) maternal death
15) Severe maternal morbidity (not primarily relates to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm. Severe maternal morbidity is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hrs.), that requires the transfusion of 4 or more units of packed red blood cells and/or admission to the intensive care unit (ICU). Admission to the ICU is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support.

Serious Reportable Events - a patient safety event as defined by the National Quality Forum (NQF) that should never occur in a hospital. The NQF-Endorsed Serious Reportable Events are an ongoing effort to enable healthcare quality and safety improvement through introduction of tools for assessing, measuring, and reporting performance.

1. SURGICAL OR INVASIVE PROCEDURE EVENTS

1A. Surgery or other invasive procedure performed on the wrong site
1B. Surgery or other invasive procedure performed on the wrong patient
1C. Wrong surgical or other invasive procedure performed on a patient
1D. **Unintended** retention of a foreign object in a patient after surgery or other invasive procedure
1E. Intraoperative or immediately postoperative/postprocedure death in an ASA Class 1 patient

2. PRODUCT OR DEVICE EVENTS

2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting
2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

3. PATIENT PROTECTION EVENTS

3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
3B. Patient death or serious injury associated with patient elopement (disappearance)
3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting

4. CARE MANAGEMENT EVENTS

4A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
4B. Patient death or serious injury associated with unsafe administration of blood products (updated)
4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting (updated)
4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy (new)
4E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting (updated)
4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/ /presentation to a healthcare setting
4G. Artificial insemination with the wrong donor sperm or wrong egg (updated)
4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen
4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

5. ENVIRONMENTAL EVENTS

5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting
5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances
5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting
5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting

6. RADIOLOGIC EVENTS

6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

7. POTENTIAL CRIMINAL EVENTS

7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
7B. Abduction of a patient/resident of any age
7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting
7D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting

8. **STATE REPORTABLE EVENTS**

Required event reports to the Georgia Department of Community Health (DCH) are as follows:
1) any unanticipated death not related to the natural course of patient's illness or underlying condition
2) any rape which occurs in a hospital
3) any surgery on the wrong patient or the wrong body part of the patient

PROCEDURE

A. Immediate Response

1. Ensure patient safety- after the event has occurred or hazardous condition has been identified, first and foremost staff should ensure the safety of the patient and notify physician as appropriate.

2. Secure involved equipment or evidence- if any device or equipment was involved in the event, remove it from service, tag it and report it to Bio Medical through proper channel and process.
    a. The equipment serial number is to be included in the report.
    b. Biomedical Engineering is responsible for impounding the equipment and can be contacted at extension 1-228; after hours through the Paging Operator "1-3893" or the Administrator on call (3-5503). It is important that no access be allowed to the equipment by anyone except Biomedical Department or Risk Management Department employees. The equipment will be secured in the Biomedical Engineering Department or by Risk Management until it is ascertained to be functioning properly.
    c. The Safe Medical Devices Act of 1990 requires a report to be filed within ten (10) working days to the FDA of patient injury or death, or the potential thereof, due to variances involving medical equipment and products. See Safe Medical Devices Policy for further information

3. Reporting- when a patient safety event has been identified, the event should be immediately reported. The preferred method of reporting is through the safety online system. At a minimum the event should be reported to the manager or immediate supervisor.
    a. Department Manager/Director- if, upon receiving a report via the safety online system or another channel of communication regarding a patient safety event the department director/manager determines the event to be a potential or actual serious reportable event, a sentinel event, or a serious harm event will immediately notify the administrator on call, Patient Safety Officer, and/or Risk Management.
        i. Risk Management Monday-Friday 8am- 5pm 706-721-RISK (7475), after business hour(s) through the Paging Operator – pager number "7475".
        ii. Administrator on call through the Paging Operator – pager number "5503"
    b. Frontline staff should immediately escalate serious patient safety events to their immediate supervisor who follows chain of command in communicating and notification to appropriate leaders.

4. Under no circumstances with the reporting of any such event serve as a basis for retaliatory actions to be taken against any patient, staff, or other persons making the report.

a. Reporting patient safety events is mandatory and persons falling to report such events may be subject to disciplinary action.

5. Immediate supervisor, or administrator on call is directed to provide relief and support of caregivers if warranted and as needed. This protocol will be made known to all caregivers and affiliated clinicians. Support services may include debriefing, pastoral care, social services, and/or referral to the Employee Assistance Program, as appropriate.

6. Upon notification and communication to leadership of a Serious Reportable Event, a Sentinel Event or a serious patient safety event the "Event Management Team" will convene.
    a. See Appendix for checklist.

7. Frontline staff will participate in any follow up investigation as necessary including:
    a. Follow up discussion with Managers or other persons assigned to conduct an investigation.
    b. Participation in the RCA² if requested and hold all conversations regarding the event as confidential.

B. Communication with Patients and Families

1. Commence communication immediately, as soon as possible and within 24 hours of discovery.
    a. The attending physician should be informed and included in all decisions/communications.
    b. Risk Management should be informed and included in all decisions/communications.

2. Assessment and Preparation
    a. Determine primary communicator and support team within the organization.
    b. Determine the facts that will be communicated based upon information available at the time of communication
    c. Determine the logistics (location, audience)

3. Communication
    a. Disclosure- tell the patient/family what happened.
    b. We will apologize to the patient/family affected by the event.
    c. Assure ongoing care
    d. Commit to continued communication and support, identifying a contact person for the patient/family and establish a communication timeline as needed.

C. Investigation and Reporting

1. If, after immediate response/ initial analysis, it is determined that a State Reportable Event, Serious Reportable Event or a Sentinel Event has occurred, the organization will: (see Appendix A for list)
    a. Report the event to DCH within 24 hours of becoming aware of the state reportable event.
    b. Waive all costs directly related to a serious reportable event (see Appendix A for list).
        i. The investigation and analysis should determine that an event meets the following criteria:

1) The event is preventable
2) Within control of the hospital
3) The result of an error
4) Results in harm

ii. The Risk Manager/Legal will notify Billing when this practice needs to be applied.

c. We will educate and inform our patients and/or families on our policy and procedure for Patient Safety Events, and provide a copy to patient's and payers upon request.
d. We will involve the patient and/or families who are willing and able to participate in the investigation process, and/ or the RCA².
e. We will inform the patient and/or his/her family of the actions(s) that our organization will take to prevent future occurrences of similar events on the finding from the root cause analysis to the extent that we are not prohibited doing so by law or policy.

2. Investigation and Reporting of **No-Harm Patient Safety Events**
    a. Patient safety events classified as a No-Harm event reported in the safety online system will require a Director/Manager to complete an initial investigation and document findings in the event follow up in the safety online system.
    b. A Patient Safety Specialist will review all such events for completeness and closure.
    c. Pertinent lessons learned from such events will be shared during Daily Safety Huddles, during monthly Events Patient Safety Team meetings, and through appropriate committee structures i.e. Quality Safety Oversight Committee, Quality Safety Councils.

3. Investigation and Reporting of **Adverse Patient Safety Events**
    a. Consideration of the extent of harm, severity, and likelihood of recurrence will determine the extent and degree of investigation following an adverse event.
    b. For Sentinel Events, Serious Reportable Events, and State Reportable Events an investigation and analysis must be conducted.
        i. The investigation and analysis shall commence within 24 hours of identification of the event and an action plan must be completed within 45 days with established due dates.
        ii. All state reportable events must include a formal RCA².
    c. Commence in-depth investigation immediately- under direction of Event Management Team utilizing Adverse Events Checklist. See appendix.
    d. Assure event is reported thoroughly in the safety online system.
    e. When there is uncertainty as to whether the event meets the above definition of a sentinel event or a state reportable event, it will be presumed to be such and should be treated as such until the investigation proves otherwise.

4. Conduct RCA²/ Comprehensive Systematic Analysis
    a. RCA² must be conducted on all state reportable events.
    b. Conduct RCA² in accordance with AU Position Statement in the AUHS Patient Safety Plan
    c. The adverse event RCA² will be conducted within the safety online system within 72 hours of the reporting of the event or as soon as the investigation is complete.
    d. Frontline staff involved in or having knowledge of the event are required to participate in the RCA²; the RCA² Facilitator, Patient Safety Specialist, and Department Director/Manager will collaborate on choosing appropriate staff and level of participation. Frontline staff are key in affecting patient safety improvement activities.

e. The RCA² will include completion of a systematic analysis for identifying factors that contributed to or caused the event to occur, corrective actions to be taken and a timeline for completion of corrective actions.
f. Departmental leaders are required to participate in adverse events occurring in their departments. Leaders are expected to arrange schedules so frontline staff, residents, and attending physicians can attend the RCA².
g. Interviews and or group meetings with the staff and physician(s) involved in the event are conducted to determine chronological order of the event findings and each participant's role perspective in the event.
h. All investigations measures, interviews, and meetings are documented and maintained as patient safety work product in the safety online system.
i. Necessary staff will be educated immediately on the actions to be implemented, to mitigate the risk of patient harm. For staff currently not on duty, the education will occur prior to staff members performing direct patient care.
j. It is the responsibility of the Clinical Quality Excellence Department to assure notification to risk management/legal department regarding the event and pending investigation. Any risk management work product developed outside the safety online system is not considered patient safety work product.
k. When applicable, the Chief Quality Officer/Patient Safety Officer will notify the Chief Medical Officer and or Clinical Service Chief of events involving physician quality of care concerns.
l. The Chief Quality Officer/Patient Safety Officer report all serious events, investigational analysis, and corrective action plans to the Quality Committee of the Board and the organization's governing body.
m. The Clinical Quality Excellence Director or designee reports serious event and RCA findings to the Quality Safety Oversight Committee for educational and improvement and to the Patient Safety Events Team for appropriate communication for learning purposes.

D. Downtime Patient Safety Event Reporting

Downtime forms for reporting variances are available on the AU Health System intranet website on the Clinical Quality Excellence Department webpage or Forms on Demand. Print and complete these forms to record variances as they occur when the computer system is unavailable. Once the downtime is over, use the paper reference as a guide to enter the event into the Safety Online System. Once entered, the paper downtime form should be shredded.

E. Safety Online System Report Completion

All reports will be closed by a Patient Safety Specialist once all required parties have accurately completed their review.

F. Patient Safety Event Grid

Patient Safety Events

	No Harm Event	Hazardous Condition	Low harm adverse event	Adverse Events		
				Sentinel Event	**Serious Reportable Event**	**State Reportable Event**
Internal Reporting	SOS	SOS	SOS	SOS RISK AOC PSO	SOS RISK AOC PSO	SOS RISK AOC PSO
Investigation Type	Manager Review	Manager Review	Manager Review	Investigation and analysis by Events Management Team with *Possible* RCA²	Investigation and analysis by Events Management Team with with *Possible* RCA²	Investigation and analysis by Events Management Team to include formal RCA²
External Reporting*	NA	NA	NA	PSO (Vizient)	PSO (Vizient)	DCH

*All events involving equipment must be reported to the FDA and/or manufacturer

REFERENCES, SUPPORTING DOCUMENTS, AND TOOLS

The Joint Commission Standards Accreditation Manual (Jul. 2019)

Centers for Medicare & Medicaid Services (CMS) 482.21(a)(2)

RELATED POLICIES

Service Recovery Policy

AU Health System Patient Safety Plan 2020-2021

AU Health System Quality Assessment & Performance Improvement Plan (QAPI) Strategic Plan 2020-2021

Safe Medical Devices Policy

Medical Product, Device & Recalls Policy