FLOYD MEDICAL CENTER
POLICY AND PROCEDURE MANUAL
ADMINISTRATION

TITLE: Adverse Events/Sentinel Events	Policy No.: AD-01-060
Purpose: ♦ To provide a process for quality and performance improvement review and analysis of potential adverse/sentinel events. ♦ To have a positive impact in improving patient care. ♦ To focus the attention of FLOYD on understanding the causes that underlie an adverse/sentinel event, and on making changes in the organization's systems and processes to reduce the probability of such an event in the future. ♦ To increase the general knowledge about adverse/sentinel events, their causes, and strategies for prevention.	**Developed Date:** 2/98 **Review Date:** 7/04, 10/09, 5/11 **Revised Date:** 10/98, 6/00, 7/02, 5/03, 11/05. 4/06, 5/08, 2/12, 5/13, 1/17, 8/17 **Review Responsibility:** Risk Manager; Accreditation/Compliance Coordinator; Patient Safety; Director Quality Management, Sr. Vice President of Patient Care Services/CNO, Chief Medical Officer; Executive Staff; Executive Committee of the Medical Staff, Hospital Counsel
Reference Standards: Joint Commission Standards ~ LD.04.04.05, DCH Rules and Regulations for Hospitals, CMS Conditions of Participation	

Policy:

FLOYD strives to continuously improve the quality and safety of patient care through the identification and evaluation of Adverse or Sentinel Events in order to take appropriate steps to mitigate the risk of such events. In response to an identified adverse or sentinel event, FLOYD will conduct a timely, thorough, and credible root cause analysis (see attachment A) or an intense analysis and will develop, implement, and monitor the effectiveness of an appropriate plan of action which is designed to reduce the risk of the occurrence of similar events in the future.

DEFINITIONS

An **Adverse Event** is a serious, undesirable and usually unanticipated patient safety event that resulted in harm to the patient but does not rise to the level of being a Sentinel Event.

A **Close Call** or **Near Miss** is a patient safety event that had no impact on a patient but could have had an impact if it was not aborted, discovered or if intervention occurred prior to it reaching the patient.

A **Hazardous or Unsafe Condition** is a circumstance (other than the patient's own disease process, or condition) that increases the probability of an Adverse or Sentinel Event.

A **No Harm Event** is a patient safety event that reaches the patient but does not cause harm.

A **Never Event** as defined by the National Quality Forum (NQF) is a medical error that should never occur. Never Events are adverse events that are unambiguous (clearly identifiable and measureable), serious (resulting in death or significant disability) and usually preventable. Never Events are considered Sentinel Events. (See Attachment B ~ NQF Never Events)

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 death, permanent harm, or severe temporary harm. Severe temporary harm is defined as 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 car for a life threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. These event are called "Sentinel" because they signal the need for immediate full investigation and response.

The terms "sentinel event" and "error" are not synonymous, not all sentinel events occur because of an error, and not all errors result in sentinel events.

Events subject to review include events that meet 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,[1,2,3] ***OR***

[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 reviewable) 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 Joint Commission's Sentinel Event Policy according to the prescribed procedures and time frames 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 Q.C.5.280, a confirmed fatal transfusion reaction must be reported to the FDA Center for Biologics and the Joint Commission ***within seven days.***

- 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***, including from the hospital's Emergency Department

  - Unanticipated death of a full-term infant

  - Abduction of any individual receiving care, treatment and services

  - Discharge of an infant to the wrong family

  - Any elopement (that is, unauthorized departure) of a patient from a staffed around the clock care setting (including the Emergency Department), leading to death, permanent harm, or severe temporary harm to the patient.

  - Rape/assault (leading to death, permanent harm, or severe temporary harm) or homicide of any patient receiving care, treatment or services when on site at FLOYD.

  - Rape, 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 FLOYD.

  - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)

  - Invasive procedure, including surgery on the wrong patient, wrong site, or wrong (unintended) procedure.

  - Unintended retention of a foreign object in a patient after an invasive procedure, including surgery.

  - Severe neonatal hyperbilirubinema (bilirubin >30 milligrams/deciliter)

  - 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

  - Fire, flame, or unanticipated smoke, heat, or flashes during an episode of patient care.

In accordance with the Georgia Department of Community Health, Healthcare Facility Regulations, Chapter 111-8-40.07(2)(a)1 Rules and Regulations for **Hospitals** the hospital's duly constituted Peer Review Committee shall report to the Department, as required below, whenever any of the following patient incidents involving hospital patients occurs or the hospital has reasonable cause to believe that a reportable incident involving a hospital patient has occurred:

- Any unanticipated patient death not related to the natural course of the patient's illness or underlying condition.
  This would include, for example, patient suicide, deaths related to procedural or drug errors, or deaths resulting from a fall or other accident while in the hospital.

- Any rape which occurs in a hospital.
  "Rape" is defined in O.C.G.A. 16-6-1. "Statutory rape" would also be included as a reportable event, and is defined under O.C.G.A. 16-6-3. O.C.G.A. 16-6-5.1 specifically includes a definition of sexual assault as any sexual contact from a person in a supervisory or authority position with a patient in a hospital.

- Any surgery on the wrong patient or the wrong body part of the patient.

Note: Additional incidents involving hospital patients which will require reporting three (3) months after the Department provides written notification to all hospitals are listed in the regulations.

In accordance with the Georgia Department of Community Health, Healthcare Facility Regulations, Chapter 111-8-40.07(2)(b)1 Rules and Regulations for **Hospitals** the following events/incidents should be reported to the extent that the event is expected to cause or causes a significant disruption of patient care:

- Any labor strike, walk-out, or sick out; or

- Any external disaster or other community emergency situations; or

- Any interruption of services vital to the continued safe operation of the facility, such as telephone, electricity, gas, or water services.

In accordance with the Georgia Department of Community Health, Healthcare Facility Regulations: Chapter 290-5-22-.07 **Diagnostic Services Unit the following Radiology** incidents should be reported:

- any incident involving any source of radiation possessed by him which may have caused exposure of the whole body of an individual to 25 rems or more of radiation; exposure of the skin of the whole body of any individual to150 rems or more of radiation; or exposure of the feet, ankles, hands, or forearms of any individual to 375 rems or more of radiation.
- any source of radiation possessed by him which may have caused exposure of the whole body of any individual to 5 rems or more of radiation; exposure of the skin of the whole body of any individual to 30 rems or more or radiation; of exposure of the feet, ankles, hands, or forearms to 75 rems or more of radiation.
- Each exposure of an individual to radiation in excess of any applicable limit set forth in the regulations
- Levels of radiation (whether or not involving excessive exposure of any individual) in an uncontrolled area in excess of 10 times any applicable limit set forth in the regulations.

In accordance with the Georgia Department of Community Health, Healthcare Facility Regulations, Chapter 111-8-10.25 Rules and Regulations the following **Laboratories** the following incidents should be reported:

- Fatal transfusion reactions or transfusion complications affecting the patients;
- Laboratory testing errors which have resulted in the death or serious injury to a patient or employee;
- Significant interruptions in service vital to the continued safe operation of the facility, such as the loss of electricity, gas or water services.

In accordance with the Georgia Department of Human Resources Office of Regulatory Services Chapter 290-9-43-.06 Rules and Regulations for **Hospice** the hospital's duly constituted Peer Review Committee shall report to the Department, as required below, whenever any of the following incidents involving hospital patients occurs or the hospital has reasonable cause to believe that a reportable incident involving a hospital patient has occurred:

- Any death of a hospice patient not related to the natural course of the patient's terminal illness or any identified underlying condition;
- Any patient rape which occurs in a residential or inpatient hospice facility or in a patient's home at the time a hospice employee or volunteer is in the patient's home;
- Any assault on a patient by a hospice employee or volunteer, or any abuse or neglect of a patient by a hospice employee or volunteer;
- Any serious injury to a patient resulting from the malfunction or intentional or accidental misuse of patient care equipment.

Identification and Reporting

Upon identification of a patient safety event, the patient care provider will immediately:

- Perform necessary healthcare interventions to protect and support the patient's clinical condition.

- As appropriate to the occurrence, perform necessary healthcare interventions to contain the risk to others (example: immediate removal of contaminated IV fluids from floor stock should it be discovered that a contaminated lot of fluid solutions was delivered and stocked).

- Contact the patient's attending physician and other physicians, as appropriate, to report the error and carry out any physician orders necessary.

- Preserve any information related to the error (including physical information). Examples of preservation of physical information include: Removal and preservation of blood unit following a suspected transfusion reaction; preservation of IV tubing and fluids bags following a severe drug reaction from IV medication; preservation of medication label for medication administered to the incorrect patient (if known at the time of administration); sequestering of equipment suspected to malfunction.

- Report the patient safety event to the staff member's immediate supervisor or the Administrative Nursing Supervisor. When any event occurs which may constitute a sentinel event as defined above, it should be reported ***immediately*** to the Risk Manager or, in her absence, the Accreditation/Compliance Coordinator or Director of Quality Management.

- Enter the Patient Safety Event in the Incident Reporting System.

All Incidents are assigned a level according to their severity and harm to the patient.

- Level 0 ~ Close Call or Near Miss (Potential Harm or Danger)
- Level 1 ~ No Harm
- Level 2 ~ Adverse Event (Minor Harm with no apparent impairment of function)
- Level 3 ~ Sentinel Even (Major Harm or Risk))

Level 0, Level 1 and Level 2 occurrences will be forwarded to the appropriate department manager for further analysis and action if necessary.

All Level 3 events will be assessed immediately by Patient Safety Peer Review Committee

- This committee will conduct a preliminary investigation sufficient to determine whether the reported event constitutes a sentinel event, as defined by the Joint Commission, or a reportable event, as defined by the Georgia Department Human Resources, Rules and Regulations for Hospitals If it does, then the Patient Safety Peer Review Committee will appoint an Investigation Team and determine whether the sentinel event is reportable to Joint Commission and/or to other outside agencies.

- Once it has been determined that a Sentinel Event has occurred, a comprehensive systematic analysis in the form of a Root Cause Analysis (RCA) will be completed no more than 45 days after the incident, or after the incident was discovered.

- The Risk Manager or Accreditation/Compliance Coordinator will facilitate the RCA and the development of an action plan when deemed necessary.

- Each event will be reviewed as to billing and determination of payment will be based on the outcome of the review.

- Periodic status reports shall be forwarded to the Board Quality Committee and other venues deemed appropriate.

Patient Safety Peer Review Committee

The Patient Safety Peer Review Committee will consist of:

- Accreditation/Compliance Coordinator (Patient Safety)
- Chief Medical Officer
- Director of Lean Six
- Director of Quality Management
- Legal Counsel
- Medical Director of Clinical and Operational Improvement
- President and CEO
- Risk Manager
- Senior VP of Patient Care Services/CNO

Investigation Team Members

The following people, or their designees, will be considered as participants of the Investigation Team:

- Risk Manager
- Director of Quality Management
- Accreditation/Compliance Coordinator; Patient Safety
- Senior VP of Patient Care Services/CNO
- Chairperson of Medical Care Evaluation Committee ***OR***
- Chief Medical Officer
- Administrative Representative
- Department leadership of area where the event occurred
- Person with technical knowledge of event, to be named by team members
- Other Ad Hoc members to be determined by team members

Responsibilities of Investigation Team

The responsibilities of the Investigation Team (tasks may be delegated to an individual or several individuals) shall be to:

- Review the medical record
- Review relevant policies, procedures and standards of care
- Interview applicable personnel, including but not limited to medical staff members, outside employees and hospital employees, who witnessed or have any knowledge or information regarding the Sentinel Event;
    - Inspect or review all relevant material, equipment and devices and secure the same;
    - Meet with and interview the patient or family of the affected patient, as appropriate
    - Document finding, conclusion, actions

The team will convene to conduct a RCA. Within 45 days of the event or of becoming aware of the event, the team will develop an action plan. The action plan will identify strategies that will be taken to reduce the risk of similar events occurring in the future. The action plan will include recommendations for assigning responsibility for the implementation of these actions, ongoing monitoring and specific time frames. In addition, strategies for measuring effectiveness and sustaining the change will be included. Ongoing compliance for implementation of the action plan will be tracked by the Patient Safety Team/Quality Steering Committee.

Reporting to External Agencies

Sentinel Events will be reported by FLOYD to external agencies to the extent required in accordance with applicable laws, regulations and rules of accrediting agencies.

FLOYD will comply with the Joint Commission requirements regarding access to the work product of the Investigation Team respecting root cause analysis and follow-up, using one of the following three options, as determined by Floyd's Chief Executive Officer:

- Submit a copy of the root cause analysis and related materials to Joint Commission.
- Permit on-site review of the root cause analysis and related materials by Joint Commission.
- Request Joint Commission to conduct on-site interviews and review documentation relevant to the root cause analysis and follow-up action.

The National Quality Forum's Health Care "Never Events" will be reported by FLOYD to at least one of the following external agencies within 10 days of becoming aware that the never event has occurred:

- ♦ Joint Commission
- ♦ State reporting program for medical errors

Confidentiality/Privilege

All documents generated as a result of a Sentinel Event, an Adverse Event or a Near Miss, including but not limited to the initial report, the findings of the Root Cause Analysis forms will be maintained in a strictly confidential manner by all parties who receive the documentation. These document are considered to be confidential reports and are part of the peer review and quality assessment process of the organization. They are protected from disclosure pursuant to the provisions of the Georgia Code Sections 31-7-130, et. seq. and 31-7-140, et. Seq. Unauthorized disclosure or duplication is absolutely prohibited.

Responsibilities

The following is a summary of the responsibilities and timetable for action respecting compliance with this policy:

WHO	WHAT	WHEN
Patient Safety Peer Review Committee	Determine if the sentinel event or near miss will be reported to any outside agency.	Within the time frame to be compliant with reporting requirements of the agency.
Risk Manager and Accreditation/Compliance Coordinator; Patient Safety	Lead investigation team	After a sentinel event has been determined
Investigation Team	Use approved root cause analysis tool	When investigating event
Investigation Team	Ensure appropriate risk reduction and measurement strategies are undertaken	After investigation of event
Risk Manager or Accreditation/Compliance Coordinator; Patient Safety	Have root cause analysis reviewed by legal counsel before submission to an outside agency.	Within the time frame to be compliant with reporting requirements of the agency
Team Leader	Report results of investigation to the Executive Committee of the Medical Staff	Within at least 3 months of results of investigation
Chief Medical Officer	Report results of investigation to the Board Quality Committee	During regular report

DISCLOSURE OF UNANTICIPATED OUTCOMES

A. Consistent with organizational ethical practices, FLOYD recognizes the importance of maintaining effective communication with patients and their families which includes providing information which fosters better decision making. Therefore it shall be the practice of FLOYD to ensure that unanticipated outcomes (either positive or negative) are to be promptly communicated to the patient and/or patient's family.

B. The following procedures will provide specific guidelines for disclosing information concerning unanticipated outcomes and measures to prevent future occurrences to the patient and/or the patient's family;

1. In the event that the results from treatment or a procedure differs significantly from what was anticipated, the physician and/or the designated organizational representative should communicate said outcome to the patient.

2. Should the patient be incapable of understanding a discussion of this nature, then the patient's guardian, agent under a healthcare power of attorney or appropriate family member should be informed.

3. Information concerning specific causation factors should not be communicated to the patient until the matter has undergone thorough investigation and review by Administration and Legal Counsel.

4. In the event that the caregiver is traumatized as a result of the outcome to the extent that he/she is unable to communicate with the patient and/or patient's family, he/she may contact their department manager, or Administrative Nursing Supervisor, who will assist them with providing the necessary information to the patient and/or family.

5. At no time shall information regarding adverse outcomes be communicated to the public or representatives of the media without explicit advanced approval and review by the President & CEO, Risk Management, and Legal Counsel. Information will be released according to the guidelines and policies set forth by the Public Relations Department.

A copy of this policy is available to patients, patients' family members, and payers upon request.

ATTACHMENT A

REVIEW OF ROOT CAUSE ANALYSES AND ACTION PLANS

A Root Cause Analysis will be considered *acceptable* if it has the following characteristics

The analysis:

- Focuses primarily on systems and processes, not individual performance
- Progresses from special causes in clinical processes to common causes in organizational processes
- Repeatedly digs deeper by asking "Why?" then, when answered, "Why?" again, and so on.
- Identifies changes, which could be made in systems and processes---that would reduce the risk of such events occurring in the future.
- Is thorough and credible

To be ***thorough,*** the root cause analysis must 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;
- Analysis of the underlying systems and processes through a series of "Why?" questions to determine where redesign might reduce risk:
- Inquiry into all areas appropriate to the specific type,
- 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 opportunity exist.

To be ***credible,*** the root cause analysis must:

- 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;
- Include patients, family, or patient representatives when appropriate to ensure thorough understanding of the facts;
- Include individuals most closely involved in the process and systems under review;
- Provide an explanation for all findings of "not applicable" or "no problem", and
- Include consideration of any relevant literature.

A ***corrective action plan*** will be considered acceptable if it:

- Identifies and implements actions to eliminate or control systems hazards or vulnerabilities
- It is recommended but not required that review teams should attempt to identify actions that are likely to reduce the risk or prevent the event from recurring and if that is not possible reduce the severity or consequences if it should recur.
- Identifies, in situations in which improvement actions are planned, who is responsible for implementation, when the action will be implemented, how the effectiveness of the actions will be evaluated, and how the actions will be sustained.
- Identifies at least one stronger or intermediate strength action for each comprehensive systemic analysis.

ATTACHMENT B

The National Quality Forum's Health Care "Never Events" (2011 Revision)

Surgical events

- Surgery or other invasive procedure performed on the wrong body part
- Surgery or other invasive procedure performed on the wrong patient
- Wrong surgical or other invasive procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately postoperative/post procedure death in an American Society of Anesthesiologists Class I patient

Product or device events

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

Patient protection events

- Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
- Patient death or serious disability associated with patient elopement (disappearance)
- Patient suicide, attempted suicide, or self-harm resulting in serious disability, while being cared for in a health care facility

Care management events

- 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)
- Patient death or serious injury associated with unsafe administration of blood products
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- Artificial insemination with the wrong donor sperm or wrong egg
- Patient death or serious injury associated with a fall while being cared for in a health care setting
- Any stage 3, stage 4, or unstageable pressure ulcers acquired after admission/presentation to a health care facility
- Patient death or serious disability resulting from the irretrievable loss of an irreplaceable biological specimen
- Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

Environmental events

- Patient or staff death or serious disability associated with an electric shock in the course of a patient care process in a health care setting
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances
- 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 health care setting
- Patient death or serious injury associated with the use of restraints or bedrails while being cared for in a health care setting

Radiologic events

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

Criminal events

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

Root Cause Analysis Matrix

Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events

	Suicide (24o care)	Medication Error	Procedural Complication	Wrong Site Surgery	Treatment Delay	Restraint Death	Elopement Death	Assault, Rape, Homicide	Transfusion Death	Patient Abduction	Unanticipated Death of Full Term Infant	Unintended Retention of Foreign Body	Fall Related
Behavioral assessment process [1]	X					X	X	X					
Physical assessment process [2]	X	X	X	X	X	X	X				X		X
Individual identification process		X		X					X				
Individual observation procedures	X				X	X	X	X	X		X		X
Care planning process	X		X			X	X				X		X
Continuum of Care	X	X			X	X							X
Staffing levels	X	X	X	X	X	X	X	X	X	X		X	X
Orientation & training of staff	X	X	X	X	X	X	X	X	X	X	X	X	X
Competency assessment/ credentialing	X	X	X	X	X	X	X	X	X	X	X	X	X
Supervision of staff [3]	X	X	X		X	X			X			X	
Communication with individual/ family	X	X		X	X	X	X			X			X
Communication among staff members	X	X	X	X	X	X	X	X	X	X	X	X	X
Availability of information	X	X	X	X	X	X			X		X		X
Adequacy of technological support		X	X										
Equipment maintenance/ management		X	X		X	X					X		X
Physical environment [4]	X	X	X	X		X	X	X	X	X			X
Security Systems and processes	X					X	X	X		X			
Medication Management [5]		X	X		X				X		X		X

1 Includes the process for assessing individual's risk to self (and to others, in cases of assault, rape, or homicide where an individual is the assailant)
2 Includes search for contraband
3 Includes supervision for physicians-in-training
4 Includes furnishings, hardware (e.g., bars, hooks, rods); lighting; distractions.
5 Includes selection and procurement, storage, ordering & transcribing, preparing and dispensing, administration and monitoring.