White Paper Series

Serious Safety Events: Getting to Zero™

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ASHRM AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT
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Forward

A core value of healthcare delivery is to heal without causing harm. Eliminating preventable harm is a top priority for the American Society for Healthcare Risk Management (ASHRM). In order to advance this core value, ASHRM is providing guidance for defining and measuring preventable harm events through a series of white papers on serious safety events (SSEs).

SSEs, sometimes called "critical events," cause harm to patients, families, significant others and the providers involved in the event. Eliminating preventable harm and SSEs remains a top challenge for the healthcare industry and a primary focus for risk management professionals.[1] ASHRM is committed to supporting the healthcare industry in delivering safe and trusted care and decreasing SSEs

Healthcare reform includes an emphasis on decreasing preventable patient harm as well. Establishing a consistent definition and measurement process helps risk management and patient safety professionals support their primary goal of preventing harm and delivering safe care to our patients by allowing the rapid identification of SSEs, quick action to correct SSEs and to prevent further harm, and the consistent evaluation of prevention methods.

Various reports on the frequency of SSEs include the Office of Inspector General's "Adverse Events in Hospitals: National Incidence among Medicare Beneficiaries," which noted that 13.5 percent of hospitalized Medicare beneficiaries experienced an adverse event during their hospital admission; an additional 13.5 percent of the Medicare beneficiaries experienced events that resulted in temporary harm during their hospital stay; 44 percent of the events were deemed preventable; and the cost to Medicare for these events was estimated to be $324 million in October of 2008 alone.[2] There are many examples of initiatives underway to eliminate preventable harm, such as the Center for Medicare & Medicaid Innovation (the CMS Innovation Center) Partnership for Patients initiative, which recently established a goal to decrease such incidents by 40 percent at the end of 2013 compared to 2010.[3] Work is being done across the United States in support of this initiative, for example, by hospitals that have been awarded Hospital Engagement Network (HEN) contracts, and by the Health Research & Educational Trust (HRET), an affiliate of the American Hospital Association (AHA), which has been awarded a contract by the CMS Innovation Center to support their Partnership for Patients. This project will help improve the quality, safety and affordability of healthcare for all Americans by assisting hospitals with the adoption of new practices that have the potential to reduce harm and unnecessary readmissions.

Thus a core competency for risk management and patient safety professionals consists of knowing how to prevent SSEs, how to investigate them when they occur and how to use the lessons learned for correction and future prevention. ASHRM's initiative Getting to Zero™ promotes this competency, which is also a core value of ASHRM and a foundation of ASHRM's vision of safe and trusted healthcare. ASHRM explains its Getting to Zero initiative in this four-part monograph series, which offers guidance on how to manage, measure and prevent SSEs.

This first paper provides background information on how SSEs were previously, and are currently, identified; recommendations for a common definition of SSEs; and investigation

techniques based on a skill-based model and measurement methodology for determining the effectiveness of prevention methods.

The second paper further describes how to measure deviations and contributing factors associated with harm and how to move from a reactionary approach to a behavior-based, high-reliability approach that prevents harm. It includes examples of how to assess and evaluate deviations and causation and how to promote the rapid development of safety culture programs that move beyond process improvement techniques by practicing behavioral and human factors solutions that prevent harm.

The third paper explains root cause analysis, including its methods and effectiveness. It also provides examples that highlight the common factors of effectiveness.

The fourth paper offers lessons learned from case studies on high-risk situations. These lessons illustrate prevention solutions and sustainability.

The guidance of these papers is not intended to be prescriptive, but rather to provide readers with a deeper understanding of how SSEs are defined, measured, investigated and analyzed for the purpose of prevention, in order to help them consider if any of the strategies described herein might be useful in their own organizations.

Introduction

ASHRM created the Getting to Zero patient safety initiative to provide ASHRM members and the healthcare community with a proactive approach to patient safety and risk reduction. A key component of this proactive process is to share the lessons that have been learned from managing and preventing SSEs. The first step is to identify a common definition within each organization and ideally, over time, to standardize a nationally accepted definition, because a shared/common definition of an SSE:

- Eliminates the confusion that arises in trying to determine if an event is an SSE.
- Leads to rapid action, and allows for the timely detection, identification, response to and correction of such an event.
- Facilitates the process to address system issues and prevent future SSEs.
- Standardizes measurement of SSE frequency and the effectiveness of prevention activities, which can advance learning and comparison within and between organizations.
- Offers the ability to study harm more broadly and to share lessons based on a common framework.

Once an event is identified as an SSE, it should be investigated by experienced professionals who use a standardized approach in order to ensure that the review is thorough and the process and results are credible. The standardized investigation process should include:

- The development of a formal, written, competency-based plan for SSE identification, investigation and action. The plan should be developed and agreed upon in advance and include the critical behaviors and skills for effective leadership and outcomes.

- An approach that balances the focus on, and review of, individual error and contributing factors with system issues such as inadequate procedures, lack of available resources and/or poor design.

Serious Safety Event History, Identification and Definition

The ability to identify preventable adverse events associated with serious harm first became important during the medical malpractice crisis in the 1970s. Prior to that time, there was broader acceptance that "the doctor knew best," and malpractice litigation was uncommon. The crisis, which involved an unprecedented wave of malpractice litigation, created an environment that made procuring malpractice insurance difficult. Adverse events associated with harm were identified as claims, lawsuits and potential compensable events (PCEs). These terms were primarily insurance terms and often were listed as part of a loss run.

The risk management profession emerged from this crisis. The goal of a good risk management program in these early years was principally to manage these exposures and to protect the assets of the organization. Because of the fear of litigation, a cloak of secrecy surrounded SSE investigation and the risk management process, and consequently, investigation results and lessons learned were rarely shared.

The U.S. government's Healthcare Quality Improvement Act (HCQIA) of 1986 recognized the need to improve the quality of patient care and to reduce the number of harmful events through fostering the investigation of SSEs. This act provided a formal professional/peer review process that offered healthcare organizations protection from discovery of their SSE investigation results. After the act was passed, accrediting agencies such as The Joint Commission and state regulatory agencies such as the Massachusetts Board of Registration in Medicine began to require the integration of hospital risk management activities with quality assurance activities in order to exchange information about patient care and safety activities.[4,5]

The introduction of regulation into risk management and SSE management required healthcare facilities to formalize the risk management process. Risk managers used incident reports as one of the main tools for risk identification within an organization. These self-reports allowed staff members to report problems or events that were out of the ordinary or that had injured patients. Because the reporting was voluntary, it was generally assumed that not all SSEs were captured in the reporting system.

In November 1999, when The Institute of Medicine (IOM) released its report "To Err is Human: Building a Safer Health System," healthcare professionals as well as the public were confronted with the information that at least 44,000 patients, and perhaps as many as 98,000, die in hospitals each year as a result of medical errors that could have been prevented.[6] For the first time, a spotlight was shining on medical errors and revealing the dangers associated with being a patient in the American healthcare system.

In addition to the publication of the IOM report, several entities attempted to facilitate the identification of those events that were causing severe injuries and death to the hospital patient population. In 1998, the Joint Commission released its Sentinel Event Policy, which required that

all accredited hospitals identify and investigate a sentinel event, defined as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof." The Joint Commission also stated that "Serious injury specifically includes loss of limb or function. The phrase 'or risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called 'sentinel' because they signal the need for immediate investigation and response." The Joint Commission suggested that hospitals report their sentinel events to the Joint Commission, but because such reporting is voluntary, the Joint Commission's repository of sentinel events represents only a small proportion of actual events that occur in hospitals.[7]

In 2001, ASHRM published a white paper titled "Perspective on Disclosure of Unanticipated Outcome Information." This paper provided guidance regarding consideration of the components that are related to disclosure and disclosure policies of unanticipated outcomes, which include SSEs. In 2003, ASHRM released a series of three monographs about disclosure, with a primary focus on the methods and models for the effective communication of unanticipated outcomes. This guidance evolved from a focus on disclosure policies to a focus on communication policies and offered direction for determining how to integrate the concept of open communication into all aspects of the healthcare environment.[8]

In 2002, The National Quality Forum (NQF) released a list of what were considered SSEs in an attempt to create a taxonomy of reportable events for a state-by-state reporting database that would enable hospitals nationwide to identify vulnerabilities and address safety problems, based on lessons learned. The list of these 27 events was communicated to the public and healthcare industry, and some individuals began to label them as issues that should never occur, or "never events." This list of events was amended in 2006 and again in 2011. The events on the list are now referred to as serious reportable events (SREs).[9] To meet the threshold of the list of SREs by the NQF, events must be unambiguous and for the most part, if not entirely, preventable and serious. The 2011 update also expanded the reporting of the events from hospitals to three new settings: office-based practices, and ambulatory surgery and skilled nursing facilities.[10]

In 2008, the Centers for Medicare and Medicaid Services (CMS) expanded the list of hospital-acquired conditions that they identified as reasonably preventable with the implementation of evidenced based guidelines. The final rule on the inpatient prospective payment systems (IPPS) bill limits payment for the care associated with such conditions as follows:

- Pressure ulcer stages III and IV.
- Falls and trauma.
- Surgical site infection after bariatric surgery for obesity.
- Certain orthopedic procedures.
- Bypass surgery (mediastinitis).
- Vascular-catheter associated infection.
- Catheter-associated urinary tract infection.
- Administration of incompatible blood.
- Air embolism.
- Foreign object unintentionally retained after surgery.[11]

Then, in 2009, a group of hospitals began collecting and studying all preventable events associated with serious harm. They went beyond the NQF list (and its spinoffs) and looked at all causes of preventable harm. Many of these hospitals adopted the definition created by Healthcare Performance Improvement, LLC (HPI), which also developed a Safety Event Classification (SEC)[SM] and a Serious Safety Event Rate (SSER)[SM]. The SEC offers common definitions and an algorithm for classifying safety events, based on descending levels of harm.[12] This serious event classification does not distinguish between a system failure or an individual causation, but rather is based on the outcome of the event or level of harm, with the analysis of the event revealing a defect in care, and the defect in care being directly related to the outcome.[13]

HPI's working definition of an SSE is "a deviation from generally accepted performance standards that reaches the patient and results in moderate to severe harm or death." As the level of harm decreases, subsequent events are classified as a Precursor Safety Event. With no harm to the patient, events are classified as a Near Miss Safety Event.[14]

In summary, a review of the literature reveals a variety of definitions and terms for SSEs. The identification of SSEs evolved primarily from a tool for malpractice claims handling, prevention of patient injury, regulatory mandates and governmental and other payer models that refuse to pay for select events.

ASHRM's Recommendation for a Common Definition

It has become clear to ASHRM leadership and members that a common definition is needed to ensure consistency in serious safety events (SSE) identification. This consistency will aid in measuring the number of SSEs and determining if prevention and correction have been effective.

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.**

The determination of deviation requires further explanation and examples. Ideally, deviation is decided through a process that uses current evidence and practice patterns. Where evidence exists that defines how practice should be carried out (evidence-based guidelines), the guidelines should serve as the basis for determining deviation from the norm or what is expected practice. It should also be noted that there are vast areas in which we have generally accepted practices, but no scientific evidence to suggest these practices are the right thing to do for patients. In such situations, it is prudent to use a peer review process to determine the generally accepted practice for the purpose of this SSE definition. Another consideration to keep in mind is that there are also situations in which deviating is acceptable, such as in the use of clinical trials.

ASHRM's definition is based on several components that ASHRM identified as key to identifying SSEs, which are:

- Healthcare setting. SSEs can occur in any setting in which healthcare is provided. Therefore, the definition indicates that it applies to wherever healthcare is delivered, which may include hospitals, physician's offices, pharmacies, clinics, nursing facilities, home settings and other environments. In addition, the harm can occur as a result of various procedures and in different settings. For example, a retained foreign body can occur during a surgical procedure, when a medical device is removed from a patient, as the result of a defective or recalled medical device, and as the failure to remove an object such as a sponge during a wound vacuum change.

- Deviation from generally accepted practice or process. An SSE should only be counted as such if the harm was preventable. The deviation is what determines that the harm was preventable. For example, a patient who is kept alive with multiple means to support the patient during a medical crisis can run the risk of serious complications, including permanent loss or harm. The outcome can be devastating, but if it was unavoidable in order to save the patient's life, and if it followed generally accepted practice or process, it would not be considered an SSE.

    - Examples of deviation might include:

        - Failure to follow standard procedures such as with medication administration and patient identification.
        - Failure to assess a patient for the risk of falling.
        - Failure to implement standard fall prevention methods for high-risk patients.
        - Failure to monitor and assess patient condition.
        - Delays in care.
        - Wrong method or process for care delivery.
        - Wrong procedure or a procedure done on wrong patient.
        - Lack of a backup generator for surgical cases.
        - Implantation after a product has been recalled.
        - Failure to upgrade substandard fire pumps.

- Harm that reaches the patient. The SSE should only be counted as such when it reaches the patient. Near misses and other errors that do not reach the patient should be tracked and used as opportunities to prevent harm, but should not be identified as SSEs.

- Causes severe harm or death. The SSE should only be counted as an SSE if the event was a deviation from generally accepted practice that causes severe harm or death. The various levels of harm identified in HPI's Safety Event Classification categories should serve as a guide to direct those who are assigned to review an event.[15]

The following provisions were considered in development of ASHRM's definition. The definition should:

- Endure over time. Once an SSE is classified as an SSE, it should continue to be classified as an SSE.

- Provide clarity. Healthcare professionals at all levels and the public should be able to understand and apply the definition.

- Be inclusive, not exclusive. An identified SSE should always be considered within the definition and not be vulnerable to elimination if there is a definition change or a change in a reportable list. It is always easier to eliminate an event after review than to have missed a significant event because it did not fall within the definition or designated list.

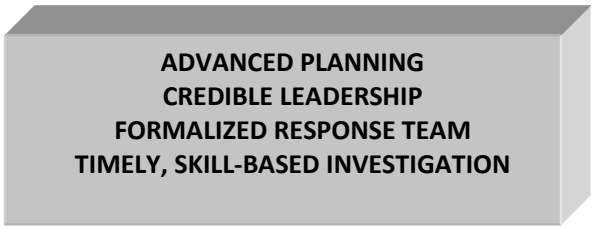
Investigating Serious Safety Events

The occurrence of a serious safety event (SSE), as defined by ASHRM, whether in a hospital or other healthcare setting, requires a planned, structured and standardized response that involves a well-rehearsed team. Because the facility risk manager is most often the first to become aware of the SSE and, subsequently, to initiate the SSE investigation, ASHRM and its nearly 6,000 members are in a unique position to make recommendations for establishing best practice in the area of SSE response and investigation.

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 skill-based approach.

Figure 1. Four Key Components of Responding to an SSE



Advanced Planning

Advanced planning is vital to the successful investigation of an SSE. Prior to the occurrence of an event, the risk manager should identify what data sources exist and devise a plan for collecting data when needed. The risk manager should determine who will constitute the investigation team (the lead investigator and key others), which service lines and stakeholders may be involved, and which, if any, laws, policies and procedures or practice standards apply to the event.

It is important to remember that each state has laws that relate to peer review protection. Be certain to comply with the facility's peer review policy in order to maintain the peer review privilege throughout the investigation (see www.ashrm.org/ashrm/education/programs/ASHRM_U/index.shtml for the "Investigation Plan/Schedule Checklist," "Witness List" and "Risk Investigation Timeline Log", which are provided in ASHRM University's online course titled "Investigations").*

ASHRM recommends that each facility have a clearly written policy statement that describes the organization's expectations following the identification of an SSE, 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.

The policy and procedure guide should also include a flowchart of the process for convening the SSE response team (see www.ashrm.org/ashrm/education/programs/ASHRM_U/index.shtml for sample flowcharts).*

Credible Leadership

Leading an investigation requires a comprehensive skill set that includes excellent and professional communication, the ability to ask probing questions and gather data and information in a non-accusatory manner, the ability to understand and analyze data and information, and integrity and professionalism.

The four guiding principles that the risk manager or other investigators should follow are:

1. Operate within your organization's, 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.
    d. Coach others on communicating pertinent information diplomatically.

* Access to these documents is available with enrollment in ASHRM's online "Investigations" course at www.ashrm.org/ashrm/education/programs/ASHRM_U/index.shtml.

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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 of the facts and the truth.
    d. Take measures to ensure that the event never happens again.

4. Maintain trust:
    a. Create and maintain relationships. This can be best accomplished by using open interview techniques, respecting confidentiality and approaching the situation and the providers with empathy and objectivity.
    b. Gain trust of colleagues, staff, patients, families, local authorities and the press. One very important component in accomplishing this goal is to keep your word. For example, if you indicate that you will get back to someone as the investigation progresses, be sure to do so.

These four guiding principles serve as the foundation of a good investigation. A good investigation is one that is objective and timely, conducted in a professional manner and is both purposeful and thorough.

Formalized Response Team

Each organization should develop an SSE response policy and procedure that outlines who will be involved and what role they will have. The team configuration will vary, depending on the type of organization (hospital, physician office, ambulatory care setting, etc.). Having a formalized, consistent team that is familiar with the policies and procedures is imperative because it allows for rapid decision making at the highest levels in the organization. Executive-level sponsorship is also needed, as are excellent cross-functional communication and respect without regard to hierarchy.

This team is often called a "critical event response team" and it includes the top executives of the organization. The goal of the critical event response team is not to conduct the investigation, but rather to oversee and direct the process and to ensure resources are available to conduct the investigation, analysis and any correction as applicable. The chief executive officer should serve as the executive sponsor of the process and investigation and of the root cause analysis team. Other executive-level staff such as the chief medical officer, chief operations officer, chief nursing officer, chief risk officer/director, risk manager and senior quality director are valuable to include in the core group if they are able to be active participants. The risk manager should lead the investigation, gather the critical event response team and provide them with information and updates. The risk manager will also identify others who are needed to aid in the investigation and analysis. Often, these others include the staff/providers/managers who are closest to the area of involvement in the event, and support departments such as information technology, infectious diseases, laboratory, patient advocate, etc.

The SSE response team serves to ensure the following:

- Oversight and support for the risk manager as the lead investigator.
- Rapid resolution and mitigation as applicable, including allocation of resources (funds, time, skill).
- Involvement in the development of the communication plan.
- Direction from the highest level of the organization to ensure future prevention of such an event.

Other stakeholders (e.g., the public relations department, the compliance department and the legal department) should be notified as soon as possible after the event, in order to be ready to respond to queries from outside sources. Human resources and the medical staff office should be made aware of the event, in case their involvement or support is needed.

Timely, Skill-Based Investigation

The authors of a documented review of the literature that pertains to the investigation and analysis of accidents in high-risk industries and of critical incidents and adverse events in healthcare concluded that there was considerable opportunity for improving investigation techniques.[16] Based on this conclusion, ASHRM sought to develop an effective, standardized approach for members and others who conduct an investigation following an SSE.

In 2010, ASHRM developed an online "Investigations" course that provides a model for risk managers and others who are involved in SSE investigation.[17] A toolkit gleaned from the course is provided at www.ashrm.org/ashrm/education/programs/ASHRM_U/index.shtml and referenced throughout this document.

Consistent with the definition of an investigation as a "searching inquiry for ascertaining facts,"[18] ASHRM's course divides the investigation into five distinct steps that should be followed in sequence when conducting an SSE investigation:

1. Respond to the event.
2. Collect data.
3. Analyze data.
4. Validate findings.
5. Communicate findings.

Respond to the event

The risk manager receives notification of the event and, after confirming that the involved patient's initial needs have been met, initiates the preliminary stage of the investigation. This will include interviewing those closest to the event and conducting a document review to determine if the event meets SSE criteria. If it is immediately clear that the event was an SSE, the response team should be activated. If it is not immediately determinable, the team should still be alerted and the core members of the team should make a decision after further information becomes available.

The core members of the SSE response team should convene immediately in person or by phone to determine who else needs to be involved. Decisions should be made quickly, based on the following considerations:[19]

- Is immediate action needed to stabilize or care for the patient or to prevent further harm?
- Is another medical provider needed to take over the care or to provide additional care?
- Does action need to be taken to reduce the likelihood of harm to other patients? (E.g., is the SSE related to an impaired provider or staff, faulty equipment, a contamination issue, etc.?)
- Have items been sequestered that were involved, such as equipment, medication, medical records, films, pathology slides?
- Is a communication or media response plan needed, and has a leader been appointed to perform as the lead communicator?
- Has appropriate notification been provided to those who may be pertinent to the situation (board members, administrators, physician and management leaders, etc.)?
- Has one person been assigned primary responsibility for communicating with the patient and family about the event? Is the designated person keeping the patient and family abreast of investigation findings?
- Has the chief executive of the facility been informed?

After all of the issues that are related to an immediate response have been addressed, a formal investigation of the event, led by the risk manager, should ensue (see Appendix A for an "Initial Response Triage Checklist" and Appendix B for a "Risk Communication Protocol Worksheet" provided by ASHRM University). Many facilities will immediately proceed to perform a root cause analysis of the event at this point.

Collect Data

After the initial response has been managed, the investigator pulls together the necessary tools and documents and collects data to support the root cause analysis process. Factors that guide the data collection include:

- Potential human factors (such as the people on the care team, witnesses and subject experts).
- Equipment factors (such as equipment used during treatment, supplies, medications and IV or other fluids).
- Environmental factors (such as floor plans or diagrams of the area, photos and timesheets) and possible latent effects, whether within or outside of the organization's control.
- Any documentation (such as medical records, including electronic records or tracings, policies, procedures and guidelines) that supports the investigation. It is important to remember that there is always the risk that data collected during an SSE investigation will be called into evidence if event-related litigation comes into play. Therefore, it is essential to maintain an inventory of all evidence collected and document its storage location.

(See www.ashrm.org/ashrm/education/programs/ASHRM_U/index.shtml for a "Data Collection Plan Checklist Template" provided by ASHRM University).*

Interviews should be conducted with individuals who were identified during the initial response phase and as additional data was gathered. Create a list of standard questions for all interviewees and specific questions for key individuals. Use interview techniques and active listening skills that will qualify, validate and verify the information that you gather, such as open-ended and clarifying questions. Confirm facts by summarizing and repeating back what you heard.

Once interviews have been conducted, construct the clinical timeline using a "Clinical Event Timeline" (see the example provided by ASHRM University at www.ashrm.org/ashrm/education/programs/ASHRM_U/index.shtml).* If there are noticeable gaps in the timeline, gather additional information to complete the clinical picture of what happened.

Analyze Data

The investigator should verify that all of the data gathered is correct and consistent and that it makes sense. If inconsistencies are found in accounts of the event told during interviews, the investigator might need to talk to people a second time to clarify or collaborate what has been learned.

If there are gaps in the data, the investigator needs to find out why, and whether additional data is available that would corroborate the data already gathered. Missing data can cause suspicion and necessitate further investigation.

There are a number of methods to evaluate the data and classify events by their root cause. Some of these include:

- Benchmarking.
- Task analysis.
- Gap analysis.
- Barrier analysis.
- Root cause analysis.
- Failure mode and effects analysis.
- Cause and effect analysis/fishbone diagram.
- Histogram.
- Pareto.
- Run chart.

* Access to this document is available with enrollment in ASHRM's online "Investigations" course at www.ashrm.org/ashrm/education/programs/ASHRM_U/index.shtml.

More information on conducting these analyses can be found in the ASHRM University "Investigations" course, available at www.ashrm.org/ashrm/education/programs/ASHRM_U/index.shtml.

Validate Findings

Once the data has been analyzed it is important to perform due diligence. Due diligence refers to the process of validating the data collected during the investigation in order to prove or disprove the findings. All facts should be verified and no assumptions should be made.

Communicate Findings

Finally, the findings need to be communicated. The findings from the investigation will need to be evaluated for potential litigation and managed accordingly. The investigator must determine who needs the information, the reasons it is needed, what information should be disseminated and the most appropriate manner for presenting the information.

Typically, information learned in the investigation will be shared face to face with family members (by the designated communicator), the patient care team and usually, with risk, quality, or patient safety committees. Written reports generally will not be widely distributed, but might be needed for external agencies that require mandatory reporting. A presentation of the findings is also shared with the facility administrators/leaders and the board of directors. Depending on the organization's culture, the lessons learned might be shared with local, regional or national organizations.

In addition, it is important to determine how best to share what was learned, and any plan or changes that will be put in place so that similar incidents will not occur again. The investigator should choose a method of dissemination that is based on the organization's protocols, philosophy and patient safety culture, as well as state law.

Note: it is also critical to keep in mind that when investigating SSEs that may also be claims, it is important to consider conducting an additional investigation as part of the claims management process.

Measurement and Metrics

It is difficult to manage that which is not measured. Therefore, the measurement of serious safety events (SSEs) is essential in order to manage them. Measurement is complex and there are different methods for measuring SSEs. There are also numerous ways to represent the metrics.

SSE data can be used for a number a different purposes. For example, measuring SSEs helps determine whether actions to prevent SSEs are effective and sustainable or if there was improvement, and to demonstrate a decrease in harm. Measuring SSEs can be correlated to both patient safety and financial loss control (see examples below). Measuring the frequency and severity of events is a method of demonstrating the progression of the risk management program and its transformation from a reactive to a proactive approach.

Measuring SSEs is also a tool for evaluating the cost of risk. "The cost of risk (COR) is a concept whereby the risks faced by the organization are identified, the costs of those risks are estimated, and the resulting information is used to manage operations and effect change."[20]

Figure 2 shows the many variables that affect the reliability, validity and importance of a measure. Though a thorough analysis of each variable is beyond this paper's scope, several elements are critical.

Figure 2. Variables Involved in Developing Actionable Metrics

There are numerous types of rates that can be used to determine frequency and/or severity of various data points in healthcare. These rates are based on a variety of denominators. However, it is necessary to select a consistent method when you are measuring over time. Examples of denominators that can be used include admissions,[21] patient days,[22] adjusted patient days,[23,24] procedures[25] or a combination of types.[26] Because there is a never-ending search for more accurate measures and new approaches such as equivalent patient units,[27] additional denominators will surface.

The rate of SSEs should be calculated to aid organizations in determining patient safety outcomes and performance outcomes, and to track the effectiveness of prevention efforts. The denominators that can be and have been used include adjusted patient days or adjusted patient discharges. The number of adjusted patient days or discharges is often calculated based on 1,000 or 10,000 episodes. Ten thousand is the preferred method because the frequency of SSEs per adjusted patient days is usually rather low. Whichever method is used, it is suggested that the frequency of SSEs be determined over a rolling 6- or 12-month period, because this will provide a more accurate determination, since SSEs do not occur that often.

See the following example for determination of SSEs.

Figure 3. A Calculation of the Rate of SEEs

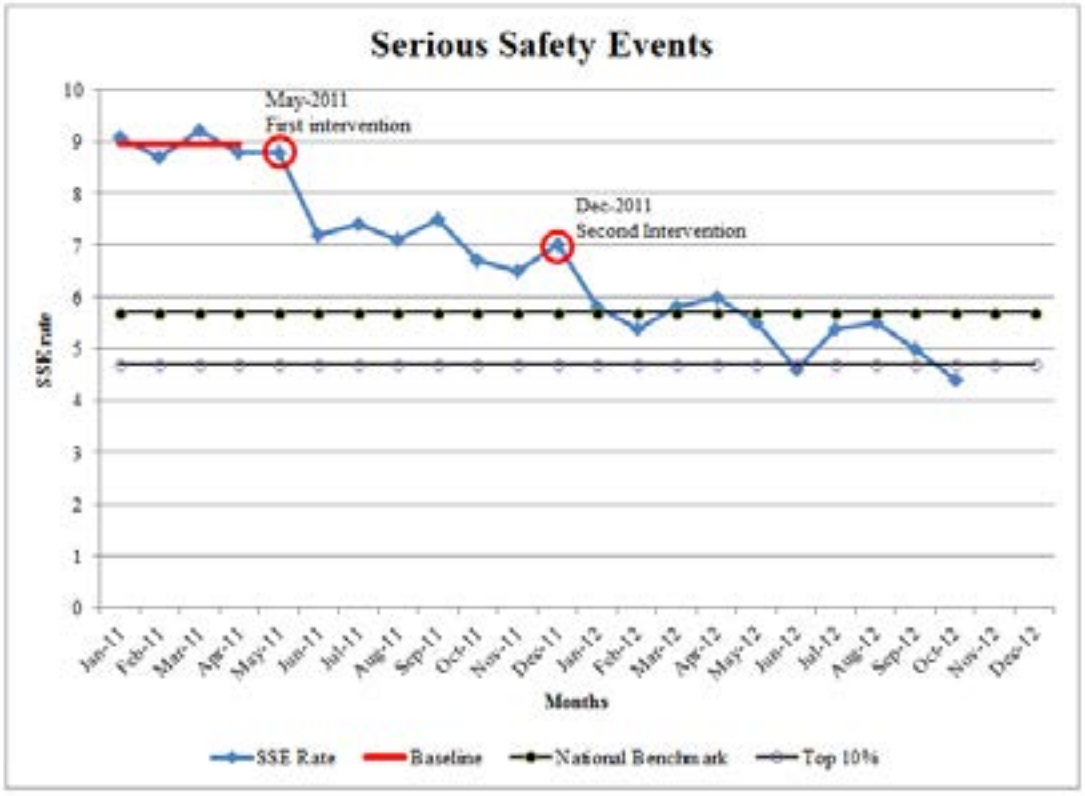
Rolling 12 months of SSEs per adjusted patient days

SSE Determination Rate = #SSE during 12-mo. period x 10,000
 # Adjusted patient days 12-mo. period

The determination of frequency helps the organization measure the overall rate of occurrence for SSEs. If measured over a longer period of time, this can be used as a measure of effectiveness. HPI's Serious Safety Event Rate uses a rolling 12-month period per 10,000 adjusted patient days to determine this rate.

Comparing data over time is enhanced if a baseline, goals and interventions are included. Figure 4 shows the baseline, two interventions, the national benchmark and the top 10% benchmark. Collecting data with this format in mind is advantageous because it allows the story to develop incrementally, illustrates the actions taken and focuses on the desired outcome.

Figure 4. Benchmarking Data Over Time



Measurement Type

There are many types of measures. The NQF groups measures into four categories. The four categories and examples follow:[28]

- Structure: Number of productive hours worked by nursing staff with direct patient care responsibilities per patient day.
- Process: Percentage of patients with pneumonia who receive their first dose of antibiotics promptly after arrival at the hospital.
- Outcome: Percentage of surgical site infections occurring within 30 days after the operative procedure.
- Patient Experience: Patient experience with care survey for patients who have been in the hospital.

Measurement Complexity

Measurement of inanimate objects is an inexact science.[29] Measurement of human outcomes is even less exact and more challenging. Valid and reliable measurement requires clear definitions and consistent, science-based methodology. The NQF uses a consensus approach to evaluate and endorse performance measurement standards.[30] The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) categorizes medication errors according to the severity of the outcome, and the NCC MERP designed the process to allow for consistent and systematic data collection and analysis.[31] It is possible to use the NQF categories and the NCC MERP categories to measure some SSEs.[32]

The NQF's 29 serious reportable events[33] are based on the premise that they are:[34]

- Unambiguous.
- Largely, if not entirely, preventable.
- Serious, and any of the following:
  - Adverse.
  - Indicative of a problem in a healthcare setting's safety systems.
  - Important for public credibility or public accountability.

In addition, events included in the list are:

- Of concern to both the public and healthcare professionals and providers.
- Clearly identifiable and measurable.
- Feasible to include in a reporting system.
- Of a nature that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare facility.

The Agency for Healthcare Research and Quality's patient safety indicators offer another way to measure some SSEs. These indicators were developed after a comprehensive literature review,

analysis of ICD-9-CM codes, review by a clinician panel, implementation of risk adjustment and empirical analyses .[35]

The Basics of Measurement: Volume versus Rate

The amount of available healthcare data is seemingly unlimited, and the quality and importance of the data are variable. Many reputable organizations, including providers, accreditation entities and governmental agencies, use volume as a measurement unit.[36,37,38,39] Measuring volume is much less informative than measuring frequency and severity. Consider the following example:

> A hospital had infections associated with 11 anterior cervical fusion procedures and 23 posterior lumbar fusion procedures. This data, as illustrated in Figure 5, clearly shows that there were more infections associated with posterior lumbar fusion procedures than with anterior cervical fusion procedures. However, the volume data reveal an incomplete picture. If there were 51 anterior cervical fusion procedures and 197 posterior lumbar fusion procedures, the infection rates would be as shown in Figure 6. This more complete picture clearly shows that the likelihood of postoperative infection was much greater with anterior cervical fusion procedures than with posterior lumbar fusion procedures. The importance of using rates instead of volumes is even more dramatic when data are analyzed over time.[40]

Figure 5. Number of Surgical Site Infections

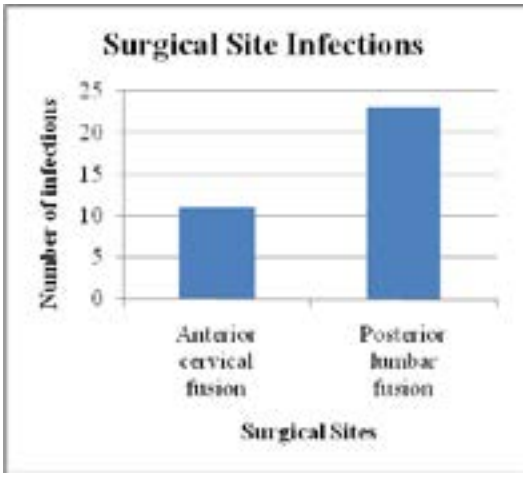
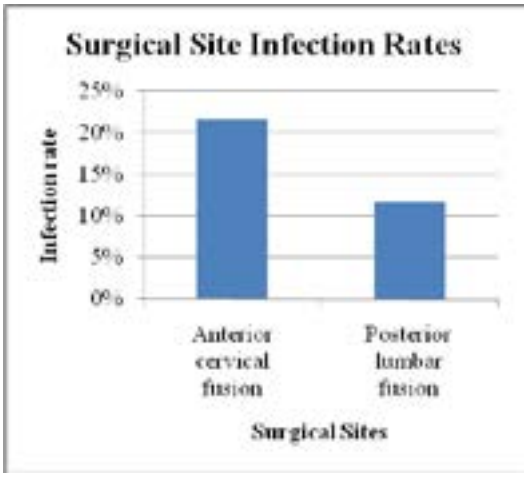


Figure 6. Surgical Site Infection Rates



Taking Action

Though measurement might be inexact, and the processes incomplete, a significant amount of actionable data exists. Even one adverse event can be actionable. For example, a fall is not just a fall, because there are many variables and contributing factors that influence how a fall is coded and classified. There are many potential root causes, so each event must be investigated to an appropriate degree.[41] The Joint Commission lists many root cause categories (available at http://www.jointcommission.org/Sentinel_Event_Statistics/), but identifying the correct cause

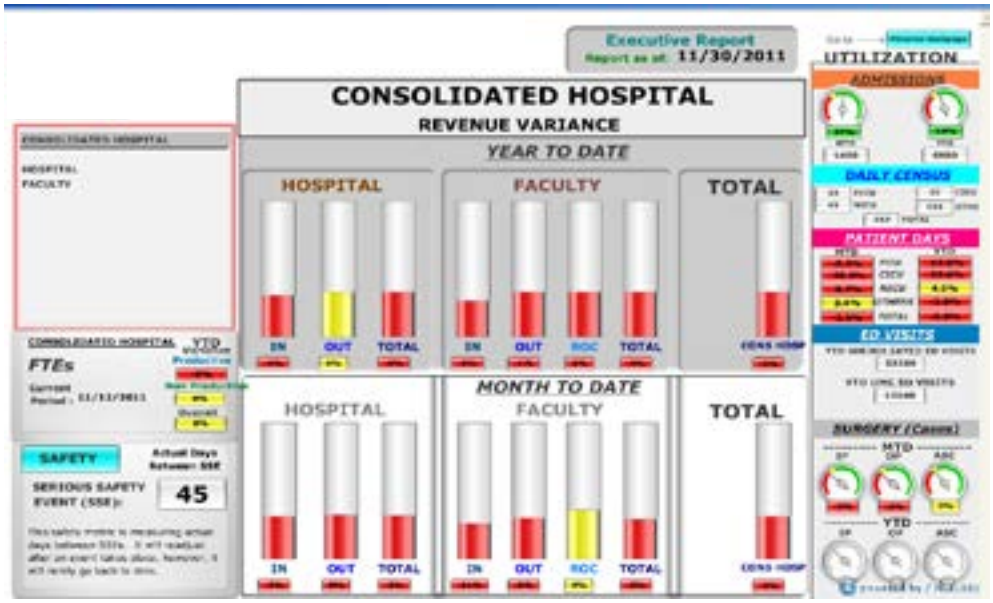
can be challenging. The importance of analyzing adverse events, whether they are SSEs or significant trends, cannot be overstated. Having appropriate and rigorous analysis and investigations is critical.

Presenting Data and Metrics

How data related to measurement of SSEs is presented is just as important as how SSEs are measured. Data needs to be accurately represented, consistently measured over time, and simple enough that it will be understood by stakeholders across the institution.

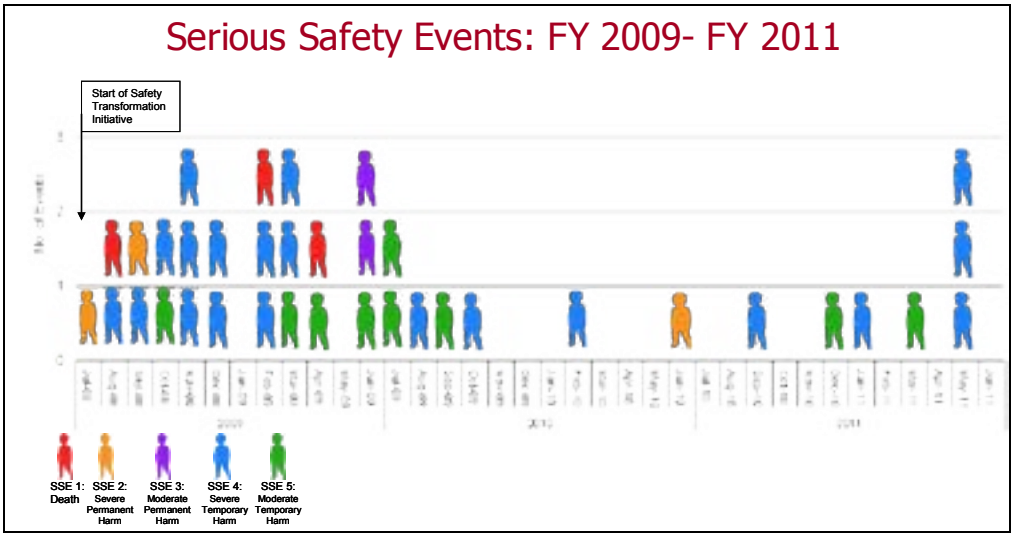
The example below includes many metrics for overall operational management, including a safety metric that measures the actual number of days since the last SSE.

Figure 7. Serious Safety Event Metrics Example



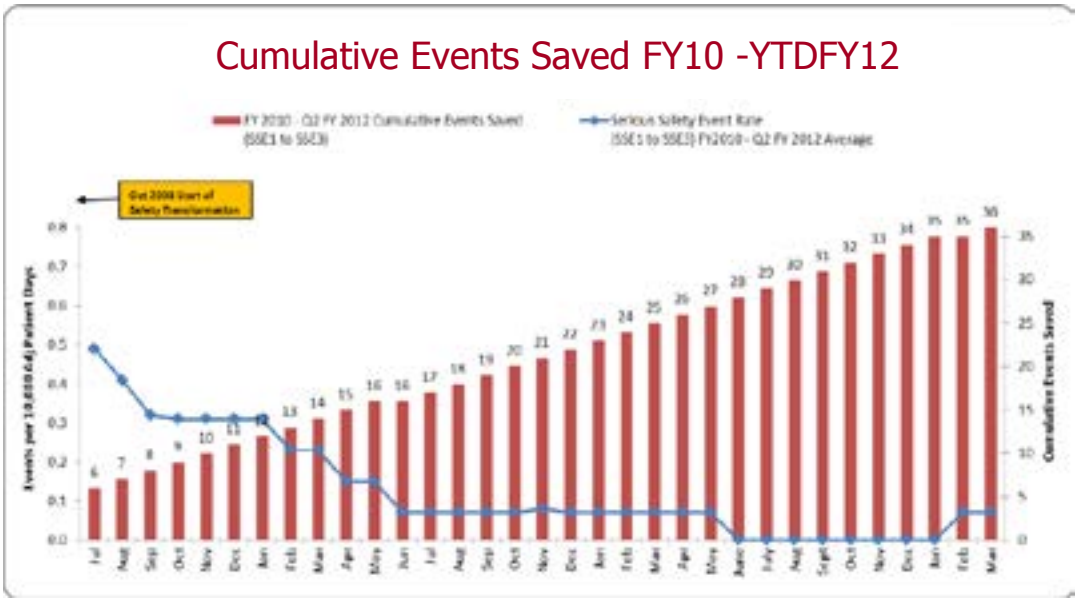
The following example shows a depiction of the number of patients harmed by an SSE per month over a three-year period. The use of the people figures in a graph brings more of a personal touch to the meaning of harm. This graph shows a significant decrease in the frequency of harm in the most recent years of care.

Figure 8. Frequency of Harm Metrics Example



The example below from shows events per 10,000 adjusted patient days by month and the cumulative events saved.

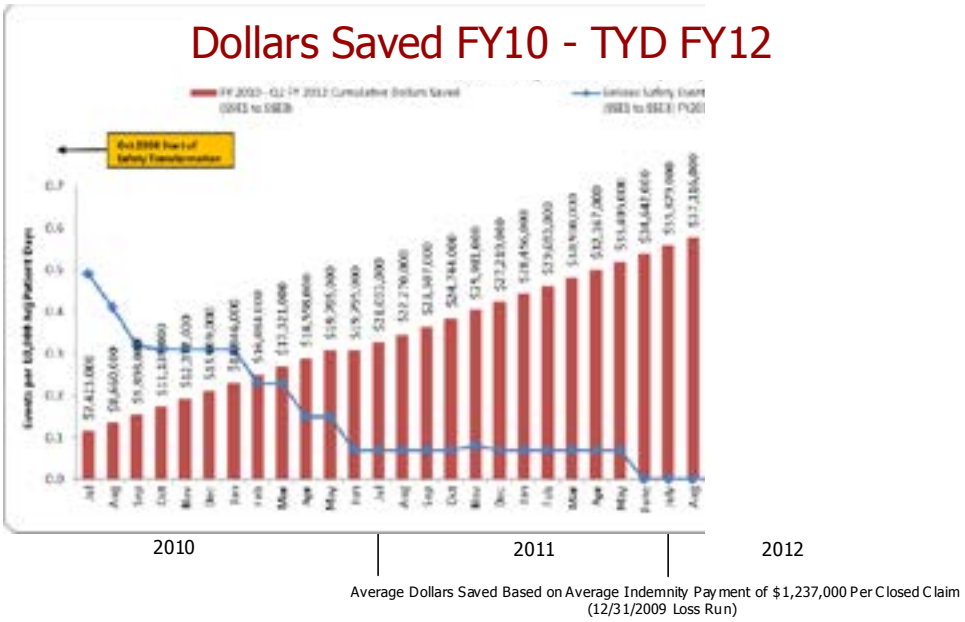
Figure 9. Cumulative Events Saved Metrics Example



The following example shows the financial connection to patient safety. The events per 10,000 adjusted patient days are compared to dollars saved, based on average indemnity payments for

closed claims. This measurement calculates the cost savings from the safety transformation, improved reliability and prevention of patient harm.

Figure 10. Cost Savings Metrics Example



There is often a level of variation in the organization's ability to capture and measure SSEs and this impacts the overall determination of frequency. An SSE frequency determination should be used as a comparative indicator within the organization to measure if there are trends of improvements following prevention efforts. Therefore, it is important to not only have a voluntary reporting system but also a system that can identify and capture such events that may not be reported. This system can be set up by capturing certain types of medical record codes that identify injury.

Summary and Conclusion

The time has come to establish a consistent and nationally accepted method of defining and measuring preventable harm events. A standardized definition and measurement system for SSEs is a component that will aid an organization in preventing patient harm. Definitions should be simply stated and understood by all levels within the organization. The investigation should follow a skill-based model and be conducted by an experienced risk management/patient safety professional. A clear plan for how and who will conduct this investigation should be established well in advance. Lastly, a measurement system should be developed to determine the frequency of SSEs. This measurement can be compared to events prevented, potential lives saved or harm prevented and the comparison to dollars saved based on average historical indemnity averages and operational costs. These methods and this approach are consistent with ASHRM's core values and mission, which is safe and trusted healthcare.

Initial Response Triage Checklist

This form is provided as a template for use in conducting a Healthcare Risk Investigation. As investigations and/or your processes evolve, this form should be amended to reflect the Enterprise Risk Management processes/procedures of your organization as well as the informational needs of the investigator.

Risk Triage

Risk Assessment Legend: 1 = Immediate Risk 2 = High Risk 3 = Moderate Risk 4 = Low Risk 5 = No Risk

Patient Risk

Risk Assessment Criteria	*1*	*2*	*3*	*4*	*5*	*Triage Action / Due Diligence*
Life / safety of one patient						
Life / safety of multiple patients						
Life / safety of healthcare staff or employees						
Department of Public Health						

Organization Risk (Defense)

Loss Risk Assessment Criteria	*1*	*2*	*3*	*4*	*5*	*Triage Action / Due Diligence*
Litigation						
Accreditation						
Reputation						
Physical Assets						
Jobs						

Evidence Triage

This list is not exhaustive. Add to or revise this list to align with your Enterprise Risk Management processes and procedures.

If life / safety risk with immediate remedies, collect, remove or secure:

Yes	*No*	*Evidence to Collect*	*Yes*	*No*	*Evidence to Collect*
		Equipment			
		Medications			
		Hazards			

If patient is stable, collect:

Yes	*No*	*Evidence to Collect*	*Yes*	*No*	*Evidence to Collect*
		Electronic Monitoring Data			
		Recorded Medical Data / Charts			
		People (Witnesses, employees, visitors, etc.)			

Communication Triage

This list is not exhaustive. Add to or revise this list to align with your Enterprise Risk Management processes and procedures.

Yes	*No*	*Who to communicate to*	*How to communicate*	*Assigned To*
		Risk Team / Peer Review Committee		
		Patient / Family Members		
		Immediate Care Staff		
		Hospital Management Stakeholders		
		Public Relations		
		Regulatory Authorities		

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Risk Communication Protocol Worksheet

This form is provided as a template for use in conducting a Healthcare Risk Investigation. As investigations and/or your processes evolve, this form should be amended to reflect the Enterprise Risk Management processes/procedures of your organization as well as the informational needs of the investigator

GENERAL ENTERPRISE COMMUNICATION PROTOCALS

Yes	*No*	*Communication Consideration*
		Have you defined a communication protocol to mobilize the investigation team or risk manager?
		Do you have a method for reporting and communicating occurrences internally?
		Do you have a method for reporting and communicating occurrences externally?
		Do you have a method for communication containment that supports patient confidentiality?
		Do you have an agreed upon method for patient / family disclosure?
		Do you have an agreed upon method for managing communication across and up/down in your organization?
		Do you have an agreed upon method for communication checkpoints within your investigation process?
		Do you have an agreed upon method communicating through standing meetings or conference call during an investigation?
		Do you have a method (or training) for communicating with the media and public relation communication?

GENERAL ENTERPRISE COMMUNICATION GUIDELINES

Priority	Who	What	When	How
	Administrator/ Administrator on Call / Operator			
	Patient Care Supervisor			
	Attending Physical			
	Department Medical Director			
	Risk Management			
	Media Relations			
	Clinical Engineering			
	Autopsy Request			
	Medical Examiner			

Risk Communication Protocol Worksheet

This form is provided as a template for use in conducting a Healthcare Risk Investigation. As investigations and/or your processes evolve, this form should be amended to reflect the Enterprise Risk Management processes/procedures of your organization as well as the informational needs of the investigator

Priority	Who	What	When	How
	Toxicology Requested			
	Safety & Security			
	Safety Officer			
	Quality Management			
	Occupational Health			
	Law Enforcement			
	Disclosure to Patient / Family			```
	Hospital Staff (involved)			
	Hospital Staff (not involved)			
	Witnesses (Non-hospital staff)			
	General Population			
	Regulatory Authorities			
	Insurance			

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