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

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Forward

Eliminating preventable harm is an American Society for Healthcare Risk Management (ASHRM) top priority. Surely, goal achievement is contingent upon many critical factors. While some factors are obvious — such as excellent clinical care and conformance to evidence-based practice — this paper focuses on less-obvious, but equally-influential, factors:

- Understanding what is preventable at the time of harm occurrence
- Defining/describing harm in terms of a classification system
- Identifying and understanding contributing factors when harm occurs
- Describing how measurement drives improvement and aids in determining effectiveness of risk management
- Outlining how deviation in care is at the core of determining what is, or isn't, preventable

In order to truly understand preventable harm, it is important to measure patient safety and to establish whether or not current and potential safety solutions are effective. Clearly, preventable harm measurement is a challenge because definitions of harm vary among different data-capture methods. Similarly, disparate classification systems make it difficult to clarify and mitigate underlying causes of harm. These challenges affect our ability to determine and demonstrate effectiveness of patient safety and risk management interventions that reduce errors and preventable harm[1].

Measures drive improvement, inform consumers and influence payment. Private and public payers use measures to make judgments about the providers with which they contract and to incentivize improvements in care. This is another reason why defining, classifying, and focusing action on prevention of harm should be a central component of any proactive risk management program.

In the first installment of ASHRM's Serious Safety Events (SSEs) *Getting to Zero*™ white paper series, we focused on event investigation process steps. One component of the investigation process is to determine a harm score, which often triggers risk management and organizational response. Without a reliable and accurate harm-score assignment, opportunities for implementing an effective response may be lacking. [1, 2]

Defining Harm

Before a preventable harm classification system can be outlined for serious safety events, a common definition should be established. ASHRM supports the following commonly-used definition:

> *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.*[3]

A common definition is central to the use of a standardized classification system. Therefore, adoption of both a common definition and a standardized classification process may reduce many current healthcare variations. Just as healthcare is striving to drive down variation in clinical practice, it also strives to reduce variation in the definition and classification systems used to determine preventable serious harm.

It is only through standardization and common methodology that a better understanding of the frequency and the overall rate of preventable harm may be determined. Clarity and uniformity will aid in better identification of contributing factors and ultimately, to a greater level of prevention.

Introduction

Core competencies for today's risk management and patient safety professionals include:

• How to prevent SSEs

• How to classify and investigate SSEs when they occur

• How to use lessons learned for correction and future prevention of SSEs

ASHRM's Getting to Zero™ initiative promotes these competencies through this white paper, which provides guidance on a classification system for preventable harm in relation to the role of deviation and type of action. The guidance in this second installment of our Getting to Zero White Paper series is not intended to be prescriptive.

Our goal is to provide readers with a deeper understanding of how SSEs are defined, classified and analyzed for harm prevention. This guide also is intended to help healthcare organizations consider strategies to reliably measure preventable harm, determine effectiveness of prevention techniques, practice consistent high-reliability methods and achieve safe and trusted healthcare.

A successful *Getting to Zero* journey is dependent upon consistent classification and reliable measurement of the rate of preventable harm. We must measure, not to *prove* impact, but to quantify and understand where *improvement* is needed. The purpose of classifying and measuring preventable harm is to learn and to improve performance and to move from a reactionary approach to a behavior-based, high-reliability approach that prevents harm.

Part of improving and moving toward a high-reliability approach is to assess and evaluate deviations in care and causation and to implement safety culture programs that focus on behavioral and human-factor solutions. By defining and classifying serious safety events, we can better:

• Determine the frequency and rate of preventable harm.

• Understand the role of deviation in determining what is preventable

• Use measurement to drive learning and improvement

• Evaluate prevention technique effectiveness

• Drive down variation and use a common process to benchmark and compare

• Enhance informed consent through a better understanding of what is preventable in relation to deviation

Learning and improvement should also occur from events that are classified as known complications or no harm, as there is often opportunity for risk reduction in complications and no harm events and/or trends of events that may not be considered preventable at the time of occurrence. Learning from near misses is one of the tenets of patient safety.

Harm Definitions/Descriptions

Proactively addressing medical errors, preventable harm and patient safety will protect patients from adverse events and lead to more affordable, effective and equitable care. Part of this proactive approach is to further explore how we capture, define, and classify harm for the purpose of measurement and action. It has been long known that there is not a standardized definition that has been accepted by healthcare regarding what harm is, or is not, or that which is considered preventable or a known complication of the care. There are varying descriptions/definitions of harm and varying sources:

- The Agency for Healthcare Research and Quality (AHRQ) created a *Harm Scale* that indicates the "extent to which the patient's functional ability is expected to be impaired subsequent to the incident and any attempts to minimize adverse consequences."[4]
- The Merriam-Webster dictionary-indicates harm is "physical or mental damage or injury: something that causes someone or something to be hurt, broken, made less valuable, or successful, etc."[5]
- The National Quality Forum (NQF)—a nonprofit organization that operates to endorse quality measures that rise to the level of being national standards — indicates serious reportable events are "largely preventable, and harmful clinical events, designed to help the healthcare field assess, measure, and report performance in providing safe care." In the NQF report, *Patient Safety-Complications Endorsement Maintenance: Phase II*, it was noted there is a lack of standardized terminology of measures, and because of the variation, NQF plans to create common definitions within the field to improve the usability of and comparability across the measures.[6]

Harm Studies and Percentages

Harm from the delivery of healthcare had been acknowledged and discussed, but not truly studied until the early 1960s. Deviation in relation to harm being preventable is just now being examined. The following studies outline percentages of harm:

1964—Dr. Elihu M. Schimmel, the chief resident at Yale from 1960 to 1961, noted that medical progress had brought dramatic advances in methods of diagnosis and treatment, but with each new advance, reports of adverse reactions followed. He noted and later published that almost 20 percent of patients in a university hospital suffered iatrogenic harm; and of those, 20 percent were serious or fatal. The risk of such serious episodes increased with the patient's length of stay.[7]

1981—Steele et al estimated that 36 percent of patients admitted to a university-based hospital suffered harm as a result of medical care. The authors wisely included patient falls in the study even though they were criticized for including that indicator of harm.[8]

1991—*The Harvard Medical Practice Study* of hospitalized patients in New York in 1984 found that nearly 4 percent suffered an injury that prolonged their stay, or resulted in a measurable disability. The study (of 30,121 randomly-selected records from 51 randomly- selected acute care hospitals in New York) found occurrence of adverse events in 3.7 percent of the hospitalizations. It was reported that 27.6 percent of the adverse events were due to negligence. This was equivalent to 98,609 patients in New York in 1984 that were estimated to have suffered potential harm from medical care. The study attributed a substantial amount of patient injury to medical management error and substandard care.[9]

A 1991 review of the *Harvard Medical Practice Study* concluded that prevention of many adverse events must await improvements in medical knowledge, but a high proportion of events were due to management errors and were potentially preventable at the time of the 1984 study.[10]

2000—Generally speaking, the public was not concerned or aware of preventable harm from healthcare until the release of the Institute of Medicine's report, *To Err is Human: Building a Safer Health System*. The report warned the public and confronted healthcare professionals with the news that at least 44,000 patients and possibly up to 98,000 patients died in hospitals annually as the result of preventable medical errors. Although the report was not a fresh harm estimate, because it was based on the previously mentioned *Harvard Study*, its impact was explosive in that the "estimates" were reported through multiple national media outlets.[18]

2010—The federal government published its own study, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, noting that 13.5 percent of a nationally-representative random sample of 780 hospitalized Medicare beneficiaries discharged during October 2008 experienced an adverse event during hospitalization that resulted in temporary harm during their hospital stay, and 44 percent were deemed as reasonably preventable with the implementation of evidence based guidelines.[11]

2012—Another report by the Office of the Inspector General (OIG), *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, indicated that hospital staffs do not report 86 percent of events to incident-reporting systems, partly because of staff misconceptions about what constitutes patient harm.[12]

It is likely that the reports of adverse events in healthcare and the percentages that have been categorized as preventable, along with the cost of providing care and treatment for such events, is what has led to the Centers for Medicare and Medicaid Services (CMS) and other payers to use financial penalties to encourage safety improvements. It is reported that estimates of preventable errors cost the United States $17- $29 billion per year in healthcare expenses, lost worker productivity and disability[4]. Enhancing patient safety, preventing patient harm, and reducing the associated costs of such events is a top healthcare priority that is best supported through common risk management processes such as those outlined in this ASHRM white paper.

Harm Classification Systems and Scales

In reviewing studies of harm, it is often difficult to distinguish between harm that is inherent from medical treatment and harm that is unnecessary or preventable. There are many challenges in classifying harm such as accurate assessment from the time of the event, patient versus provider perspectives, and the consideration of whether or not the harm is actually a known complication. To mitigate challenges, several organizations are working to define classification systems for harm. However, the distinction between preventable and unpreventable harm as an analysis component is not yet universally agreed upon.

The examples below are from organizations involved in developing harm classification scales:

- The World Health Organization's term of Healthcare-associated harm is harm arising from or associated with, plans or actions undertaken during the provision of healthcare, rather from the underlying disease or injury and differentiates between medical harm and preventable harm. They developed a five level classification harm scale. The scale ranges from "No Harm to Death" with levels such as from "Mild," "Moderate," "Severe," and "Death." A large number of international safety experts played a role in the development of that 2009 scale—*Conceptual Framework for the International Classification for Patient Safety*.
- The National Quality Forum (NQF), in its work with the Agency for Healthcare Research and Quality has been attempting to develop "Common Formats" for its definition of the different levels of unnecessary harm in healthcare. Common Formats refer to common definitions and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety and quality.
- The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) in 2001 created its own index for categorizing medication errors by intensifying levels of harm. The levels of harm take into consideration differences of duration and permanency of harm. The NCC MERP defines harm as "impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom."
- The Institute for Healthcare Improvement (IHI) developed Global Trigger Tools to identify adverse events (AEs) and to measure harm in a healthcare organization. These tools help organizations to identify events that do cause harm

to patients, in order to select and test changes to reduce harm. Over time, multiple topic and location-specific Trigger Tools have been developed and the IHI Global Trigger Tool combines several of these into one tool that can be used to measure harm at the hospital level.[15]

- The Patient Safety and Quality Improvement Act of 2005 requires that event report data be collected and categorized by PSOs in a standardized manner with a common set of data elements for aggregation and analysis across all providers.[16] These elements, the "Common Formats," capture event-specific data, including the degree of harm. In 2010, AHRQ issued version 1.1 of the Common Formats Harm Scale—a 7-point scale with five categories between "No Harm" and "Death," that classifies an event's impact on a patient's functional ability.[4] In April 2012, AHRQ released version 1.2 of the Harm Scale which uses a two-part assessment of harm and asks the user to categorize the degree of harm on a 5-point scale, with three categories between no harm and death, and then indicate separately the duration of harm as indicated below:

Scale for Harm

- A—**Death**: Dead at time of assessment
- B—**Severe harm**: Bodily or psychological injury (including pain or disfigurement) that interferes significantly with functional ability or quality of life
- C—**Moderate harm**: Bodily or psychological injury adversely affecting functional ability or quality of life, but not at the level of severe harm
- D—**Mild harm**: Minimal symptoms or loss of function, or injury limited to additional treatment, monitoring, and/or increased length of stay
- E—**No harm**: Event reached patient, but no harm was evident
- F—**Unknown**

Scale for duration of harm to the patient

- A—**Permanent** (one year or greater)
- B—**Temporary** (less than one year)
- C—**Unknown**

As is apparent from these studies, developing a harm scale that is easily and consistently applied to a wide range of event types and situations is a challenge.

As indicated above, all harm needs to be investigated and understood for risk reduction, however distinguishing between harm that is preventable or not preventable is another area of the analysis that needs to be considered. As such and after reviewing the different classifications of harm, ASHRM has used the AHRQ harm scale as the primary resource, and is providing a process for consideration to aid in determining whether or not the harm was preventable based on deviation in practice. Understanding preventability and deviation is directly linked to causation and the type of correction action and improvement that will be needed to reduce patient harm.

Classifying Preventable Harm: Deviation as the Link

Deviation is the link to classifying preventable harm. It is often deviation in the healthcare delivery process that aids in

the determination of whether harm was preventable or not. The first and primary question that needs to be answered is whether or not deviation in care occurred. How deviation is determined should generally include the following:

- Evidenced-based guidelines should be used for determining deviation from the norm, or what is expected practice
- Non-compliance with procedures, policies, and protocols
- Peer review determination for the areas in which we have generally accepted practices but no scientific evidence to suggest that these practices are the right thing to do for patients
- A multi-disciplinary review in determining when deviating is acceptable, such as in the use of clinical trials
- Comparison to current practice patterns
- Reasonable person comparison (the manner in which the majority of other peers practice)

If it is determined that deviation in practice led to the event, then it should, generally, indicate preventability. If the event is determined to be preventable, then analysis should be done to understand the reasons for the deviation, the contributing factors, and the process for corrective action. If the harm is determined to be unpreventable, a known complication of the care provided, it should still be reviewed to explore possible opportunity for future avoidance.

The concept of deviation is critical in relation to classifying harm and thus in determining action to ensure patient safety and risk reduction. Although not all deviation results in harm or significant harm, it should be reviewed and understood because this is where opportunity to improve generally resides.

General concepts in relation to deviation include:

- It is the deviation that determines whether the harm is preventable
- In general it is the combination of both deviation and the type of harm that aids in determining the level of preventable harm classification (trends in deviation regardless of level of harm are often escalated for more intense review and action)
- Deviation without harm and low potential for harm, impact and influence processes for action but generally at a lower level of resource allocation
- Deviation without harm yet with a high impact for harm influence levels of action with generally a higher level of resource allocation
- Harm without deviation is classified as a complication and generally a risk factor. Complications should be studied for possible prevention and trended for frequency and severity. If frequency and/or severity are determined to be outside an acceptable range, action should be taken.

When there is an event, the following questions must be answered by those trying to determine if harm was or wasn't preventable:

- Is there deviation in care?
- Was the deviation justifiable?
- If there is deviation, was it preventable?
    - o (If there is not deviation it is likely a complication)
- If there is deviation and harm, what is the level of classification?
    - o (Classification level guides action)

How to determine deviation:

Table 1: Deviation Decision Tool (see Table 2/page 13)

Clinical trial used and harm occurs

- ✓ If no deviation: Harm not classified as preventable, classified as complication/adverse outcome of trial.
- ✓ If deviation: It is classified as preventable—go to the Harm Classification Tool to determine level.

Evidenced-based practice used and harm occurs

- ✓ If no deviation: Harm not classified as preventable, classified as complication.
- ✓ If deviation: it is classified as preventable—go to the Harm Classification Tool to determine level.

Compliance with updated procedures, policies, protocols, standards of care used and harm occurs

- ✓ If no deviation: Harm not classified as preventable, classified as complication.
- ✓ If deviation: it is classified as preventable—go to the Harm Classification Tool to determine level.

Deviation from standard practice, yet appears justifiable and applicable for the situation

- ✓ Refer to peer review for majority decision using the reasonable person criteria—if deemed the deviation is appropriate—not classified as preventable, if harm classified as complication/adverse outcome
- ✓ If deviation is not considered justified, it is classified as preventable—go to the Harm Classification Tool to determine level.

Emergency situation to save life, limb, function where no other known established treatment exists

- ✓ Refer to peer review for majority decision using the reasonable person criteria—if deemed the deviation is appropriate—not classified as preventable, if harm classified as complication / adverse outcome.
- ✓ If deviation is not considered justifiable, classified as preventable—go to the Harm Classification Tool to determine level.

If there is harm from a known complication, was there timely intervention and treatment?

- ✓ If yes, the harm was not preventable
- ✓ If no, harm was preventable—go to the Harm Classification Tool to determine level.

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/page13)
❑ 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 classifcation • 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

Known Complication as Preventable Harm

Known complications from the delivery of healthcare are inescapable. However, there are times when a known complication may also be considered preventable harm. When classifying such consider the following:

Harm occurred when risk of such was known?
❑ If Yes 1. Likely a complication 2. Track/Trend
❑ If No 1. Classify the level of harm—5 levels /1 near miss 2. Take action guided by serious safety event classification (see Table 2/page13)

Things to consider:

- Tracking and trending complications should be part of the peer review process and continuous performance improvement
- 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

Healthcare Associated Preventable Harm Level Classification Tool

ASHRM developed the *Healthcare Associated Preventable Harm Level Classification* Tool to aid risk managers and healthcare leaders in classifying an event when deviation has occurred, and then to aid in determining what actions may be generally considered. The tool complements the AHRQ Harm Scale.

The three-category guide below classifies preventable harm levels when deviation occurs and arises out of, or is associated with, plans or actions undertaken during the provision of healthcare, rather from the underlying disease or injury.

1. Serious Safety Event

2. Safety Event

3. Pre-Patient Event

In the first two of the three categories, the incident reaches the patient with the various levels of harm that can occur.

Only in Category 3, *Pre-Patient Event*, are formal or informal harm-prevention barriers in place to protect the patient.

The *Healthcare Associated Preventable Harm Level Classification Tool* was developed to help:

- Determine preventable harm based on deviation
- Differentiate between events that reach the patient and events that do not
- Determine the significance of the event itself rather than base it on the duration of harm (permanent or temporary). Accomplished by outlining three primary categories: *Pre-Patient Event, Safety Event and Serious Safety Event*
- Guide action for follow-up analysis
- Recommend culpability analyses
- Reduce classification confusion
- Standardize a measurement process based on preventability with deviation

The tool included in this white paper was peer reviewed by risk management professionals with varying levels of experience and from diverse geographies. They were presented with event scenarios and were asked to individually obtain the classification outcome. The findings of this validation study determined that when risk managers/safety professionals individually classified events using the scale, the determination was the same nearly 70 percent of the time.

However, when determination variation existed, it was most often seen between levels SSE-2 and SE-3. This variation seemed to relate to determining harm in relation to moderate and severe classification. The significant issue is ensuring that the reviewers classifying the outcome pay attention to the different components, whereby SSE-2 requires life-saving intervention or major medical- surgical intervention, shortening life expectancy or causing major, permanent or temporary harm, or loss of function; and SE-3 requires intervention that may include procedures but is not considered lifesaving or major.

- This peer review process highlighted the need for organizational coordination of reviewers and commitment to ensured consistency in coding outcomes. Further peer review and validation of the tool/classification determination should be considered.

Six defined Levels of Harm correspond with the three Safety Event Class categories. This six-prong delineation attempts to consolidate areas of conflict between the descriptions of permanent versus temporary levels of harm. The consolidation of harm levels should reduce potential subjectivity because permanent versus temporary harm status often determines the type of subsequent analysis

Table 2: Safety Event Classification, Patient Outcome, and Follow-Up Analysis

Healthcare Associated Preventable Harm Level Classification

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 (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

Suggested Follow-Up Analysis Acronyms Defined:

RCA—Root Cause Analysis: A multidisciplinary process of study or analysis that uses a detailed, structured process to examine factors contributing to a specific outcome such as an adverse event. *(Risk Management Handbook)*

CCA—Common Cause Analysis: Review of all findings from root cause analyses of serious safety events with the goal of identifying and addressing systemwide vulnerabilities. (AHRQ Healthcare Innovations Exchange: Common Cause Analysis: A Hospital's Review of Vulnerabilities During Which Common Themes are Identified, Prioritized, and Addressed).

ACA—Apparent Cause Analysis: The nuclear power industry offers several definitions, such as: the most probable cause for an event based on readily available information, a likely cause for an event that is determined by less rigorous means of evaluation than a root cause.

Barrier or Error-Detection Analysis: An incident analysis that identifies barriers used to protect a patient (target) from harm and analyzes the event to determine if the barriers held, failed, or were compromised in some way by tracing the path of the threat from the harmful action to the patient. [20]

Patient Outcome-Table 2 also defines "Patient Outcome" to correspond with the associated levels of harm. Again, the scale intentionally does not distinguish between permanent and temporary harm, as this will vary with the individual patient and the timeliness of the recognition of harm and subsequent treatment of the patient as a result of the patient safety event. While some classifications of harm attempt to make a distinction for different levels of harm based on the duration of harm, many times it is the individual characteristics of the patient and not the nature of the incident that determines if the injury is of short duration or is life-changing.

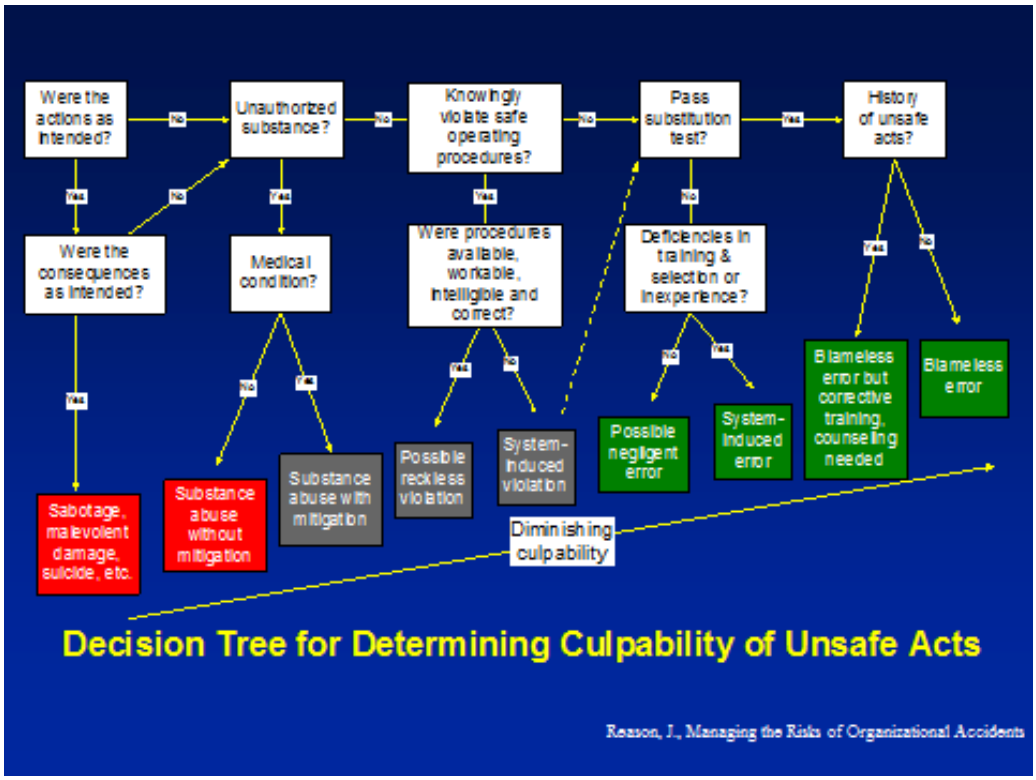
Patient characteristics may include age, chronic and acute diseases, prior condition and psychological well-being. For instance, a healthy 25-year-old undergoing an elective procedure who falls and sustains a fractured femur will, in most cases, suffer temporary harm. Meanwhile, the outcome for a frail 85-year-old osteoarthritic patient who falls and sustains the same injury may be quite different. Both injuries were the result of the same event—failure to respond to a request for assistance to the bathroom after administration of a nighttime sleep medication. Yet both patients can have vastly different outcomes from the same patient safety event.

The Suggested Follow-Up Analysis is based on the Level of Harm and Patient Outcome. Logically, the most serious events will require the most rigorous analyses. Lower levels of harm from specific safety incidents can also use a more thorough analysis, but might be better suited to less time and resource-dedicated analysis.

Culpability/Accountability Review-As part of the follow-up analysis a culpability/accountability review should be undertaken.

Originally developed by James Reason, Ph.D. various versions of his original, "Decision Tree for Determining Culpability of Unsafe Acts" tree or diagram are in existence. The tool can be used for any healthcare provider involved in a patient safety incident. Ideally, it should be applied as soon as possible after the event, so that facts are still fresh. The tool can always be reapplied if new facts become evident, although most times, it may not necessarily change the outcome of the culpability/ accountability review.

While the tool comprises an algorithm with accompanying guidelines that pose a series of structured questions to help managers decide in terms of individual accountability, it also encourages key decision makers to consider systems and organizational issues in the management of a patient safety event[21]



Conclusion—Deviation as the Link

This white paper describes a method and provides a tool or scale through which to classify preventable harm in terms of deviation. Using the harm-classification tool to determine what was preventable at the time of the event will aid the learning process and will support continuous patient safety improvement and harm prevention.

A classification system for harm also aids in forming a reliable measurement process that helps to determine improvement and to create effective evaluation methods. The next serious safety event whitepaper will aid in:

- Identifying and understanding causal factors when harm occurs
- Describing the role of human factors as a primary contributor to medical error and preventable harm
- Demonstrating how measurement of preventable harm drives improvement and aids in determining effectiveness of risk management
- Outlining the concepts of highly reliable organizations and the connection to driving down serious safety events and preventable harm

Determining deviation is at the core of the classification system. It is the critical link to determining whether harm is preventable. If deviation is the link to harm, then reducing it may also be a link to improving patient safety.

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