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WHITE PAPER

HPI SEC & SSER

Patient safety measurement system for healthcare

"As to diseases, make a habit of two things: to help, or at least to do no harm."

Source: Hippocrates, Of the Epidemics, Book 1, Section XI, 400 BC

The healthcare industry has continued in recent years to focus more attentively on patient safety. Specific actions of necessity include the necessity to measure improvement and identify performance benchmarks.

While healthcare holds healing without harm as its core value, we still lack a consistent nationally accepted method to measure performance against this promise. Several patient safety event taxonomies have emerged in past years, yet these category-based classifications do not provide a universally recognized means of consistently measuring the harm that results from safety events. This lack of a standard definition of patient harm leads organizations to use disparate, subjective determinations that require significant interpretation which add to the shortcomings already identified.[1, 2, 3]

Concern about these issues was first voiced at the 2006 HPI Safety Summit, an annual gathering of organizations engaged with Healthcare Performance Improvement (HPI) in safety culture improvement. These client organizations expressed the need for a reliable outcome measure for patient safety that can be used to appropriately measure performance within an individual site of care in an organization and by comparing progress to zero harm across an organization or between organizations on the same journey.

In response, Safety Event Classification (SEC®) and the Serious Safety Event Rate (SSER®) were developed. Safety Event Classification provides common definitions and an algorithm for the classification of safety events. The classification is based on the degree of harm that results from a deviation from expected performance standards. It serves as the foundation for the calculation of the Serious Safety Event Rate (SSER®), a volume-adjusted measure of events resulting in moderate to severe harm, including death.

Together, the SEC® and SSER® provide a consistent methodology for measuring patient harm and improvement in reducing harm. Thousands of hospitals, ambulatory, and long-term care sites across the United States, Canada and other countries are currently using the SEC® and SSER®.

This revision encompasses refinements from the 2019 release and also provides further clarity and guidance in conducting SEC® and using the SSER® as a key measure of patient harm. Updates include:

- Changes to the Levels of Harm (Appendix A) that provide more guidance in applying the SEC® process to alternative sites of care.
- Working with common classification challenges (Appendix C), additional guidance in addressing questions of causation, and applying the Known Complications Test.
- Focus on other frequently encountered issues such as Emotional Harm, Unconscious Bias and Diagnostic Error.
- Safety Event Classification Process (Appendix H) guidance for organizations to implement an effective structure for conducting safety classification and monitoring of the SSER® on an ongoing basis.

The application of these concepts has been expanded in this White Paper with distinctions relevant to all sites of care from acute to long term care, to hospice, home care and ambulatory care. The title we give to the person(s) for whom we provide care is important. When specifically discussing those post-acute situations, we have purposely and respectfully used the term resident or client.

But for efficiency, during the larger narrative, the term patient is used to refer to the person to whom we provide care whatever the site of that care may be.

Revision 5 - October 2022
Revision 4 – December 2020
Revision 3 – October 2019
Revision 2 – May 2011
Revision 1 – December 2009
Revision 0 – May 2009

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1 Event Classification in healthcare

Past History of Safety Event Review and Classification

Since the publication in November 1999 of the Institute of Medicine report on patient safety, To Err is Human, national and international organizations have focused on mechanisms to describe and classify events of harm. Some of these efforts have used collaborative approaches to achieve consensus on a universal, standardized patient safety event classification system. Numerous event classification systems have emerged, and some organizations have begun working together to harmonize, or align, existing taxonomies and definitions. The Joint Commission, the National Quality Forum (NQF) and the World Health Organization (WHO) led the initial efforts to classify events that cause harm to patients.

The Joint Commission took the first step in 1996 by defining a sentinel event as the following:

"any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, 'or the 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."[4]

In 2002, the National Quality Forum[5] endorsed a set of 27 serious reportable events in healthcare, or "never events."

To qualify for this core list of serious reportable events, an event had to be unambiguous, usually preventable, serious, and one or more of the following: adverse, indicative of a problem in a health care facility's safety systems, or important for public credibility or public accountability.[6] Requiring that an event be usually preventable recognizes that some of these events are not always avoidable, given the complexity of healthcare.

The presence of an event on the list, therefore, is not an a priori judgment either of a systems failure or lack of due care. With new evidence and innovation, this initial list of serious reportable events was expanded in 2006 to include 28 events.[7]

In early 2005, the Joint Commission developed a Patient Safety Event Taxonomy (PSET™).[8] The PSET outlined terminology and classification schema for near misses and adverse events. The goal of the Joint Commission PSET was to facilitate a common approach for collecting and organizing patient safety data. This taxonomy was endorsed later that year by the NQF as a framework for aggregating, classifying, and reporting data for national patient safety improvement.

The World Health Organization (WHO) established the World Alliance for Patient Safety in October 2004. It was the first time that health focused agencies, health policy-makers, and representatives or patients' groups and the WHO came together to advance the patient safety goal of "First do no harm". They recognized healthcare's current inability to classify, aggregate, and compare patient safety information across organizations internationally. They began working in 2005 on an event classification structure. Their goal was to enable categorization of patient safety information using standardized sets of concepts with agreed definitions and preferred terms. In January 2009 the WHO published the International Classification for Patient Safety[9] (ICPS). ICPS draws upon the work of the Joint Commission's PSET as well as other national safety event classifications of the United Kingdom, Australia, and the Netherlands.

In December 2008, the Department of Health and Human Services reported that 26 states had adverse event reporting systems and another state had taken action to develop one[10]. Eleven of the 26 states adopted – unaltered or with modifications – the NQF list of serious reportable events as the foundation for their adverse event reporting system, while 15 states use a state-generated list.

The Patient Safety and Quality Improvement Act of 2005 guided the Department of Health and Human Services (HHS) to begin the process of creating structure and guidance for Patient Safety Organizations (PSOs) [11]. By conferring privilege and confidentiality protections on providers who work with listed PSOs, the Act was intended to promote shared learning to enhance quality and safety nationally. The Agency for Health Research and Quality (AHRQ) completed this work in 2008 and organizations began to be officially listed as PSOs.

As part of the implementation of PSOs, the AHRQ worked with the NQF, a Federal Patient Safety Work Group and expert panels to create an event reporting taxonomy called Common Formats for Event Reporting.

The first version of the Common Formats was published in August 2008. Throughout the years and with the support of expert panels and PSO members, updates were released including Version 1.0 in September 2009 and Version 1.1 in March 2010. Versions for specific healthcare settings have been subsequently released such as nursing homes (2011), hospitals (2014), and community pharmacies (2016). The most recent release was the Hospital Version 2.0. in May 2017.[12]

Development of HPI Safety Event Classification

As HPI began its work with healthcare organizations around the country it was recognized that there was no consistent methodology for classification of all types of events in all settings. In 2007, HPI developed and implemented a standardized process for safety event classification for all of its client organizations. This classification methodology, the Safety Event Classification® (SEC) provides common definitions and an algorithm for the classification of safety events. The classification is based on the degree of harm that results from a deviation from expected performance standards. It serves as the foundation for the calculation of the Serious Safety Event Rate (SSER)®, a volume-adjusted measure of events resulting in moderate to severe harm, including death. It blended the need to standardize the organization of events by the level of harm experienced by the patient, but classifying them based on whether they were indeed preventable safety events. They also compiled a nationally recognized and/or endorsed safety event nomenclatures. The HPI Taxonomy of Safety Events in Healthcare, the results of examination of the compilation, reflected an alignment, or harmonization, of various classification systems. The first White Paper, The HPI SEC & SSER Patient Safety Measurement System for Healthcare was published May 2009.[13]

In 2011, an extensive evaluation of the event types was conducted and informed from internal data analytics. A refined version reflected the consequences, rather than the causal factors that contributed to the event. The refinement logic was based on capturing the type of event that the patient experienced. The event causal factors are more appropriately captured as part of the performance of cause analysis that is intended to identify the high leverage areas for targeted action. These changes and others were reflected in an updated White Paper in May 2011.[14]

The SEC® process and the Safety Event Taxonomy continues to be periodically evaluated for possible updates to reflect changes as nationally endorsed safety event reporting standards and taxonomies continue to evolve. Whenever there is a revision, the harmonization, current with the publication of this paper, is also updated. With the listing of the HPI Press Ganey PSO in December 2016, extensive experience has also been gained from organizations using the SEC.

Recent history of Safety Event Review Classification

All of the above-mentioned organizations have continued to focus on the subject of patient safety event classification and review. In some cases, updates to taxonomies have occurred. AHRQ continues to update their quality and safety indicators. The most recent update in 2019 indicated that 21 Quality Indicators were retired for various reasons.[15] As part of the implementation of the Patient Safety Act of 2005, AHRQ continues the analysis of their Common Formats for hospitals, community pharmacies and nursing homes. The most recent update to the hospital data set occurred in August 2018.[16]

The Joint Commission continues to update their Sentinel Event Policy every 2-3 years. In 2016 they updated their definition of severe temporary harm to reflect the HPI definition of this level of harm.[17]

In 2015, a diverse coalition of health care leaders, the Core Quality Measures Collaborative (CQMC) was convened by America's Health Insurance Providers (AHIP), the Centers for Medicare & Medicaid Services (CMS) and the National Quality Forum (NQF). They represent over 75 consumer groups, medical associations, health insurance providers, purchasers and other quality stakeholders. The purpose of the CQMC was to develop and recommend sets of core quality measures. These measures cover more specific clinical settings such as Accountable Care Organizations, primary care and patient centered medical homes and specific clinical topics such as gastroenterology and obstetrics and gynecology. They recently published the first four of 10 anticipated new measure sets.[18]

Finally, per a 2014 report, 28 states and the District of Columbia now require adverse event reporting.[19]

Since 2007 and 2016 respectively, HPI and the HPI Press Ganey PSO has had extensive experience with hundreds of healthcare systems and thousands of healthcare settings who have used the SEC and the SSER as a core component of their patient safety program. These experiences have provided significant opportunities to understand what issues should be addressed during the journey to reliable and safe patient care. This current White Paper update is a reflection of the hard work, the questions, and the struggles of all of these organizations across the United States and the world in the journey toward Zero Harm.

2

HPI Safety Event Classification (SEC)

2
HPI Safety Event Classification (SEC®)

The goal of excellence in healthcare focuses on reducing patient suffering. Unfortunate outcomes in healthcare do occur. Inherent or unavoidable suffering includes the experience related to the disease process itself. It can also include the known complications of treatments and procedures deemed "worth the risk" when considering the likely outcome if the procedure is not performed. True accidents, such as a slip and fall of a patient, appropriately evaluated as low fall risk, sometimes happen. And eventually, the human body fails despite all efforts. The reality is that not all bad outcomes result from defects in care.

Despite these truths, thousands of healthcare leaders, clinicians and staff have worked tirelessly toward a goal of reducing harm. Many have set a goal of zero harm because "Zero is the only acceptable number in safety."[20] Avoidable suffering is the focus of healthcare organizations as they work toward this goal. Events of harm are outcomes that do result from defects in care. The healthcare industry has an obligation to protect patients from harm – to keep them safe while under our care. To be useful in measuring performance to this obligation, a patient safety measurement system must distinguish preventable harm from bad outcomes through a reliable, repeatable method.

The Safety Event Classification (SEC) system, shown in Figure 1, provides this method and is the foundation for a fundamental lagging measure of patient safety outcomes.

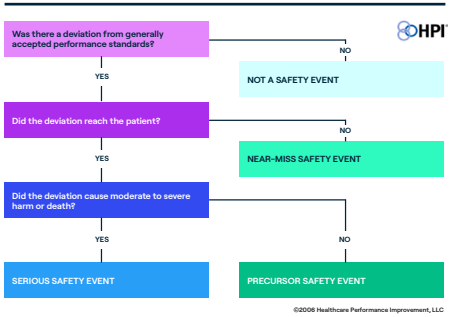
Most current event taxonomies are structured within categorical classification domains. Events are identified by event type, such as a wrong site procedure, fall with injury, or burn. In contrast, the SEC is an outcome-based classification system that takes event classification 3 steps further:

1. the event is assessed for defects in care, or deviations from generally accepted performance standards (GAPS);
2. a direct cause-and-effect relationship between deviations and the outcome is established, and
3. the safety event is classified according to level of patient harm resulting from the event.

The SEC follows an algorithm based on these three steps and is illustrated in Figure 2. This algorithm should be consistently applied when conducting safety event classification that leads to either determining that this is not a preventable safety event or that it is a safety event of one of three types – a near miss, a precursor event, or a serious safety event. These classifications are further explained in this narrative in the Assessing Outcome to the Patient section.

Figure 2

Safety Event Decision Algorithm



High Reliability Principles in Safety Event Classification

Notwithstanding all the details of the SEC® described elsewhere, the primary goal of any safety classification effort is to identify opportunities for improvement and assure that we have done all we can to best protect a patient from harm.

For almost two decades, healthcare organizations have focused on applying principles of high reliability in their work to achieve safe outcomes for patients, family, visitors, and the workforce in these organizations. The five principles described by Weick and Sutcliffe[21] are all relevant to the process of safety event classification and ultimately the analysis of events to identify root causes so that corrective actions can be put in place.

In particular, the principle of a preoccupation with failure is important to consider in the SEC process, both when considering deviations from GAPS and the level of harm.

The recognition that small, seemingly inconsequential errors are a symptom that something is wrong enables an organization to pay attention to deviations and what can be learned from them, irrespective of the outcome to the patient.

One challenge in any event review process is the realization that sometimes the safety event is caused by an action that is not taken rather than a wrong action; an error of omission not commission. Also, at times there can be a reluctance to identify a case as a preventable safety event because those reviewing the case do not want to make assumptions about the decisions made or actions that are taken as they put themselves in the shoes of the caregiver. During a review of an event, it can be difficult at times to recreate those "in-the-moment" decisions that are made to determine if they were correct or not correct.

When faced with this situation it is recommended that an organization do the following:

1. Ask the question "Are we holding ourselves to the highest standard of care"? The difference here is that we are focusing on standards of reliability and safety, not legality.
2. Incorporate other principles of high reliability into the discussion as relevant, in particular a "sensitivity to operations" (paying attention to what's happening on the front line) and a "reluctance to simplify interpretations" (encouraging diversity in perspectives to avoid quick decisions).

Assessing for deviations

Before addressing the extent of harm that the patient experiences in an event, it is critical to confirm that in fact the event was avoidable or preventable. For this reason, the first two of the defining considerations of the SEC are 1) the presence of a deviation from generally accepted performance standards (GAPS) and 2) the extent to which the deviation caused, contributed to or otherwise worsened an already existing condition.

Types of deviations

There are two predominant types of human performance deviations: (1) human acts, hereafter called human errors, and (2) equipment, device, and technology failures, hereafter called equipment failures. In addition, although they are a relatively small contributor, there is the potential for natural disasters such as wildfires, hurricanes, pandemics to place extreme pressures on normal human performance.

Human errors are the most common deviations leading to safety events. Human errors fall into five categories in the HPI Taxonomy of Individual Failure Mechanisms (Appendix F-1):

- Competency of the individual
- Consciousness of the task at hand
- Communication of information
- Critical thinking in decision making
- Compliance with known procedures and standards of care.

A brief mention regarding equipment failures as deviations is appropriate at this time. At times, patient care equipment or other mechanical tools in the organization appear to be the proximate cause of an event. The consideration regarding whether these failures are entirely unpredictable and therefore not a preventable failure should take into consideration factors such as:

- Confirmation that there was no user error or technique failure
- Was the equipment created or manufactured in-house and not by professional engineers
- Was there an issue with preventive maintenance of the equipment?
- Did a failure occur at an earlier time and not get reported or addressed appropriately or in a timely manner?
- Would an equipment failure have been predictable if there was a sufficient "preoccupation with failure" culture?

While human errors are the most proximate, or immediate, causes of safety events, human performance, however, is heavily influenced by conditions in the organization's systems. Failures in the system might actually be the more significant deviation or root cause that leads to a patient safety event. This topic is addressed in more detail in *Appendix C (Frequently Asked Questions in Using Safety Event Classification).*

System weaknesses fall into five categories in the HPI Taxonomy of System Failure Mechanisms (Appendix F-2):

- Organizational Structure
- Organizational Culture
- Work processes
- Policies and protocol
- Environment and technology.
- Identifying Deviations.

A deviation from GAPS is defined as any time a difference is detected between expected and actual performance. This includes times that expected performance may not be industry best practice. Wherever a difference exists between expected and actual performance, a deviation from GAPS exists.

Identifying deviations

A deviation from GAPS is defined as any time a difference is detected between expected and actual performance. This includes times that expected performance may not be industry best practice. Wherever a difference exists between expected and actual performance, a deviation from GAPS exists.

There are two factors which should be considered when identifying deviations. First, organizational practice expectations (written or unwritten) do not always reflect national best practice performance standards in protecting patients from harm. When reflecting on whether performance standards have been met, consideration should include external as well as internal sources of information such as established policies, procedures, and protocols; nationally recognized best practices and standards of care; industry-imposed practice mandates and requirements; implied professional practice standards; and objective clinical review by other experts (e.g., peer review). And most importantly it is important to confirm that the organization met its obligation to best protect the patient from harm.

Second, is the fact that standards continue to rise over time as a result of process improvements, advancements in technology, and clinical breakthroughs. What is considered a "generally accepted performance standard" today may, in the future, be assessed as a deficiency in care.

Considering "known complications"

Clinical complications are a known risk of certain procedures, treatments, or tests. Yet the decision is made to continue with the procedure, treatment, or test because the potential benefit is thought to be worth the risk associated with the intervention. Known complications should be distinguished from safety events resulting from deviations from GAPS.

Distinguishing between known complications and safety events, however, can be challenging. In order to support this process HPI defined a Known Complications "Test" to help determine if an event is a known complication and, if so, whether providers did everything possible to prevent the negative outcome. The Known Complications Test consists of 4 questions that should be applied when an organization is attempting

Known complications test

When faced with the need to determine if there is a deviation from GAPS and therefore a preventable safety event in the case of a known or anticipated complication, the review team should consider four questions.

- Answering 'Yes" to each question in the table suggests the outcome should be classified as a "known complication", therefore essentially saying that there was no deviation from generally accepted performance standards and for which there was no organizational causation.
- Answering "No" to any of the questions suggests that there was a deviation from GAPS and the event is classified as a preventable safety event.

Figure 3

Identifying Deviations from GAPS

Deviations from generally accepted performance standards are determined by comparing actual performance to expected performance. Internal practice expectations do not always reflect industry practice expectations in protecting patients from harm. Consideration of performance expectations should include external as well as internal sources such as: Internal policies, procedures or protocols

- Nationally recognized best practices and standards of care
- Industry-imposed practice mandates and requirements
- Professional practice standards
- Objective review by other experts
- Organization's obligation to best protect the patient from harm

If any of the above are answered **YES**, proceed with safety events classification

Table 1

The known complication test

Known complication questions	Considerations
1 Was the procedure, treatment, or test appropriate or warranted for the patient based on nationally recognized standards of care?	– Was the planned test or procedural appropriate given the condition and urgency at the time? – Were there tests, treatments or procedures available that had the potential to address the identified problem with less risk? – Was this an appropriate time for the procedure to be performed, e.g. there were other medical instability factors to consider, was it critical to do the test or procedure at this time or could the patient have been stabilized first?
2 Since the complication is a known risk, was it anticipated before the test, treatment or procedure and was the standard of care employed to mitigate that risk?	– With knowledge of the potential risks or complications, was sufficient effort made to avoid any anticipated problems? – These efforts could include type of equipment used, expertise available to perform the procedure, test or treatment, preparation of a team to be aware of the risks and readiness to address them quickly
3 Was the complication identified in a timely manner?	– What was the earliest possible time that the complication would have been expected to be identified, e.g. during the procedure or treatment itself or within a short period of time after the test treatment or procedure is completed? – Was monitoring or observation in place long enough to detect the condition, and if so, was it recognized as early as possible?
4 Was the complication treated according to the standard of care?	– If despite all efforts to prevent the complication, and having recognized its presence as soon as possible, was the appropriate or most effective care provided to reverse the effects of the complication?

To prevent inappropriately labeling true safety events as known complications, conservative assessment should be applied. As discussed later, the burden of proof should rest in demonstrating that the outcome was a known but also not preventable complication, rather than demonstrating that the outcome was just a known complication. The experience from the thousands of healthcare settings who have to date used the SEC process has shown that it isn't always easy to accurately work through the Known Complications Test.

Further guidance is provided in *Appendix H (Implementing an On-Going Safety Event Classification Process)*, but the primary recommendation is to have a group of well-respected medical and other clinical staff participate in the discussion and keep in mind the previously identified primary goal - to identify opportunities for improvement and assure that we have done all we can to best protect a patient from harm.

Based on this assessment using the Known Complications Test, the safety event classification team determined that there was a deviation in GAPS and this was a Safety Event

Figure 4

Example of the application of the HPI known complications test

Case Example: A patient had a procedure performed that involved a complex lysis of adhesions for small bowel obstruction. Forty-eight hours post-operative, the patient developed increasing abdominal pain and sepsis. A second operation showed a small perforation of the small bowel wall which was repaired successfully. In reviewing this case, the safety event classification team recognized that although a small bowel injury in such a procedure was not unusual, they wanted to confirm that this was a preventable safety event. They applied the Known Complication Test with the support of their Peer Review Committee

- If the answer to **ALL** four questions is **YES**: The event is considered a Known Complication and not a Safety Event.
- If the answer to **ANY** question is **NO**: The event is a Safety Event.

Q1: Was the procedure, treatment, or test appropriate or warranted for the patient based on nationally recognized standards of care?
There was agreement that this patient's condition required emergent surgery. While there was a history of other medical conditions, none were felt to be significant with this procedure. **YES**

Q2: Was the complication a known risk and were standard of care steps taken to mitigate it?
The surgeon performing the surgery was very experienced in this procedure and before they began the surgery, she informed the team that she needed to be able to concentrate carefully as this patient's anatomy was potentially problematic to avoid lacerations or other complications. **YES**

Q3: Was the complication identified in a timely manner?
The patient's symptoms of bowel pain, abdominal swelling and nausea began a couple hours after surgery. The surgeon when notified believed that these were normal post-operative problems given the difficulties during the surgery and chose not to take the patient back to surgery until the symptoms worsened almost 48 hours later. **NO**

Q4: Was the complication treated according to standard of care and in a timely manner?
The patient returned to surgery where a small bowel laceration was identified. It was repaired successfully. **YES**

Assessing for causation

A direct, or a possible to likely cause-and-effect relationship between the deviation and the outcome to the patient is the second consideration in the SEC. Did the deviation cause, contribute to, or in some way influence the resulting outcome to the patient?

While deviations from performance standards may coincide with a serious outcome, a direct cause and effect relationship between deviations and outcome may be difficult, and sometimes impossible, to determine. This may be the case when a patient is in critical condition or has other complications or co-morbidities (e.g., "the patient would have died anyway"). In such a case, the organization may be reluctant to declare a safety event or tend to downgrade the safety event classification.

The Ultimate Goal...

of safety event classification and subsequent cause analysis of the event is the identification and correction of root causes to prevent future events of harm. The organization can safeguard against safety event under-classification by considering its obligation to do everything possible to provide an uncompromised, safe experience. Did the organization best protect the patient from harm, regardless of the ability to definitively prove a direct cause-and-effect relationship.

During discussions within organizations as they wrestle with this challenge, it is often identified that if an unexpected patient outcome is to be identified as a preventable patient safety event, there needs to be proof. Addressing this topic of the burden of proof provides an insightful perspective when causation is questioned and requires shifting the assessment of an event from "prove to me that this is a safety event" to "prove to me that this is not a safety event".

Figure 5 illustrates this different, and more helpful perspective on a burden of proof in any event discussion. This approach puts the emphasis on our duty to protect the patient from harm. The following 3 questions can support this approach. They address the care that has been delivered to the patient from a reliability lens and encourage the identification of any opportunity for improvement that is not addressed:

1. Were there conditions adverse to quality?
2. Did we do everything possible to provide an uncompromised safe experience?
3. Would we have expected or wanted this level of care for ourselves or loved one?

Figure 5

The goal of event classification is to drive urgency of response and the initiation of the root cause analysis process.

As described previously, sometimes events are not caused entirely or at all by direct human error.
Organizational causation is often a factor and may not be immediately apparent. More evaluation, such as in medical staff or nursing peer review, or conducting a cause analysis may be necessary to determine whether the organization enabled the opportunity for a deviation from performance standards and therefore caused a preventable safety event. Organizations are wise to be aware that if there will be a delay in a final safety event classification, that strategies are in place to assure effective root cause analysis.

This can include the collection and/or preservation of critical information (e.g., statements from involved individuals, physical evidence) and the initiation of an RCA, based on what is known to be adverse through the initial evaluation process.

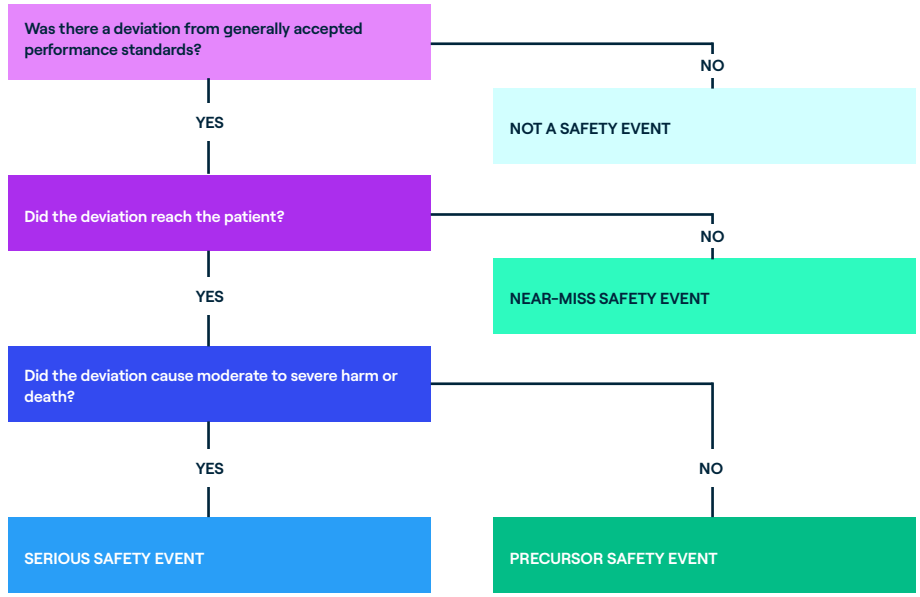
Assessing Outcome to the Patient

Once a deviation from generally accepted performance standards (GAPS) is identified, and a causal connection is established, the third level of assessment is focused on the level of harm experienced by the patient and determination of the safety event classification. Figure 2 illustrating the algorithm for SEC is displayed again to the right.

- A **Serious Safety Event (SSE)** results in harm that ranges from moderate to severe patient harm or death.
- A **Precursor Safety Event (PSE)** results in minor harm, no detectable harm, or no harm.
- In a **Near Miss Safety Event (NME)**, the initiating error is caught before it reaches the patient by either a detection barrier built into the process or, sometimes, by chance. The algorithm for determining safety event classification is shown in Figure 2.

Figure 4

Safety Event Decision Algorithm



The SEC Levels of Harm are outlined in Table 2 and detailed definitions and event examples of each SEC level of harm are provided in Appendix A. A harmonization of the SEC and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Severity Index is found in Appendix B.

Note that the Severe, Moderate and Minor levels all have two designations – permanent or temporary.

Some classification approaches differentiate levels of harm using the difference between these two designations, considering harm that is permanent to be of a higher severity irrespective of how significant the harm. The SEC levels of harm do not take this approach but use permanent and temporary as descriptors of harm rather than differentiators.

Table 2

HPI SEC	CODE	LEVEL OF HARM
SERIOUS SAFETY EVENT	SSE 1	Death
	SSE 2	Severe permanent harm
	SSE 3	Moderate permanent harm
	SSE 4	Severe temporary harm
	SSE 5	Moderate temporary harm
PRECURSOR SAFETY EVENT (PSE)	PSE 1	Minor permanent harm
	PSE 2	Minor temporary harm
	PSE 3	No detectable harm
	PSE 4	No harm
NEAR-MISS SAFETY EVENT (NME)	NME 1	Unplanned catch
	NME 2	Last strong barrier catch
	NME 3	Early barrier catch

Serious Safety Event Classification

Serious safety events range from death to severe and moderate temporary harm. The differentiation addresses unintended outcomes for the patient due to deviations in generally accepted performance standards that range from the need for a higher level of care, delays in discharge, readmissions, additional procedures, or lost function in activities of daily living up to death.

Precursor Safety Event Classification

Precursor safety events focus on minor harm or no harm. The term precursor is a deliberate one because regarding these events as potential "precursors" to more serious events reinforces that they are equally important to address and pay attention to. Recall the high reliability principle of a "preoccupation with failure". There is a wide range of outcomes that are considered minor including the need for additional medication or short-term monitoring or simple procedures or diagnostic tests.

In addition to an event that fortunately results in no harm to the patient, there is a level (PSE 3) in which the presence or absence of harm can't be confirmed or determined for various reasons including the possibility that unintended outcomes happen long after the patient is being cared for or perhaps is lost to follow up for various reasons.

Erik Hollnagel in his book Safety-I and Safety-II[22] identified these "lessor events" as fertile soil for organizational learning. His argument was that real learning comes from the repetition of corrections to earlier events. SSEs, by their nature are relatively rare, usually complex sequences of events that may never replicate themselves in the future. Whereas PSEs and near miss events are often instances of less-complex failure sequences that are likely to be repeated in the future before actually resulting in an outcome that energizes the organization to take action. Capturing, studying, and communicating these lessor events is at the essence of Safety-II.

Near Miss Safety Event Classification

Although Near Miss Safety Events are reported far less often, they are still valuable in the understanding of human error and the potential system issues that allow error to happen. The classification of Near Miss Safety Events is premised on the strength of the detection barrier that caught the error before it reached the patient. Increases in NME reporting are to be encouraged as they are an important sign of an improving culture of reliability, particularly reflected in this Preoccupation with Failure.

The most significant Near Miss Safety Event is the Unplanned Catch. The error passes through all detection barriers designed into the process (or there may be no detection barriers designed into the process at all), and it is caught by chance. For example, a patient recognizes that they are being given a medication they are unfamiliar with and they ask questions. There is much to be learned by collecting and analyzing this type of event in developing a strong high reliability operating system.

In a Last Strong Barrier Catch, the error passes undetected through nearly all defense-in-depth barriers designed into the process and is caught by a last strong barrier. As an example, consider an event sequence set in motion when a physician, acting quickly under time pressure to get to the operating room to begin a surgical case, writes an order for an unsafe dose of Heparin. This is the active, initiating error. The pharmacist who receives the order thinks the dose is high but does not seek clarification and fills the order. The order entry system, designed with system alerts, does not have an established alert for this abnormally high dose. The patient's nurse, a new graduate with 3 months of experience, doesn't recognize the dose as abnormally high. According to hospital policy, the nurse calls upon another nurse to verify this high-risk drug prior to administration. The high dose is recognized by a last strong detection barrier of the independent verification by the second nurse, and a call is placed to the ordering physician to correct the dose

The last strong detection barrier may reside early in related processes and not at the point of direct patient contact. Consider as an example the blood administration process which requires a type and-crossmatch of patient blood and blood product. Early in the process, a blood sample is drawn from the patient and a patient identification label is affixed to the sample. A break down in a two-person independent verification of the accuracy of specimen identification results in a switch of the labels of two patients requiring the type and cross-match process. Each label is affixed to the other patient's blood sample. While the rest of the process is performed accurately – blood type is determined, the blood product is matched to the identified blood type, and patient identification to ensure that the identifiers on the blood product match those of the patient and on the patient armband – it was performed accurately on the wrong blood sample. In this case, the last opportunity to detect the mislabeled specimen occurs early in the process. The error travels throughout the rest of the flawlessly performed process unbeknownst to the care providers processing the specimen or administering the blood.

Now replay the Heparin example. The ordering physician writes an order for an inappropriately high dose of Heparin. Yet this time, the receiving pharmacist, who is concerned by the dose, calls the ordering physician to clarify the order. A correction is made, and the error does not reach the patient. This type of Near Miss Safety Event is classified as an Early Barrier Catch. While an error occurred, it is detected early within a well-functioning safety net of detection barriers. The Early Barrier Catch is the least significant of the Near Miss Safety Event categories.

Additional Considerations in Safety Event Classification

Although the identification of a deviation from GAPS is usually easy to identify, given the complexities of patient situations, ever-changing care methods, organizational systems and other factors, there are times that reaching consensus that a deviation exists may be difficult. As discussed previously, there may also be difficulty reaching consensus on whether that deviation caused the unintended outcome. Implementing an effective, collaborative team process in an organization is an important step in effective safety event classification. This topic will be addressed in more detail in Appendix H.

The experience of the thousands of organizations around the United States and elsewhere in the world who have implemented the SEC has helped to identify some common dilemmas in the process. In Appendix C are a list of FAQs regarding classification and recommended approaches.

In addition to these specific questions, there are also broader topics that apply to many different types of safety events. These are discussed below.

Emotional Harm

While most of the harm examples in this document focus on physical injury or harm, there is no doubt that harm which is emotional, yet without immediate physical consequence, can be significant. Emotional harm is distinct from physical harm. It is harm experienced by a patient or family member which may erode trust and damage the patient-provider-healthcare system relationship. While this type of harm may be subjective in nature, it is characterized as unnecessary suffering that may not be physical. It is often based in a failure to demonstrate adequate respect for the patient or family member as a human being, sometimes negatively impacting the patient's or family member's dignity.

Unconscious Bias

At times during the SEC process, safety event classification teams find that there are different opinions not based on specific facts of the case, but other factors such as the person's age (e.g. the patient was 98 so she didn't have much productive life left anyway) or the patient's medical history (a patient with reports of chest pain isn't triaged quickly in the ED because the nurse knew he came into the ED often with pain to get more narcotics). In addition, personal experiences with harm can affect one's perspective on the level of harm. This problem is best thought of as bias – usually unconscious.

Unconscious biases are learned stereotypes that are automatic, unintentional, deeply ingrained, universal, and able to influence our behavior. Research has indicated that our brain makes up its mind up to ten seconds before we realize it.

There are a wide range of bias oriented situations that can affect not only how we provide care, but how we analyze events.

Press Ganey has addressed the larger subject of bias elsewhere, however, as it relates to this topic of SEC, the following may often be present during discussions about safety events:

1. Hindsight Bias – Take care as a safety event classification team to avoid the tendency to perceive events that have already occurred as having been more predictable than they actually were, particularly knowing retrospectively that the outcome was not a good one.
2. Confirmation Bias – It is easy to favor ideas that confirm our existing beliefs and what we think we know and not be able to see all sides of the situation
3. Attribution Bias – At times we can make judgments based only on the information we have available at hand that incorporates beliefs that include gender, race, education, disability and socioeconomic status.

Safety event classification teams avoid problems with biases that affect their consistency by encouraging the following:

1. Recognize stereotypical thinking and replace biases and assumptions with facts
2. Seek to understand the perspective of the individual within a system that may be flawed
3. Explore a new perspective and increase opportunities for positive contact

Diagnostic Error

The topic of diagnostic error is both significant and large. Since the publication of the IOM report Improving Diagnosis in Healthcare, published in 2015[23], there has been increasing attention on the contribution of this source of error in the occurrence of safety events. This report defined diagnostic error as *"The failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient."* Data from HPI and the HPI Press Ganey PSO indicate that the safety event type of Delay in Diagnosis and Treatment is the greatest in number out of the total of 40 event types (Appendix D).

In addition, further analysis of these events by HPI Press Ganey has shown that variations on the issue of diagnostic error are one of the major common cause analysis themes of these event types.

It is not the intent in this document to focus on the topic of diagnostic error in depth. However, it is an important source of error that should be considered during considerations of the SEC process, in particular when identifying a deviation in GAPS or when applying the Known Complications Test. In particular a common source of diagnostic error has been identified as cognitive bias. This can be defined as a predisposition to think in a certain way, perhaps using known patterns of thought or heuristics, that can at times lead to a failure in judgment when applied at the wrong time or incorrectly.

Safety event classification teams can incorporate key principles of diagnostic error in their SEC process by the following actions:

1. 1) Educating the team (along with the rest of the organization) on the topic of diagnostic error. Excellent resources are available from the Society to Improve Diagnosis in Medicine.
2. 2) Incorporate key principles of causes of diagnostic error in the SEC process when considering deviations in GAPS or causation of event questions. These can include issue of teamwork and communication, system support for effective decision making including electronic tools, etc.
3. 3) Focus efforts to support more consistent and comprehensive reporting of safety events that could include causes related to diagnostic error.

3 HPI Serious Safety Event Rate (SSER)

SSER SERIOUS SAFETY EVENT RATE®
HPI PRESS GANEY

In order to maintain a regular and quick sense of the impact of embracing and implementing a safety and high reliability management system, organizations must have the ability to clearly measure and display their progress toward Zero Harm. Therein lies the value of the Serious Safety Event Rate (SSER). The SEC serves as the foundation for the calculation of the SSER.

The SSER is a volume- adjusted measure of Serious Safety Events, those events occurring from a deviation from generally accepted performance standards that result in moderate to severe patient harm or death. The SSER is calculated monthly as the number of Serious Safety Events for the previous 12 months per 10,000 adjusted patient days (or other volume measure) for the same time period, as shown in **Figure 6.**

The volume adjustment is important as it helps to account for organizational size. Consider the following example: A system has two hospitals: a 300-bed facility that has had fifteen (15) events in a 12-month period and a 60-bed facility that had two (2) events in the same twelve-month period. The SSER's for the two facilities are 2.6 and 2.8, respectively, because they are adjusted for volume.

Particularly within healthcare systems, the volume adjustment helps to create comparable SSER metrics for the various facilities.

Calculating the SSER as a 12-month rolling rate provides two benefits. First, as Serious Safety Events do not occur frequently, it presents a clearer picture of an event rate trend. Second, and most importantly, it rewards sustained improvement, rather than episodic improvement, in preventing Serious Safety Events. To achieve a "zero" SSER, the hospital must provide care that results in 12 consecutive Serious Safety Event-free months. The SSER can be used to determine baseline safety performance and to track effectiveness of efforts to improve reliability in patient safety performance.

Figure 6

SSER for Acute Care Settings

Rolling 12-month rate of Serious Safety Events per 10,000 adjusted patient days

$$\text{SSER} = \frac{\#\text{SSE during past 12 months}}{\#\text{APD for past 12 months}} \times 10\text{K}$$

SSER for Ambulatory Care Settings

Rolling 12-month rate of Serious Safety Events per 100,000 visits

$$\text{SSER} = \frac{\#\text{SSE during past 12 months}}{\#\text{visits for past 12 months}} \times 100\text{K}$$

Choosing a denominator

The identification of the numerator (the number of SSEs) in the SSER is standard across all sites of care. The denominator however, while always a number representing care volume, needs to reflect the type of organization being represented and should be repeatable, reliable, and valid. In addition, it is important to know that the denominator is not risk-adjusted. An error or deviation from generally accepted performance standards that reaches the patient and has a negative effect is harm, regardless of comorbidities or severity of the patient condition. There is no risk-adjusting for preventable harm.

For acute care facilities, the most commonly chosen denominator is adjusted or equivalent patient days. Adjusted Patient Days (APD) is a standardized metric developed by the American Hospital Association and is calculated by taking the weighted sum of "inpatient days" and "outpatient visits". The weights are the proportion of revenue derived from inpatient and outpatient activities, respectively[24]. This number is generally a metric that is readily available from an organization's finance department.

One issue that is important to consider is that the denominator should be inclusive of all the facilities that contribute data (events) to the numerator. For example: A hospital operates a surgical center and two free- standing emergency care centers in addition to their inpatient services. If the numerator includes events from the hospital, surgery center, and two ECCs then the volume data in denominator must include all of those facilities as well.

While APDs may be an appropriate denominator for hospitals, there are other denominators that can be considered for alternative care settings. Table 3 illustrates these options. When the volume number is particularly high, e.g. in ambulatory settings, the SSER formula may be adjusted to "per 100,000" encounters/visits rather than the 10,000 used for inpatient settings.

Table 3

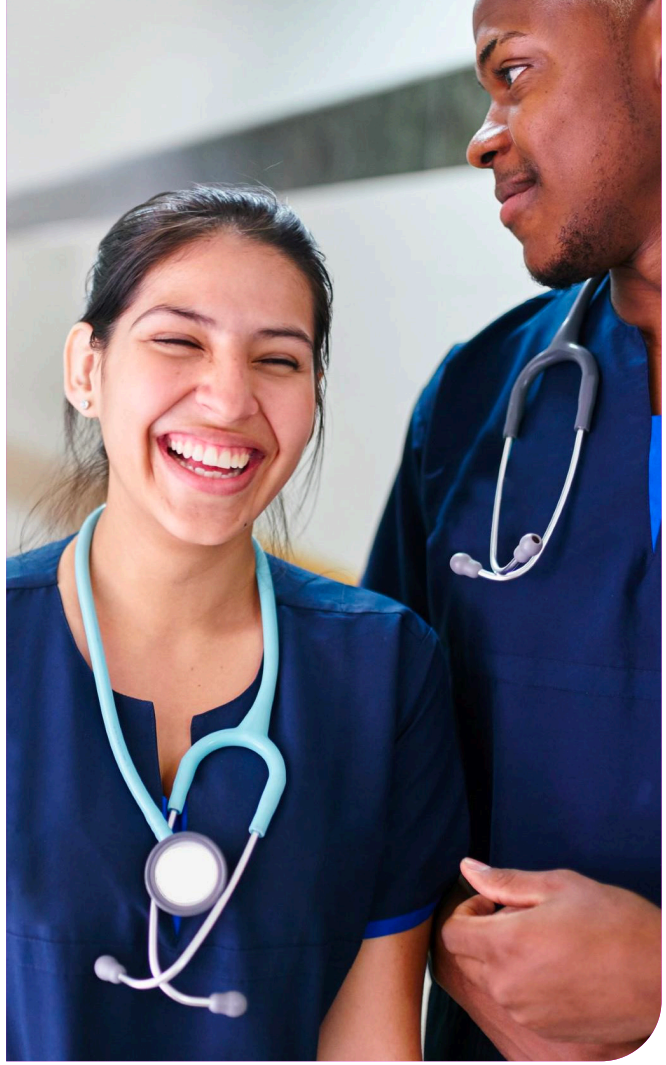
SITE OF CARE	VOLUME OPTIONS
Physician offices, ambulatory clinics or outpatient centers	Patient visits or encounters
Nursing homes and assisted living facilities	Nursing Home Days Resident Days
Home health & hospice care	Patient visits or encounters Specially calculated patient days (for Hospice settings)

3
HPI Serious Safety Event Rate (SSER®)

Due to variation in event detection and capture, HPI-Press Ganey does not recommend comparison of the actual SSER between organizations, even facilities within one organization. What is suggested, however, is that a comparison of the percent of SSER reduction following the stabilization of the safety and reliability culture interventions (i.e. establishing a baseline) is a valuable comparative metric within systems.

Organizations may identify other particular reasons to define a different denominator from those mentioned above. This decision should take into consideration a list of what distinguishes a great denominator, such as: being readily available, reproducible over time, meaningful to operations, and reflective of resource consumption (volume).

However, while the actual number might be slightly different from organization to organization, the important focus is not the actual number, but the display or "curve" of the rate line. The focus is the percent decrease in serious safety events, not the actual number.



4

Applying the HPI SEC® & SSER® Patient Safety Measurement System

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The SEC and SSER complement the tracking and reporting of Joint Commission-defined Sentinel Events, NQF Serious Reportable Events, and other state-required or industry-imposed reportable events. They also serve to transcend variation in different event taxonomies that exist in healthcare today.

To enable a reliable safety measurement system that provides a valid measure of safety performance over time, two factors are important, 1) comprehensive capture of events and 2) consistent application of the SEC classification criteria.

Comprehensive Capture of Events

Full knowledge of safety events ultimately begins with a culture that encourages reporting adverse outcomes and sharing information about errors and mistakes that are made in providing care and service. While a reporting culture is not the focus of this paper, brief comment is offered on three factors that influence the health of a successful reporting culture.

First, leaders, staff, and medical staff members must know what events are expected to be reported.

Most individuals report events that result in harm to the patient or have the significant potential to result in harm. Many staff have identified however that it is less clear, of the need to report events that did not result in harm or errors or mistakes that were caught before they reached the patient.

The second issue impacting reporting is the fear employees have about error reporting. When the organizational response to reporting is perceived as punitive to those involved in the event, rather than seeking to understand the process and system factors that influenced the individual's decision, employees are less inclined to report an event. Medical staff may believe that it isn't expected that they participate in the process of event reporting.

Finally, the reporting process must be as simple as possible. Everyone in the organization needs to perceive that the burden to report is worth the effort.

Building and sustaining a healthy reporting culture is an ongoing process, yet it is important to recognize this as a factor that can influence the accuracy of SSER in reflecting the safety performance of the organization.

Comprehensive capture of safety events requires that the organization proactively seek possible events that might qualify as a safety event. Rather than waiting for events to be "pushed" for consideration, having a clearly defined "pull system" is important. While most healthcare organizations have adopted centralized reporting and data repository for error and events, some have multiple reporting processes and information systems particularly for different sites of care or different types of reporting (e.g. regulatory reporting vs. complaints vs. patient experience or emotional harm). Experience with event reporting systems in recent years has also shown that the easier it is for all staff (direct and indirect caregivers) and members of the medical staff to quickly and effectively report an event, the more likely that the collection of events will be as comprehensive as possible.

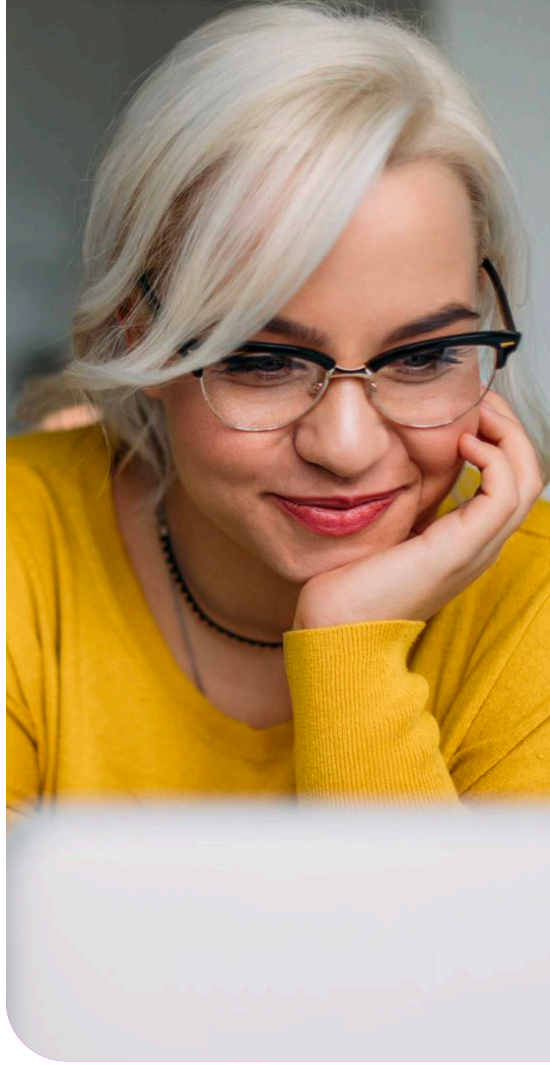
There are multiple sources for the identification of events. The following can be considered as opportunities for the reporting and collection of events for assessment as Safety Events of any type:

- Events qualifying as Joint Commission-defined sentinel events;
- State-reportable safety events and/or other regionally recognized reportable event;
- Clinical quality indicator incident and surveillance data including, but not limited to, nationally established NQF Serious Reportable Events and AHRQ Adult and Pediatric Patient Safety Indicator variances such as falls with injury, stage 3 and 4 pressure ulcers, restraint use with injury, hospital-acquired infection, and resuscitation codes (See Appendix E HPI Taxonomy of Safety Events in Healthcare Harmonization);
- CMS defined Hospital Acquired Conditions
- Events reported through the medical and nursing peer review process;
- Global triggers or adverse drug events classified by NCC MERP criteria B through I
- Patient concerns or reports; and
- Claims and suits.

Consistent Application of HPI SEC Criteria

Several factors may contribute to variation in accuracy of event detection and thus lead to an SSER numerator that does not reflect the true number of Serious Safety Events in the organization. The first factor is deficiencies in event reporting, as discussed above under “Comprehensive Capture of Events.” Second, the organization may exclude, or omit, certain types of Serious Safety Events (e.g., hospital acquired infections, safety events classified as peer review cases) from the SSER calculation.

These may be deliberate exclusions, or the exclusions may not be recognized because these types of events have been normalized and not perceived as a Serious Safety Event. The third factor is inter-rater variation in classification of safety events with outcomes that fall at the border of moderate to minimal harm.



Accuracy to the SEC criteria is important, but consistency is king

Practices to Support Safety Event Classification:

One of the more important strategies that organizations using the SEC process have identified is to implement a strong safety event review process. Appendix H illustrates further details for establishing this process. ingrained, universal, and able to influence our behavior. Research has indicated that our brain makes up its mind up to ten seconds before we realize it.

Key practices for this process include:

1. Identify a consistent group of people to serve as a "SEC Panel or Team" to provide expertise, consistency, and integrity in event classification. The group should be a mix of clinicians, non-clinicians, SEC methodology experts and leadership senior enough to gain organizational trust.
2. When deciding is difficult, use a consensus scale such as the example in Figure 7.
3. When classifying an event, always use the SEC algorithm and always ask ALL the questions: Was there a deviation? Did the deviation reach the patient? What was the level of harm?
4. Keep a record of challenging event classification cases and classification rationale. This record provides a useful reference when assessing similar future cases and enables the group to look at changes in their own perspectives in event classification. This becomes your organizational "case law" that can be referred to when ensuring organizational consistency in classification.
5. Charge one person with the responsibility for thinking/asking about precedent, i.e. how has the organization addressed a similar event in the past – your Case Law
6. What happens in the discussions, stays in the discussions. Ensure that the group speaks with one voice outside the meetings.

HPI Safety Event Detection Assessment Survey for Hospitals©

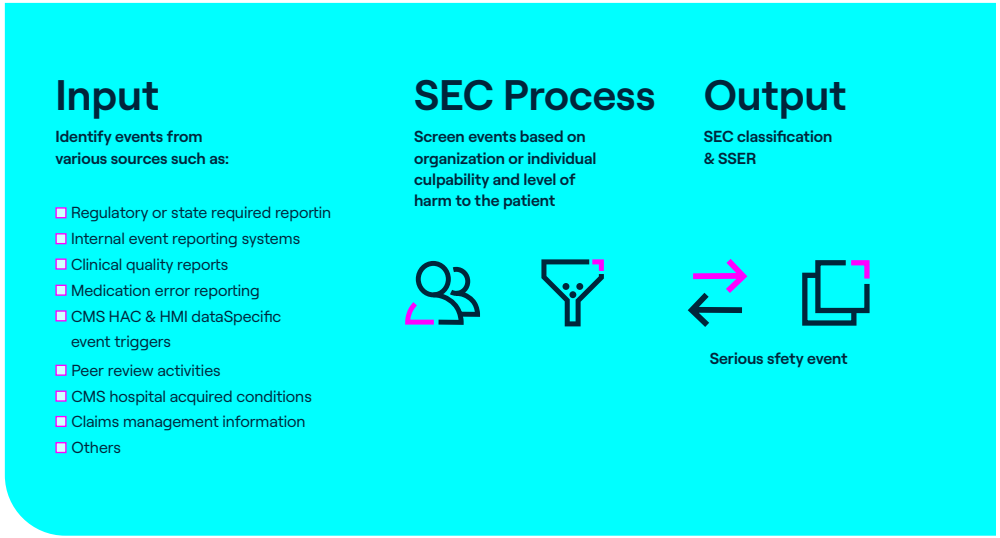
The stepwise approach for identifying possible safety events, accurately screening events to determine if they are Serious Safety Events and calculating the SSER has been described previously. HPI developed the Safety Event Detection Assessment Survey for Hospitals© to aid organizations in assessing the comprehensiveness of safety event detection capabilities and effectiveness of event classification processes.

Survey questions are designed to assess the health of the organization's reporting culture, safety event reporting processes, structures for "casting a wide net" to ensure comprehensive identification of potential safety events, and methods of screening potential events to urgently determine classification as a safety event. Survey results assist the organization in identifying strengths and gaps in safety event detection and screening processes for actionable improvement that are informed from identified better practices.

In addition, the Survey assesses the degree of transparency of lessons from the cause analysis of internal/external events to demonstrate the degree of reinforcement of a commitment to learning from errors, Results from the Survey administration can be compared to organizations with more SEC experience for benchmarking.

Figure 7

Serious safety event detection & screening



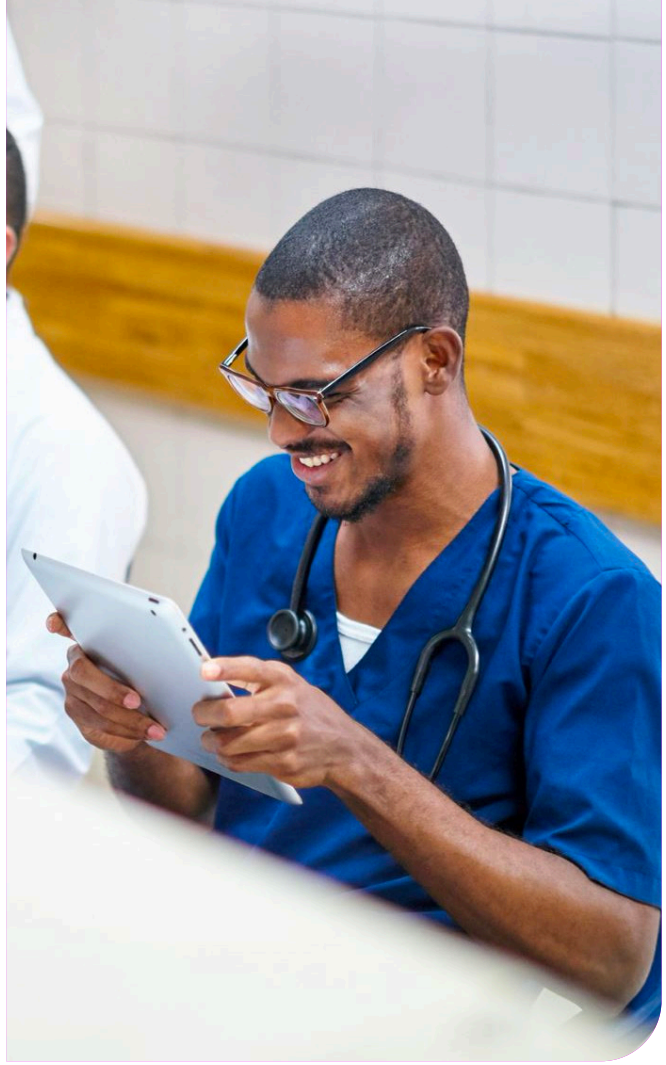
Application of SSER as a Safety Metric

Due to variation in event capture across organizations in the healthcare industry, HPI does not recommend comparing the actual, discrete SSER of one organization, and including internally across distinct facilities within a system, with the SSER of another organization for benchmark purposes.

However, within systems where there is consistency in event classification processes, comparisons of the percent of SSER reduction following implementation of safety/reliability culture improvement efforts, is encouraged and may provide valuable learning insights.

Within and across organizations using the SEC and SSER, HPI sees and expects to continue to see a decrease in the variation of SEC application. This occurs as organizations strengthen event reporting, increase awareness of system contribution to safety events, and build consistency in the determination of event classification.

Organizations have engaged in self-assessing their safety event detection and screening capabilities, identifying best practices in these areas, and refining processes to reduce cross organization variability in event detection and screening. As hospitals work collaboratively to reduce event capture variation and improve inter-rater reliability of SEC, the SSER has the potential to become a very useful comparative indicator across organizations.



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Appendix

APPENDIX A

The HPI safety event classification (SEC®) levels of harm

	CODE	LEVEL OF HARM	DESCRIPTION A deviation in Generally Accepted Performance Standards (GAPS) that causes, contributes to or worsens an already existing condition and results in:	EXAMPLES To be used as illustrations only; Specific patient or resident situation may vary Ambulatory care	Acute care	Post-acute care
SERIOUS SAFETY EVENT	SSE 1	Death	Death of the patient	• Delay of several months in communicating diagnostic tests that resulted in patient dying from unrecognized lung cancer • Patient had symptoms of liver problems that weren't followed or addressed in timely manner over period of 18 months. Patient eventually expired of liver cancer.	• Delay in treating symptoms of sepsis resulting in patient death • Patient complained of chest pain and shortness of breath after triage that showed worsening vital signs; went into cardiac arrest and not able to be resuscitated.	• Resident that was high risk to fall did not have prevention measures in place, fell, experienced subdural hematoma and died. • A Home Care Hospice client expired without nursing support including necessary medications. The patient's death was imminent, but there was a significant gap in comfort and standard hospice care resulting in an unattended death.
	SSE 2	Severe Permanent Harm	Life-changing unintended outcomes or suffering. This can include events resulting in permanent loss of organ, limb, or vital physiologic or neurologic function. There is no expected change in the patient's status or condition.	• Incorrect radiologic contrast dosing in outpatient CT resulted in need for permanent dialysis • Tissue specimen from two patients mixed up resulted in a patient having a partial pancreatectomy and splenectomy that wasn't needed.	• Wrong site procedure performed resulting in removal of healthy limb • Missed diagnosis of stroke resulting in permanent impairment	• Compression wraps/stocking incorrectly applied to resident resulting in limb ischemia and partial amputation • Venous irritant, administered to client on home care, undiluted by IV bolus through peripheral IV; extravasation resulted in loss of thumb & index finger
	SSE 3	Moderate Permanent Harm	Unintended outcomes or suffering that are significant but not sufficiently severe to impact activities of daily living or business functioning. This can include events that result in permanent reduction in physiologic reserve, disfigurement, or impaired or aided sense or function. There is no expected change in the patient's status or condition.	• During outpatient ENT procedure a paralytic was administered. Monitoring was ineffective with nerve damage and resultant facial paralysis. • Incorrect radiology contrast dosing administered in outpatient CT resultingin reduced renal function	• Delay in treatment of limb ischemia post-surgery requiring fasciotomy with disfiguring scars on leg • Patient inappropriately discharged from ED and returned next day in worse shape needing additional surgery for colon resection.	• Preventive maintenance of ventilator in SNF not performed resulting in pulmonary function changes in patient not recognized • Home Care Aide did not regularly adjust client's head band resulting in pressure ulcer and permanent loss of hair on scalp
	SSE 4	Severe Temporary Harm	Critical, potentially life-threatening unintended outcomes or suffering. Response to this deviation can include: a prolonged transfer to a higher level of care/ monitoring; an additional major surgery, procedure or substantial treatment to resolve the condition; or an unnecessary significant treatment or procedure. The unintended outcomes last for a limited period of time with no permanent residual.	• Urinalysis from regular PCP visit showed abnormalities but no infection. Follow up not done though patient called describing being unwell. Patient admitted 2 days later with pyelonephritis and sepsis. • Outpatient pharmacy incorrectly filled patient's medication. After several days of wrong doses, he became dizzy, fell and fractured femur requiring surgery.	• Patient had unrecognized fluid overload progressing to pulmonary edema requiring resuscitation and transfer to the ICU • Failure to diagnose respiratory insufficiency resulting in temporary intubation; earlier recognition would have avoided the intubation	• Patient in SNF had preventable fall with hip fracture that requires surgical repair and further rehabilitation • Nursing Home resident with wound vac not correctly managed by nurse resulting in serious infection and requiring multiple other surgical procedures to address
	SSE 5	Moderate Temporary Harm	Significant unintended outcomes or suffering. Response to the deviation can include: a higher level of care or more extensive monitoring; an additional invasive procedure1 or treatment to resolve the condition; delay in discharge or readmission; or the performance of an unnecessary invasive procedure. The unintended outcomes last for a limited period with no permanent residual.	• Patient complained of respiratory problems during Outpatient PT, wasn't referred for assessment, and two days later transferred to ED for acute care • Ordering and dispensing of incorrect infant formula in Pediatric Clinic led to admission for electrolyte imbalance	• Incorrect dose of dilaudid for pain resulting in over-sedation requiring transfer to ICU for short period of time after Narcan was ineffective in treating • Failure to routinely assess IV site results in infection requiring extensive surgical incision and drainage	• Incorrect wound care technique at home care visit leads to infected wound requiring ED visit and IV antibiotics • High risk patient in SNF fell and sustained hairline ankle fracture. Placed in splint for a week affecting mobility and ADLs

1 An invasive procedure is one where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice. Further details available at Sian Cousins, et al., "What is an invasive procedure? A definition to inform study design, evidence synthesis and research tracking," British Medical Journal, 2019; 9(7): e028576. Published online 2019 Jul 30.

The HPI safety event classification (SEC®) levels of harm – continued

	CODE	LEVEL OF HARM	DESCRIPTION A deviation in Generally Accepted Performance Standards (GAPS) that causes, contributes to or worsens an already existing condition and results in:	EXAMPLES To be used as illustrations only; Specific patient or resident situation may vary Ambulatory care	Acute care	Post-acute care
PRECOURSOR SAFETY EVENT	PSE 1	Minor Permanent Harm	Unintended outcomes or suffering in which the response to the event requires little or no intervention. May also include performing an unnecessary minor procedure. There is no expected change in the patient's status or condition.	• In outpatient surgery center, a knee procedure initiated then stopped on wrong side resulting in extra incision and small scar on knee. • Excess outpatient radiation therapy received resulting in skin color change in non-critical cosmetic area.	• Inadequate protection of ulnar nerve during an operation resulting in permanent numbness of 4th and 5th fingers • Rh-negative patient delivered without getting Rh immune-globulin shot as ordered. Future pregnancies will require higher monitoring and potential interventions.	• Lack of attention to skin care in a temporarily bedbound resident of assisted living center caused skin breakdown and scarring on hip • Home Care client on oxygen experienced stage 2 pressure injury behind ear that eventually healed but left marks and tenderness
	PSE 2	Minor Temporary Harm	Unintended outcomes or suffering in which the response to the event requires little or no intervention. May also include performing an unnecessary minor procedure. The unintended outcomes last for a limited period of time with no permanent residual.	• Results of breast biopsy specimen obtained in outpatient surgery center were inconclusive due to size of specimen resulting in need for additional ultrasound exams Physician in OB Clinic inserted an expired IUD requiring removal and reinsertion several months after procedure – much sooner than necessary.	• Retained sponge in vaginal cavity post C-Section found and removed during office exam; although no sign of infection MD orders prophylactic antibiotic • Incorrect dose of dilaudid for pain resulting in over-sedation and Narcan resuscitation with quick resolution of symptoms	• Failure to assess IV site of patient on home care resulting in infection requiring oral antibiotics • Incorrect transfer of nursing home resident to wheelchair resulting in laceration to toe managed with steri- strips and dressing.
	PSE 3	No Detectable Harm	An event in which harm may exist, yet the ability to determineor confirm the existence or fact of harm is not possible. This can include events where the onset of harm may occur later in time but can't be confirmed.	• Procedure performed in Outpatient Surgery Center with un-sterile instruments with no detectable post-procedure complications or infection. • Pt came into PCP office with abdominal pain. Initial UA showed positive for pregnancy. After patient left, a second test done was negative. No information regarding effect on patient after informed as she switched PCPs.	• Inappropriate technique resulting in losing coronary artery stent into systemic circulation with no evidence of limb or organ ischemia • After a difficult Delivery an infant's Apgar was 4 and improved to 6 and then 9. Infant observed closely before discharge with no problems but there was some concern for possible difficulty in the future	• Home care client not contacted in timely concerning need for custom compression stockings leading to delay in physical therapy • Single dose vial of lidocaine used with multiple patients - multiple times. Several dozen patients involved in event; some were not able to be contacted for follow-up.
	PSE 4	No Harm	An event that results in no harm. There is sufficient information available to determine that no harm occurred.	• During a procedure in Urgent Care clinic, MD using cautery pin sparked a small fire but there was no burn on patient. • HIM analyst for a large medical practice was conducting research project and noticed in a patient's electronic record that a physician's notes referred to a different patient's name and lab results that didn't match the patient's diagnosis. She brought it to the physician's attention who realized that he had inadvertently been charting in the wrong patient's record and the lab results had been also mismatched. No harm occurred to either patient.	• Patient received blood transfusion intended for another patient, but both had the same blood type; no adverse reaction as a result • Administration of an adult dose of vitamin K to full-term newborn infant with no effect on infant clinical status	• Significant delay in setting up homecare equipment affected timeliness of discharge to home • Resident in Assisted Living Center eloped and was missing for 6 hours. Returned to facility with no observed adverse effects

The HPI safety event classification (SEC®) levels of harm – continued

	CODE	LEVEL OF HARM	DESCRIPTION A deviation in Generally Accepted Performance Standards (GAPS) that...	EXAMPLES To be used as illustrations only; Specific patient or resident situation may vary		
				Ambulatory care	Acute care	Post-acute care
NEAR MISS EVENT	NME 1	Unplanned Barrier Catch	Passes through one or more error detection barriers but does not reach the patient because it is caught by chance. May also involve a barrier not designed or planned into the system.	• During night shift Security officer notices EVS worker starting to go into MRI suite with metal bucket and stops him. • A clinic's Medical Assistant went out to the waiting room to call for the next patient. She didn't double check the patient's ID but before care was provided the front desk clerk came to tell her another patient had come up to say that she thought the wrong patient had come up because he had told her his name as they chatted and it wasn't the name the MA had called.	• Family member who reminds of a known medication allergy immediately before the medication is to be administered to the patient • Environment Services Associate points out the need to perform a time out prior to a bedside procedure resulting in awareness that the procedure was about to be performed on the incorrect limb.	• Food Services associate notices pills in waste basket, thrown away by the patient, and alerts the resident's nurse who ensures medication administration • Home Care Nurse Aide was helping family prepare a client's medications. One of the meds appeared to require 5 pills for each daily dose. She thought this was unusual although the pill bottle said to give 5 pills. She contacted the retail pharmacy who realized a serious error had been made.
	NME 2	Last Strong Barrier Catch	Passes through all the possible early error detection barriers and is caught by a last strong error detection barrier designed in the system.	• EVS worker questions colleagues regarding new chemicals on her cart for cleaning. Still not comfortable she contacts her supervisor who says it's OK to mix the chemicals. Still not comfortable she contacts the manufacturer who says that the chemicals should NOT be mixed • Patient presented to Urgent Care Center with bleeding, nausea, and vomiting and ready to deliver a pre-term fetus. The resident was inexperienced and began to have difficulty. A nurse in the next care pod noticed the problem, stepped in and reminded the team of their TeamSTEPPS© actions. Everyone relaxed and prevented complications as they delivered the baby.	• Medication error that started with incorrect dose missed by MD and pharmacist but caught by nurse performing "5 Rights" prior to administration • Wrong patient brought to the OR and identified during the team time out	• Nurse in SNF double checks on comatose patient's record regarding latex allergy (which patient had) prior to catheter insertion even though son said that patient didn't have the allergy • LPN at Assisted Living Center helped new resident admitted from a nearby Rehab Center organize her self- medications. She thought the list was unusual as the patient had nothing ordered for her Diabetes. Though the orders had already been checked by the pharmacist and the admitting nurse, she pursued the problem and it was discovered that the patient was indeed missing an important medication.
	NME 3	Early Barrier Catch	Is caught by an error detection barrier that occurs early in the process. This barrier is planned for or designed into the system's defense in depth.	• Scheduling clerk uses phonetic and numeric clarification when registering a patient for colonoscopy and discovers that the wrong information had been sent from the PCP's office • Medical assistant who was last to leave Clinic noticed back door that was normally locked was unsecured and notified security officer who took action to fix door.	• Medication error identified when a contraindication alert fires in the medication electronic order entry system • During bedside shift change report, care team identifies that multiple IV lines in a complex ICU patient are not labeled and makes the correction to minimize risk of confusion	• Equipment technician delivering oxygen equipment to client's home and during standard checking process finds a heating unit behind her chair that could cause problem • NA at a SNF started to leave resident's room after putting him to bed. She noticed the STAR/Attention to Detail reminder and went back to make sure she had taken all necessary precautions to protect patient from a fall.

APPENDIX B

The HPI safety event classification (SEC®) levels of harm

Harmonization with NCC MERP severity index coding

	CODE	LEVEL OF HARM	DESCRIPTION A deviation in Generally Accepted Performance Standards (GAPS) that causes, contributes to or worsens an already existing condition and results in:	NCC MERP INDEX FOR CATEGORIZING MEDICATION ERRORS[1,2] National Coordinating Council for Medication Error Reporting and Prevention	
				Code	Description
SERIOUS SAFETY EVENT	SSE 1	Death	Death of the patient	I	An error occurred that may have contributed to or resulted in the patient's death
	SSE 2	Severe Permanent Harm	Life-changing unintended outcomes or suffering. This can include events resulting in permanent loss of organ, limb, or vital physiologic or neurologic function. There is no expected change in the patient's status or condition.	H Also Consider SSE 4	An error occurred that required intervention necessary to sustain life
				G Also Consider PSE 1	An error occurred that may have contributed to or resulted in permanent patient harm
	SSE 3	Moderate Permanent Harm	Unintended outcomes or suffering that are significant but not sufficiently severe to impact activities of daily living or business functioning. This can include events that result in permanent reduction in physiologic reserve, disfigurement, or impaired or aided sense or function. There is no expected change in the patient's status or condition.	G Also Consider PSE 1	An error occurred that may have contributed to or resulted in permanent patient harm
	SSE 4	Severe Temporary Harm	Critical, potentially life-threatening unintended outcomes or suffering. Response to this deviation can include: a prolonged transfer to a higher level of care/ monitoring; an additional major surgery, procedure or substantial treatment to resolve the condition; or an unnecessary significant treatment or procedure. The unintended outcomes last for a limited period of time with no permanent residual.	H Also Consider SSE 5	An error occurred that required intervention necessary to sustain life
	SSE 5	Moderate Temporary Harm	Significant unintended outcomes or suffering. Response to the deviation can include: a higher level of care or more extensive monitoring; an additional invasive procedure1 or treatment to resolve the condition; delay in discharge or readmission; or the performance of an unnecessary invasive procedure. The unintended outcomes last for a limited period with no permanent residual.	F Also Consider SSE 4	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization

[1] NCC MERP Index for Categorizing Medication Errors © 2001. https://www.nccmerp.org/types-medication-errors. Accessed online 29 September, 2020.

[2] NCC MERP Index for Categorizing Medication Errors Algorithm © 2001. https://www.nccmerp.org/types-medication-errors. Accessed online 29 September, 2020.

[3] An invasive procedure is one where purposeful/deliberate access to the body is gained via an incision, percutaneous puncture, where instrumentation is used in addition to the puncture needle, or instrumentation via a natural orifice. Further details available at Sian Cousins, et al., "What is an invasive procedure? A definition to inform study design, evidence synthesis and research tracking," British Medical Journal, 2019; 9(7): e028576 . Published online 2019 Jul 30.

HPI Safety Event Classification (SEC) Levels of Harm Harmonization with NCC MERP Severity Index Coding

The HPI safety event classification (SEC®) levels of harm – continued

Harmonization with NCC MERP severity index coding

	CODE	LEVEL OF HARM	DESCRIPTION A deviation in Generally Accepted Performance Standards (GAPS) that causes, contributes to or worsens an already existing condition and results in:	NCC MERP INDEX FOR CATEGORIZING MEDICATION ERRORS National Coordinating Council for Medication Error Reporting and Prevention[1]	
				Code	Description
PRECOURSOR SAFETY EVENT	PSE 1	Minor Permanent Harm	Unintended outcomes or suffering in which the response to the event requires little or no intervention. May also include performing an unnecessary minor procedure. There is no expected change in the patient's status or condition.	G Also Consider SSE 2 SSE 3	An error occurred that may have contributed to or resulted in permanent patient harm
	PSE 2	Minor Temporary Harm	Unintended outcomes or suffering in which the response to the event requires little or no intervention. May also include performing an unnecessary minor procedure. The unintended outcomes last for a limited period of time with no permanent residual	E Also Consider SSE 5	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
				D Also Consider PSE 3	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
	PSE 3	No Detectable Harm	An event in which harm may exist, yet the ability to determine or confirm the existence or fact of harm is not possible. This can include events where the onset of harm may occur later in time but can't be confirmed.	C Also Consider PSE 2	An error occurred that reached the patient but did not cause patient harm
	PSE 4	No Harm	An event that results in no harm. There is sufficient information available to determine that no harm occurred.	C	An error occurred that reached the patient but did not cause patient harm
NEAR MISS EVENT	NME 1	Unplanned Barrier Catch	A deviation in Generally Accepted Performance Standards (GAPS) that passes through one or more error detection barriers but does not reach the patient because it is caught by chance. May also involve a barrier not designed or planned into the system.	B Also Consider NME 2 NME 3	An error occurred but the error did not reach the patient (an "error of omission" **does** reach the patient)
	NME 2	Last Strong Barrier Catch	A deviation in Generally Accepted Performance Standards (GAPS) that passes through all the possible early error detection barriers and is caught by a last strong error detection barrier designed in the system.	B Also Consider NME 1 NME 3	An error occurred but the error did not reach the patient (an "error of omission" **does** reach the patient)
	NME 3	Early Barrier Catch	A deviation in Generally Accepted Performance Standards (GAPS) that Is caught by an error detection barrier that occurs early in the process. This barrier is planned for or designed into the system's defense in depth.	B Also Consider NME 1 NME 2	An error occurred but the error did not reach the patient (an "error of omission" **does** reach the patient)

HPI Safety Event Classification (SEC) Levels of Harm Harmonization with NCC MERP Severity Index Coding

APPENDIX C

Frequently asked questions in using safety event classification

The experience of thousands of health care settings in using SEC® has highlighted some of the challenges in applying criteria to make an accurate, but internally consistent classification decision. The issues described below are illustrative of common questions and are offered as guidance by experts in this process.

	FAQ	CASE EXAMPLE	KEY CONSIDERATIONS (✓) & SEC® APPROACHES	KEY WORDS
1	**What if an event occurs with significant harm to a patient, even up to death, but the "errors" on the part of the individuals occurred because of failings in the system of care? Can we say there was a deviation in GAPS and therefore it is a safety event?**	**Background:** A patient was admitted to the hospital by a neurosurgeon for a procedure using equipment and methods very new to the surgical team. Major complications occurred during the procedure. **What Happened that shouldn't have happened?** The surgeon was very experienced in this procedure and with this equipment, but the surgical team was not. The hospital had been anxious to bring this physician on board to increase market share and didn't take sufficient special action to prepare for this new surgery, assuming the surgical team would learn the new process. **Patient Outcome: T**here were several intraoperative complications which the team had difficulty dealing with. The patient was transferred to the ICU for two days rather than the expected surgical unit and was ultimately discharged home. **SEC Challenge:** The real deviation wasn't really related to the lack of preparation on the part of team when beginning a new procedure. Is that still considered a deviation from GAPS?	✓ While most safety events involve some element of human error, at times the deviation occurs because of problems within the organization or the system of care, including unclear procedures, lack of education, ineffective monitoring to assure individual accountability, or a culture enabling proceeding despite uncertainty. ✓ These situations meet the criteria for a "deviation in GAPS" even though it was not a specific individual(s) who experience the deviation. ✓ **High Reliability Organizing principles** such as a preoccupation with failure and a sensitivity to operations are important tools to prepare for and manage to safe outcomes. A recognition that small, insignificant situations can lead to bigger problems and that strong teamwork can overcome problems more quickly and effectively enables the ability to manage for reliability and safety. Ask the question "Are we holding ourselves to the highest standard of care?" The difference here is that we are focusing on standards of reliability and safety, not legality. Complexity is not an excuse for unsafe care. *Tools such as a proactive risk analysis using FMEA or other similar tools prior to beginning new processes or programs reinforces the principle of a "preoccupation with failure'.* **Recommended SEC Approach:** The team reached consensus that if the organization had prepared more effectively for the arrival of this physician with new procedures and equipment the complications would not have occurred or at least would have been less severe. **Recommended Classification: SSE 4**	System Failures; Preoccupation with Failure; Sensitivity to Operations
2	**How do we handle an event involving patient suicide when it's difficult to be certain that it is a preventable safety event?**	**Background**: A patient was admitted to the Emergency Department with suicidal ideation. The patient was admitted but the next day he chose to leave AMA. **What Happened that shouldn't have happened?** The behavioral health social work assessment was not completed prior to the patient being discharged. **Patient Outcome**: Patient committed suicide two days after returning home **SEC Challenge:** While the patient was classified as a suicide risk, his primary care physician, who had known him for several years, determined his risk was very low and the patient promised he would seek care the next day. Was there a clear causation?	✓ Causation is at times difficult to confirm. The question to ask is, "Did we do everything possible to provide an uncompromised, safe experience, regardless of the ability to definitively prove a direct cause-and-effect relationship?" ✓ Strategies that can assist the SEC decision process particularly in difficult psychiatric situations include a good Task Analysis to confirm deviations in GAPS, assuring that the standard of review isn't just a legal one and considering the "do no harm" standard. In addition, consider the Burden of Proof mindset (above). **Recommended SEC Approach:** The team was concerned about looking at this event and building in hindsight bias (See *Unconscious Bias* in White Paper Narrative). They agreed there was a deviation involving the delay in the social work assessment. However, although his PCP was not experienced in behavioral health evaluation factors, the team decided that they were not able to establish a direct causation, although many lessons were learned from this event. **Recommended Classification: Not a Safety Event**	Suicide; Causation; Hindsight Bias

Frequently asked questions in using safety event classification – continued

	FAQ	CASE EXAMPLE	KEY CONSIDERATIONS (✓) & SEC® APPROACHES	KEY WORDS
3	**Is it really a deviation from GAPS if we do a procedure without waiting for diagnostic tests that turn out to demonstrate that the procedure was unnecessary?**	**Background:** A patient was admitted with chest pain and SOB. Diagnostic tests were ordered and performed, but results had not been received before the physician decided to insert a chest tube. A later review of the tests indicated that a chest tube was unnecessary. **What Happened that shouldn't have happened?** The ED physician didn't wait for test results to confirm the necessity. **Patient Outcome:** The patient experienced an unnecessary invasive procedure **SEC Challenge:** Was there really a deviation in GAPS?	✓ The importance of clinical judgment at the time should not be underestimated. But when it's difficult to determine if there is a deviation in GAPS, using the tool of Task Analysis can be effective. **Task Analysis** is an effective tool in situations where the event is more about what action isn't taken, or is not taken effectively, during key processes, rather than actual errors made. Task/process expectations are compared with what was done to identify the deviations. **Recommended SEC Approach:** The SEC team focused on three questions in a simple task analysis: 1 Did the physical assessment or other parameters justify intervention at the time (e.g., appeared life threatening)? *No, the patient's condition wasn't life threatening.* 2 Why did it make sense to the physician at that time to insert the chest tube? *The ED physician was very busy with several other patients and decided in his judgement it wouldn't hurt to go ahead and have this patient taken care of just in case.* 3 What standards for chest tube insertion exist? *Agreed that chest tube insertion protocols needed to be clearer.* **Recommended Classification: SSE 5**	Task Analysis; Unnecessary Procedure; Chest Tube
4	**Sometimes there are safety events in which there clearly is a deviation in GAPS in which the outcome was a patient death. But what if the patient's clinical condition was such that they were not expected to live? Should these events be counted as preventable patient deaths and therefore an SSE 1?**	**Example #1** **Background:** A patient receiving Hospice care expires without nursing support when it was known that death was imminent in the next 24 hours What Happened that shouldn't have happened? The team identified a clear deviation from the hospice's stated standard of care for a patient close to death. **SEC Challenge:** Should this be considered an SSE 1 or some other level of harm since death was expected? **Example #2:** **Background:** A patient was terminally ill and in the ICU. Death was expected within the next couple of weeks. What Happened that shouldn't have happened? A patient received a morphine overdose due to a medication error. **Patient Outcome:** The patient expired and his family was not able to be with him at the time the event occurred. **SEC Challenge:** Would this be an SSE 1 since the patient's death was expected?	✓ At times, a team reviewing an event has considered that the patient was terminally ill and death was expected. But in the case that that death has been hastened because of an error, most organizations reach the conclusion that the earlier death was unnecessary and therefore is a preventable safety event. ✓ It is recommended that outcomes such as these be considered a preventable patient death, i.e., an SSE 1, if the error or omission shortened the patient's life by even one minute. **Recommended SEC Approach:** **In Example #1,** even though the patient's death was imminent, there was a significant gap in comfort or other appropriate hospice care resulting in an unattended death, including the possibility of not receiving necessary comfort medications. **In Example #2**, aside from the death that occurred earlier and for a different reason than the patient's health status there is also the significance of the emotional harm that the family experienced. **Recommended Classification: SSE 1 for both events**	Terminally ill; Expected death; Hospice; Emotional Harm

Frequently asked questions in using safety event classification – continued

	FAQ	CASE EXAMPLE	KEY CONSIDERATIONS (✓) & SEC® APPROACHES	KEY WORDS
5	**In our healthcare system we have been working for several years, in both our ambulatory and acute care sites, on reducing healthcare acquired infections.** **We consider them "never events", but sometimes we aren't able to clearly identify a "deviation from GAPS" so do we still consider this a preventable safety event, sometimes an SSE?**	**Background:** In an Outpatient Dialysis Center, a patient developed an infection in his central venous catheter. It wasn't clear how this infection occurred. **What Happened that shouldn't have happened?** It was suspected that staff did not perform the Central Line Infection Prevention Protocol correctly, but no one was certain or could identify who did not. **Patient Outcome:** The patient required only a course of oral antibiotics for two weeks, **SEC Challenge:** Can the event be classified if the department can't identify the specific deviation from GAPS? Also do we even have to classify this since it doesn't appear to have harm level of an SSE?	✓ It may not always be clear if there is a deviation in GAPS, what the specific deviation was or which caregiver experienced the deviation when there is an unintended outcome such as a Healthcare Acquired Infection or a Pressure Injury. ✓ At a minimum, consider if the organization did everything possible to protect the patient from harm regardless of the ability to definitively prove a direct cause-and-effect relationship. ✓ Some organizations have decided that certain types of events are universally preventable, irrespective of whether the specific deviation from GAPS is able to be identified. This should be an organizational decision, but when making the decision there should be: 1 Clarity in how and when the decision is made that it is a safety event, e.g. if a HAI meets the NHSN criteria for this event, and 2 No event is automatically an SSE. The decision regarding level of harm is made separately **Recommended SEC Approach:** The Infection Prevention Specialist suspected that the staff weren't consistent in the standard protocol of "scrub the hub" for 15 seconds even though most staff believed they were doing this correctly. He separately asked each nurse to demonstrate how they do the process. He didn't tell them he was actually timing them and discovered the average time was actually 8 seconds not the required 15. The review team agreed there was a deviation in GAPS. **Recommended Classification: PSE 2**	Universally Preventable Events; Difficult to Identify Deviations; Organizational Case Law; Causation
6	**How do we handle a safety event that involves a patient fall? We have a fall risk program that includes bed alarms, but these don't often actually "prevent" a fall.**	**Background:** A resident in a long-term care facility was identified as high risk to fall. A volunteer had returned the resident to bed after returning from a PCP visit outside the facility. She put the side rails up, the call bell in reach and left the room. A half hour later the patient got out of bed unassisted to go to the bathroom. **What Happened that shouldn't have happened?** The volunteer didn't activate the bed alarm nor notify the nurse that the resident had returned. **Resident Outcome:** The resident fell and fractured his arm. He was taken to the ED for evaluation. No surgery was needed but a cast was applied, and he stayed in the hospital overnight before returning to the facility. **SEC Challenge:** Was this really a preventable event? Bed alarms don't really stop the patient from falling. Some nursing homes don't even use them any more thinking that they make things worse.	✓ Much has been written about the value of alarms in preventing falls. Other than "alarm fatigue" – present in most care settings, other factors have been identified in long term care facilities that support not using alarms, including that the alarms sometimes confuse the residents, they don't like them turned on and staffing to respond to alarms is lower than acute care. ✓ Research on this subject is often anecdotal, but recent meta-analysis1 has identified that whatever fall prevention program is in place, that it should be a comprehensive well thought out strategy relevant to the particular care setting. **Recommended SEC Approach:** The review team identified that some LTC facilities in their area were not using alarms. However, it was also noted that irrespective of the presence of the alarm, notification that the resident was back in his room would have been an important action that was also missed. All agreed that a more deliberate and comprehensive research-based approach to fall prevention was necessary. **Recommended Classification: SSE 5**	Fall Prevention; Bed alarms; long term care; alarm fatigue

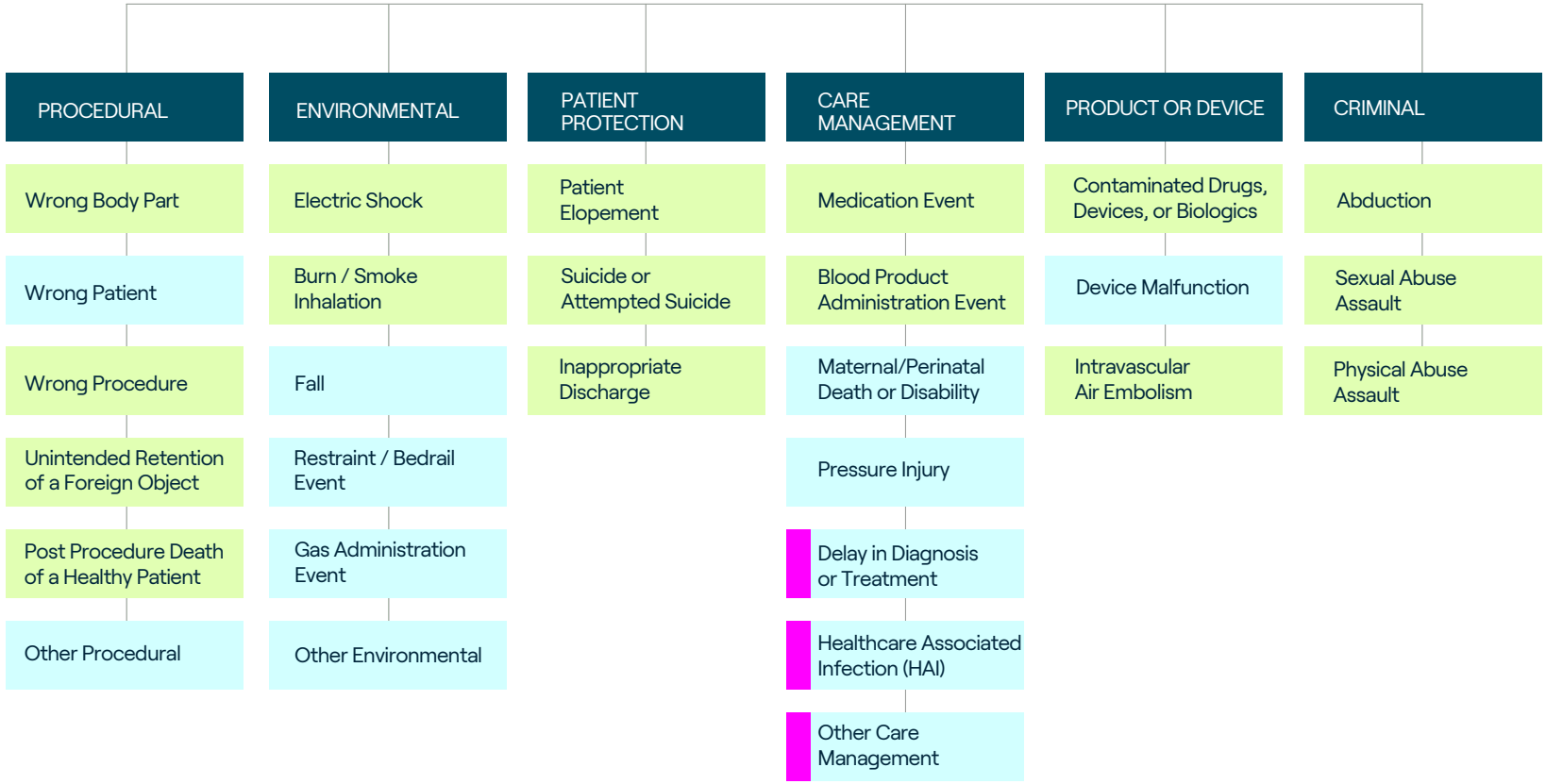
Frequently asked questions in using safety event classification – continued

FAQ	CASE EXAMPLE	KEY CONSIDERATIONS (✓) & SEC® APPROACHES	KEY WORDS
7 **What do we do when an event occurs and the SEC team has difficulty reaching a decision about SEC because there is a difference of opinion between members of the team and the input from a Medical Staff Peer Review Committee?**	**Background:** A patient with a history of colon cancer arrived in the ED with a fever and a possible rectal abscess. **What Happened that shouldn't have happened?** The order for the CT scan did not include details of the patient's medical history and the CT was incorrectly interpreted as a mass and not an abscess. **Patient Outcome:** The patient was discharged home but returned the next day in septic shock and was admitted to the ICU and discharged a week later. **SEC Challenge:** There wasn't a clear consensus in the SEC team on the presence of a deviation. They asked the Medical Staff Peer Review Committee for input and they had other physicians review the CT scan. They were split on whether it was correctly read although most believed if the correct patient history were known, it was more clearly an abscess.	✓ Any professional peer review activity is a process that is designed to address individual performance issues. While related to SEC, it is nevertheless a separate activity that may be able to inform the SEC, but need not prescribe it. ✓ Waiting for a "decision" in a peer review committee may unnecessarily delay a decision by the SEC team and cause a delay in effective event analysis. ✓ Even if the SEC team determines that there was a preventable serious safety event, and subsequent in-depth analysis activities provide further information that changes understanding of the event, it can be re-classified. ✓ An effective SEC team has membership representing an interdisciplinary team including broad physician expertise and the ability to reference subject experts when necessary in a timely fashion. (See Appendix H -Implementing an On-Going Safety Event Classification Process) ✓ Organizations experienced in SEC have made improvements in their professional peer review process including: • Incorporating the Known Complication questions into the process. • Separating the presence of human or system error from decisions regarding performance management (see Just Culture). • A "Nationally Recognized Standard of Care" is intended to mean the "best" standard of care and does not necessarily come from a national body or directive. A best standard may be local. **Recommended SEC Approach:** The SEC team agreed that aside from the possibility of a "misread" of the CT Scan, there clearly was a deviation in communication involving several care team members, enabled in part by EHR system issues. The consensus was that they did not do their best to "protect the patient from harm", enabling a series of individual and system errors. Any other performance culpability decisions rested with the peer review committee and other HR processes and was not a focus of SEC. **Recommended Classification: SSE 4**	Medical Staff Peer Review; National Standards of Care; Medical Staff Just Culture; Burden of Proof; Best Practice
8 **We had a potential safety event that involved clear deviations from GAPS with a resulting patient death. However, the autopsy report indicated a different and apparently unrelated cause of death. How do we address the issue of causation?**	**Background:** A patient is in the hospital for care related to various medical and behavioral health issues. One evening the patient was found non-responsive and attempts to revive him were unsuccessful. **What Happened that shouldn't have happened?** All agreed that there was a delay in recognition of the patient's deterioration and getting a Code Blue started. **Patient Outcome:** An autopsy was performed and indicated cause of death as pneumonia, which was not part of his original diagnosis. **SEC Challenge:** The SEC team was concerned about calling this a preventable safety event.	✓ Don't confuse autopsy results with the analysis of an unexpected death when deviations are clearly present that at least contribute to the death. ✓ Studies have shown that autopsy results can be inaccurate and/or incomplete in cases involving circulatory and respiratory disorders. 2,3 **Recommended SEC Approach:** Even though the "cause of death" was reported as pneumonia, relying **solely** on the medical examiner's report was unreliable as this organization doesn't typically have the context of the circumstances surrounding the death and therefore the results can be inaccurate and/or incomplete. In addition, if the cause of death actually was pneumonia, then there was likely a missed diagnosis and treatment of the pneumonia. ✓ **Recommended Classification: SSE 1**	Autopsy results; Pneumonia; Delay in Diagnosis

[1] CMileski, M et al. Alarming and/or Alerting Device Effectiveness in Reducing Falls in Long-Term Care (LTC) Facilities? A Systematic Review. Healthcare (Basel). 2019 Mar; 7(1): 51. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6473316/

[2] Kircher T, Nelson J, & Burdo H. (1985). The Autopsy as a Measure of Accuracy of the Death Certificate. New England Journal of Medicine, 313:1263-1269. https://www.nejm.org/doi/full/10.1056/NEJM198511143132005

[3] Mieno, M. N., Tanaka, N., Arai, T., Kawahara, T., Kuchiba, A., Ishikawa, S., & Sawabe, M. (2016). Accuracy of Death Certificates and Assessment of Factors for Misclassification of Underlying Cause of Death. Journal of Epidemiology, 26(4), 191–198. https://doi.org/10.2188/jea.JE20150010



APPENDIX E

HPI Taxonomy of Safety Events in Healthcare©

Harmonization with other Nationally Recognized Safety Event Reporting Taxonomies and Related Indicator Sets

This document is offered as a tool to complement other nationally recognized safety event taxonomies or safety/quality indicator sets used in healthcare settings. It is not all-inclusive, but incorporates common structures in use at this time in healthcare. Its intent is to provide guidance in mapping data collected with the HPI safety data systems of SEC® and SSER®.

	HPI Safety Event Category	National Quality Forum (NQF) Serious Reportable Events1 (SREs)	The Joint Commission Sentinel Events[2]	HEDIS® Clinical Measures[3]	AHRQ Quality Indicators[4]: Patient Safety Indicators (PSI), Prevention Quality Indicators (PQI); Inpatient Quality Indicators (IQI) & Pediatric (PDI) Indicators	CMS Value-Based Purchasing Program5
PROCEDURAL	**PR1: Wrong Body Part**	1A. Surgery or other invasive procedure performed on the wrong site	Surgery or other Invasive procedure performed at the wrong site, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure for a patient			
	PR2: Wrong Patient	1B. Surgery or other invasive procedure performed on the wrong patient	Surgery or other Invasive procedure performed at the wrong site, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure for a patient			
	PR3: Wrong Procedure	1C. Wrong surgical or other invasive procedure performed on a patient	Surgery or other Invasive procedure performed at the wrong site, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure for a patient		PSI 05: Retained Surgical Item or Unretrieved Device Fragment Count	
	PR4: Unintended Retention of a Foreign Object	1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure	Unintended retention of a foreign object in a patient after an invasive procedure, including surgery		PSI 02 Death Rate in Low Mortality DRGs; IQI 08 Esophageal Resection Mortality Rate; IQI 09 Pancreatic Resection Mortality Ratel; IQI 19 Hip Fracture Mortality Rate	
	PR5: Post Procedure Death of l Healthy Patient	1E. Intraoperative or immediately postoperative/post procedure death in an ASA Class 1 patient			PSI 02 Death Rate in Low Mortality DRGs; IQI 08 Esophageal Resection Mortality Rate; IQI 09 Pancreatic Resection Mortality Ratel; IQI 19 Hip Fracture Mortality Rate	Clinical Care Domain: Total Hip or Total Knee Arthroplasty Complication Rate (COMP-HIP-KNEE)
	PR6: Other Procedural accidental puncture, laceration or other issues in technique **PR6.1 Puncture/ Laceration** **PR6.2 Mislabeled/Lost Specimen**				PSI 15: Abdominopelvic Accidental Puncture or Laceration & PDI 1: Accidental Puncture or Laceration PSI 06, & PDI 05: Iatrogenic pneumothorax rate PSI 14: Postoperative wound dehiscence rate PSI 09 & PDI 08: Perioperative hemorrhage or hematoma rate; IQI 11 AAA Repair Mortality Rate, IQI 12 CABG Mortality Rate, PDI 01 Accidental Puncture or Laceration Rate, Intervention Rate, IQI 30 Percutaneous Coronary IQI 31 Carotid Endarterectomy Mortality Rate	

APPENDIX E

HPI Taxonomy of Safety Events in Healthcare© – continued

	HPI Safety Event Category	National Quality Forum (NQF) Serious Reportable Events1 (SREs)	The Joint Commission Sentinel Events[2]	HEDIS® Clinical Measures[3]	AHRQ Quality Indicators[4]: Patient Safety Indicators (PSI), Prevention Quality Indicators (PQI); Inpatient Quality Indicators (IQI) & Pediatric (PDI) Indicators	CMS Value-Based Purchasing Program[5]
ENVIRONMENTAL	**EE1: Electric Shock**	5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting				
	EE2: Burn/Smoke Inhalation	5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting	Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the hospital			
	EE3: Fall	4E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting			Effectiveness of Care: Fall Risk Management; Physical Activity in Older Adults	PSI 08 In Hospital Fall with Hip Fracture Rate
	EE4: Restraints/ Bedrail Event	5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting				
	EE5: Gas Administration Event (no gas, wrong gas, contaminated gas)	5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances				
	EE6: Other Environmental electrical power loss; fires; environment of care issues	6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area	Fire, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the hospital			

APPENDIX E

HPI Taxonomy of Safety Events in Healthcare© – continued

	HPI Safety Event Category	National Quality Forum (NQF) Serious Reportable Events1 (SREs)	The Joint Commission Sentinel Events[2]	HEDIS® Clinical Measures[3]	AHRQ Quality Indicators[4]: Patient Safety Indicators (PSI), Prevention Quality Indicators (PQI); Inpatient Quality Indicators (IQI) & Pediatric (PDI) Indicators	CMS Value-Based Purchasing Program[5]
PATIENT PROTECTION	**PP2: Patient Elopement**	3B. Patient death or serious injury associated with patient elopement (disappearance)	Any elopement (that is, unauthorized departure) of a patient from a staffed around the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient			
	PP3: Suicide or Attempted Suicide	3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting	Suicide of any patient receiving care, treatment, and services in a staffed around-the clock care setting or within 72 hours of discharge, including from the hospital's emergency department (ED)	Effectiveness of Care: Behavioral Health – Antidepressant Medication Management; Follow-Up Care measures for hospitalization or ED Visit for Mental Illness, ED visit for ETOH and Other Drug Dependence; Adherence to Antipsychotic Meds for patients with Schizophrenia		
	PP4: Inappropriate Discharge	3A. Discharge or release of a patient/ resident of any age, who is unable to make decisions, to other than an authorized person				
	PP4.1: Infant Discharged to Wrong Person	3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than authorized person	Discharge of an infant to the wrong family			

HPI Taxonomy of Safety Events in Healthcare© – continued

CARE MANAGEMENT

HPI Safety Event Category	National Quality Forum (NQF) Serious Reportable Events1 (SREs)	The Joint Commission Sentinel Events[2]	HEDIS® Clinical Measures[3]	AHRQ Quality Indicators[4]: Patient Safety Indicators (PSI), Prevention Quality Indicators (PQI); Inpatient Quality Indicators (IQI) & Pediatric (PDI) Indicators	CMS Value-Based Purchasing Program[5]
CM1: Medication Error wrong drug, dose, patient, time, rate, preparation, or routek	4A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)	Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose	Effectiveness of Care: Respiratory – Pharmacotherapy Management of COPD Exacerbation; Medication Management for People with Asthma Cardiac – Persistence of Beta Blocker Treatment after AMI; Statin Therapy for Patients with Cardiovascular and Diabetes Musculoskeletal – Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis Behavioral Health – Antidepressant Medication Management; Metabolic Monitoring for Children on Antipsychotics Medication Management – Medication Reconciliation Post Discharge; Transitions of Care; Follow-Up after ED Visit for patients with Multiple Chronic Conditions Overuse/Appropriateness – Avoidance of Antibiotics with Acute Bronchitis; Medication Management in the Elderly; Use of Opioids Utilization – Antibiotic Utilization		HCAHPS – Communication About Medicines
CM2: Blood Product Administration Event	4B. Patient death or serious injury associated with unsafe administration of blood products	Administration of blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities, Hemolytic transfusion reactions or transfusions resulting in severe temporary harm, permanent harm, or death.			
CM3: Maternal/ Perinatal Death or					
CM3.1: Maternal Death/ Serious Injury	4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Any intrapartum (related to the birth process) maternal death. Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm		PSI 18: Obstetric Trauma – Vaginal Delivery with Instrument PSI 19: Obstetric Trauma – Vaginal Delivery Without Instrument	

HPI Taxonomy of Safety Events in Healthcare© – continued

CARE MANAGEMENT

HPI Safety Event Category	National Quality Forum (NQF) Serious Reportable Events1 (SREs)	The Joint Commission Sentinel Events[2]	HEDIS® Clinical Measures[3]	AHRQ Quality Indicators[4]: Patient Safety Indicators (PSI), Prevention Quality Indicators (PQI); Inpatient Quality Indicators (IQI) & Pediatric (PDI) Indicators	CMS Value-Based Purchasing Program[5]
CM3.2: Neonatal Death/ Serious Injury	4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy	Unanticipated death of a full-term infant	PSI 17: Birth Trauma – Injury to Neonate		
CM7: Pressure Injury	4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/ presentation to a healthcare setting			PSI 3: Pressure Ulcer rate	
CM8: Delay in Diagnosis or Treatment **CM8.1 Wrong Diagnosis** **CM8.2 Missed Diagnosis** **CM8.3 Delayed Diagnosis** **CM 8.4 Wrong Treatment** **CM8.5 Missed Treatment** **CM8.6 Delayed Treatment**	4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen 4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results	Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)	• **Effectiveness of Care:** All 10 Prevention and Screening Measures – Adult BMI, Nutrition Assessment, Immunization, Screening for Lead; Breast, Cervical and Colorectal Cancer; Chlamydia and Care for Older Adults • Respiratory Conditions – Testing for Children with Pharyngitis; Spirometry Testing in Assessment & Diagnosis of COPD • Cardiovascular – Controlling High Blood Pressure • Musculoskeletal – Osteoporosis Testing	IQI 15 & IQI 32 Acute Myocardial Infarction Mortality Rate; IQI 16 Heart Failure Mortality Rate; IQI 17 Acute Stroke Mortality Rate; IQI 18 Gastrointestinal Hemorrhage Mortality Rate; IQI 20 Pneumonia Mortality Rate; IQI 90 Mortality for Selected Procedures; IQI 91 Mortality for Selected Conditions; PSI 04 Death Rate among Surgical Inpatients with Serious Treatable Complications; PSI 06 Iatrogenic Pneumothorax Rate; PSI 09 & PDI 08: Perioperative Hemorrhage or Hematoma Rate; PSI 11 & PDI 09: Postoperative Respiratory Failure Rate; PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate;	Clinical Care Domain: 30 Day Mortality Rate for AMI (MORT-30-AMI), Heart Failure (MORT-30-HF), Pneumonia (MORT-30-PN), Chronic Obstructive Pulmonary Disease, (MORT-30-COPD), Coronary Artery Bypass Graft (MORT-30-CABG),
CM10: Other Care Management (coordination or continuity of care; other event incidental to general care)	4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting	Effectiveness of Care: Diabetes – Comprehensive Diabetes Care Behavioral Health – Follow-Up Care for Children with ADHD meds; Diabetes and Cardiovascular Screening for patients with Schizophrenia or Bipolar Risk Adjusted Utilization – All Cause Readmissions; Hospitalization for Potentially Preventable Conditions.		PSI 18: Obstetric Trauma – Vaginal Delivery with Instrument PSI 19: Obstetric Trauma – Vaginal Delivery Without Instrument	HCAHPS – Care Transition

HPI Taxonomy of Safety Events in Healthcare© – continued

CARE MANAGEMENT

HPI Safety Event Category	National Quality Forum (NQF) Serious Reportable Events1 (SREs)	The Joint Commission Sentinel Events[2]	HEDIS® Clinical Measures[3]	AHRQ Quality Indicators[4]: Patient Safety Indicators (PSI), Prevention Quality Indicators (PQI); Inpatient Quality Indicators (IQI) & Pediatric (PDI) Indicators	CMS Value-Based Purchasing Program[5]
CM11: Healthcare Associated Infection (HAI)			Utilization & Risk Adjusted Utilization: • HAI Standard Infection Ratio • Antibiotic Utilization	NQI 03: Neonatal Blood Stream Infection Rate PSI 13 & PDI 10: Postoperative Sepsis Rate PSI 07, & PDI 12: Central venous catheter-related blood stream infection rate	Catheter-Associated Urinary Tract Infection (CAUTI); Central Line-Associated Blood Stream Infection (CLABSI); Clostridium difficile Infection (CDI) Methicillin-Resistant Staphylococcus aureus Bacteremia Infection (MRSA); Surgical Site Infection (SSI)

PRODUCT OR DEVICE

HPI Safety Event Category	National Quality Forum (NQF) Serious Reportable Events1 (SREs)	The Joint Commission Sentinel Events[2]	HEDIS® Clinical Measures[3]	AHRQ Quality Indicators[4]: Patient Safety Indicators (PSI), Prevention Quality Indicators (PQI); Inpatient Quality Indicators (IQI) & Pediatric (PDI) Indicators	CMS Value-Based Purchasing Program[5]
PD1: Contaminated Drugs, Devices or Biologics	2A. Patient death or serious injury associated with use of contaminated drugs, devices, or biologics provided by the healthcare setting				
PD2: Device Malfunction	2B. Patient death or serious injury associated with use or function of a device in patient care, in which the device is used or functions other than as intended				
PD3: Intravascular Air Embolism	2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting				

APPENDIX E

HPI Taxonomy of Safety Events in Healthcare© – continued

	HPI Safety Event Category	National Quality Forum (NQF) Serious Reportable Events1 (SREs)	The Joint Commission Sentinel Events[2]	HEDIS® Clinical Measures[3]	AHRQ Quality Indicators[4]: Patient Safety Indicators (PSI), Prevention Quality Indicators (PQI); Inpatient Quality Indicators (IQI) & Pediatric (PDI) Indicators	CMS Value-Based Purchasing Program[5]
CRIMINAL	**CE1: Abduction**	7B. Abduction of a patient/ resident of any age	Abduction of any patient receiving care, treatment and services			
	CE2: Sexual Abuse/ Assault	7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting	Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the healthcare setting			
	CE3: Physical Abuse/ Assault	7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider 7D. Death or serious injury of a patient resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare	Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on site at the healthcare setting			

Sources

[1]National Quality Forum Endorsed Serious Reportable Events in Healthcare: www.qualityforum.org. Last Accessed 23 September 2020

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[3] The Healthcare Effectiveness Data and Information Set (HEDIS) used to measure performance in Managed Care settings. Used by to the National Committee for Quality Assurance (NCQA) to rate quality of health plans. Only those measures potentially related to safety events are included, however all HEDIS measures have value when combining with other safety measures of care. https://www.ncqa.org/hedis/measures/. Last Accessed 29 September 2020

[4] AHRQ Patient Safety and Quality Indicators Version 2020: https://www.qualityindicators.ahrq.gov/Modules/all_resources.aspx. Last Accessed 23 September 2020

[5] Hospital Value Based Purchasing (HVBP) Program FY 2018 - 2025 Measures. https://www.qualitynet.org/inpatient/hvbp/measures#tab1. Last Accessed 29 September 2020

HPI Safety Event Classification® (SEC) Case Studies

These case studies are offered to provide examples in applying the Safety Event Classification process. Although cases are set in various sites of care, with some adaptation the principles behind the classification decisions are adaptable to most care situations. Many health care organizations have used these cases as an Interrater Reliability exercise with their safety event review team or others.

Acute care examples

CASE # 1 - ACUTE

A patient was admitted to the critical care unit with congestive heart failure and later has a new complaint of chest pain persisting over several hours. Tylenol is administered but does not decrease the patient's pain scale rating. The Resident orders a laboratory work-up. An EKG shows that the patient is experiencing an acute ST-elevation myocardial infarction. The attending cardiologist is called, but does not respond to multiple pages. The nurse does not escalate the patient's emergent condition to other physicians or the rapid response team. The patient continues to decompensate, codes and expires.

Deviation from GAPS	Yes. Although an adequate assessment indicating the patient's need for immediate intervention for acute myocardial infarction was performed, there was a significant delay in initiating treatment.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 1: Death
Taxonomy Event Type:	CM8: Delay in Diagnosis or Treatment

CASE # 2 - ACUTE

A patient presented to the Emergency Department complaining of chest pain and is admitted to rule out myocardial infarction (MI). A CT scan is performed with an incidental finding of a "questionable atrial thrombus". The ED physician and admitting intern are notified. The ED physician includes this information in his dictated report, but the intern does not include this information in the H&P. The attending cardiologist misses this information. The patient is discharged after an acute MI is ruled out. No assessment of the atrial thrombus was done. Two weeks later, the patient presents to the ED complaining of right sided flank pain. A CT scan shows a renal thrombus causing a right kidney infarction rendering the kidney non-functional which is further confirmed by additional flow scans.

Deviation from GAPS	Yes. The information needed to diagnose the patient was available at the time of the initial hospitalization, the condition was not adequately assessed or appropriately treated.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 2: Severe Permanent Harm (delay in treatment resulted in loss of function of one kidney)
Taxonomy Event Type:	CM8: Delay in Diagnosis or Treatment

CASE # 3 - ACUTE

Patient 'A' is admitted for treatment of pneumonia. Admitting orders for "Lorazepam 1mg PO three times daily" is intended for another patient 'B' but inadvertently entered on patient 'A's' medical record. Patient A receives six doses of Lorazepam. He requires a Foley catheter and due to his confusion, pulls it out causing damage to his urethra. This required significant urological surgery to correct the urethral damage an extension of hospital stay.

Deviation from GAPS	Yes. An order was written on the wrong patient. It wasn't caught by the physician, the pharmacist or the nurses administering the drug
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 5: Severe Temporary Harm (serious medication event leading to situation requiring significant surgical intervention and extended hospitalization)
Taxonomy Event Type:	CM1: Medication Error

CASE # 4 - ACUTE

A patient was admitted with congestive heart failure and received multiple medications including sedative agents. A fall risk assessment was done and the patient was identified as high risk to fall. The Fall Prevention interventions, including use of bed alarm and rounding procedures were completed consistently. However, family members who usually spent the whole day at the bedside weren't educated about the importance of keeping the alarm on even if they were in the room. One day they were standing just outside the room talking with the patient's physician when the patient got out of bed to go to the bathroom. The family had turned off the alarm because it kept going off and didn't think to put it back on when they left the patient alone. The patient fell and complained of intense hip and leg pain. Evaluation determines that that patient had a hip fracture as a result of this fall, requiring surgical repair and rehabilitation therapy.

Deviation from GAPS	Yes. Although the protocol-defined interventions were usually carried out by staff per protocol, in this case other important prevention strategies such as assuring that family members were clearly educated on importance of prevention methods were not implemented, enabling a situation where the patient was able to get OOB unnoticed.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 4: Severe Temporary Harm (hip fracture requiring surgical repair and rehabilitation) It is unknown at the time of discharge whether there would be permanent lifestyle changes so the harm was not determined to be an SSE2.
Taxonomy Event Type:	EE3: Fall

CASE # 5 - ACUTE

A healthy Gravida 2 Para1 40-week gestation mother presents in active labor requiring routine monitoring according to Labor & Delivery protocols. Labor progresses to delivery of a healthy 6-pound infant with Apgar scores of 10 and 10. Within 2 minutes post-delivery, the mother, who is still being monitored, begins to develop extreme respiratory distress and signs of disseminated intravascular clotting (DIC) syndrome. Despite all emergent efforts to reverse the situation, the mother succumbs to what is later diagnosed as an amniotic fluid embolism.

Deviation from GAPS	No. Medical Staff Peer Review committee used the Known Complication Questions. They focused discussion primarily on questions 2 – 4. The risk of an amniotic fluid embolism occurring was identified as an extremely rare and, in most cases, unpredictable. This patient in particular had no know risk factors. Once the complication began the team recognized the problem quickly and took action. Literature shows that there is a mortality rate of 80% or greater with this condition and the team and made all efforts to save the patient. They answered "Yes" to all the questions and it was determined not to be a safety event.
Deviation reached the patient?	Yes, but the event was not preventable. Not Applicable
SEC Level of Harm	-
Taxonomy Event Type:	-

CASE # 6 - ACUTE

A patient was receiving treatment for rhabdomyosarcoma. The physician ordered methadone for the post-surgical pain control. The nurse administering the medication, double-checked the medication calculation with another RN but did not request verification of the medication infusion pump setting as per hospital policy. The patient subsequently receives a 10-fold dose. Shortly thereafter the patient experienced signs of respiratory compromise and the nurse realized the setting error and immediately stops the pump, contacted the physician, and closely monitored the patient. A reversal agent was administered and appeared successful. But the patient was moved to the ICU for 12 hours for further monitoring in case of further problems.

Deviation from GAPS	Yes. The medication infusion pump setting was not double-checked by another RN according to hospital policy.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 5: Moderate Temporary Harm (respiratory compromise required a reversal agent and more intense monitoring including a brief stay in a high level of care)
Taxonomy Event Type:	CM1: Medication Error

CASE # 7 - ACUTE

A patient was being treated in the Cardiac Progressive Care Unit and had a heparin lock in place. As part of the routine hep-lock care, the nurse administered what she thought was the usual hep-lock flush solution from an unlabeled syringe she previously placed at the bedside. However, the syringe actually contained Cardizem, which she administered to the patient. The patient experienced an immediate hypotensive reaction, which quickly resolved without further incident.

Deviation from GAPS	Yes. The nurse did not follow medication labeling requirements or medication verification procedures prior to medication administration.
Deviation reached the patient?	Yes
SEC Level of Harm	PSE 2: Minor Temporary Harm (no apparent harm beyond the initial hypotensive reaction)
Taxonomy Event Type:	CM1: Medication Error

CASE # 8 - ACUTE

Patient #1, was admitted with severe anemia and required a blood transfusion. Another patient, #2 was admitted to the same hematology unit with severe anemia and also required a blood transfusion. Patient #1 had Type O blood; patient 2 had Type A+ blood. Per protocol, two nurses did a double check when blood was administered to patient #1, but they didn't realize that the blood was an incorrect type. Patient #1 received the wrong transfusion (patient #2's transfusion) but fortunately suffered no immediate blood reaction. However, over the long term, this patient may have a suppressed reaction with another transfusion due to the presence of A antigens.

Deviation from GAPS	Yes. All verifications prior to blood administration were either not performed or not performed effectively.
Deviation reached the patient?	Yes
SEC Level of Harm	PSE 3: No Detectable Harm (no apparent harm at the time, though patient may have a suppressed reaction with another transfusion)
Taxonomy Event Type:	CM1: Medication Error

CASE # 9 - ACUTE

A patient had a laparoscopic hysterectomy and was discharged post-operatively without complications. She had discharge instructions for a follow-up visit which was scheduled for several days after discharge. During an examination at this follow-up visit, the surgeon discovered and removed a surgical sponge which had been placed in the vaginal space as part of the procedure. There was no infection noted.

Deviation from GAPS	Yes. The sponge count procedure was either not performed or not performed effectively and was not removed at the end of the procedure.
Deviation reached the patient?	Yes
SEC Level of Harm	PSE4: No Harm (sponge was removed during a routine examination with no additional required intervention)
Taxonomy Event Type:	PR4: Unintended Retention of a Foreign Object

CASE # 10 - ACUTE

A Sterile Processing Technician was cleaning three flexible endoscopes when he was interrupted to do another task in the OR. He handed off the cleaning task to second technician. In the hand-off, Tech #1 tells Tech #2 that enzymatic flush "was yet to be done", but Tech #2 hears this as the flush "had been done". No repeat back is performed. Tech #2 noted that this step in the cleaning checklist had not been initialed by Tech #1, but does not ask clarifying questions. She completed the task but left the checklist to be completed by the other Tech later that day. All three endoscopes were returned to service and used that afternoon, having manual brush cleaning only. When presented with the checklist the next day, Tech #1 confirmed that he had not done the enzymatic cleaning. Patients and families notified, and all started on prophylactic antibiotics as a precaution. No signs of infection reported at time of contact.

Deviation from GAPS	Yes. An incomplete cleaning process for instruments occurred, cascading from a series of communication failures.
Deviation reached the patient?	Yes
SEC Level of Harm	PSE3: No Detectable Harm Individual patient harm and suffering: Each endoscopy patient, in this scenario, is considered an individual event. It is possible that one or more of the patients were extremely distressed and may have suffered significant emotional harm and/or suffering that required additional treatment or support. The patient's experience is their reality. In these situations where the patient has expressed psychological harm, SSE 5 (moderate temporary harm) is the appropriate classification).
Taxonomy Event Type:	PD1: Contaminated Drugs, Devices, or Biologics

Post-acute care examples

CASE # 1 - POST-ACUTE

A client of a Home Care program who was recovering at home after a traumatic brain injury. She was getting home therapy and during an OT appointment, the therapist applied a wet heat pack for treatment. The pack was heated in the microwave and had a washcloth rolled around it. The therapist thought the temperature was fine but didn't notice that the patient winced when it was applied to her wrist and hand. When she checked it about 15 minutes later, she discovered that the patient had experienced a second-degree burn - red area and small blister - to his hand and wrist. Ointment and a gauze bandage were applied and the patient had no further problem.

Deviation from GAPS	Yes. The therapist should have confirmed that the pack wasn't too hot and checked the patient sooner to confirm all was well.
Deviation reached the patient?	Yes
SEC Level of Harm	PSE 2 Minor Temporary Harm (The effect on the patient involved only minor treatment to heal the burn. No scarring as a result)
Taxonomy Event Type:	EE2: Burn/Smoke Inhalation

CASE # 2 - POST-ACUTE

A client of a Home Care program was receiving care post hospitalization for a leg injury that involved a wound vac. During an early wound case session, a nurse packed the wound with a small amount of white foam covered by black foam because there wasn't enough of the white foam. She didn't document the details of this so subsequent wound care visits by a nurse and dressing changes by the patient didn't focus on the white foam, just the black. It was during a procedure to remove the wound vac the remaining white foam was discovered. The wound was very infected and required hospitalization for a short time with IV antibiotics and several procedures to address and resolve the problem.

Deviation from GAPS	Yes. Nurse#1 didn't handoff effectively in writing and subsequent caregivers didn't probe wound carefully because they knew patient was doing the dressing changes and assumed it was OK.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 2 Severe Temporary Harm (While the hospitalization and IV antibiotics alone might have ended up as an SSE 5, the addition of several procedures to fix the problem elevated the harm to severe)
Taxonomy Event Type:	PR4: Unintended Retention of Foreign Object

CASE # 3 – POST–ACUTE

A resident of a SNF had recently been admitted from an acute care hospital. The resident had been taking coumadin in the hospital, but the medication wasn't included in the order list. It was included in the discharge summary problem list and medications, but the admitting physician didn't order this medication. The pharmacist at the SNF did a medication reconciliation but despite mentions of the med in the discharge summary (which was not electronic) and recommended blood work related to the mediation didn't pick up on the discrepancy to discover the error. The resident missed the medication for 5 days when the error was discovered. The resident didn't appear to experience any harm but there was concern for problems later in their care.

Deviation from GAPS	Yes. Both the physician and the pharmacist missed opportunities to identify the need for the med (albeit not clearly available in past documentation).
Deviation reached the patient?	Yes
SEC Level of Harm	PSE 3 No Apparent Harm (although patient seemed OK and current bloodwork was WNL, there was concern that problems may occur in the future and the patient should be monitored closely)
Taxonomy Event Type:	CM1: Medication Event

CASE # 4 – POST–ACUTE

A resident in a long-term care facility with left sided weakness from a previous stroke was identified as high risk to fall because of the weakness. A volunteer had returned the resident to bed after returning from a PCP visit outside the facility. She put the side rails up, the call bell in reach and left the room. A half hour later the patient got out of bed unassisted to go to the bathroom, injuring his right wrist requiring a splint to be placed for two weeks for stabilization while the injury healed.

Deviation from GAPS	Yes. The deviation in this case was that the volunteer didn't notify the nursing staff that the resident had returned so that they could make sure he was in a safe situation and possibly bring him out to join other residents in the day room. This nursing center does not use bed alarms as it was shown to further confuse the residents.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 5 Moderate Temporary Harm (While the treatment for this resident wasn't significant in itself, it hampered his ability to perform ADLs without a level of assistance that wasn't needed previously.
Taxonomy Event Type:	EE3: Fall

CASE # 5 – POST–ACUTE

A nurse in a health care systems' float pool is assigned to work at the organization's Assisted Living Facility for several days. He begins passing out medications to the residents and some of them aren't in their room but in the facility's Day Room. Most of the resident's don't wear arm bands but have pictures inside their rooms for identification. The nurse depended on patient's self–identifying when passing meds in the Day Room. He had been introduced to the patients earlier that day and thinking he knew the patients, did the identification with saying the patient's name as it seemed quicker and he was behind in this task. When the patient agreed, he gave the pill packet to them. Another resident hearing what transpired walked up to tell the nurse that this patient was responding to the wrong name. The nurse took the medications back and began to perform the identification process correctly by asking the patient to state name and DOB.

Deviation from GAPS	Yes. The nurse
Deviation reached the patient?	No
SEC Level of Harm	NME 3 Unplanned Barrier Catch (It was fortunate that another resident overheard the error and stopped things before it was too late. Good medication practices, adapted for the setting shouldn't require that another person stops the nurse from an error.
Taxonomy Event Type:	CM1: Medication Event

CASE # 6 – POST–ACUTE

A patient was discharged to home with trach and PEG tube. Home Care services were ordered prior to discharge but the orders for the home care equipment were written by the physician overseeing the Home Care Division. These orders did not include details related to the respiratory needs including a nebulizer and trach care kit. The nurse coordinator for the Home Care service assumed that the previous DME company the patient had used would take care of this so didn't take any action. That evening, the patient had respiratory problems that required readmission back to the hospital for 2 days.

Deviation from GAPS	Yes (While there were errors on the part of the hospital staff by not arranging for home DME, both the physician and the nurse from the Home Care Division involved in this event contributed to this event, with an error in order writing (physician) and a failure to validate and verify (nurse).
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 5 Moderate Temporary Harm (The patient required a return to a higher level of care)
Taxonomy Event Type:	CM10: Other Care Management

CASE # 7 – POST–ACUTE

A patient was admitted to a SNF after a long hospitalization for several medical issues. The patient had a special catheter/IV in his hand that required that no labs be drawn from that side. Because the dressing had been changed by the County's ambulance staff during transport, the warning not to draw blood from that side which was present in the hospital was missing. Information about this was mentioned once in the patient record but not highlighted as an important care notification. The nurse caring for the patient wanted to get the blood tests done before she left for the day. Because the patient had a cast on his other arm, she obtained the blood using this IV site and the pt ended up with a large hematoma requiring readmission to the hospital overnight to manage.

Deviation from GAPS	No. The initial error was on the part of staff not part of the facility or the organization. And while it would have been possible to eventually find the one mention of not using this IV to get blood, there was no significant reason at that time for the nurse to go looking for this information.
Deviation reached the patient?	Yes. Although this was not a preventable event from the perspective of the SNF, they did however learn from the experience and instituted some new practices to avoid this problem in the future.
SEC Level of Harm	–
Taxonomy Event Type:	–

CASE # 8 - POST-ACUTE

A patient (#1) of a Rehabilitation Center had been admitted after acute care for a head injury. As part of the initial assessment he was identified as a low risk for elopement. Several weeks after admission however, his mental cognition began to change a bit. Some staff caring for him for the past two days noticed the difference and began to talk about it. Also, another patient (#2) had told a therapist that he (#1) had been talking about wanting to "get out".

Because he (#1) was within days of discharge, she assumed that what he meant about "getting out". The therapist intended to discuss this at the team meeting that day but it was canceled and she forgot. The next morning, he went outside the facility but no one stopped him to check as he seemed to be OK. They realized two hours later he had eloped. He was found about 6 hours after leaving and seemed to have no apparent physical injury but was found comatose later that evening. After admission to the hospital they discovered that he was experiences some cranial rebleeding. If it had been discovered and addressed sooner, it was likely they would have been able to prevent the more severe physical limitations that resulted.

This is an example of two events occurring with one patient:

1

Deviation from GAPS	Yes. While it was not unusual for some patients to ambulate outside the front entrance, the expectation was that the security staff should keep an eye on them and ask questions of clinical staff to confirm it was OK.
Deviation reached the patient?	Yes
SEC Level of Harm	PSE 4 No Harm (for the elopement it seemed at the time the resident was OK with no physical injuries)
Taxonomy Event Type:	PP2 Patient Elopement

2

Deviation from GAPS	Yes. There were signs that several team members had noticed that indicated the patient's clinical status was changing but they weren't followed up for various reasons. While the symptoms were subtle, the team in reviewing the case using the Known Complication Questions concluded that could have identified the problem sooner but better team communication.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 2 Severe Permanent Harm (Although there wasn't 100% certainty that they could have prevented the resident's resulting left sided paralysis, it was agreed that they didn't do everything possible to reduce or eliminate this outcome)
Taxonomy Event Type:	CM8 Delay in Diagnosis or Treatment - CM8.3 Delayed Diagnosis

CASE # 9 - POST–ACUTE

A patient was admitted from the hospital to a Rehabilitation facility with a history of a stroke and an AMI. A month after admission she was SOB but this was attributed to seasonal allergies. It was also noted that she'd had 12 lb. weight gain but most though it was because of her decreased activity. Clinical staff didn't put together the weight gain and her respiratory issues and this was more difficult to assess because the facility was not on the same EHR as the hospital so they weren't able to confirm details of her past medical history. Several days later she continued to have issues and was more SOB and wheezing but she told the NP it was something she ate so the NP didn't do anything further. That night when she began getting more SOB, the nurse contacted the MD who ordered a nebulizer treatment. That seemed to help but the next morning she was more hypoxic with a PO2 of 87%. She arrested shortly thereafter. The Code Blue was unsuccessful and she expired.

Deviation from GAPS	Yes. There were multiple opportunities for various members of the clinical care team to pursue other options for this patient's symptoms. System problems with the electronic record made this more difficult, but not impossible.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 1 Death (It's possible that this patient may have expired anyway as she had a history of AMI, but recognition of the possibility of other medical problems was delayed too long to assure greater chance of avoiding the unfortunate outcome)
Taxonomy Event Type:	CM8 Delay in Diagnosis or Treatment - CM8.2 Missed Diagnosis

CASE # 10 - POST–ACUTE

A patient was in the end stages of her illness from lung cancer and was receiving Hospice care. The nurse caring for the patient recognized that the patient was likely to expire within the next 24 hours. The program's care standards were that patients without family or others who could stay with them at this stage (such as this patient) should be provided in person care and support. The nurse contacted the agency office because he was leaving for a trip that evening. Because it was a major holiday the next day, they were unable to find any staff willing to care for this patient. The patient expired the next day alone and likely in some pain.

Deviation from GAPS	YES. The Hospice staff did not follow their stated policy not to allow a patient to die alone and in pain, although it would have been difficult to do because of the holiday situation.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 1 (Although death was the expected outcome, it was agreed that the team did not do everything that they could to assure the death was not unattended and that the patient was not uncomfortable or in pain.
Taxonomy Event Type:	CM10: Other Care Management

Ambulatory care examples

CASE # 1 – AMBULATORY

A physician was providing care via the TeleHealth service for a Primary Care Clinic. A patient with a history of atrial fibrillation needed a new prescription for coumadin. Blood work had been obtained and after talking with the patient, the physician ordered the new prescription dose electronically. However, he inadvertently ordered a much higher does than intended. It wasn't high enough for the EHR alert to fire. The Pharmacy Tech prepared the medication for the patient to pick up. When the pharmacist in the clinic reviewed the work the Tech had done, he thought the dose seemed much higher than the patient (who he was familiar with) had originally taken and checked the lab results. Realizing the possibility of an error he contacted the physician who was able to correct the error before the medication was dispensed.

Deviation from GAPS	Yes. The physician didn't realize he'd ordered a dose of medication that was not what he intended.
Deviation reached the patient?	Yes
SEC Level of Harm	NME 2 Last Strong Barrier Catch (If the pharmacist hadn't paid attention and used his questioning attitude to validate and verify the incorrect medication would have been provided to the patient and he would have taken it.
Taxonomy Event Type:	CM1 Medication Event

CASE # 2 – AMBULATORY

A patient presents for a surgical revision of a vascular shunt at an Ambulatory Surgery Center. The patient had a documented history of MRSA. This organization's practice was to use Vancomycin for SSI prophylaxis particularly in procedures such as these. The information concerning the MRSA was not available to the surgical team preoperatively due to an unrecognized error in the coding of a new electronic health record. The patient did not receive the correct preoperative antibiotic and as a result developed a surgical site infection requiring several returns to the OR for debridement/washout and prolonged intravenous treatment with Vancomycin.

Deviation from GAPS	Yes. Although the correct SSI prophylaxis was not used, this was due less to a human error, but to a system problem in the coding of information about some elements of past medical history that didn't always flow effectively to outpatient settings.
Deviation reached the patient?	Yes
SEC Level of Harm	SE4: Severe Temporary Harm (multiple returns to the OR and prolonged antibiotic therapy)
Taxonomy Event Type:	CM11 Healthcare Associated Infection (HAI)

CASE # 3 – AMBULATORY

An OB patient was receiving Rhogam shots during her pregnancy. She was given the 50 mcg dose instead of a 300 mcg dose. This was discovered the next day. In total, three patients received the wrong dose and they all had to come back to the clinic to receive the correct dose. The problem occurred because the pharmacy tech inadvertently ordered wrong dose vials of drug and the CMA and LPN who administered the doses didn't double check that they had the wrong amount because the vials looked the same and this was the amount they always gave.

Deviation from GAPS	Yes. Errors included inadvertent ordering error and not following medication administration policy.
Deviation reached the patient?	Yes – Actually 3 different patients (therefore three different events)
SEC Level of Harm	PSE 2 Minor Temporary Harm (Patients had to come back for another visit and get extra injections.
Taxonomy Event Type:	CM1 Medication Event

CASE # 4 – AMBULATORY

A patient came to an Urgent Care Clinic with an ankle injury. The treatment for the injury included a special "boot" for stabilization of the joint. Over next couple of weeks the patient came back to the clinic 3 more times complaining of pain and swelling around her ankle. Xray's taken didn't indicate and further ankle injury and the caregivers (different each time) just determined the patient was using her foot too much and not elevating as instructed. A day after her last visit she came to the ED with complaints of chest pain and it was determined she had blood clots in her lung that had originated from the ankle injury. The patient was hospitalized for 3 days.

Deviation from GAPS	Yes. Staff may not have considered the need for prophylactic anticoagulants, but primary error was not assessing the situation further when there was indications that something was wrong.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 4 Moderate Temporary Harm (Patient was admitted for 3 days – a higher level of care.
Taxonomy Event Type:	CM8 Delay in Diagnosis or Treatment - CM8.2 Missed Diagnosis

CASE # 5 - AMBULATORY

While receiving care in an Outpatient Dialysis Center for approximately two weeks a patient developed an infection in his central venous catheter. It wasn't clear how this infection occurred. It was suspected that staff did not perform the central line infection prevention protocol correctly or perhaps performed the correct actions inconsistently. No one was certain or could identify where the error occurred. The patient required IV antibiotics and was admitted to the hospital for several days.

Deviation from GAPS	Yes. Most organizations see infections such as these as able to be prevented absent any specific reason why this was not possible. In particular when it is known that adherence to protocols is inconsistent.
Deviation reached the patient?	Yes – Actually 3 different patients (therefore three different events)
SEC Level of Harm	SSE 5 Moderate Temporary Harm (patient required hospitalization for the infection)
Taxonomy Event Type:	CM11 Healthcare Associated Infection (HAI)

CASE # 6 - AMBULATORY

A patient was receiving care in an OB Clinic. This patient had a history of insulin dependent gestational diabetes. Although the clinic did instruct the patient in how to care for the problem, she was known to have some behavioral health and social issues and was inconsistent in self-care and didn't always keep her visits. They discussed options to more safely care for this patient but hadn't implemented a plan of care. Ultimately the patient delivered the infant via c section, but there was unfortunately a fetal demise.

Deviation from GAPS	Yes. The Known Complication Questions are useful in this case. Question 2 – knowing there was a risk of a complication and taking steps to mitigate the risk was the one in which the answer would be No. Although the care team did consider how to more effectively care for this patient with difficult circumstances who also had the possibility of behavioral health problems, they never actually took the necessary steps.
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 1 Death
Taxonomy Event Type:	CM3.2: Neonatal death/serious injury

CASE # 7 - AMBULATORY

A patient came to an Urgent Care Clinic after slamming a hammer on his finger at a construction site. During the procedure to treat the serious injury, the MD made an incision to drain hematoma using cautery pin. She had a dry gauze in her other hand and it inadvertently came in contact with the cautery. This sparked a fire and the patient received a second degree burn to his hand. They decided to admit the patient overnight for IV antibiotics as an extra precaution.

Deviation from GAPS	Yes. There wasn't enough care taken in avoiding sparking a fire with the instruments and materials used in the procedure
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 5 Moderate Temporary Harm Although it's possible to determine that an overnight stay wasn't critically necessary, given the circumstances, it was the appropriate level of care.)
Taxonomy Event Type:	EE2 Burn

CASE # 8 - AMBULATORY

A Scheduling Clerk in a large Ambulatory Care Practice was scheduling an Xray procedure for a patient. While doing this she inadvertently chose the wrong patient's name in the list on the computer. It turned out that the two patients in the list were actually a father and a son. They had the same name (except for a Jr and a Sr) and the same month and year as a birthday. She chose the son's name instead of the father. The error was discovered when the father showed up for the procedure and the Radiology Tech realized there was a problem because the birth year was 2005 and this patient clearly wasn't 15 years old! The error was corrected in the computer and the patient received the correct procedure.

Deviation from GAPS	Yes. The clerk inadvertently chose the wrong name to register a patient for a procedure. The fact that most of the pertinent details were the same for both contributed to the error. (This is a true story!)
Deviation reached the patient?	Yes
SEC Level of Harm	PSE 4 No Harm (Although there wasn't a danger that the wrong patient would have gotten a procedure it was possible that the wrong information/test results might have gone into the wrong record.
Taxonomy Event Type:	CM10 Other Care Management

CASE # 9 – AMBULATORY

A patient had a procedure for a breast biopsy in an Outpatient Women's Center. The information concerning the side intended for the procedure was unclear but the patient said she believed it was going to be on the left side. The technician prepared the patient for this side and the physician arrived and did the procedure. When the physician got the results several days later, he realized that the incorrect side had been done. Because of the concern for possible cancer diagnosis, the patient had to return for another procedure the next day.

Deviation from GAPS	Yes. Both the caregivers involved (individually and collectively did not take all necessary steps to assure a procedure was done on the correct side)
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 5 Moderate Temporary Harm. (The patient required a second biopsy procedure)
Taxonomy Event Type:	PR1 Wrong Body Part

CASE # 10 – AMBULATORY

A patient was at an ambulatory radiology department at a rural health clinic. In order to have the procedure done, the patient needed to get up on the table. While he was doing this he cut his leg on the edge of the table. This required several stiches to repair the laceration. The problem was that the extension for the table wasn't pulled out all the way because it was old and had some rust on it. The table had to be replaced, but the Clinic hadn't yet done that despite some complaints from the staff.

Deviation from GAPS	Yes. This error was on the part of the clinic administration in not repairing or replacing the Xray table before a patient was harmed
Deviation reached the patient?	Yes
SEC Level of Harm	SSE 5 Moderate Temporary Harm (Laceration severe enough to require several stitches.
Taxonomy Event Type:	PD2 Device Malfunction

Implementing an On-Going Safety Event Classification Process

In order to maintain regular and consistent safety event review using the SEC® process, healthcare organizations need to create a structure and standard approach. The purpose of establishing a standard process is to ensure the appropriate response to events (more serious events warrant a higher level of response) and to support the calculation of the organization's serious safety event rate (SSER®) and other safety metrics.

Key steps in establishing an effective SEC process

1.

Cast a Wide Net to Identify Safety Events

Data about safety events can be found from a variety of sources. When setting up event review structures and processes be sure to consider all of the relevant sources of data for your organization.

Event reporting system	General safety event data, Near misses
Patient Relations	Non-service-related patient complaints (delays in treatment, med errors, etc.)
Pharmacy	Medication errors, Adverse drug reaction, Drug utilization reviews
Case Management	Returns to surgery Unplanned readmissions Unplanned extended LOS
Peer Review (MD and Nursing)	Mortality and morbidity reviews Department specific indicators
Lab	Transfusion errors/ Blood Use Review Mislabeled specimens
Legal	Claims/lawsuits
Infection Control	HAI's
PI Teams	Events/issues that led to process teams
Other	AHRQ PSI Indicators, CMS HAC's IHI Trigger tool

2.
Establish an Event Classification Team

For consistent classification, it is best to charter a small group of knowledgeable and objective individuals to determine the final classification of safety events.

Example of a Safety Event Classification Team Membership

- Approximate an interdisciplinary clinical team for broad input
- Assure different medical/ clinical perspectives and invite others as needed
- In addition to standing members of the team, invite leaders of departments where events being discussed occurred.

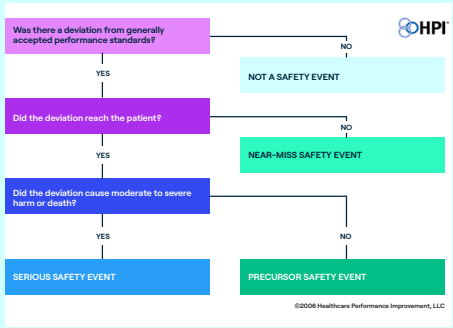
Membership of a Safety Event Classification Team:

- Size and structure vary based on organization size and the types of care sites
- Team led by classification subject expert, e.g. Risk, Quality or Safety leader
- Incorporate owners of various data types, e.g. medications, HAIs, peer review etc.
- Assure representative senior leadership
- Include one or two non-clinical members that can ask the "dumb questions" that ultimately focus the team's effort
- At System level, consider chartering an oversight team (with the chairpersons of each facility event review team and others as members) to ensure classification consistency across business units.

3.
Create a Charter for the team's functioning

Meeting Frequency	• Start at least weekly • Focus efforts primarily on potential serious safety events with periodic confirmation of precursor and near miss events for consistency • Establish a rapid review process for events that may need action to prevent further harm before a regularly scheduled process. Confirm if necessary, at next meeting • When your SSER has sufficiently decreased, frequency can be adjusted, but no less frequently than monthly
Team Purpose and Responsibilities	1. Review and make final SEC® determinations for safety events. 2. Maintain the organization's SSER® statistics and rate as well as tracking precursor and near miss events 3. Monitor organization for effective event reporting and consistent classification.
Decision Making	1. Classification decisions should be reached by consensus. If consensus not possible, then majority. 2. Each member of the team has a responsibility to participate in full and complete discussion about each case and to raise concerns if they disagree with the recommendations of the group. 3. If consensus cannot be reached, a vote can be taken (majority rules). 4. The classification decisions of the team will be considered final, unless new information comes to light that the team did not have available at the time the case was classified. 5. Members of the team are expected to support the full team's decisions.
Appeal Process	In the event that an organizational leader disagrees with a safety event classification by the team, a senior leader such as the Chief Medical Officer, Chief Safety Officer, Chief Nursing Officer is designated as final arbitrator.

4.
Strive for Consistency and Team Effectiveness



Organizations experienced in SEC® & SSER® suggest…

1. When adding ad hoc team members avoid the individuals involved in the event. Their participation is best used during cause analysis activities.
2. Defer the classification of events if there is insufficient information to make an informed decision. Come prepared with answers.
3. Consider keeping a secured table or spreadsheet which can be pre-populated with events and preliminary classifications by the data "owners" for efficient team functioning
4. Keep an organizational "Case Law" list of difficult to classify cases and issues. Refer to Case Law when considering similar cases. The HPI Press Ganey PSO can provide members a template to record deliberations.
   - **Details on how classification decisions were reached for the "tricky" cases.**
   - **Document the source of the disagreement and the different opinions and why they were held.**
   - **Keep track of the type of disagreement, i.e. Deviation from GAPS; Causation; Level of Harm.**
   - **Also include cases that were deemed "not a safety event"**
5. Only with good event reporting statistics and team inter-rater reliability, can the percent of SSER reduction become a comparative metric between system facilities over time.

Don't forget that membership in the HPI Press Ganey PSO provides an excellent source for support beyond your organization!!

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