Tracking, Monitoring, and Addressing Near Misses, Adverse Events, and Sentinel Events

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U.S. Department of Health and Human Services (HHS)

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Reminders

- Please complete a post webinar survey.
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Learning Objectives

- Discuss why a culture of safety is the foundation for event reporting.
- Recognize why a robust process for reporting of near misses and adverse events is important for a risk management program.
- Create more robust action plans to address near misses and adverse events.

Polling Question #1

Health Center Program FTCA Deeming Application

Application for Health Center Program Award Recipients for Deemed Public Health Service Employment with Liability Protections Under the Federal Tort Claims Act (FTCA)

- I attest that my health center has implemented risk management procedures to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation. At a minimum, these procedures specifically address the following:
  - Documenting, analyzing, and addressing clinically-related complaints, **"near misses," and clinically sentinel events** reported by health center employees, patients, and other individuals.

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Why is Event Reporting Important?

Capturing information about events, including hazardous conditions, near misses, adverse events, and sentinel events, helps an organization learn and improve continuously while creating safer care for patients and safer conditions for staff.

What is the Goal of Event Reporting?

The ultimate goal is to implement system improvements that reduce the frequency of events, mitigate their effects, and possibly prevent the occurrence of events altogether.

Definitions

Hazardous Condition

- A hazardous condition is defined as a circumstance (other than the patient's own disease process or condition) that increases the probability of an adverse event.*

*The Joint Commission

Courtesy of ISMP

Near Miss Events

- Near-miss events are errors that occur in the process of providing medical care that are detected and corrected before a patient is harmed,* either by chance or through timely intervention.

*AHRQ, Advances in Patient Safety and Medical Liability, 2017

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Adverse Events

- An adverse event is an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.*

*National Quality Forum

Sentinel Events

- A sentinel event is defined as a patient safety event that results in death, permanent harm, or severe temporary harm.*
- Some definitions include those events that are so severe that they result in a loss of trust in the organization.

*The Joint Commission

Near Miss Events

Polling Question #2

Near Miss Events (Slide 1 of 2)

- The Institute of Medicine (IOM) and others have identified near-miss reporting and analysis as vital to understanding and correcting weaknesses in the health care delivery system and to preventing actual adverse events (AEs) that harm patients.
  - Although the majority of health care encounters take place in ambulatory settings, most attempts to record and address near-miss events to date have been carried out in hospitals.

AHRQ, Advances in Patient Safety and Medical Liability, 2017

Near Miss Events (Slide 2 of 2)

- The IOM and others have called for the creation of voluntary reporting systems to detect near-miss events to allow for analysis of patterns of errors.
  - Widespread adoption of near-miss reporting systems in primary care could improve safety in that setting where more than 70 percent of medical encounters occur.

AHRQ, Advances in Patient Safety and Medical Liability, 2017

Safety Culture

Safety Culture (Slide 1 of 8)

- The safety culture of an organization is the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization's commitment to quality and patient safety.*
  - Numerous studies show a link between a positive safety culture and improved patient safety within a healthcare organization.**

*The Joint Commission
**ECRI, Culture of Safety: An Overview, 2019

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Safety Culture (Slide 2 of 8)

The single greatest impediment to error prevention in the medical industry is that we "punish people for making mistakes."

Dr. Lucian Leape, Professor, Harvard School of Public Health. (2000).
Testimony before Congress.

Safety Culture (Slide 3 of 8)

- In a robust safety culture, the support of safety is the highest priority of the organization.
  - Every error (regardless of outcome) represents an opportunity to improve health care delivery.
  - Errors are recognized and reported so they can be analyzed as appropriate.
  - The focus is on how and why a problem occurred rather than on the person whose action or inaction caused the error.
  - Organizations are committed to relentless self examination and continuous improvement.

Safety Culture (Slide 4 of 8)

The safety culture in the healthcare industry is weak compared to other high-risk industries.

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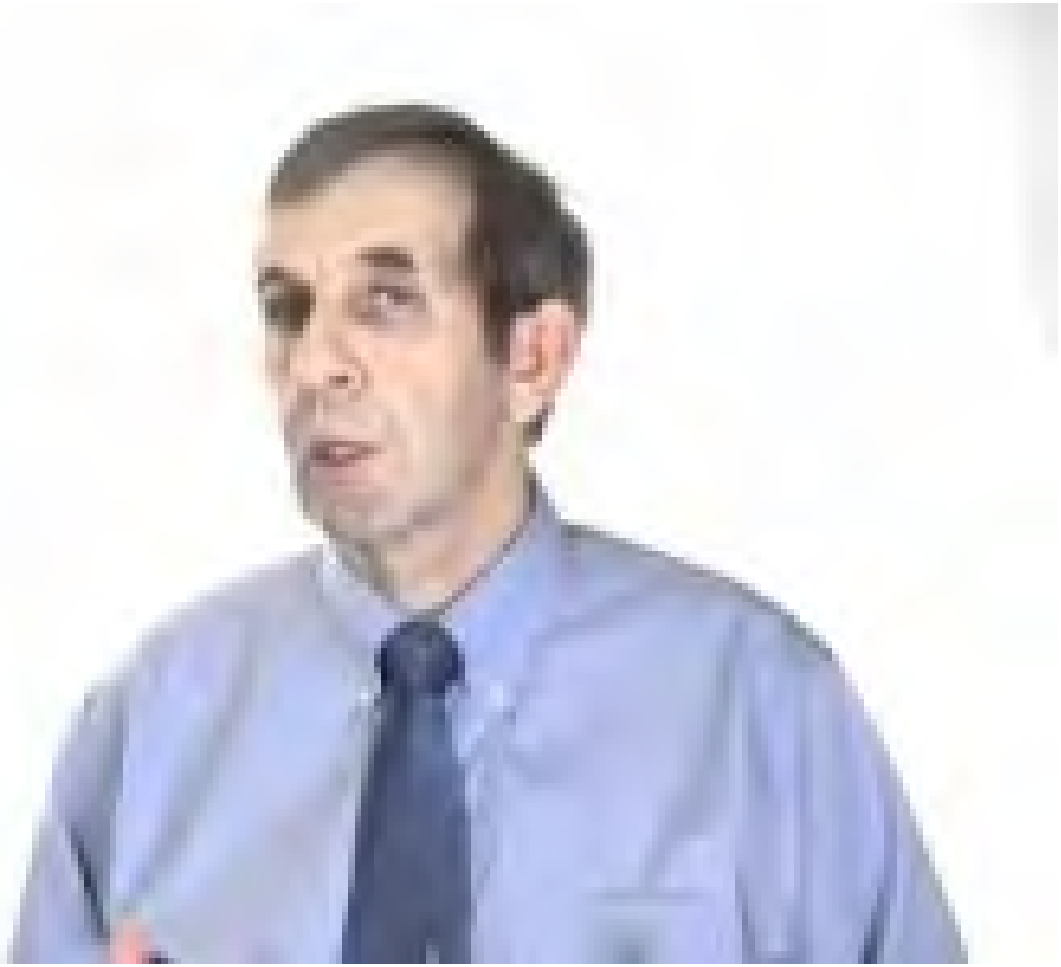
Safety Culture (Slide 5 of 8)

- Effective teamwork and communication are critical elements in a safety culture.
- A safety culture requires an atmosphere of mutual trust in which all staff members are comfortable speaking up and talking freely about safety problems (sometimes referred to as psychological safety).

Safety Culture (Slide 6 of 8)



Michael Leonard, MD
IHI Open School, 2011

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Safety Culture (Slide 7 of 8)

Michael Leonard, MD
IHI Open School, 2011

Safety Culture (Slide 8 of 8)

- Leadership is the foundation of risk management and patient safety.
  - Practice managers and executives (not just providers and clinical staff) play a key role in establishing a culture of safety in the office setting.
- Leaders set the tone and expectations for their organization.
  - Leaders need to communicate the importance of a culture of safety and model and practice safe behaviors (transparency, teamwork, effective communication, direct and timely feedback).

Just Culture

Polling Question #3

Just Culture (Slide 1 of 8)

- A fair and just culture is an important component of a safety culture.
  - Emphasizes learning from error and giving constructive feedback rather than blaming individuals and punishing them.
  - Individuals are held accountable for their own performance in accordance with job responsibilities.
    - Individuals are not expected to carry the burden of system flaws over which they have no control.

Just Culture (Slide 2 of 8)

- A just culture focuses on identifying and addressing systems issues that lead individuals to engage in unsafe behaviors, while maintaining individual accountability by establishing zero tolerance for reckless behavior.
  - It distinguishes between human error, at-risk behavior, and reckless behavior.

AHRQ, Culture of Safety Primer, 2019

Just Culture (Slide 3 of 8)

Human Error	• Slip, lapse, mistake
At Risk Behavior	• Intentional behavioral choice (i.e., shortcut) that increases risk • Know what the rules are but feel safe breaking them • Risk is not recognized or is mistakenly believed to be justified
Reckless Behavior	• A behavioral choice to consciously disregard a substantial and significant risk • Choosing to put others in harms way

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Just Culture (Slide 4 of 8)

- Two just culture decision trees – one developed by James Reason and the second by David Marx – serve as a primary basis for distinguishing between errors that occur because we are imperfect humans who make mistakes and actions considered to be at-risk or reckless.

Human Error	**At Risk Behavior**	**Reckless Behavior**
Product of current system design	Unintentional risk taking	Conscious disregard of unjustifiable risk
Console	Coach	Punish
		David Marx, JD. Just Culture Organization.

Just Culture (Slide 5 of 8)

- All staff must see that those making human errors will be consoled, those responsible for at risk behaviors will be coached, and those committing reckless acts will be disciplined fairly and equitably, no matter the outcome of the reckless act.
- Senior leaders, practice managers, physicians, nurses, and all other staff must be held to the same standards.

Just Culture (Slide 6 of 8)

- A fair and just culture recognizes that:
  - Most errors cannot be linked to individual performance.
  - Errors are the result of flawed processes or systems that work together to yield unsafe situations.
  - System issues that cause errors are often preventable.

Just Culture (Slide 7 of 8)

- In a fair and just culture:
  - Organizations are accountable for designing systems that support and promote safe choices by staff.
  - Staff are accountable for the quality of their choices within the system.

Just Culture (Slide 8 of 8)

*"Rather than being the main instigators of an accident, operators tend to be the inheritors of **system** defects… Their part is that of adding the final garnish to a lethal brew that has been long in the cooking."*

James Reason, Human Error, 1990

Polling Question #4

Event Reporting

Goals of Event Reporting

Analysis and identification of trends

- The focus should be on identification of near misses and events that occur with high frequency or have a high potential to result in patient harm.

Prevention

- Knowledge of near misses and adverse events allows the organization to analyze the cause of systems breakdowns and other factors contributing to their occurrence and take preventive actions to protect patients, visitors, and staff from similar risk.

Improvement

- Knowledge of the type and number of events allows an organization to implement process improvements.

Event Reporting (Slide 1 of 4)

- All unexpected and unanticipated events must be reviewed and handled in a consistent and deliberate manner.
  - Preparation for an unanticipated event begins with the development, implementation, and communication of a comprehensive event management plan.

Event Reporting (Slide 2 of 4)

- Staff members should be well trained on the types of events that should be reported and the process for reporting events.
- Staff members should be well trained on the event response that is used in an organization.
- Training should be provided during orientation, annually, and when changes are made to the system.
- Event reporting and event response should be included in the annual risk management training plan.

Polling Question #5

Event Reporting (Slide 3 of 4)

- Systems, forms, and other ways to report events will vary by organization.
- Simple spreadsheet or relational database software can be used to compile, analyze, and trend data obtained from event reports.
- Electronic or web-based systems are increasingly being used to report, track, and trend events for ease of data analysis.

Event Reporting (Slide 4 of 4)

- Tracking and trending events by type, frequency, and severity will help to prioritize risk management and patient safety efforts.
- A taxonomy should be created for categories and sub-categories of events to facilitate analysis and reporting.
- A taxonomy should be used to categorize the severity of events
  - E.g., National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) algorithm for categorizing event severity

Taxonomy: Examples of Event Categories

- Falls
- Medications
- Adverse drug reaction
- Surgery/procedure
- Lab specimen/test
- Diagnostic test
- Infection prevention
- Diagnosis/treatment
- Documentation
- Consent
- Care/service coordination
- Environment
- Security/safety
- Professional conduct

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Taxonomy: Examples of Event Sub-Categories

Lab Specimen/Test

- Delayed critical result
- Delayed abnormal result
- Clotted specimen
- Lost specimen
- Mislabeled specimen
- Wrong patient

Event Investigation

Event Investigation (Slide 1 of 5)

- The severity of an event will dictate the actions to be taken and the people who need to be involved in its aftermath.
  - Investigations of lower severity events may be conducted by staff members or department managers who have been trained to do so.
  - More severe events are typically investigated by a risk manager, risk management designee, practice manager, or administrator.

Event Investigation (Slide 2 of 5)

- Management of serious or sentinel events typically requires an enhanced investigation process.
- The investigation should be organized and efficient, building on the gathering of physical evidence and statements from interviews.
  - The goal of the investigation is to determine where and when the event occurred, who was involved, what happened, how the event occurred, and any preliminary occurrences leading up to the event.

Event Investigation (Slide 3 of 5)

- The scene and physical evidence should be secured.
  - The scene often holds significant clues regarding the “how” and “why” of the incident.
  - Equipment and/or supplies should be sequestered in a locked area with limited access.
  - A chain-of-custody document should be used if the equipment and/or supplies is later handed off.

Event Investigation (Slide 4 of 5)

- A systems approach should be used to analyze all safety issues.
  - The focus should be on physical causes, human causes, and organizational causes, not individual blame.
    - E.g., Training and orientation, culture, communication & teamwork, information management & technology, processes & procedures, work environment, equipment/supplies, human factors.

Event Investigation (Slide 5 of 5)

- Root Cause Analysis (RCA) should be conducted for all severe and potentially severe events, including all sentinel events.
  - Retrospective, analytical approach that seeks to identify why an event happened and how to prevent if from happening again
  - Designed to identify the most causal or basic factors that underlie a variation in performance
  - Focuses primarily on systems and processes, not individual performance

Event Follow Up

Event Follow Up

- Identify performance improvement strategies
- Identify individual(s) responsible for each strategy
- Identify a specific, **measurable** goal for each strategy
  - Goals should be challenging but attainable
- Identify a specific date to reach the goal
- Determine a plan to monitor for sustained change

Adapted from ECRI Practice Alert. *Conducting Risk Assessments: A Checklist*. 2018.

Improvement Strategies

- Research guidelines and best practices published by authoritative organizations
- Consider strategies that have been successful at other sites within your organization or at other organizations
- Customize strategies to the practice setting based on available resources and existing workflow

Improvement Strategies: Fall Prevention

- Perform risk assessment
- Minimize environmental risk factors
- Communicate risk
- Implement fall prevention interventions based on risk factors

Improvement Strategies (Slide 1 of 3)

Strong	• Likely to eliminate or greatly reduce the likelihood of an event
Intermediate	• Likely to control the root cause or vulnerability
Weak	• Less likely to be effective

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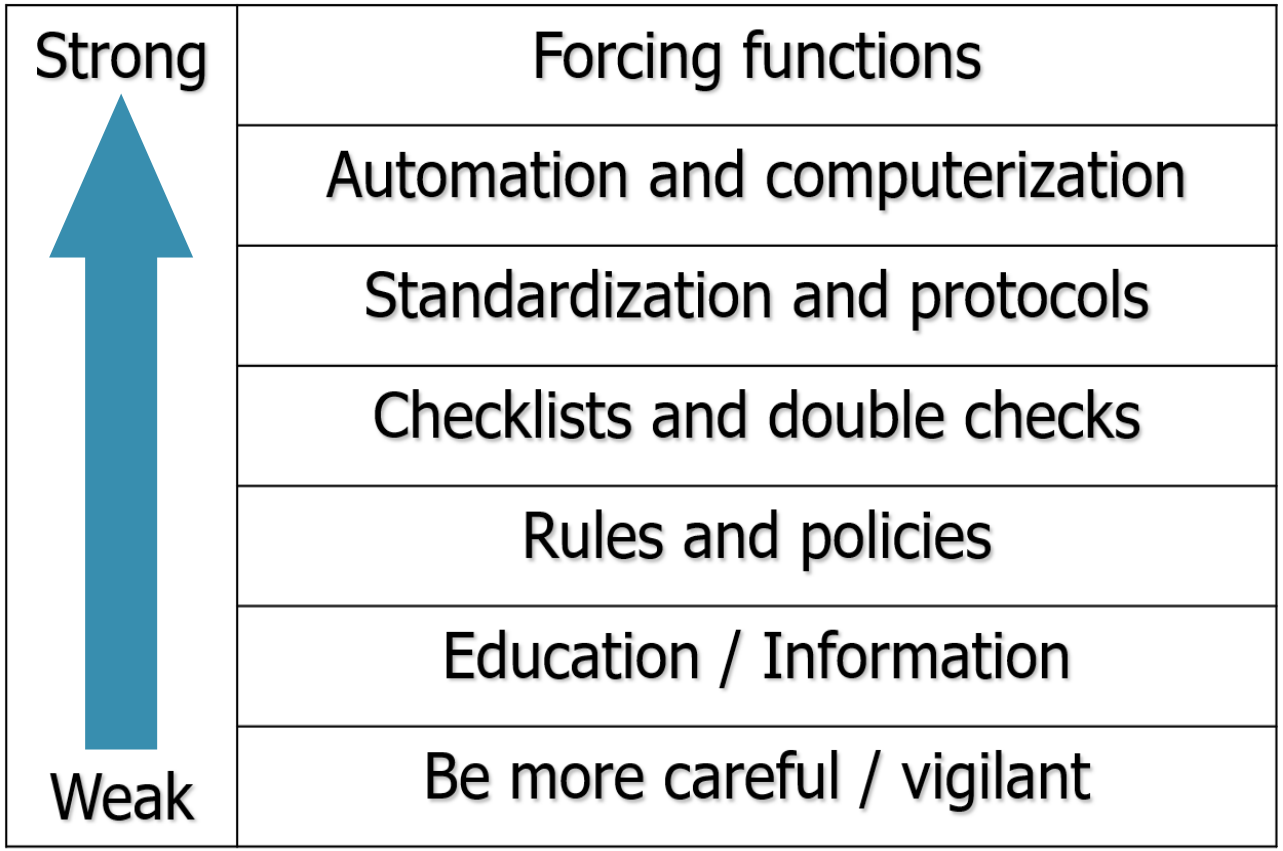
Improvement Strategies (Slide 2 of 3)



Improvement Strategies (Slide 3 of 3)

- A variety of methods for planning, executing, and monitoring patient safety improvement strategies are available.
  - One technique is the PDSA (Plan, Do, Study, Act) method.

Engage Stakeholders in Improvement Strategies

- Tell a story
  - Communicate impact in human terms
    - Jane, a 65-year-old patient with four grandchildren, fell and broke her hip last week.

- Solicit and leverage executive support
  - Calculate impact in financial terms
    - Showcase potential aggregate savings

Goals for Improvement Strategies (Slide 1 of 2)

- Specific and measurable
- E.g., Education will be completed for L&D staff, OB residents, OB physicians, and anesthesia physicians.
  - Goal: 100%
  - Metric: # staff educated / # eligible staff

Goals for Improvement Strategies (Slide 2 of 2)

- Specific and measurable.
- E.g., Complete time out information will be documented in the medical record.
  - Goal: 100%
  - Metric:
    - Sample size: Minimum of 5% or at least 30 (whichever is greater) medical records audited per quarter
    - Numerator: Number of records in which complete time out information was documented
    - Denominator: Total number of records reviewed

Benchmarking

- Measures performance compared with others or best in class
- Compares data for the purpose of goal setting
- External benchmark: Comparison to similar organizations
- Internal benchmark: Comparison to previous data from your organization or data from other sites within your organization

Documentation

Corrective action plans should be documented.

Documents generated during follow up of an event should be treated as confidential in order to optimize legal protection.

Documentation of an Action Plan

Issue	Improvement Strategy	Responsible Party	Timetable for Implementation	Measures of Effectiveness	Status

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RCA Action Plan

Issue	Improvement Strategy	Responsible Party	Timetable for Implementation	Measures of Effectiveness	Status
Patient Factors					
Communication/Teamwork					
Process/Procedures					
People/Human Resources					

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Close the Loop (Slide 1 of 2)

- Action plans must be monitored to verify that goals are reached by target dates.

Close the Loop (Slide 2 of 2)

- Closing the loop via feedback to staff is an important aspect of the management of near misses and adverse events.
  - Staff should be confident that reporting will lead to learning and proactive efforts to prevent similar concerns.
  - Event reports increase when staff see that reports have a positive impact on patient safety.

Monitor for Sustained Change

- There should be a plan to monitor for sustained change.
- It is also important to monitor for unintended consequences of improvement strategies.
  - E.g., Workarounds, alert fatigue

External Reporting

- Depending on a facility's state regulations, regulatory agencies may need to be notified of sentinel events.
- If a medical device is involved in an event, a Safe Medical Devices Act (SMDA) report may be required.

Event Follow Up Exercise (Slide 1 of 2)

Issue

- Event reports show a trend in near misses related incorrect patient identification.

Performance Improvement Strategy

The Joint Commission

National Patient Safety Goals®
Effective January 2021 for the Ambulatory Health Care Program

Goal 1

Improve the accuracy of patient identification.

NPSG.01.01.01

Use at least two patient identifiers when providing care, treatment, or services.

--Rationale for NPSG.01.01.01--

Wrong-patient errors occur in virtually all stages of diagnosis and treatment. The intent for this goal is two-fold: first, to reliably identify the individual as the person for whom the service or treatment is intended; second, to match the service or treatment to that individual. Acceptable identifiers may be the individual's name, an assigned identification number, telephone number, or other person-specific identifier.

Element(s) of Performance for NPSG.01.01.01

1. Use at least two patient identifiers when administering medications, blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing treatments or procedures. The patient's room number or physical location is not used as an identifier. (See also MM.05.01.09, EPs 7, 10; PC.02.01.01, EP 10) R

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Event Follow Up Exercise (Slide 2 of 2)

Issue	Improvement Strategy	Responsible Party	Timetable for Implementation	Measures of Effectiveness	Status
Event reports show a trend in near misses related incorrect patient identification	Provide education on correct patient identification to non-clinical and clinical staff	D. Jones	Complete education by 10/30/21	Goal : 100% Metric: # staff educated / # eligible staff	In progress
Event reports show a trend in near misses related incorrect patient identification	Create and implement a process for real time monitoring and "just in time" education intended to drive compliance with correct patient identification	Practice Managers (C. Smith, D. Jones, B. Lee)	Start 11/2021	Compliance will be determined by monthly random direct observation audits Goal : 100% Sample size: Minimum of 5% of patient visits per month Numerator: Number of observations in which two correct patient identifiers were used Denominator: Total number of observations	Pending

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Disclosure

- Disclosure is communication with patients and families about unanticipated outcomes.
  - Disclosure requires mindful communication.
  - Establishing guidelines and policies can help promote effective communication.
  - Providers should seek assistance from legal counsel when communicating with patients about serious events.

Caring for the Caregiver

- When a patient suffers an adverse event, the provider(s) directly involved in the event becomes the second victim.*
  - The provider may be emotionally traumatized and have lasting effects that persist for months or years.

*A term coined by Dr. Albert Wu, a professor of health policy and management at the John Hopkins School of Public Health

- Support should be offered to a traumatized provider as soon as possible after an adverse event.

Reference List

- ECRI Institute
- Agency for Healthcare Research and Quality
- National Quality Forum
- Institute for Healthcare Improvement
- The Joint Commission
- Outcome Engenuity, LLC (The Just Culture Company)

Polling Question #6

Final Reminders

- Please send an email to hrsaftcadeeming@kepro.com to request a post webinar survey and obtain a Certificate of Completion.
  - Include “survey” and “Certificate of Completion” in the subject line of the email.
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Questions

- Contact hrsaftcadeeming@kepro.com if you have questions about the webinar.

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Thank You!