MSHRM MICHIGAN SOCIETY OF HEALTHCARE RISK MANAGEMENT

Preventing a Medical Thriller (Identification, Investigation, Litigation and More)

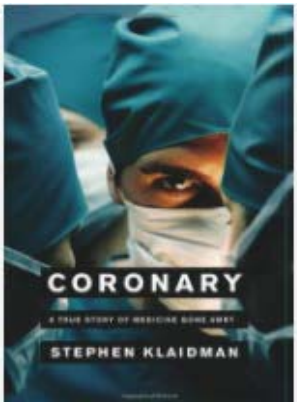
Conflict of Interest Disclosure

All presenters have no apparent conflict(s) of interests or vested interest(s) that may have a direct bearing on the subject matter of the continuing education activity.

Learning Objectives

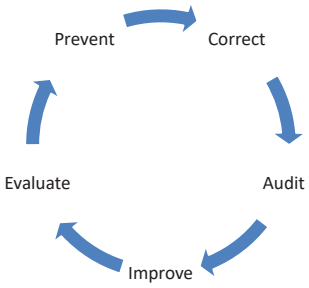
- Discuss the key elements of a credible and thorough critical event/serious safety event investigation.
- Define how to handle the complexities that arise from union representation, peer review, work product protections, subpoena's, discoverability and police involvement and record production.
- Demonstrate positive and negative deposition outcomes in relation to the effectiveness of the investigation.

What is a Medical Thriller?



Steps

- **Standardize**
- **Identify**
- **Investigate**
- **Interview**
- **Analyze**
- **Complexity**
- **Prevent Litigation**
- **Prepare Litigation**



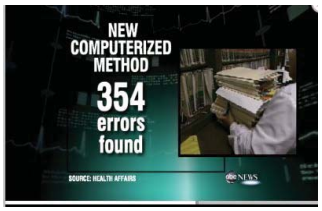
Simulation

- Key components
- Handbook-resource
- Case scenarios
- Complexities and legal issues---call the attorney
- Risk manager as defendant in deposition

Identification

- Incident/occurrence reporting systems
- Hotlines
- Medical record review-computerized triggers
- Quality review/peer review
- Where else?

Identification



Proactive Critical Event & High Exposure Management

Classify Event Quickly for Right Action-Right Timing
Have a Plan
Have Resources

Critical Event Investigation → CAT Management → Claims Management

Checklist | **Checklist/Guide/Principles**

Classify Event ASHRM SSE Definition

ASHRM believes the commonly used definition should be:

A Serious Safety Event (SSE), in any healthcare setting, is a deviation from generally accepted practice or process that reaches the patient and causes severe harm or death.

Healthcare Associated Preventable Harm Classification ASHRM-SSE Whitepaper #2-2014

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 patients 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 (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

High Exposure/CAT Classification (Potential)

Generate $500,000 or more in indemnity exposure

Reserve exceeds 50% of aggregate limits

Extra contractual or significant bad faith exposure

Multiple claim or class action exposure from one event

Injury type

CAT Injury Type / CAT Potential / "Large Loss Exposure"

- Paraplegia
- Quadriplegia
- Blindness
- Multiple amputation
- Severe birth trauma
- Birth hypoxia

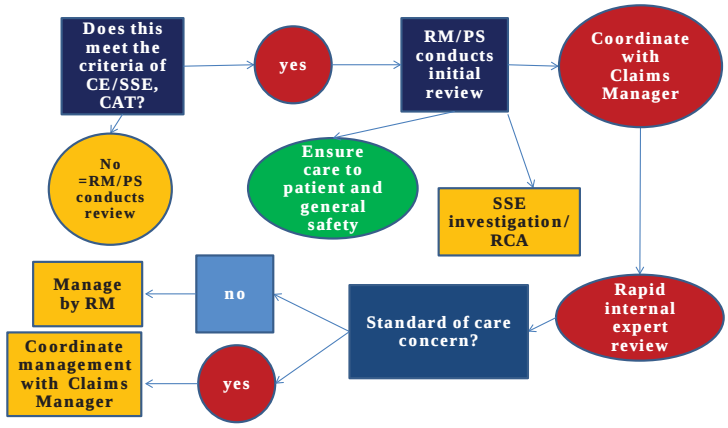
- Severe burns
- Permanent disfigurement
- Brain trauma
- Reproductive organ loss/ permanent impairment
- High profile case

- Cancer misdiagnosis
- Sexual abuse/ molestation
- AIDS/hepatitis
- Multiple event infection exposure
- Elder abuse
- Wrongful death

Methods for Identification

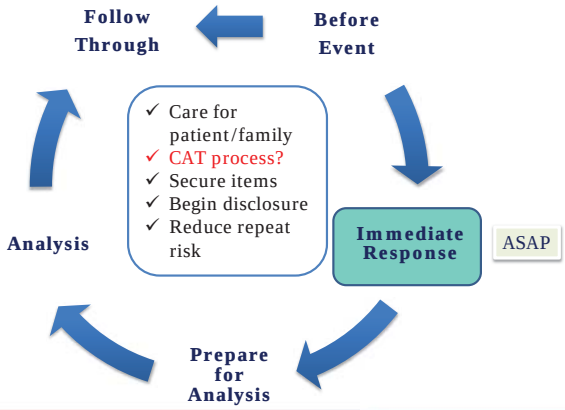
HOW

CAT Decision Tool – Rapid Action

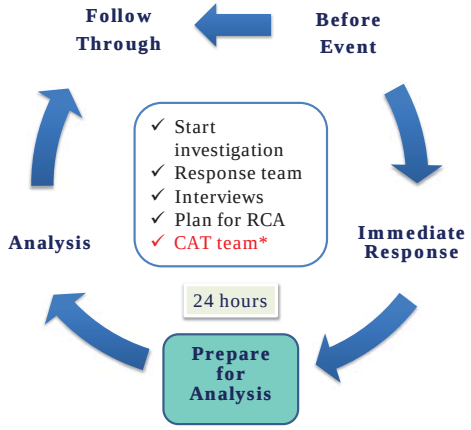


Risk Management/Patient Safety Action and Claims Management Simultaneous

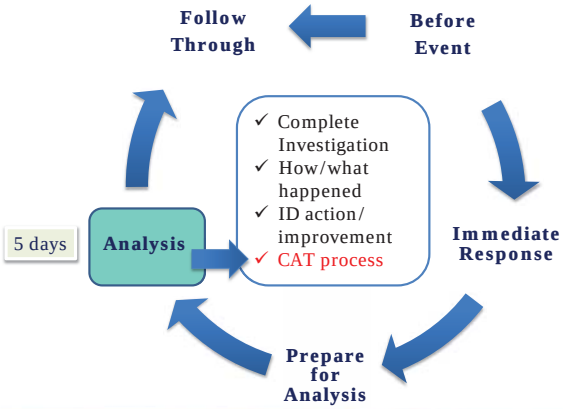
Immediate Response



Prepare for Analysis



Analysis to Action



First 24 Hours-Summary

Quick action	• Put employees at ease • Fact find not fault find • Interview near site of event-triggers memories
Spot issues	• Interview witnesses separately • Ask open ended questions • Gaps need further investigation – translate to Claims Manager

Disclosure process starts – communication
Rapid review expert? Standard of care concern

Deviation Classification

When deviation is acceptable

Deviation as preventable harm

Harm without Deviation

ASHRM AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT

safe and trusted healthcare

White Paper Series

Serious Safety Events:

A Focus on Harm Classification: Deviation in Care as Link
Getting to Zero™ White Paper Series — Edition No. 2

Authors:
Michelle Hoppes, RN, MS, DFASHRM: CEO at Michigan Professional Insurance Exchange-MPIE
Jacque Mitchell, RN, BSN, CPHRM, FASHRM: Risk Manager at Sentara Healthcare

Contributors:
Stephen Pavkovic, RN, JD., Director Patient Safety at University Health System Consortium
Ellen Grady Venditti, RN, MS, CPHRM, FASHRM, Healthcare Risk Manager and Patient Safety Consultant
Faye Sheppard, RN, MSN, JD, CPHRM, CPPS: former ASHRM board member
Mary Ann Hilliard, BSN, JD: Chief Risk Counsel, VP Safety and Patient Experience at Children's National Medical Center

Reviewed by:
William B. Munier, MD: Director, Patient Safety Organization Program Center for Quality Improvement and Patient Safety Agency for Healthcare Research and Quality

Deviation Determination Guide

Deviation Determination Guide
The following guide will aid in determining action following an event.

When an Event/Adverse Outcome Occurs
• Was there a deviation?
❑ **If Yes** 1. Classify the level of harm—5 levels/1 near miss 2. Take action guided by the serious safety event classification (see Table 2/page12)
❑ **If No** 1. Likely a complication 2. Track/Trend
❑ **Not Sure** 1. Use peer review process and complication guide (see Table 1/page 8) • If deviation is yes—Classify the level of harm (use 5 levels of harm/1 near miss); take action guided by the SSE classification • If no to deviation—Likely a complication; track/trend

Things to consider:
- Determine the SSE rate of all events—SSE rate = frequency of preventable harm
- All deviation should be understood for future prevention
- This is intended to serve as a guide and is not prescriptive

Connection to Deviation

Understanding what is preventable—defining in terms of classification

DEVIATION IS AT THE CORE

CAT cases additional classification—but deviation is central to causation

Determining Deviation

- Evidence based guidelines
- Non-compliance
- Use peer review/expert review
- Multi-disciplinary review to determine when deviation is acceptable

- Compare to current practice patterns
- Reasonable person method

If deviation = usually preventable

General Concepts

- Both deviation and type of harm determines level of classification
- Deviation without harm and low potential influence action
- Deviation without harm and high potential influence action with higher resource use

- Harm without deviation classified as complication and risk factor

Can deviation be justifiable?

Appendix || 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 patients 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,*		

CAT Checklist

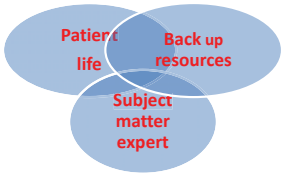
- Key Areas for Discussion
  - Media involvement
  - Disclosure
  - Second victim-stress management
  - CAT Nurse Case Manager


Catastrophic Event Management Checklist for Claim Manager Use

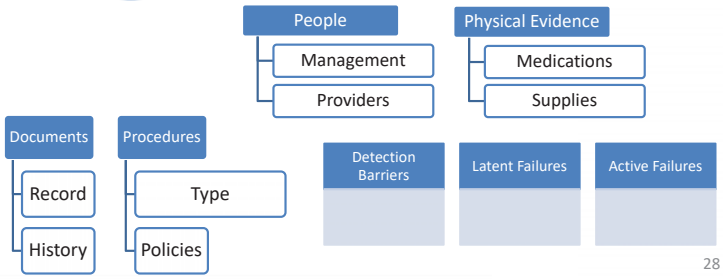
(Label with work product-anticipation of litigation provisions on each page)

Immediate Action Response to Day 30		Complete
Patient Care	Care providers focus	On-going
Roundtable Immediate Issues	Investigation initial facts, timeline of event, care needs	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 until formal handoff **Communication** Patient/family—RM owns-includes coordinating leadership, physicians, staff • 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 • Common communication approach—providers—RM to coordinate and conduct debriefing of event **Expenses/family care** • Immediate expense issues for patient/family • Food and space for family **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	24 -72 hours

Immediate Thoughts



Human Factors	Pharmacy	Environment
• Skill • Rule • Knowledge	• Med Vials • Syringes • Supplies • Dosing and half life	• Staffing • Disruptions • Throughput • Surge



Conduct Debriefing

- Determine goals of immediate debriefing
  - Gather immediate facts
  - Support staff
  - Provide confidential venue to share
  - Explain investigation process and next steps
  - Medically Induced Trauma Support Services-www.mitss.org

Investigation- Interview

Interview Techniques

Timing	• Conduct interview ASAP • People's memories and willingness to assist can be related to the way they are questioned and the timing of such. Do not make this an interrogation.
Components	• Review the critical components of the medical record before the interview when possible
Who	• Focus on interviewing the people directly involved • Caregivers need to feel involved in the investigation and a part of preventing future events

Interview –Prepare Yourself

Purpose	• Establish the purpose • Establishing the chronology of events • As close to the event as possible
Information	• Verify accuracy of information • Verify medical record documentation
Approach	• **Individual interviews -**obtain an independent story and avoid group think

Setting the Stage

- Quiet place
- Schedule people who know the least about the event first
- Have all the relevant documentation available
- Be at eye level with the interviewee
- Avoid a physical set up that may be perceived as establishing you as an authority figure
- Limit those in attendance
- Open-ended questions to encourage conversation
- Questions must be framed so they are non-accusatory
- Have water and tissues available
- Check your appearance

Conducting the Interview

- Reluctant to speak up talk about known procedures or equipment before getting into details of the event
- Non-verbal cues are 50% of the overall message, whereas verbal cues are 20-40 %
- Repeat what the interviewee has shared
- Interviewee to tell their story without interruption
- Avoid yes or no questions
- Staff not to make personal notes
- Be aware of your body language
- Pauses are useful
- Avoid leading questions
- Conclude on a positive note

Interview Tips

- How would you respond if during an interview the provider made the comment- "I am responsible for this patients death"

- Tell me why you think that
- I appreciate that you are taking responsibility
- Remorse is a very positive sign
- No one individual is responsible
- Nobody is to blame for this-it was just an accident

Case Scenario

Paralytic Given by Mistake-Not Revealed

You are called from the ICU and told that a patient who came up from the ED and who was intubated is now alert and writing big signs that they tried to kill her in the ED and she wants out of here now. She is writing that they gave her the wrong drug, and that she heard the whole thing – but could not move and could not breathe. You learn she was given a paralytic in the ED in error and that is the reason she had to be intubated as she stopped breathing. This was not revealed until you contacted the ED provider and the patient/family was not informed.

Paralytic Instead of .....Drug

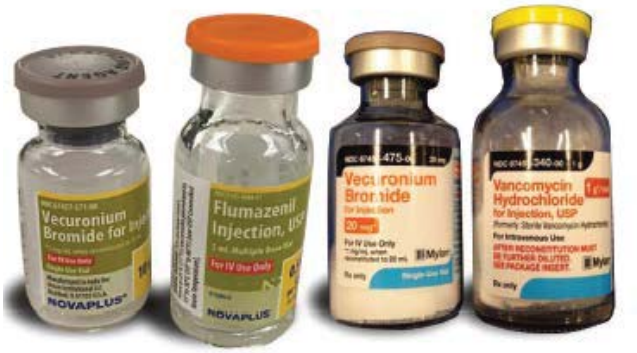


Figure 1. Once the caps are removed, these vials look very similar. However, a mix-up could be catastrophic.

Prepare

- Is this a serious safety event-why or why not?
- What is your immediate response and to who?
- What information will you collect and when?
- Will you conduct a debriefing?
- Who will you interview?
- What root causes do you think you will find?
- Will HR need to be involved?
- What will you ask the nurse?

Simulation

More Information

- Patient intubated—was resuscitated within minutes and will likely recover with no deficits
- Staff are refusing to talk without a union representative
- Family has demanded the medical record now
- Police arrived as the family reported criminal allegations against the hospital and staff
- Now what??

Simulation

Legal/Claims Perspective

- Police
  - Want medical record and names of all staff and incident report
- Staff refuse to talk without union representative
- No patient/family communication/disclosure

Legal Protections and Privileges

- Apologies
- Peer review
- Attorney-client privilege

Expressions of Sympathy

Michigan law protects:

Statements, writings or actions that express sympathy, compassion, commiseration or a general sense of benevolence relating to the

- Pain, suffering
- Death

These are NOT admissible as admissions of liability in a medical malpractice case.

Peer Review

- Records, data and knowledge
  - Collected for or by
  - Individuals or committees
  - Assigned a professional review function

Are confidential

Are not public records

Are not subject to court subpoena

What Can a Court Consider?

- Hospital by-laws
- Internal rules and regulations
- Whether a committee's function is that of retrospective review for purposes of improvement and self-analysis or current patient care

Protection applies to…

- Criminal investigation
- Search warrants
- Civil suits
- Board of Medicine investigations

Attorney-Client Privilege

- Is it DEAD?
- Is it a magic blanket?

- How can a corporation waive this protection…let me count the ways.

Medical Records Access Act

Production "as promptly as required under the circumstances"

- Not later than 30 days after request or 60 days if off-site

Union Representation

- What does your contract promise?
- Any third party inclusion in communications will waive the privilege unless…

Shared with permission from the Institute for Safe Medication Practices

ISMP Institute for Safe Medication Practices

MSA! ARTICLES (/TAXONOMY/TERM/11)

Paralyzed by Mistakes - Reassess the Safety of Neuromuscular Blockers in Your Facility

June 16, 2016

3 Months Later

- NOI received
- Allegations of deceit, cover up, attempt to kill patient and name risk manager as defendant in concealment and fraudulent cover up

Case Scenario Two

Case Scenario Two

- Inpatient geriatric –medical psychiatric unit
- 75 yr frail female with dementia and psychosis
- Posey restraint and 15 minute checks
- Found hanging from the side of the bed on the side rail with the posey up around her neck
- Code called-patient deceased
- Family is on way to hospital now

Facts

- Body cleaned, moved and posey removed
- Documentation regarding checks inconsistent and false charting of checks by tech
- Last check documented 45 minutes prior to patient being found by RN
  - RN thinks a check was done and asks Risk Manager how to chart

Facts

- Interviews resulted in discrepancy re who was checking patient and when-assigned
- Tech lied about whereabouts
- Others indicated he falsified the check documentation all the time

Prepare

Family

- Want to see body, take pictures
  - Upset that body moved
- Call police
  - Requesting security film
  - Want to photograph area
- Call media
  - Want a statement

Whistleblower

- Calls
  - Department of mental health
    - Immediate survey—want all records and staff interviews
  - TJC

Simulation

Mental Health Code MLC 330.1748 Release of Mental Health/Substance Abuse Records

- Mental Health Code is more restrictive than HIPAA as it relates to a covered entity's ability to release mental health records.
- Must adhere to one of the specifically enumerated sections of MCL 330.1748 in order to "share" or release information regarding a patient's mental health or substance abuse treatment.
- MCL 300.1748(9) provides for peer review protection in the mental health context.

Now What

Teams--Brainstorm

Legal Input/Questions

Media Statement Provided

- 3 days have went by and the media has relayed much incorrect information and several media blasts of the family
- On day 4 the Risk Manager responds to news media

Media Statement Provided

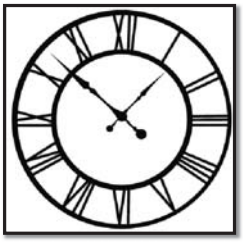
– Hospital ABC is one of the top ten best hospitals in the US according to Press Ganey, we have received magnet status and awards for excellence in behavioral health. Our mission is patient safety and we will investigate to understand any opportunities to improve as we are dedicated to serving our community.

Media Plan

Media Coordinator	Writer	Spokesperson
• Personable • Willing to spend much time on the phone • Press releases • Media updates • Behind the scenes	• Clear • Concise • Tight • Sound bites • www.tenant.net/organize/media	• Articulate • Good listener • Think quickly • Credibility • Humble • Always have more to learn

Timing of Communication

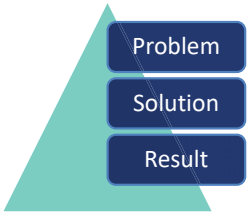
- Most important lesson is that it doesn't matter what you say as long as you say it first.
- What is printed about an issue first is what the public remembers. Everything from there is catch-up and defense.



Reagan Administration used this tactic masterfully.
It became known as "*disinformation*."

Process for Communication

Opening anchor statement



Speak in 3's

Power of comparisons (other safe industries)

Anchor Statements and Theme

Statements

- Dedicated to saving lives
- Prevent harm by managing risk
- Patients are dying from medical error

Themes

- Patient harm—never again
- Saving lives—every life

Audience Wants

Redefine reality

- So what, who cares, what's in it for me

Humble to power

- Me to we to you….

About Relationship

Nobody invests in yesterday

- Define the solution of the future

Speak Top Down

- Headline
- Subject line most important
- Don't put conclusion at the end

Rich with Info

Short

Concise

Predictable

Prepare to Compare

- Teach by comparison
- Numerics
- Visuals
- Stories
- Historic
- Prove point with one tight comparison

One Core Theme

Change Hope

Media Response

- Who should do it
- When should they have done it
- What should they say

MSHRM MICHIGAN SOCIETY OF HEALTHCARE RISK MANAGEMENT

Questions?

MSHRM MICHIGAN SOCIETY OF HEALTHCARE RISK MANAGEMENT

Thank you!