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Critical Event Investigation Tools

Standardize
Identify
Classify
Investigate
Interview

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The purpose of this resource is to provide guiding documents and tools to aid in the process and methods and should not be considered an authority or legal advice but rather is for general risk management guidance.

Introduction

The purpose of this toolkit is to provide resources and standardization in the methods related to identification and investigation of critical events/serious safety events and in preparing for litigation. This document will serve as a guide for further understanding the process and will highlight methods and examples for implementing a standardized approach in complex situations.

This toolkit is not intended to be prescriptive regarding which tools must be used, but rather will recommend the combination of tools and methods that have demonstrated the most effective steps in the process for investigation, identifying root causes, preventing litigation and when prevention is not possible preparing for litigation.

Note: there are additional resources and tools to assist in preventing a repeat incident, including a RCA toolkit.

There are five primary goals of a critical event investigation that will be outlined in this toolkit.

1. Rapid identification
2. Quick action
3. Thorough analysis
4. Prevention of recurrence
5. Communication/disclosure

Key Points

- ✓ ***Prepare***
- ✓ ***Standardize***
- ✓ ***Expert resources***
- ✓ ***Classify quickly***
- ✓ ***Investigate timely***
- ✓ ***Elicit external resources***

Guidance is provided in this resource for 1-3 above. Contact MPIE for additional guidance and support for 4 and 5.

Standardize

It is recommended that every organization plan in advance the process for critical event investigation. This plan should include:

- who will be involved,
- what type of role and skill is required to lead and participate in directing or conducting the investigation and a
- standardized approach including a plan and tools

Standardization brings consistency and consistency of proven methods increases the reliability of a process. Often there are several people in an organization involved in, or conducting critical event investigations and that requires a standardized approach to increase overall effectiveness. Standardization includes outlining the steps in a process including who will be involved and when. Often this is done through a checklist or process map and incorporated into operating manuals. If the standards are followed the benefits include increased productivity, reduced variability, enhanced cross training, improved quality and reduced costs.

"ASHRM recommends that each facility have a clearly written policy statement that describes the organization's expectations following the identification of a critical event/serious safety event,

accompanied by a clearly written policy and procedure guide that has been reviewed and understood by those who are central to the response process. The SSE policy should:

- List the title of the members of the SSE response team.
- Delineate the roles of the team members.
- Identify the steps in the process." (ASHRM 2012).

"There are four key components to keep in mind when responding to an SSE:

- Have a plan in advance with the methods and steps for investigation.
- Require that the investigation be carried out by a person who is skilled in investigation techniques, in order to ensure the process/investigation is thorough and credible and balances individual and system issues.
- Involve the support of leadership through a formalized response team.
- Complete the investigation in a timely manner using a skills-based approach." (ASHRM 2012)

Four Key Components of Responding to an SSE

ADVANCED PLANNING
CREDIBLE LEADERSHIP
FORMALIZED RESPONSE TEAM
TIMELY, SKILL-BASED INVESTIGATION

Critical Event Investigation Components

Expertise and Skill

Individuals involved in investigating must have a comprehensive skill level that includes excellent communication, interview expertise, data analysis, integrity and professionalism. ASHRM lists four guiding principles that the risk manager or other investigators should follow:

"1. Operate within your organizations, state's and own legal authority:
   a. Protect legal privilege.
   b. Know and adhere to HIPAA and other confidentiality rules.
   c. Know your organization's policy for dealing with the press.
2. Understand your organization and be sensitive to organizational ethics:
   a. Know the reporting relationships of everyone involved.
   b. Follow communication protocols.
   c. Establish a clear and timely communication timeline.
3. Investigate with purpose:
   a. Stay focused on and know what question(s) to ask.
   b. Do not succumb to pressure.
   c. Seek out all the facts and the truth.
   d. Take measures to ensure that the event never happens again." (ASHRM 2012)

Leadership should be involved and aware of all critical event investigations. A formal escalation process should be established as well as a formal critical event response team.

Identify and Classify

The identification phase is about prioritizing risk and determining what method to use to quickly and accurately identify those events that require a critical event investigation.

Identification includes ID of the problem, notifications of appropriate leaders, sequestering evidence, and implementing any immediate risk reduction actions. The components below are included in the identification phase:

- Department manager or on-call supervisor is notified at the time of the event.
- Risk manager is notified timely (within minutes to hours) 100% of the time of a critical event.
- The investigation is started immediately (within 24 hours).
- The approach to the event is done so in a just culture environment.
- Physical evidence is sequestered.
- Common sources of data and information are collected for use in the RCA process.
- Critical event response team is involved when a serious safety event has been identified.
- Resources are clearly outlined for management of situation.
- Family/patient communication/disclosure is started within minutes to hours of the event.

There are various methods used for identification of critical events and a few are listed below:

VA National Center for Patient Safety THE SAFETY ASSESSMENT CODE (SAC) MATRIX, Department of Veterans Affairs, Veterans Health Administration Patient Safety Handbook, May 2008.

AHRQ Harm Scale created by the US Federal Government.

ASHRM Serious Safety Event Severity Scale was developed as a preventable harm classification scale that is also used to determine the scope of analysis as outlined below:

Healthcare Associated Preventable Harm Level Classification
(ASHRM Serious Safety Event Paper #2)

Safety Event Class	Level of Harm	Code	Patient Outcome	Suggested Follow-Up Analysis
Serious Safety Event (Reaches the patient)	**Death**	**SSE-1**	Unexpected death not related to the natural or expected course of the patient's illness or underlying condition. On balance of probabilities, was caused by or brought forward in the short term by the incident.	RCA, including culpability/ accountability review (CCA)
	Severe **Permanent or Temporary Harm**	**SSE-2**	Patient outcome is symptomatic, requiring life-saving intervention or major medical- surgical intervention, shortening life expectancy or causing major, permanent or temporary harm or loss of function.	RCA, including culpability/ accountability review (CCA)

Safety Event Class	Level of Harm	Code	Patient Outcome	Suggested Follow-Up Analysis
Safety Event (Reaches the patient)	**Moderate Permanent or Temporary Harm**	**SE-3**	Patient outcome is symptomatic, requiring intervention (e.g. additional operative procedure, additional therapeutic treatment), an increased length of stay, or causing permanent or temporary harm, or loss of function.	**Options:** RCA, ACA, barrier analysis, including culpability/ accountability review
	Mild Temporary Harm or None	**SE-4**	Patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate, but short-term, and minimal or no intervention (e.g., extra observation, investigation, review, or minor treatment), is required.	**Options:** ACA, barrier analysis, trending analysis, including culpability/ accountability review
	No Detectable Harm/No Harm	**SE-5**	Patient outcome is asymptomatic. No symptoms are detected and no treatment is required. Not able to discover or ascertain the existence, presence, or fact of harm, but harm may exist; insufficient information is available, or unable to determine any harm. Harm may appear later.	**Options:** ACA, barrier analysis, trending analysis, including culpability/ accountability review
Pre-Patient Event (Does not reach the patient)	**Almost Happened**	**PPE-6**	Error or capacity to cause harm was caught by an error detection barrier prior to reaching the patient. The system worked.	Review barrier detection, celebrate success

The Joint Commissions Sentinel Event Classification

According to The Joint Commission, as of 2015, 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:

- Death
- Permanent harm
- Severe temporary harm

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

- 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)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment and services
- 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
- Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)

- Rape, 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
- 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 the hospital
- Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of a radiotherapy to the wrong body region >25% above the planned radiotherapy dose

Classify and Investigate

Classifying the event is about determining the severity or significance of the event if that is not clear and about organizing and preparing for the investigation and ultimately the RCA. The components below are included in the classification phase:

- It is likely that the classification of the event was completed in the identification phase above as the outcome was obvious, if not, classification of the event needs to occur quickly as the investigation needs to start asap, but no later than 24 hours
- If the event was not identified as serious or it is unknown, a small group of individuals review events to determine significance and organization response. Significance of the event in relation to deviation in practice and harm to a patient is determined within the first 24 hours of the event
- Subject matter expert may be needed as a resource during the investigation to assist with clinical clarification

Use the following tool to guide the process for investigation:

Critical Event/Serious Safety Event Investigation Checklist and Analysis for Risk Manager Use

(Label with confidentiality provisions on each page)

IMMEDIATE ACTION/RESPONSE		Complete	Pending
Department/area			
Time/date of event			
Primary investigator	*(Risk Manager)*		
Determine method for investigation	*(Depending on the type of event, the investigation will be protected under auspices of peer/professional review committee/quality improvement committee/in anticipation of litigation—attorney/client privilege.)* *(Contact Home Office Risk Management to determine if investigation needs protection under attorney/client privilege. If external peer review may be applicable, consult with Risk Management.)* *(Remember as the investigation progresses to focus on identifying contributing factors and possible solutions.)*		
Step 1: gather initial facts	*(What happened when, why – determine if the event has happened before and if any immediate actions need to occur to prevent recurrence or further harm.)* *(Obtain brief statement from person reporting event. Ensure event report is completed.)* *Determine if the event meets the definition of a catastrophic event**		
Step 2: patient care and management	*(Ensure patient is cared for, and applicable staff and providers are notified including patient's physician.)* *(If death, is this a medical examiner case?)*		
Step 3: sequester and manage evidence	*(Remove from service and store in secure area all equipment attached or contiguous to the patient, all documents, disposable products, packaging, medications/vials that may have been involved.)* • *Equipment – ensure any dates/times in machines are stored, obtain equipment documentation including purchase*		

	information/vendor instructions, operating manuals, maintenance records, repair records • *Establish chain of custody* • *Document pre- and post-event position of equipment; involve bio-med to determine if equipment was working properly* • *Determine if a medical device reportable event under SMDA* • *Make a duplicate of the medical record and place in secure file; if EMR observe chain of documentation by date and person; observe timing of documentation in accordance with event* • *Medical tracings, monitor strips* • *Security video* • *Switchboard and telephone records – response and call times, beeper records, phone call logs* • *Medications – open vials, syringes, IV bags and tubing* • *Supplies with wrappers and lot or serial numbers* • *Photographs (check with VP of RM before taking photographs)* • *Maintenance records, purchase records* • *Staffing assignments* • *Diagnostics/lab – secure all specimens past 7 days, pathology slides, x-ray, cath film, video, etc.*		
INITIAL INVESTIGATION			
Step 4: form critical response team/notification—chain of command	*(Determine level of actual or potential severity or harm to determine what type of response, notification and investigation per policy. If a critical event or sentinel event, ensure risk manager/administrator on-call is notified immediately.)* *(Determine who needs to be on the team and what role they will undertake—senior leadership, medical director, manager, expert in area, other experts needed—infection control, bio-med, etc.)* *(If sentinel event, follow policy regarding notifications.)* *If this is a catastrophic event contact Claims Manager.***		
Step 5: conduct immediate debriefing with staff	*(Use a debriefing tool as a guide.)*		

	(The debriefing is often done by the house supervisor or supervisor of the area where the event occurred. They will seek input from risk management as applicable.)		
Step 6: determine if outside expertise is needed	*(Determine if outside expertise is needed – forensic review, biomedical engineering, etc.)* *(If the investigation is under attorney-client privilege, outside experts and any documents/reports shall go through counsel.)*		
Step 7: determine communication plan	*(Establish communication plan with patient/family/staff/physicians/leadership.)* • *Determine disclosure process—who will be involved, timing of such, etc.* • *Make contact early with patient/family. Be sure to talk with the providers first so that it is known what has been explained so far. Explain facts as known, inform about review process and action, seek their input and keep them updated on your progress in the evaluation.* • *Remember that disclosure is a process not an event.* • *Involve marketing as outlined in the sentinel event policy and prepare for potential media contact.* • *Determine who will be the public point person.*		
Step 8: determine if site visit is needed	*(Evaluate if a site visit is needed. Determine if physical environment was a factor. Determine if re-construction of the event is needed.)*		
Step 9: prepare for regulatory and public inquiry	*(Begin determination if this is a reportable event to state or federal authorities. Is this a criminal event requiring notification of the police? Is this a medical examiner case? Prepare for regulatory survey, if applicable.)*		
Step 10: conduct initial formal interviews	*(Determine who to interview and when – should be very timely. Interviews will be conducted by the risk manager, but may also be conducted separately by the supervisor of the area.)* • *Use the interview guide.* • *Be prepared – review background information and medical record before the interview, when possible.* • *Interview one person at a time.* • *Advise staff not to complete personal notes of the event.*		

	• *Risk management notes should be attached to the event report document and kept confidential.*		
Step 11: continue regulatory compliance	*(Make final determination if this is a reportable event to state or federal authorities. Complete fact gathering and start timeline for presentation to the sentinel event resource team.)*		
INFORMATION COLLECTION AND ANALYSIS			
Step 12: collect documents and review	*(Event report, medical record, procedures, protocols, pathways, handoff tools, staffing assignments, job descriptions, competency checklists for involved staff, performance evaluations, credential files, etc.)* *(EMR – review charting entries and look for dates entered, determine if entries made before or after event, can determine everyone who has accessed records)* *(Performance data – involve supervisors and HR to access information, contact medical staff to obtain historical data for physicians)* *(Secure all records and logs and may need to obtain from referring providers.) (If possible, review medical record before the interview.)*		
Step 13: suspend billing	*(Suspend all billing during investigation and request medical staff to do so, if applicable.)*		
Step 14: complete a notice of loss form for insurance	*(Complete the NOL form per established policy and send to insurance company timely). Coordinate management of the claims portion of the event with insurance managers.*		
Step 15: create timeline/flowchart	*(Create sequence of events in chronological order.)* *(Review current procedures, protocols for comparison to actual—identify gaps.)* *(Timeline needs to be started prior to the conference call with sentinel event resource team as above—risk management and clinical affairs.)*		
Step 16: conduct additional interviews	*(Conduct additional interviews as needed based on findings thus far.)*		

PREPARATION FOR ROOT CAUSE ANALYSIS			
Step 17: identify contributing factors/use causal factor chart	*(Use contributing factors investigation tool and identify human issues, equipment, technology, supplies, task factors, management/culture, patient factors, team factors, environmental factors, etc.)*		
Step 18: complete cause and effect diagram or events and casual factors chart	*(Complete cause and effect with providers/staff involved in event and prepare for RCA.)* *(Consider the use of an events and causal factor chart.)*		
Step 19: complete detection barrier analysis	*(Determine what detection barriers were in place, or could have been, that could have prevented this event and why they failed or were not in place.)*		
Step 20: determine accountability within a Just Culture	*(Use the shared accountability decision making model and Just Culture components.)* *(Involve Human resources.)*		
Step 21: peer review referral	*(Determine if a nursing or medical staff peer review referral needs to be made.)*		
Step 22: conduct RCA	(Conduct RCA. if applicable. *Examples include: deaths related to event, patient needed intervention/was seriously harmed, permanent injury, near miss with potential for significant adverse outcome, TJC sentinel event list.)*		
VALIDATION, RESULTS AND EVALUATION			
Step 23: create action plan	*(This is done as part of the RCA.)*		
Step 24: results dissemination	*(Determine reporting of RCA results, i.e., sentinel event resource team.)* *(Do not release RCA to a third party without input from VP of RM.)*		
Step 25: on-going evaluation	*(Implement measures and methods to determine effectiveness of prevention.)*		

INVESTIGATION RESULTS

Summary of investigation and findings: _____

Conclusions from investigation: _____

Additional comments of importance: _____

Signature Date

A catastrophic event may be defined as any of the following: paraplegia, quadriplegia, blindness, multiple amputations, birth injury or hypoxia, high profile case, severe burns, permanent disfigurement, brain trauma, reproductive organ loss/permanent impairment, cancer misdiagnosis, sexual abuse/molestation, AIDS/hepatitis exposure, multiple event infection exposure, elder abuse, or wrongful death.

If this is a catastrophic type of event, the internal investigation for risk management/patient safety needs to be conducted while the event needs to be managed from a claims mitigation perspective. See resource tool below regarding checklist for catastrophic event management:

Catastrophic Event Management Checklist

(Label with work product-anticipation of litigation provisions on each page)

IMMEDIATE ACTION | RESPONSE TO DAY 30		Goals	Completed
Patient care	*Care providers focus on care and treatment for patient.*	*On-going*	
Roundtable immediate issues	*Investigation of initial facts, timeline of event and care needs. Obtain internal expert review re: standard of care concerns.*	*24 – 72 hours*	
Leadership awareness	*SSE internal leadership team*	*24 hours*	
Immediate plan • **Involve insurance carrier** • **Communication** • **Expenses** • **Care decisions** • **Media** • **Regulatory** • **Defense counsel** • **Second victims**	***Involve insurance carrier*** • *Advisor and guide for internal risk management until formal handoff* ***Communication*** *Patient/family—RM owns the process and coordination of all communication including coordinating leadership, physicians, and staff.* • *Establish/restore trust, single point of contact, CAT manager as advisor in background, document communication* • *Disclosure begins* • *Structure frequency of communication to family—be prepared for common questions/needs* • *Use a common communication approach for all providers—RM to coordinate and conduct debriefing of event* ***Expenses/family care*** • *Identify if any immediate expense issues for patient/family* • *Food and space for family*	*24 – 72 hours*	

	Care decisions • *Post event care adequate? —second opinion* ***Media*** • *Prepare for media and regulatory attention* ***Regulatory*** • *TJC, State investigation* ***Defense counsel*** • *Retain by CAT claims manager* • *Guide—communication strategy, retaining experts, avoiding pitfalls* ***Second victims—stress management*** • *ID providers who are second victims—evaluate stress potential and support needs—arrange* • *Determine assignments and potential for contact with patient/family*		
Determine potential compensability	*Must move quickly on understanding compensability potential as this drives decision making. Speed must not compromise accuracy as these decisions are high loss impact.* *Expedite expert review (internal peer review) and external expert.*	*3 days – 14 days*	
Management of CAT case	*Determine timing of handoff from Risk Manager to CAT Claims Manager—can be immediate to several days.* • *Contact with who is providing treatment* • *Who is communicating what and when to family—establish common approach* • *Who is point person on unit overseeing all aspects of day to day* • *Communication high—compassionate message and building trust are primary goals with patient/family—structure—avoid unplanned meetings* • *Communication with care providers on-going* • *CAT nurse case manager early involvement and role* • *Coordination with internal risk management*	*Handoff TBD*	
Reinsurance notification/involvement	*Policy will indicate requirements for reporting* *Timeliness and accuracy of information*	*0-5 days*	

	Involvement of claims/risk as advisors *If compensability is high and admitted liability involve in disclosure plan and document*		

SECOND PHASE | 30 DAYS – 180 DAYS AND BEYOND			
CAT nurse case manager	• ***Early involvement with family-independent advisor*** • *Patient achieving a baseline?* • *Contact with claims manager*		
Claim management	• *Reserve setting* • *Expenses accruing early* • *Agreements for care costs/denial of compensability* • *Compassionate denial of compensability* • *Emerging concerns-daily availability* • *Segment issues versus litigating totality of the case* • *Breach of standard of care versus scope of damages* • *Attempt to stipulate/reach agreement on as many issues as possible to focus litigation on primary issues, not have global complex case go to jury* • *Long term care planning and life expectancy experts are key to measure exposure*		

Additional comments of importance: _____

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Contributing Factors Framework-Investigation Tool

Use this tool to help determine the type of contributing factors for the event. This tool can be used in conjunction with the event investigation checklist.

- Human Factors
  - ☐ Knowledge based violation
    - Chose incorrect goal or strategy, lacks competence
  - ☐ Skill based violation
    - Slip, lapse, mistake in executing an action, action triggered by info in the environment, haste, inattention
  - ☐ Rule based violation
    - Mistake—chose incorrect procedure or violated procedure, standard, guideline, failed to act on available information
  - ☐ Physical or mental health
    - Stress, fatigue, work relationships
  - ☐ Violations of procedure
    - ☐ Did not know procedure
    - ☐ Not aware of or took short cut
    - ☐ Situation dictated deviation
    - ☐ Procedure not practiced or out of date (substitution test)
  - ☐ Education/experience
    - Training lacking or novice
  - ☐ Not seeking help when should have
  - ☐ Other_____

- Task/Procedural Factors
  - ☐ Clarity and design of structure lacking
  - ☐ Availability and use of protocols lacking
  - ☐ Availability and/or accuracy of tests, results, etc. lacking
  - ☐ Decision making aids lacking or wrong
  - ☐ Lack of monitoring or assessment
  - ☐ Other_____

- Teamwork Related Factors
  - ☐ Supervision
    - Lacking, inadequate, did not seek out
  - ☐ Communication (gaps, omissions, misunderstandings, or a lack of a safe environment to communicate)
    - Written
    - Verbal
  - ☐ Culture and teamwork
    - Lack teamwork
    - Breakdown, management style, hierarchical structure
  - ☐ Team structure
    - Consistency, leadership, intimidation, disruptive behavior
  - ☐ Other_____

- Technology/Equipment/Supplies Factors
  - ☐ Design lacking
  - ☐ Availability lacking
  - ☐ Maintenance issue
  - ☐ Failure/malfunction
  - ☐ Improper use
  - ☐ Outdated
  - ☐ Other_____

- Management Factors
  - ☐ Constraints
  - ☐ Organizational structure
  - ☐ Policy, standards, goals
  - ☐ Safety culture and priorities
  - ☐ Planning
  - ☐ Other_____

- Work/Environmental Factors
  - ☐ Staffing
    - Levels, skill mix
  - ☐ Workload
    - Shift patterns, influx of patients
  - ☐ Time delays
  - ☐ Environment
    - Distractions, interruptions
  - ☐ Administrative/managerial support issues
  - ☐ Other_____

- Patient Factors
  - ☐ Condition
    - Complexity, severity of illness
  - ☐ Communication
    - Language barrier, interpretation
  - ☐ Psychosocial
    - Personality or social factors

- Detection Barriers in Place
  - ☐ Physical barriers (such as bar coding, locked cabinets, etc.)
    List: _____
    _____
    Effective: □ Yes □ No

  - ☐ Human action detection barriers (such as patient identity check, surgical site marking, etc.) List: _____
    _____
    Effective: □ Yes □ No

  - ☐ Administrative detection barriers (such as procedures, checklists, alert notices, etc.)
    List: _____
    _____
    Effective: □ Yes □ No

Interview Guide

A critical part of the investigation is the gathering of information and establishing the correct sequence of events. However, it is often quite challenging to acquire accurate information because we do not always have exact records and must rely on people's memories of events, which are sometimes unintentionally incomplete, partially constructed, unreliable and inaccurate. Law enforcement people are experts at both interviews and investigations. A technique called the "Cognitive Interview" (CI) is widely used by law enforcement investigative personnel and these techniques have been adapted to obtain information from those involved in a critical event in a healthcare setting. It is important to arrange the interview(s) as soon as possible following the event so memory and details are fresh; ideally, between two and 72 hours.

We have prepared this guide to assist you through all phases of the interview process, including framing questions to elicit the most complete and thoughtful response and how to obtain the maximum amount of information. We suggest you refer to this guide each time you are called upon to interview participants in a critical event (and also anytime you need to get additional information and details about an event or occurrence).

GOALS

It is important to establish the goals of the interview process and they generally include:

- Collection of facts
- Construction of timeline
- Clarification of key elements and discovery of systemic problems

BASICS

- Conduct the interview ASAP – generally between two and 72 hours.
- Review the critical components of the medical record before the interview, when possible.
- Focus on interviewing the people directly involved.
- People's memories and willingness to assist can be related to the way they are questioned and the timing of such. Avoid the perception that a critical event interview is an interrogation.
- Caregivers need to feel involved in the investigation and a part of preventing future events.

PREPARE YOURSELF

It is important to be well prepared and take steps to ensure an effective and comfortable interview. Establish the purpose(s) of the interview in your mind before approaching staff. These will generally be consistent and usually include:

- Obtaining information related to the event from the interviewee
- Establishing the chronology of events
- Conducting the interview as close to the event as possible when memories are freshest
- Verifying the accuracy of information received from others
- Adding to the information received from others
- Verifying medical record documentation
- **Conduct interviews individually as we believe there are significant advantages to this approach versus a group interview.** These advantages include the ability to obtain an independent story, ability to establish rapport, and create the specifics of the event based on all individuals' independent recollection versus group think.

INITIATING THE INTERVIEW

- Ensure the staff person's manager is aware of the interview request and determine if it is best to have the manager reach out to the person as the first contact (not to conduct the interview, but to explain the purpose and process of the interview itself).
- Issue a personal invitation to the interview (make the phone call yourself if possible) and inform the caregiver that follow up interviews are a normal part of the process and will help with risk reduction – this is not about placing blame.
- Do not use e-mail to discuss events as it may not be privileged and can be forwarded without your knowledge.
- Explain the purpose of the meeting to the interviewee:
    - To gather and document information about the event
    - Explain what they need to do to prepare for the meeting, if anything.
    - Explain who will be present.
    - Assure the interviewee that the interview is confidential. Be clear in regards to the purpose of the interview process; explain the purpose, such as:
        - To learn about the facts of the situation and where individual and/or system factors contributed to the issue
        - May lead to Human Resource intervention – or not. (When the risk manager is the person conducting the interview, be sure to make clear in advance that the interview IS NOT for HR purposes and will generally not lead to HR corrective action.)
- Inform the interviewee how long the interview will likely take.
- Prepare a list of questions for each interviewee and specific questions for key individuals.

SETTING THE STAGE – PREPARING THE SPACE

- Arrange a quiet place without interruptions – away from the interviewee's workspace.
- Schedule people who know the least about the event first; this will allow you to obtain the "big picture" view before obtaining specific details.
- Ensure that you have all the relevant documentation available for reference.
- Turn off cell phones and beepers and instruct staff not to interrupt you.
- Make sure you will be at eye level with the interviewee.
- Avoid a physical set up that may be perceived as establishing you as an authority figure. For example, in your office with you seated behind the desk. If this is the office set up, move the chairs in a manner that connects the individuals versus setting a barrier.
- Limit those in attendance – ideally to only the interviewer and witness.
- Prepare questions – know up front what you need to find out.
    - Ask what happened; make sure questions are open-ended to encourage conversation. The associate should be doing most of the talking at this point and you should be listening.
    - Ask the associate to walk you through the process—what normally happens?
    - Lastly, ask about what procedures they are aware of that may pertain to the issue and what is required to comply with such.
    - Questions must be framed so they are non-accusatory and do not appear judgmental. For example, ask, "What was going through your mind at that point?" instead of "Why would you do that?"

- Make sure the room is neither too cold nor too hot.
- Have water and tissues available.
- Check your appearance. You should be professionally dressed, but dressed so that the interviewee will be at ease. For example, a business suit may be intimidating to front-line staff; a dress shirt or sweater may make them feel more at ease.

CONDUCTING THE INTERVIEW

- Begin with a handshake and express your genuine gratitude to the interviewee for attending the interview.
- **Fully explain the interview and subsequent RCA process.**
    - Explain that there will be notes transcribed and that the notes will be used for the internal investigation as part of the risk/patient safety improvement process and RCA, or as part of work product in anticipation of litigation (risk manager only).
    - Put the interviewee at ease. Ask them how they are doing. Acknowledge their feelings related to the event – be empathetic.
    - Ensure that the interviewee knows that this is their interview and they are in control, not you. This is their opportunity to tell their story.
    - Reconfirm that this is not a disciplinary meeting.
- If individuals seem reluctant to speak up, talk about known procedures or equipment before getting into details of the event.
- **Watch for non-verbal cues.** Depending upon which study is cited, non-verbal communication constitutes anywhere from 50 to 90% of any face-to-face message, even those with words…lending true power to the old saying, "It's not what you say; it's how you say it." When observing non-verbal cues:
    - **Pay attention to inconsistencies.** Non-verbal communication should reinforce what is being said. Is the person saying one thing, and their body language something else? For example, are they telling you "yes" while shaking their head no?
    - **Look at non-verbal communication signals as a group.** Don't read too much into a single gesture or non-verbal cue. Consider all of the non-verbal signals you are receiving, from eye contact to tone of voice and body language. Taken together, are their non-verbal cues consistent – or inconsistent – with what their words are saying?
- **General guidance**
    - Repeat what the interviewee has shared to verify your understanding, show that you are listening and encourage the interviewee to clarify, add to, or correct the information they have given.
    - Allow the interviewee to tell their story without interruption. Interrupting them will only reduce memory recall and lead to incomplete information. Use reflective listening.
    - Ask questions in an orderly fashion and in concert with the series of events – this will facilitate recall.
    - Avoid yes or no questions; rather, ask open ended questions that encourage dialogue and details.
    - Use language that the interviewee will understand. Complex terminology that the interviewee may not understand could be intimidating and make the interviewee uncomfortable.
    - The story and the facts are the first stage in understanding what happened. The staff needs to be encouraged to identify the care delivery problems (identify facts with hindsight, breakdowns in clinical process that lead to the event).

- Look for times in the sequence of events when care delivery went outside acceptable limits – these may be acts or omissions.
- Have staff identify the contributing factors and causes.
- Pauses are useful to allow the interviewee time to gather their thoughts and recall additional information – avoid the urge to speak during pauses.
- Remain cordial and professional, especially if the interviewee is defensive or uncooperative.
- Avoid judgmental and accusatory comments (whether these are directed at the interviewee or someone else); they may make the interviewee defensive and uncomfortable.
- Avoid leading questions. For example, instead of asking, "Do you think the physician's past interactions with staff may have made them less likely to question her?" ask "Do you know if the physician was aware of these questions?"
- Interviewers must not suggest any information to the interviewee. "Language is a loaded weapon" and must be used with care.
- After the interviewee has told their story and you have restated and verified your understanding, you may want to ask a series of focused questions. "Now I am going to ask you a series of questions based on what you have already told me., If you don't know the answer just tell me 'I don't know'."
- Ask staff not to make personal notes or to keep them. If a written statement is advised, do so under legal direction.

- **Be aware of your body language.**
  - Lean forward to show interest.
  - Acknowledge what the interviewee is relating, without interrupting, by nodding your head and other non-verbal acknowledgements.
  - Maintain eye contact.
  - Be aware of facial expressions.
  - Avoid fidgeting, glancing at your watch or the clock.
  - Watch your tone of voice.
- **Observe the interviewee's body language.**
  - Sweating and increased respiratory rate may indicate discomfort.
  - Watch for inconsistencies between what the interviewee is saying and what their body language is saying. Shifting of feet, drumming fingers, and/or avoiding eye contact may indicate the person is withholding information or not being completely truthful.
  - Covering the mouth with the hand can indicate the interviewee may be being untruthful.
  - Do not make judgments based solely on body language, but be aware of it – yours and theirs.
- **Effective questioning techniques**
  - Treat all witnesses with respect, but don't be reluctant to ask any witness probing questions about material facts.
  - Focus on what the witness did or observed (i.e., saw or heard) rather than what they thought about it (unless their thoughts are themselves material facts).
  - Ask not only what a witness knows, but also how they know it.
  - Once you have firm statements on the relevant facts, ask the witness about any areas of inconsistency.

- Look for and follow up on leads. Ask questions that may lead to new or corroborating evidence (e.g., identification of date, time, and other witnesses to a significant act or conversation) and then check leads out.
- Ask witnesses whether they have discussed the matters with others and why. Have a list of questions or points to address, starting with less controversial, embarrassing, or confrontational matters.
- Phrase questions in a manner that will elicit full explanations, and then ask narrower follow-up questions as needed for clarity. Constructing questions too narrowly might impede your efforts to learn all of the facts.
- Listen to the answers instead of thinking about the next question.
- Cover all of the bases regarding the event (i.e., who, what, when, where, how, and why). Ask the witness to be specific in describing the incident or describing/demonstrating inappropriate physical contact.
- If the witness rambles into irrelevant matters or becomes evasive, bring the witness back on to track with more specific questions.
- Use open ended questions (questions that require a narrative response) to determine the extent of a witness' knowledge or to obtain general recollections from the witness' point of view. (Open question: "Please describe what you did when ...") Use closed questions (questions that call for a "yes," "no," or short answer response) to "nail down" the specifics of the testimony.
- Generally, avoid using leading questions (questions that suggest or encourage a particular "preferred" answer) except where necessary to elicit specific answers from an evasive or uncooperative witness. These types of questions often make it look like the interviewer is testifying or pressuring the witness.
- If a witness does not appear to remember incidents or seems to have difficulty recollecting specifics, it is permissible to refresh their recollection with documents or other items, but use only items that they previously had access to (notes, correspondence, etc.).
- Ask questions about apparent exaggerations, inconsistencies, gaps, etc., whether internal to the interview, or between the interview account and a previous statement. Give the witness an opportunity to explain any inconsistency.
- Do not be reluctant to clarify statements if it is necessary to fully develop the chronology of events, even if it might make the person uncomfortable.
- You may ask the same question repeatedly, particularly if answers seem evasive.
- Review your witness plan again before concluding the interview to ensure that all necessary points have been covered.

- **Concluding the interview**
  - Always try to conclude on a positive note. This is apt to be quite emotional for the interviewee, so do your best to put them at ease before concluding the interview. Thank them for their time and engage in some neutral conversation.
  - Be empathetic to their emotions.
  - Draw no conclusions about root causes at this time with the interviewee.
  - Caution them about keeping the process confidential, avoiding conversations with others outside the confidential process, not to make personal notes.
  - Have information available for the interviewee on staff support/counseling, if applicable.

- A goal of the interview and the investigation is to explain the causes behind each human error and the at-risk behavior. What is the incentive that created or supported this behavioral norm? This is the key to preventing future error.

INTERVIEWING PHYSICIANS WHEN A CRITICAL EVENT APPEARS TO BE PRIMARILY ONE OF PHYSICIAN PERFORMANCE

In addition to the tips above, you might also consider the following:

- Meet with the physician, the CMO or Department Head and establish a partnership and understanding that the joint goal is to identify and address opportunities for process improvements.
- Review documentation in advance of the interview, including informed consent documents.
- Interview the doctor. Consider using tips from "The Field Guide to Human Errors Investigation" to identify how the situation looked to the person on the inside at each of the critical junctures, such as:
  - What happened?
    - Cues – What were you seeing, focusing on or expecting to happen?
    - Interpretation – If you were describing the situation to a fellow surgeon at that point, what would you have told them?
    - Previous experience/knowledge – Did this situation fit a standard scenario? Were you reminded of any previous experience? Were you trained to react to this situation? Did you rely on other sources of knowledge to guide you?
  - Discuss possible contributing factors – communication issues, doctor's schedule, personal issues (i.e., overloading of cases, lack of sleep due to being on call, etc.).
    - Errors – What mistakes were likely (i.e., in interpretation) at this point?
    - Goals – What goals governed your actions at the time, were there conflicts or tradeoffs to make between goals? Was there time pressure?
    - Taking action – How did you judge you could influence the course of events? Did you discuss or mentally imagine a number of options, or did you know straight away what to do?
    - Outcome – Did the outcome fit your expectation? Did you have to update your assessment of the situation? Was this a known and communicated risk of the procedure?
  - Discuss whether disclosure has occurred in the medical record and/or verbally to patient/family.
  - Assess if organizational process is involved as a primary or contributing factor to the event (for example, structure of count process in the OR or procedure for medication labeling).
  - Discuss patient's pathology, risk of procedure (known and communicated), patient's risks score, indications for procedure, and treatment alternatives offered.
- Consider internal peer review and external peer results to assist with next steps. Ensure peer review results are placed in physician's quality credentialing file, as applicable and consistent with state requirements.
- Determine at this point, whether to conduct an RCA. The RCA team may be limited to department head, physician, PI and RM. Consider other PI committee members or, if organizational factors may be involved, include additional team members present during the procedure.

- Recognize that the event provides an opportunity to review the organization's processes, such as credentialing/privileging and ongoing PI monitoring processes. Questions to ask may include: Are we using evidence based best practices for patient selection, technique, assessment, preparation, standing orders…or were alternative methods for treating the condition considered? Review the orientation/training/competency of support staff, nurses, etc. for experienced response when an event occurs.

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