



Catholic Healthcare Partners

Guidelines for Responding to Serious Adverse Events

2010

INDEX

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Purpose

These guidelines apply to Serious Adverse Events, including events involving potential or actual harm that require medical intervention. This document outlines the administrative components of a comprehensive institutional process, and supports an organizational culture that values transparency, safety, new knowledge, unfettered reporting, structured analytics, and information dissemination.

These guidelines focus on four main components in the management of Adverse Event and other Medical Errors:

- 1. Immediate Action following an Adverse Event or Serious Events**
- 2. Communication to Patients, with emotional support to patients and families who experience Adverse Events.**
- 3. Support of Clinicians and all Staff who are involved in Adverse Events.**
- 4. Investigation and Reporting of Adverse Events.**

The Chief Medical or Nursing Officer should always be informed when a decision is made to disclose an Adverse Event, and should be consulted when there is any uncertainty with regard to the need to disclose an event to a patient and/or family.

All staff and affiliated care providers should be familiar with these recommendations and the processes stated herein.

Serious Adverse Events

Serious Adverse Events which include Serious Reportable Events and Sentinel Events require immediate verbal notification to the CEO/Administrator, Risk Management on call and the Divisional Patient Safety Officer.

Supervisors should be consulted and staff/providers should err on the side of immediate reporting when there is any uncertainty regarding the need for immediate verbal communication about an Adverse Event.

The criteria below are not intended to be all inclusive, but serve as an indication of the types of events which require immediate action, require a Root Cause Analysis, and which invoke these guidelines.

Serious Adverse Events (Serious Reportable Events (SREs) defined by NQF)

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately postoperative death in an ASA Class I patient
- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility
- Infant discharged to the wrong person
- Patient death or serious disability associated with patient elopement (disappearance)
- Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility
- Patient death or serious disability 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 disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- Patient death or serious disability due to spinal manipulative therapy
- Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- Any event in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- Patient death or serious disability associated with a fall while being cared for in a healthcare facility
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility
- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
- Abduction of a patient of any age
- Sexual assault on a patient within or on the grounds of a healthcare facility
- 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 healthcare facility

CHP Event Management Guidelines

A **Sentinel Event**, as defined by the Joint Commission is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. 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. Such events are called “sentinel” because they signal the need for immediate investigation and response. The terms “sentinel event” and “medical error” are not synonymous; not all sentinel events occur because of an error and not all errors result in sentinel events. The subset of sentinel events that is subject to review by the Joint Commission includes any occurrence that meets any of 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 or
- 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 patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 of discharge
 - Unanticipated death of a full-term infant
 - Abduction of any patient receiving care, treatment, and services
 - Discharge of an infant to the wrong family
 - Rape
 - Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities
 - Surgery on the wrong patient or wrong body part
 - Unintended retention of a foreign object in a patient after surgery or other procedure
 - Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
 - Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to wrong body region or >25% above the planned radiotherapy dose

Serious Adverse Event Management

Part I – Immediate Response Following a Serious Adverse Event

This section outlines the steps necessary in ensuring that a swift and thorough response to Adverse Events occurs. It is recommended that facilities designate various clinical and administrative leaders, as well as members of Risk Management and Quality to serve as designated Event Management Team members. Physicians, staff and managers will also play key roles in the initial stages of Adverse Event Management.

1. Ensure patient safety

- Stabilize the patient; provide necessary and appropriate medical care
- Notify the attending physician if not present; obtain additional orders if necessary
- Remove all unsafe devices, equipment, medications
- Determine whether the Adverse Event puts other patients at immediate risk and address accordingly

2. Internal Notification & Communication

- Immediate verbal notification to administrative and clinical leaders
- Immediate verbal notification to Risk Management
- Risk management will notify CHP Claims Manager/Risk Services
- Verbal consultation with the Divisional Patient Safety Officer should occur within the first 24 hours

3. Preserve Evidence

- Secure physical evidence involved in the adverse event, including but not limited to:
 - Medical devices and equipment
 - Retained foreign objects
 - Medications, containers, package labels or inserts
 - IV bags and tubing, syringes
 - Supply containers and packaging
 - Lab and pathology specimens
 - Any other applicable physical evidence that might be of use in an investigation
- Take pictures, where appropriate
- Do not tamper with, clean or otherwise modify any physical evidence
- Preserve electronic data
 - Consult with IT regarding preservation of the integrity of electronic data
 - Back up or otherwise preserve electronic data
 - Obtain printout of electronically stored data if the information may be overwritten

4. Relief and Support of Caregivers

- Clinical Supervisors and/or CNOs should immediately evaluate the impact of the Adverse Event on involved staff and provide support accordingly
- CMOs should immediately evaluate the impact of involved physicians and provide support accordingly
- Immediately address patient ratios and redistribute patient loads to allow involved caregivers time to cope with the situation
- Promote a just culture by consistent and transparent application of the accountability algorithm

CHP Event Management Guidelines

5. Documentation

- Ensure that the medical record is appropriately documented regarding the event and communication with the patient and/or family
- Ensure that a SafeCARE report is completed in a timely manner

6. Convene Event Management Team

- Collaborate among care providers to ensure that the ongoing needs of the patient are met
- Determine which members of the Event Management Team are critical to the initial stages of the process
- Begin to determine the scope of the investigation and scheduling of participants for the RCA
- Determine which member of the Event Management Team is the primary contact
- Delegate responsibilities for follow up among team members

Part II - Communication with Patients and Families

This section applies to the communication with patients and families regarding Adverse Events. When an Adverse Event occurs, patients and family members, or designated representatives, must be informed as soon as practical. This applies to Adverse Events that are immediately apparent as well as to those that become evident only after a period of time.

NOTE: When a potentially significant event does not result in harm, consideration should be given to disclosing the event to patients and/or families, taking into account the circumstances of the event and the patient.

1. Commence Communication Immediately

- As soon as possible and within 24 hours of the discovery of any Adverse Event, initial communications with the patient and/or family or representative will occur. Initial communications may be limited to general information and concern (if that is all that is available) a promise that it is being looked into, and identification of who will be communicating with the family/who is their contact.
- The attending physician should be informed and included in all decisions/communications - to the extent they are willing to do so.

2. Assessment and Preparation

- Determine primary communicator and support team
 - The initial communication should be by or at least in the presence of a caregiver with a prior relation of trust with the patient
 - At least one member of the support team should be familiar with the patient's situation and competent to address any clinical questions or concerns of the patient or family
- Determine the facts that will be communicated based upon information available at the time of the communication
- Determine the location based upon the patient or family's situation
- Determine the audience
 - Patients and families should have the opportunity to determine who should be present on their behalf.
 - If communication directly with the patient is not possible, initial discussions should commence with family members or health care proxy as designated by the patient upon admission

3. Communication

- Disclose - tell the patient/family what happened
 - Provide full explanation based upon information available at the time
 - Be factual – avoid speculation, blame, opinion
 - Be truthful and compassionate
 - Promise investigation and further disclosure of facts as they become known
 - Ensure that the patient/family understand what they are being told
- Apologize
 - Express empathy, sincerity and regret that the event occurred
 - Apologies should be very clear and distinct statements (ie: “We are very sorry that this happened to you/your loved one”)
 - Avoid finger pointing or blame
- Assure ongoing care

CHP Event Management Guidelines

- Consider concerns of patients about being told the truth or being abandoned
- Assure the patient/family of the Hospital's commitment to be consistently available to them for care and support.
- Identify who will manage ongoing care of the patient and provide contact information to the patient
- Offer assistance in obtaining second opinions or transferring care if so requested by the patient
- Commit to continued communication and support
 - Establish a contact person for the patient/family
 - Identify who will manage ongoing communication with the patient and/or family regarding the investigation
 - Provide the patient/family with names and phone numbers of individuals to whom the patient and family may address questions, complaints or concerns regarding the investigation
 - If the patient requires ongoing care within the facility, advise all caregivers of the designated communicator and encourage staff to assist in facilitation of communication between the designee and patient/family
 - Establish communication timeline; let the patient know when they should expect more information as the investigation moves forward

4. Follow-up Communications and Ongoing Patient and Family support

- Follow-up communication sessions should be arranged as soon as significant additional information is available
- At the appropriate time, explain what will be done to prevent similar future events
- Needed psychological and social support should be provided
- Follow-up encounters should be planned and continued until reasonable resolution of major issues

Part III - Assessment and Support of Involved Physicians and Staff

This section applies to addressing the impact of Adverse Events upon involved care providers. When patients are harmed, the empathy and sense of responsibility that defines caregivers also increases the likelihood that the emotional toll of these events may render the caregiver less capable of carrying on their immediate responsibilities. Dedication to a culture of safety and support of staff requires the acknowledgement of this type of trauma, and the commitment of the organization to timely assess and support involved care providers.

1. Assess the Impact of an Adverse Event upon Clinicians

- CMO/VPMA will assess the impact and support needs of the physician(s) involved
- Management/HR will assess the impact and support needs of the staff involved
- Immediately following a serious Adverse Event, patient care loads and physician coverage of involved providers significantly impacted by the event should be addressed in order to allow caregivers time to adjust, and in the interest of patient safety

2. Identify Appropriate Support for Clinicians

- Consideration should be given to any immediate support or mental health needs that of care providers involved in serious Adverse Events, such as:
 - Employee Assistance Program (EAP), offer or, if appropriate require
 - Internal crisis management teams
 - Regional crisis center
 - Referral for mental health services through the individual's health insurance coverage
- Temporary relief from assignment should be considered paid administrative leave

Part IV – Adverse Event Investigation and Reporting

This section applies to the in-depth investigation, and the external reporting of serious Adverse Events. Consideration of the extent of harm, severity and likelihood of recurrence will determine the extent and degree of an investigation following a serious Adverse Event. For Sentinel Events and Serious Reportable Events a Root Cause Analysis must be conducted. The RCA should commence within 24 hours and must be completed within 45 days.

Internal and external/regulatory reporting requirements and guidelines must be evaluated following events, with clear delineation of duties with respect to reporting.

1. Commence in-depth investigation Immediately

- Determine Adverse Event status and scope of investigation
- Risk Management will conduct the investigation in conjunction with involved parties and department managers
- Investigations should begin immediately following awareness/notification of the event in order to obtain as accurate information as possible
- Process
 - Secure and analyze evidence
 - Secure medical record and other documentation necessary for investigation
 - Identify and interview witnesses
 - Walk through processes
 - Develop flowcharts and timelines
 - Document findings

2. Root Cause Analysis Process

- Conduct RCAs in accordance with CHP Position Statement and facility policies. Initial RCA meetings should be convened within 24 hours after the event is discovered
- RCA meeting participants need to make the meeting a priority over usual business
- Participants
 - The Chief Medical and Nursing leaders, who should generally serve as meeting leaders or facilitators
 - Senior Administration Representative(s)
 - Physicians involved
 - Staff members who are identified as key witnesses or participants
 - Quality/Performance Improvement
 - Risk Management
- Process
 - RCAs generally require at least two meetings for the purposes of fact finding, identification of root and latent causes and development of corrective action plans
 - RCAs must be completed within 45 days of the identification of an Adverse Event
 - Factual information must be analyzed, and processes and system failures evaluated and addressed with the participation of those most knowledgeable
- Action Plans
 - Action plans must address the root causes of system failures and patient safety concerns
 - Action plans must be detailed, with clear identification of and distinction between issues, root causes and action items
 - The responsibility for action plan implementation must be delegated to appropriate departmental leaders
 - Those responsible for action plan implementation must be accountable for timely and effective implementation, and for reporting of progress to the Quality/Performance Improvement designee responsible for tracking RCAs

CHP Event Management Guidelines

- Follow up and reporting - Corrective actions developed as a result of the root cause analysis are a high priority, and must be tracked to ensure that the changes occur, and to monitor both the effectiveness and possible undesirable effects of the changes.
 - Quality/Performance Improvement is responsible for tracking progress of action plan items
 - Quality/Performance Improvement is responsible for reporting progress of action plan implementation to senior administrative and clinical leadership
 - Senior leaders are responsible for reporting serious Adverse Events, identified system failures and implemented action items to the Board and/or Quality Committee

3. External Reporting

- Federal, State and Local reporting requirements must be considered following any adverse event
- CHP position statements and existing policies, procedures or guidelines of the system or facility regarding reporting to outside entities are to be followed
- Responsibility for external reporting must be clearly defined and delegated to ensure timely compliance with reporting requirements
- Risk Management is responsible for timely reporting of actual or potential claims to the CHP Home Office, Risk and Insurance Department in accordance with established Standard Operating Procedures
- Notify the Divisional Patient Safety Officer of any event that has system wide implications and/or for assistance with serious event management.

Adverse Events for Checklist

(Event Management Team responsible for overseeing checklist completion)

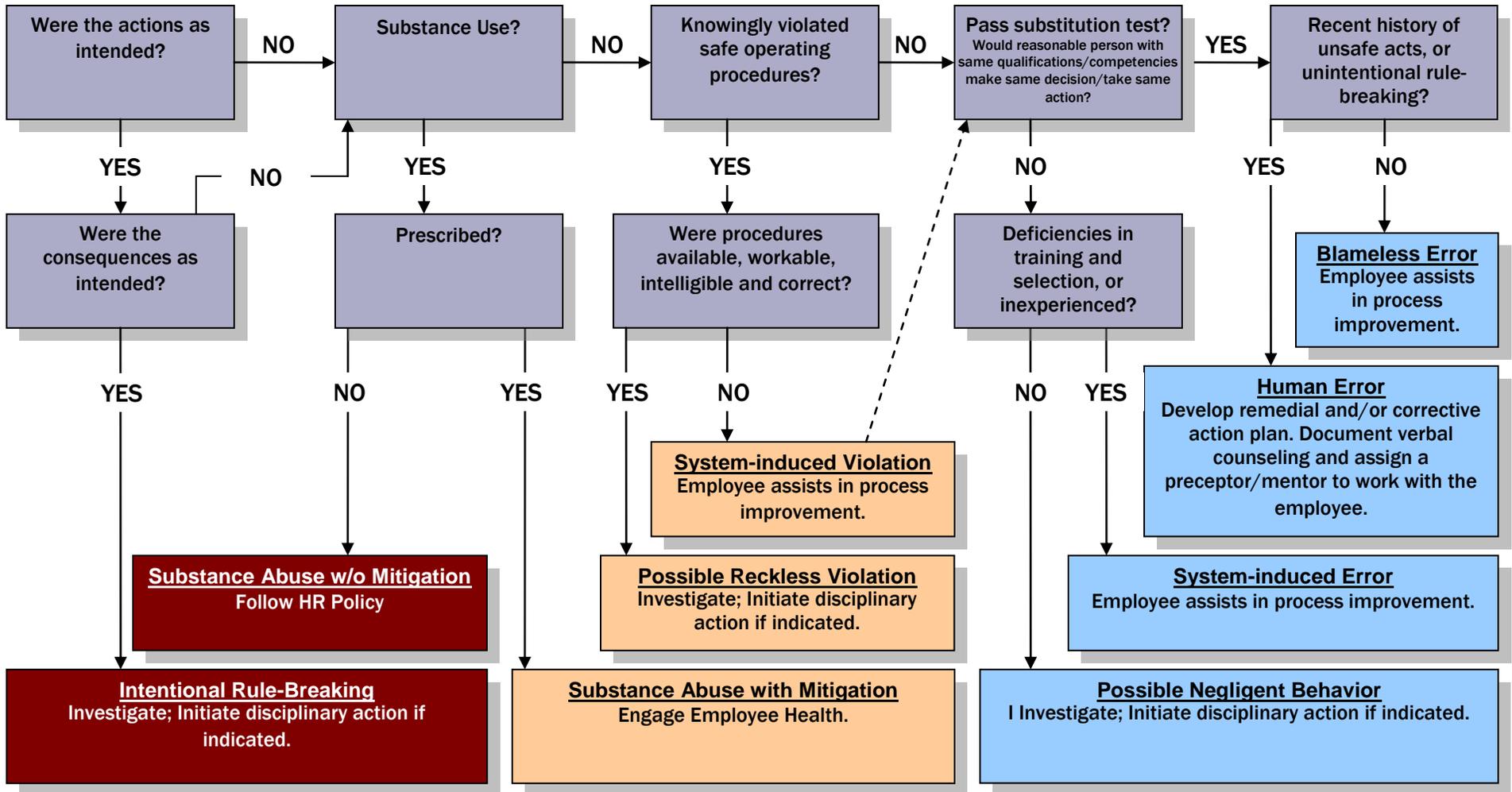
Patient information: _____		Date of event: _____
		Location of Event: _____
Time Begun	Immediate Tasks	Initials/Time Completed
_____	Assure Patient Stabilization <input type="checkbox"/> Notify primary care physician of event <input type="checkbox"/> Address immediate patient care issues and mitigate patient harm <input type="checkbox"/> Remove all unsafe devices	_____ _____
_____	Notifications <input type="checkbox"/> Nursing Supervisor/Clinical Manager <input type="checkbox"/> Managing MD _____ Phone: _____ <input type="checkbox"/> Attending MD _____ Phone: _____ <input type="checkbox"/> Risk Management (will notify CHP Risk Services/Claims Manager) <input type="checkbox"/> Hospital CEO/Administrator on call <input type="checkbox"/> Divisional PSO (should be consulted within 24 hours) <input type="checkbox"/> Public Relations Department <input type="checkbox"/> Communication with staff on unit regarding contact person for family, HIPAA and confidentiality issues, etc.	_____ _____
_____	Preserve Evidence - Equipment/Medications Collection (Do NOT change settings, contents, or clean) <input type="checkbox"/> Syringes <input type="checkbox"/> Medication Containers/Vials <input type="checkbox"/> Equipment/Machines <input type="checkbox"/> IV bags/Tubing <input type="checkbox"/> Samples from lab <input type="checkbox"/> Other: _____	_____ _____
_____	Evaluation and support of involved care providers <input type="checkbox"/> Evaluate immediate patient safety concerns <input type="checkbox"/> Assess state of mind of employees following an event and relieve from immediate duties if indicated <input type="checkbox"/> Evaluate and support physicians and other involved non-employed practitioners <input type="checkbox"/> Initiate crisis management, social work, pastoral care or other supportive intervention for care providers <input type="checkbox"/> Contact human resources and/or ethics committee for guidance	_____ _____
_____	Support for family <input type="checkbox"/> Chaplaincy for spiritual support <input type="checkbox"/> Social Work for mental health crisis <input type="checkbox"/> Referral for ongoing mental health support	_____ _____
_____	Documentation and Information Collection <input type="checkbox"/> Ensure completion of SafeCARE Report <input type="checkbox"/> Ensure appropriate and timely medical record documentation regarding adverse events and communication <input type="checkbox"/> Secure medical record	_____ _____
_____	Convene Serious Event Management Team <input type="checkbox"/> Chief Nursing Officer <input type="checkbox"/> Chief Medical Officer <input type="checkbox"/> Involved Physicians: _____ <input type="checkbox"/> Risk Management <input type="checkbox"/> Quality/Performance Improvement <input type="checkbox"/> Hospital CEO <input type="checkbox"/> Human Resources <input type="checkbox"/> Public Relations/Communications <input type="checkbox"/> CHP Resources as needed – may include PSO, Risk Management/Claims Manager, CRO, Communications	_____ _____

Adverse Events - Checklist

(Event Management Team responsible for overseeing checklist completion)

Patient Information		Date of event: _____
Date/Time Begun	Follow Up Tasks	Initials/Time Completed
_____	Communication with Patient / Family <input type="checkbox"/> Ongoing communication with patient/family <input type="checkbox"/> Disclose facts known about the event; follow up with the patient/family when additional information is available <input type="checkbox"/> Apologize/empathize with patient <input type="checkbox"/> Make sure patient/family understand what they are being told and have the opportunity to ask questions <input type="checkbox"/> Provide Patient/family with contact information <input type="checkbox"/> Establish a timeline for follow up with the family <input type="checkbox"/> Ensure that Staff are aware of the primary contact person with respect to updates regarding the investigation	_____ _____
_____	Addressing ongoing needs of Patient / Family <input type="checkbox"/> Establish a contact person for coordination of ongoing needs of the patient <input type="checkbox"/> Ensure patient/family are aware of who to contact for assistance <input type="checkbox"/> Ensure that staff are aware of the primary contact person with respect to ongoing care	_____ _____
_____	Ongoing Assessment and Support of Staff <input type="checkbox"/> Evaluate ongoing needs of staff (ie: EAP, counseling, crisis management, etc.) <input type="checkbox"/> Assess the needs of involved physicians and non-employed practitioners and facilitate support <input type="checkbox"/> Utilization of Accountability Algorithm by front line managers and Human Resources	_____ _____
_____	Investigation & Internal Communication <input type="checkbox"/> Walk through processes and create flowcharts <input type="checkbox"/> Determine involved staff and key witnesses and commence and document interviews <input type="checkbox"/> Secure medical records and other necessary documents for investigation <input type="checkbox"/> Consult literature and outside resources for additional necessary information <input type="checkbox"/> Develop timelines <input type="checkbox"/> Keep the patient liaisons and senior leaders apprised of developments in the investigation <input type="checkbox"/> Compile and analyze information for RCA (if applicable)	_____ _____
_____	Root Cause Analysis (for all SREs, Sentinel events, other events in which a RCA may be beneficial) <input type="checkbox"/> Determine participants: <input type="checkbox"/> CEO, CMO, CNO _____ <input type="checkbox"/> Nursing Supervisor/Clinical Manager _____ <input type="checkbox"/> Managing MD _____ <input type="checkbox"/> Attending MD _____ <input type="checkbox"/> Key Staff Involved _____ <input type="checkbox"/> Quality/PI _____ <input type="checkbox"/> Risk Management _____ <input type="checkbox"/> Other _____ <input type="checkbox"/> Schedule and conduct subsequent meetings in a timely manner <input type="checkbox"/> Creation of substantive corrective action plan; incorporate quantifiable measures <input type="checkbox"/> Dissemination of corrective action plan implementation responsibility <input type="checkbox"/> Complete RCA within 45 days of SRE or Sentinel Event <input type="checkbox"/> Designate Quality/PI person responsible for follow up	_____ _____
_____	Internal Communication and Reporting <input type="checkbox"/> Ensure SafeCARE report is completed <input type="checkbox"/> Document investigation; invoke Quality, Peer Review, Attorney-Client, other available protection <input type="checkbox"/> Keep senior leaders apprised of progress <input type="checkbox"/> Notify CHP Home Office Risk Services of claims or potential claims in accordance with SOPs <input type="checkbox"/> Leadership reports to the Board, Quality Committee of the Board and/or Peer Review committee	_____ _____
_____	External Reporting <input type="checkbox"/> Evaluate Federal, State and Local reporting requirements and report accordingly <input type="checkbox"/> Evaluate internal policies regarding external reporting of adverse events	_____ _____

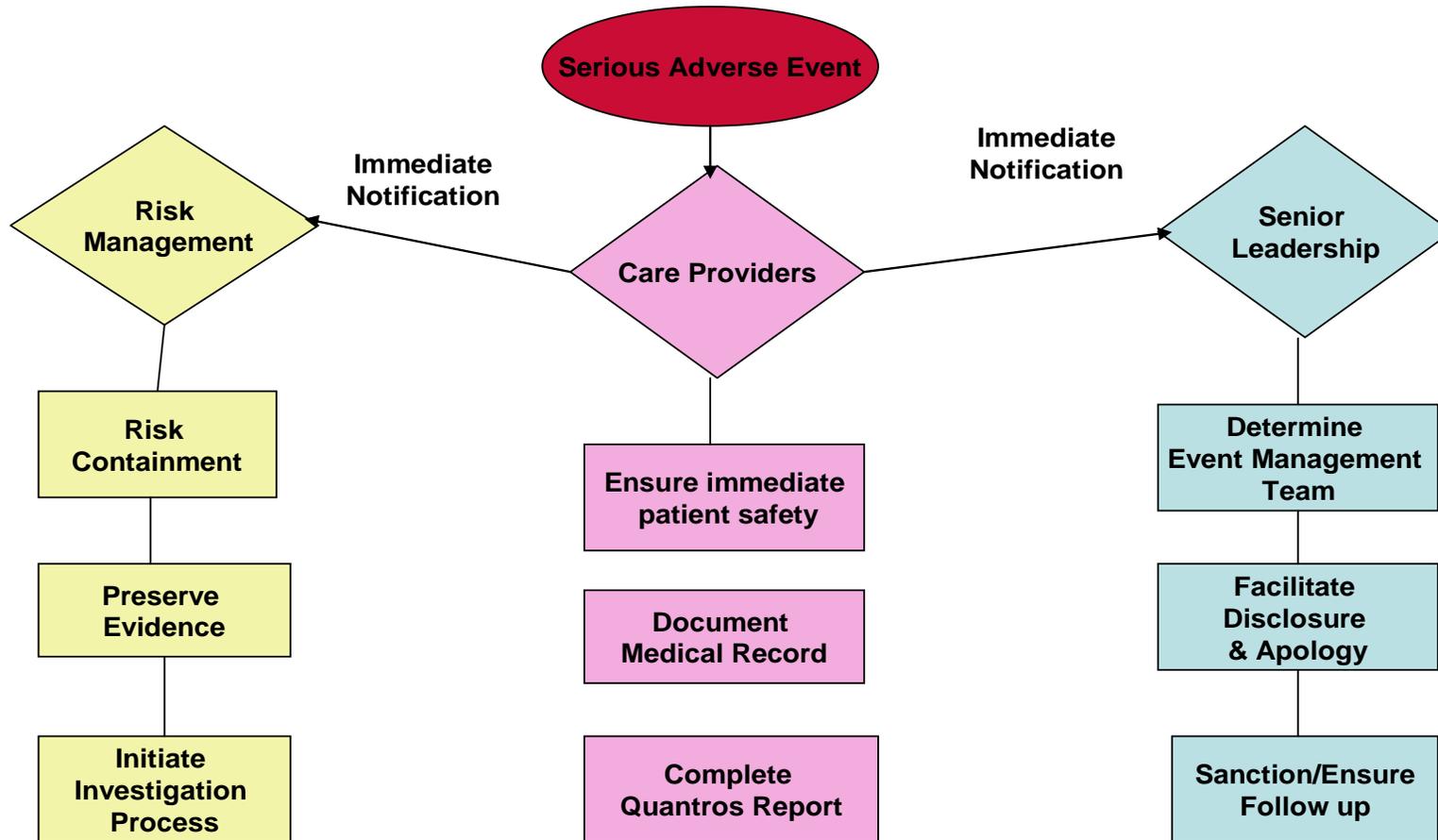
Accountability Algorithm



From: James Reason
 "Managing the Risks of Organizational Accidents"
 Modified by Allan Frankel and Lynda Hooper 2007

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Flowchart for Initial Response to Serious Adverse Events



Flowchart for Ongoing Response to Serious Adverse Events

