SEC & SSER Patient Safety Measurement System for Healthcare

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The HPI SEC & SSER Patient Safety Measurement System for Healthcare

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Executive Summary

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

*Hippocrates, **Of the Epidemics**, Book 1, Section XI, 400 BC*

While healthcare holds healing without harm as its core value, the industry has lacked a consistent nationally accepted method by which to measure performance against this promise. Several patient safety event taxonomies have emerged, yet these category-based classifications do not provide a means of consistently measuring harm resulting from safety events. Harm as a hospital-induced patient outcome has not been well defined in healthcare. The lack of a standard definition of patient harm leads organizations to use disparate, subjective determination that requires significant interpretation. These inconsistencies and shortcomings have become even more apparent as the healthcare industry focuses more intently on patient safety and as organizations try to measure improvement and identify benchmark performers in this area.[1]

Concern about these issues was voiced at the 2006 Safety Summit, an annual gathering of organizations engaged with Healthcare Performance Improvement (HPI) in safety culture improvement. Advocate Healthcare, Memorial Health University Medical Center, OhioHealth, Sentara Healthcare, and other HPI client organizations expressed the need for a reliable outcome measure for patient safety that can be used to measure performance within a hospital as well as compare performance across hospitals.

In response, HPI developed the **Safety Event Classification (SEC)** and the **Serious Safety Event Rate (SSER)**. The 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 or standard of care. The SEC serves as the foundation for the calculation of the Serious Safety Event Rate, 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 patient harm. Over 100 hospitals across the United States are using the SEC and SSER.

The four sections of this paper provide an overview of the **HPI SEC & SSER Patient Safety Measurement System for Healthcare**. Section 1 provides an overview of current category-based approaches to safety event classification. In Section 2, the SEC is introduced as an outcomes-based classification system, and levels of harm are defined. The implication of known complications specifically is discussed in this section. Section 3 describes the SSER calculation method. Finally, Section 4 provides commentary about the application of the HPI SEC & SSER Patient Safety Measurement System, including the use of SSER as an internal organizational measure and as a cross-industry comparative measure.

[1] Institute of Medicine. Patient Safety: Achieving a New Standard for Care. Washington, DC: National Academy Press, 2003.

Section 1:
Event Classification in Healthcare

National and international patient safety organizations have yet to reach 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) have led efforts to classify events that cause harm to patients.

The Joint Commission defines a sentinel event as the following:

> "an 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."[2]

In early 2003, the Joint Commission developed a Patient Safety Event Taxonomy (PSET ™).[3] The PSET outlines terminology and classification schema for near misses and adverse events. The goal of the Joint Commission PSET is to facilitate a common approach for collecting and organizing patient safety data. This taxonomy was endorsed by the NQF in 2005 as a framework for aggregating, classifying, and reporting data for national patient safety improvement. However, it has yet to be implemented nationally. With the advent of nationally recognized patient safety organizations (PSO)[4], there continues to be a need for the universal adoption of a standardized safety event taxonomy.

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 health care. 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 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[8]. 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.

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[2] The Joint Commission is an independent, not-for-profit organization that accredits and certifies healthcare organizations and programs in the United States. The definition of a sentinel event is found on the Joint Commission website at www.jointcommission.org/sentinelevents. Accessed on 1 March 2009.

[3] A. Chang, P. Schyve, R. Croteau, D. O'Leary, and J. Loeb, "The JCAHO Patient Safety Taxonomy: A Standardized Terminology and Classification Schema for Near Misses and Adverse Events," *International Journal for Quality in Health Care*, 17 April 2005, 17(2):95-105.

[4] Patient Safety Organization (PSO) is a designation established as part of the Patient Safety & Quality Improvement Act of 2005 for qualified organizations to collect, aggregate, and analyze information on medical errors reported by healthcare providers.

[5] The National Quality Forum is a not-for profit public-private partnership working to promote common healthcare measures.

[6] The National Quality Forum, "Serious Reportable Events in Healthcare: A Consensus Report," 2002. Available online at http://www.qualityforum.org/pdf/reports/sre.pdf. Accessed on 1 March 2009.

[7] The National Quality Forum, "The National Quality Forum Updates Endorsement of Serious Reportable Events in Healthcare," Press Release, 16 October 2006. Available online at http://www.qualityforum.org/pdf/news/prSeriousReportableEvents10-15-06.pdf. Accessed on 1 March 2009.

[8] Department of Health & Human Services, "Adverse Events in Hospitals: State Reporting Systems," OIE -06-07-00471, December 2008. Available online at http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf. Accessed on 1 March 2008.

The World Alliance for Patient Safety of the World Health Organization recognized healthcare's current inability to classify, aggregate, and compare patient safety information across organizations internationally. In 2005, the WHO, the international agency that coordinates public health for the United Nations, initiated the International Classification for Patient Safety (IC4PS). IC4PS 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. The goal of the WHO is to define, harmonize, and group patient safety concepts through a classification that links closely with other WHO Family of International Classifications.[9]

In 2007, HPI compiled the current nationally recognized and/or endorsed safety event nomenclatures. The HPI Safety Event Taxonomy (Appendix A) reflects an alignment, or harmonization, of various classification systems. The Safety Event Taxonomy periodically is updated to reflect changes as nationally endorsed safety event reporting standards and taxonomies continue to evolve. The harmonization current with the publication of this paper is found in Appendix B.

Section 2:
HPI Safety Event Classification (SEC)

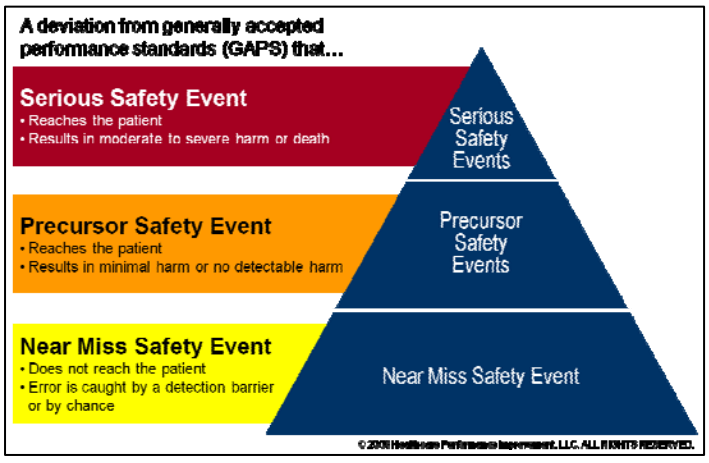
Unfortunate outcomes in healthcare occur. There are known complications of treatments and procedures deemed "worth the risk" when considering the likely outcome if the procedure is not performed. True accidents, such as a slip and fall of a patient appropriately evaluated as low fall risk, sometimes happen. And eventually, the human body fails despite all efforts. The reality is that not all bad outcomes result from defects in care.

Events of harm, however, 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 *harm* from *bad outcomes* through a reliable, repeatable method.

The Safety Event Classification (SEC), shown in Figure 1, provides this method and is the foundation for patient safety measurement.

Most current event taxonomies are categorical classifications in that 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 three steps further – the event is assessed for defects in care, or *deviations from generally accepted performance standards* (GAPS); a direct *cause-and-effect relationship* between deviations and the outcome is established, and, in the case of organizational or individual causation, the safety event is *classified according to level of patient harm* resulting from the event.

Figure 1. HPI Safety Event Classification (SEC)



[9] The World Health Organization, "The Conceptual Framework for the International Classification for Patient Safety," January 2009. Available online at http://www.who.int/patientsafety/taxonomy/en/. Accessed on 1March 2009.

Assessing for Deviations & Causation

Two of the three defining considerations of the SEC are the presence of a deviation from generally accepted performance standards (GAPS) and the extent to which the deviation caused the event.

Types of Deviations. There are two predominant types of performance deviations: (1) human acts, hereafter call *human errors*, and (2) equipment, device, and technology failures, hereafter called *equipment failures*. Human errors are the most common deviations leading to safety events. Human errors fall into five categories in the HPI Taxonomy of Individual Failure Modes (Appendix C-1) – competency of the individual, consciousness of the task at hand, communication of information, critical thinking in decision making, and compliance with known procedures and standards of care.

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. System weaknesses fall into five categories in the HPI Taxonomy of System Failure Modes (Appendix C-2) – organizational structure, organizational culture, work processes, policies and protocol, and environment and technology. Root causes of events nearly always are found as deficiencies in organizational systems.

Identifying Deviations. An organization can confirm deviations from GAPS by comparing expected performance with actual performance. Wherever a difference exists between expected and actual performance, a deviation from GAPS exists. Two things should be considered when identifying deviations. First, internal practice expectations do not always reflect best practice performance standards in protecting patients from harm. Consideration of performance standards 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). Second, standards rise over 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.

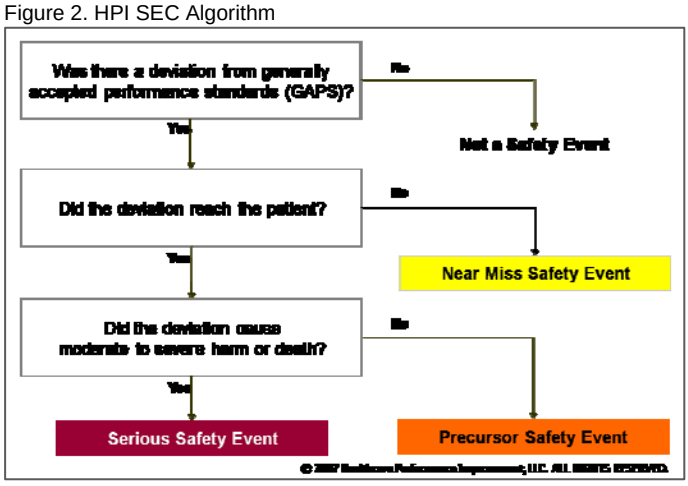
Assessing Causation. A direct cause-and-effect relationship between the deviation and the outcome to the patient is the second consideration in the SEC – did the deviation result in harm to the patient? While deviations from performance standards may coincide with a serious outcome, a direct cause and 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 cause analysis 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.

Organizational causation may not be immediately apparent. More evaluation, such as medical staff or nursing peer review, may be necessary to determine whether the organization deviated from performance standards. However, waiting until this determination is made could have an unacceptable impact on the quality of root cause analysis as information may be lost or degrade in the intervening time. Hospitals should move to collect and preserve critical information (e.g., statements from involved individuals, physical evidence) should a root cause analysis be deemed necessary based on the peer review results or other evaluation processes.

Assessing Outcome to the Patient

Once a deviation from generally accepted performance standards is identified, the third level of assessment assesses the level of harm experienced by the patient and determines the safety event classification. A **Serious Safety Event** results in harm that ranges from moderate to severe patient harm or death. A **Precursor Safety Event** results in minimal harm, no detectable harm, or no harm. In a **Near Miss Safety Event**, 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 2. HPI SEC Algorithm



The SEC Levels of Harm are outlined below in Table 1, and detailed definitions and event examples of each SEC level of harm are provided in Appendix D. A harmonization of the SEC and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) severity index is found in Appendix E. The SEC also has been harmonized with numerous state-specific reporting systems including Pennsylvania, Texas, and Florida. Harmonizations of the SEC with these and other state reporting system requirements are available upon request.

Table 1. HPI SEC Levels of Harm

HPI SEC	Code	Level of Harm
Serious Safety Event (SSE)	**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**	Minimal Permanent Harm
	PSE 2	Minimal 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

Near Miss Safety Event Classification

When it comes to Near Miss Safety Events, classification is all about the strength of the detection barrier that caught the error before it reached the patient. 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.

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-cross-match 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.

Considering "Known Complications"

As previously referenced, clinical complications are a known and understood possible result of certain high-risk 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 generally accepted standards of care. Distinguishing between known complications and safety events, however, can be challenging. 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.

Four questions comprise the Known Complications Test and can be applied when a potential complication is identified. The first question considers the decision to proceed with the procedure, treatment, or test:

1. Was the procedure, treatment, or test appropriate or warranted for the patient based on nationally recognized standards of care?

If it is determined that care was not warranted, the decision to provide the procedure, treatment, or test should be considered a deviation from expected procedures or standards of care, and the event should be classified as a safety event for further evaluation. If the procedure, treatment, or test is determined to be appropriate and warranted, the next step is to determine if the event was either a known complication or a safety event using the following three questions:

2. Was the complication a known risk and was the standard of care employed to mitigate risk?
3. Was the complication identified in a timely manner?
4. Was the complication treated according to the standard of care and done in a timely manner?

An affirmative answer to each question suggests the outcome should be classified as a "known complication" in which there was no deviation from generally accepted performance standards and for which there was no organizational causation. If the answer to any of the questions is negative, the event is classified as a safety event. To prevent inappropriately labeling true safety events as known complications, conservative assessment should be applied. The burden of proof should rest in demonstrating that the outcome is not the result of a known complication, rather than demonstrating that the outcome was a known complication. An application example of the Known Complications Test is shown below.

Application Example of the HPI Known Complications Test

Consider a case of an undiscovered small bowel injury in 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. Specific questions that the hospital may consider when applying the Known Complications Test are suggested below:

Question 1: Was the complication a known risk and were standard of care steps taken to mitigate it?

- *Does unplanned small bowel injury fall within the range of expected outcomes for a lysis of adhesions in a patient with multiple prior abdominal operations based on current literature and clinical experience?*
- *Was small bowel injury identified as a known risk in the informed consent process?*
- *Did the surgeon exhibit sufficient care in avoiding small bowel injury and did he/she take all reasonable steps to ascertain whether injury had occurred at the first procedure?*

Question 2: Was the complication identified in a timely manner?

- *Should the injury have been identified in the original procedure?*
- *Given that the injury was not identified at the original procedure, was the patient promptly and correctly treated once symptoms of the complication were manifest?*

Question 3: Was the complication treated according to standard of care and in a timely manner?

- *Was the failure to identify the injury at the original operation clearly below standard of care?*
- *Was the treatment of the complication, once apparent, promptly implemented and were all aspects of the repair procedure and the care of the patient in the perioperative period within the highest standards of care?*

Are All "Sentinel Events" & "Never Events" SEC Serious Safety Events?

Joint Commission sentinel events and NQF never events are *not necessarily* Serious Safety Events in the SEC. While Joint Commission sentinel events and NQF never events reach the patient, there are two reasons why these events may not qualify as a Serious Safety Event. First, the organization may have provided care that met standard of care and practice expectations. Second, the event may not result in level of harm associated with a SEC Serious Safety Event. A wrong site laminectomy provides an example of the second condition. A patient requires a laminectomy on vertebral levels 3

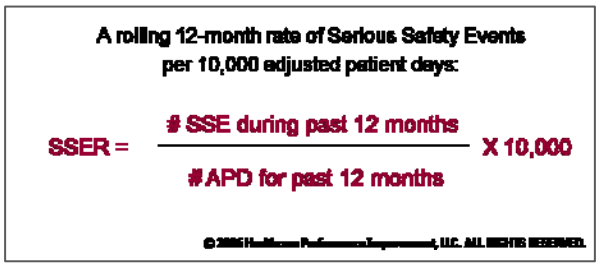
and 4. The plan of care is to perform the procedures in two separate operations. The patient consents for the procedure on vertebral level 3, however, the laminectomy is incorrectly performed on level 4. The event qualifies as a Joint Commission sentinel event and NQF never event, however, as the procedure resulted in no harm to the patient, the event is classified as a Precursor Safety Event in the SEC.

Case studies in safety event classification using the HPI SEC are found in Appendix F and can be used for individual or team consideration.

Section 3:
HPI Serious Safety Event Rate (SSER)

The SEC serves as the foundation for the calculation of the Serious Safety Event Rate (SSER). The SSER is a volume-adjusted measure of Serious Safety Events, those events occurring from a deviation from generally accepted performance standards and resulting 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 for the same time period, as shown in Figure 3.

Figure 3. Serious Safety Event Rate calculation



The 12-month rolling rate provides two benefits. First, as Serious Safety Events do not occur frequently, it presents a clearer picture of event rate trend. Second, 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.

Section 4:
Applying the HPI SEC & SSER Patient Safety Measurement System

The SEC and SSER complement the required and/or desired tracking and reporting of Joint Commission-defined sentinel events, NQF serious adverse safety events, and other state-required reportable events and serves to transcend variation in different event taxonomies that exist in healthcare today. Yet to enable a safety measurement system that provides a reliable and valid measure of safety performance over time, two factors are important – comprehensive capture of events and 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 reporting culture is not the focus of this paper, brief comment is offered on three factors that influence the health of reporting culture.

First, leaders, workers, and medical staff members have to know what should be reported. Most individuals report events that result in harm to the patient or have the significant potential to result in harm. It is less clear, however, 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 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 making, employees are less inclined to report an event. Finally, the reporting process must be as simple as possible, i.e., employees need 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 some hospitals have adopted centralized reporting and data repository for error and events, most hospitals have multiple reporting processes and information systems. At a minimum, the following should be considered as sources of events for assessment as Serious Safety Events:

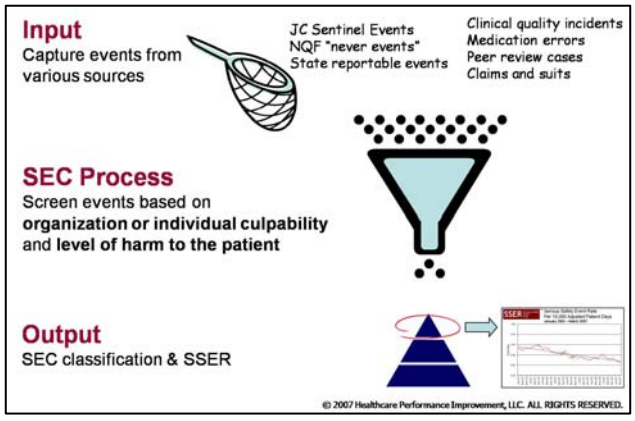
- Events qualifying as Joint Commission-defined sentinel events;
- State-reportable safety events and/or other regionally recognized reportable event;
- Clinical quality indicator incident and surveillance data including, but not limited to, nationally established NQF never events and AHRQ Adult and Pediatric Patient Safety Indicator variances such as falls with injury, stage 3 and 4 pressure ulcers, restraint use with injury, and hospital-acquired infections resuscitation codes;
- Events reported through the medical and nursing peer review process;
- Global triggers or adverse drug events classified by NCC MERP criteria C through I
- Patient concerns or complaints; and
- Claims and suits.

Consistent Application of HPI SEC Criteria

Several factors may contribute to variation in accuracy of event capture 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 the event has 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.

The effectiveness of any measurement system requires consistent application over time. While it is important to accurately classify events in the SEC, it is more important to *consistently* classify events in the SEC categories to ensure a reliable lagging indicator of organizational patient safety performance. This requires that the safety event determination is made by a group of knowledgeable, objective individuals. To maximize consistency in event classification, many organizations using the SEC have trained a small, defined group in safety event classification and charged this group with the responsibility of determining the final classification of a safety event.

Figure 4. Serious Safety Event detection and screening



HPI Safety Event Detection Assessment Survey for Hospitals℠

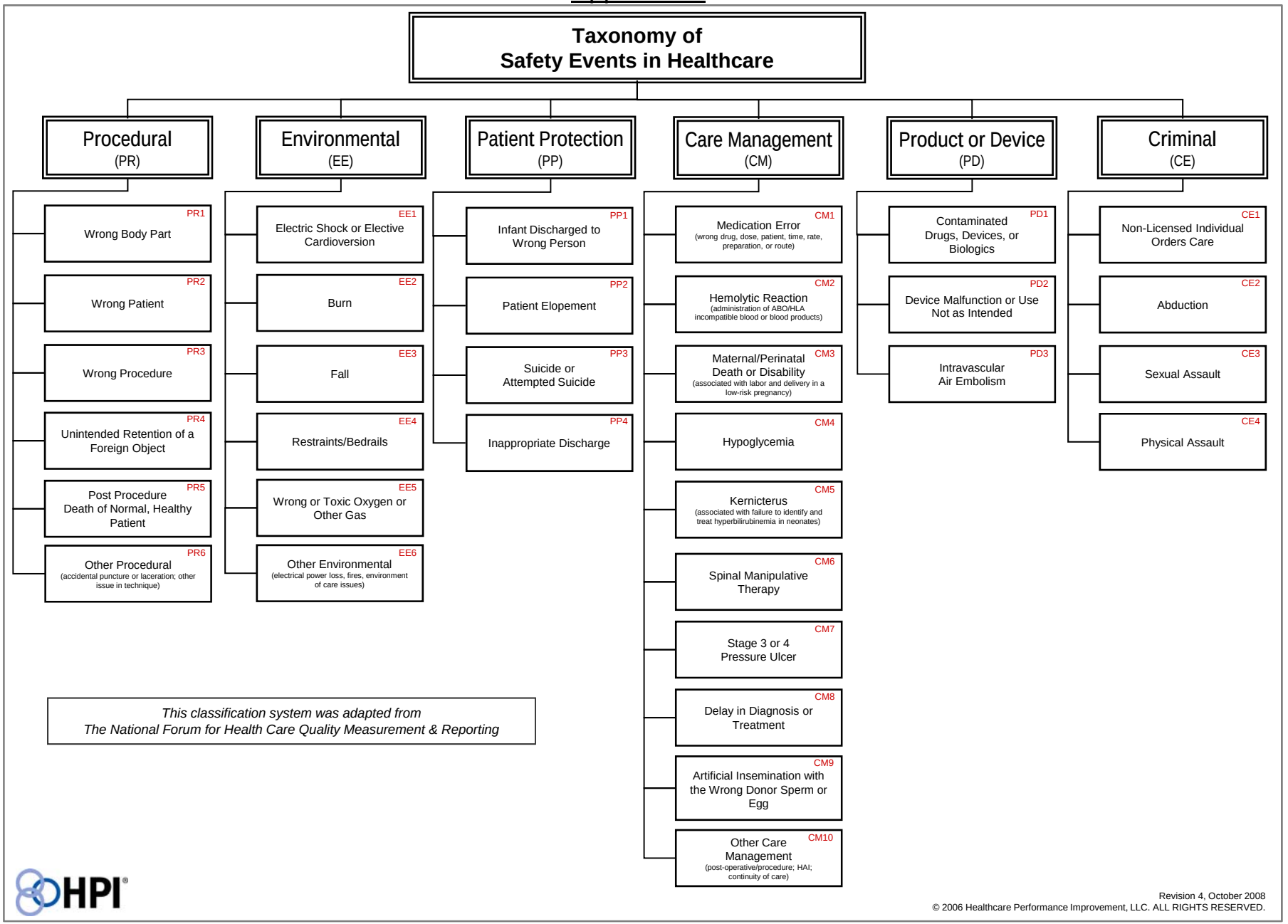
The step-wise approach for identifying possible safety events, accurately screening events to determine if they are Serious Safety Events, and calculating the SSER is shown in Figure 4. HPI developed the Safety Event Detection Assessment Survey for Hospitals to aid organizations in assessing the comprehensiveness 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 determine classification as a safety event. Survey results assist the organization in identifying strengths and gaps in safety event detection and screening processes that enable action planning to further develop and advance capabilities. Results from the survey administration can be compared to better practice organizations for benchmarking.

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 with the SSER of another organization for the purpose of goal setting or drawing conclusions about which organization is more or less safe. However, comparisons of the direction of SSER trend lines based on marked milestones and comparisons of the percent of SSER reduction following implementation of safety culture improvement efforts provide valuable benchmarking information.

Within organizations 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 self-awareness of organization contribution to safety events, and refine event classification at the line of moderate harm and minimal harm. At the time of this writing, a pilot group of 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 variation and improve inter-rater reliability, the SSER has the potential to become a very useful comparative indicator across organizations.

Appendix A



Appendix B
HPI Taxonomy of Safety Events in Healthcare
Harmonization with Event Classifications

This crosswalk aligns HPI Safety Event Taxonomy categories with nationally recognized and other endorsed healthcare related safety events. Nationally endorsed metrics designed as patient safety "triggers" or markers have been incorporated. It is based on information published and available as of March 2009.

HPI Safety Event Category	NQF Serious Event[2]	Joint Commission Voluntary Reportable Events[4]	Joint Commission Sentinel Event Alerts[4]	DoD Safety Center Safety Alert[5]	VA National Center for Patient Safety SAC Matrix[6]	Harvard Risk Foundation High Risk Areas[3]	AHRQ PSI Indicator[1]
PR: PROCEDURAL			Issue 12: Operative and Post-Operative Complications – Lessons for the Future (2000)			Surgical (see also Care Management)	
PR1: Wrong Body Part	Surgery performed on wrong body part	Surgery on the wrong individual or wrong body part	Issue 24: A Follow-Up Review of Wrong Site Surgery (2001) Issue 6: Lessons Learned: Wrong Site Surgery (1998)		Surgery/Procedure on the wrong patient or body part		
PR2: Wrong Patient	Surgery performed on wrong patient						
PR3: Wrong Procedure	Wrong surgical procedure performed on a patient						
PR4: Unintended Retention of a Foreign Object	Unintended retention of a foreign object in a patient after surgery or other procedure	Surgical instrument or object left in a patient after surgery or another procedure					PSI 5 & PDI 3: Foreign Body Left During Procedure
PR5: Post Procedure Death of Normal Healthy Patient	Intraoperative or immediately post-operative death in an ASA Class I patient						
PR6: Other Procedural *accidental puncture, laceration or other issues in technique*							PSI 15 & PDI 1: Accidental Puncture or Laceration
EE: ENVIRONMENTAL							
EE1: Electric Shock or Elective Cardioversion	Patient death or serious disability associated with an electric shock or electric cardioversion while being cared for in a healthcare facility						

HPI Safety Event Category	NQF Serious Event[2]	Joint Commission Voluntary Reportable Events[4]	Joint Commission Sentinel Event Alerts[4]	DoD Safety Center Safety Alert[5]	VA National Center for Patient Safety SAC Matrix[6]	Harvard Risk Foundation High Risk Areas[3]	AHRQ PSI Indicator[1]
EE2: Burn	Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility		Issue 38: Prevent Accidents/Injuries in MRI Suite				
EE3: Fall	Patient death or serious disability associated with a fall while being cared for in a healthcare facility		Issue 14: Fatal Falls – Lessons for the Future (2000)		Death or major permanent loss of function that is a direct result of injuries sustained in a fall		
EE4: Restraints/Bedrails	Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility		Issue 27: Bed Rail-Related Entrapment Deaths (2002) Issue 8: Preventing Restraint Deaths				
EE5: Wrong or Toxic Oxygen or Other Gas	Any incident in which a line designated for oxygen or other gas to be delivered to the patient contains the wrong gas or is contaminated by toxic substances		Issue 21: Medical Gas Mix-Ups (2001)	Issue 4: Medical Gas Sentinel Event (2005)			
EE6: Other Environmental *electrical power loss; fires; environment of care issues*			Issue 38: Prevent Accidents/Injuries in MRI Suite Issue 37: Preventing Adverse Events Caused by Emergency Electrical Power Failures (2006) Issue 29: Preventing Surgical Fires (2003) Issue 17: Lessons Learned – Fires in the Home Care Setting (2001)				
PP: PATIENT PROTECTION							
PP1: Infant Discharged to Wrong Person	Infant discharged to the wrong person	Infant abduction, or discharge to the wrong family			Infant discharge to wrong family		

HPI Safety Event Category	NQF Serious Event[2]	Joint Commission Voluntary Reportable Events[4]	Joint Commission Sentinel Event Alerts[4]	DoD Safety Center Safety Alert[5]	VA National Center for Patient Safety SAC Matrix[6]	Harvard Risk Foundation High Risk Areas[3]	AHRQ PSI Indicator[1]
PP2: Patient Elopement	Patient death or serious disability associated with patient elopement (disappearance)				Death or major permanent loss of function that is associated with an unauthorized departure from an around-the-clock treatment setting		
PP3: Suicide or Attempt	Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	Suicide in a continuous care setting, or within 72 hours of discharge	Issue 7: Inpatient Suicides – Recommendations for Prevention (1998)		Suicide		
PP4: Inappropriate Discharge							
CM: CARE MANAGEMENT							
CM1: Medication Error *wrong drug, dose, patient, time, rate, preparation, or route*	Patient death or serious disability associated with medication error (e.g. errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	Radiation therapy to wrong body region or 25% above the planned dose	Issue 41: Preventing Errors Related to Commonly Used Anticoagulants Issue 39: Preventing Pediatric Medication Error Issue 35: Using Medication Reconciliation to Prevent Errors (2006) Issue 34: Preventing Vincristine Administration Errors (2005) Issue 33: Patient Controlled Analgesia by Proxy (2004) Issue 23: Medication Errors Related to Potentially Dangerous Abbreviations (2001) Issue 19: Look-Alike Sound-alike Drug Names (2001) Issue 16: Mix-Up Leads to a Medication Error (2001) Issue 11: High-Alert Medications & Patient Safety	Issue 8: Fentanyl Transdermal Patches (2006) Issue 7: Topical Benzocaine Spray (2006) Issue 5: Acetic Acid & Trichloracetic Acid Solution Mix-Up Result in Patient Harm (2005) Issue 3: Acetaminophen & Ibruprofen Pediatric Liquid (2005) Issue 2: Insulin & Tuberculin Syringe Packaging (2004) Issue 1: Electrolyte Solutions & High Dose Epinephrine (2003)		Medication -related Events	

HPI Safety Event Category	NQF Serious Event[2]	Joint Commission Voluntary Reportable Events[4]	Joint Commission Sentinel Event Alerts[4]	DoD Safety Center Safety Alert[5]	VA National Center for Patient Safety SAC Matrix[6]	Harvard Risk Foundation High Risk Areas[3]	AHRQ PSI Indicator[1]
CM2: Hemolytic Reaction *administration of ABO/HLA-incompatible blood or blood products*	Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products	Hemolytic transfusion reaction due to blood group incompatibilities	Issue 10: Blood Transfusion Errors – Preventing Future Occurrences (1999)		Hemolytic transfusion reaction		PSI 16 & PDI 13: Transfusion Reaction
CM3: Maternal/Perinatal Death or Disability *associated with labor and delivery in a low-risk pregnancy*	Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Unexpected death of a full term infant	Issue 30: Preventing Infant Death & Injury During Delivery (2004)			Obstetrical Complications	PSI 17: Birth Trauma – Injury to Neonate PSI 18: Obstetric Trauma – vaginal Delivery with Instrument PSI 19: Obstetric Trauma – Vaginal Delivery Without Instrument PSI 20: Obstetric Trauma – Cesarean Delivery
CM4: Hypoglycemia	Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility						
CM5: Kernicterus *associated with failure to identify and treat hyperbilirubinemia in neonates*	Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	Severe neonatal jaundice (billirubin greater than 30 milligrams /deciliter	Issue 31: Revised Guidance to Help Prevent Kernicterus (2004) Issue 18: Kernicterus Threatens Healthy Newborns (2001)				
CM6: Spinal Manipulative Therapy	Patient death or serious disability due to spinal manipulative therapy						
CM7: Stage 3 or 4 Pressure Ulcer	Stage 3 or 4 pressure ulcers acquired after admission to the healthcare facility						PSI 3: Decubitus Ulcer
CM8: Delay in Diagnosis or Treatment			Issue 26: Delays in Treatment (2002)			Missed, Delayed, or Incorrect Diagnosis	PDI 4: Failure to Rescue
CM9: Artificial Insemination with Wrong Donor Sperm or Egg	Artificial Insemination with wrong donor sperm or donor egg						

HPI Safety Event Category	NQF Serious Event[2]	Joint Commission Voluntary Reportable Events[4]	Joint Commission Sentinel Event Alerts[4]	DoD Safety Center Safety Alert[5]	VA National Center for Patient Safety SAC Matrix[6]	Harvard Risk Foundation High Risk Areas[3]	AHRQ PSI Indicator[1]
CM10: Other Care Management *post-operative; post-procedure; hospital-acquired infections; continuity of care issues*			*(see also Issue 12: Procedural)* Issue 32: Preventing & Managing Impact of Anesthesia Awareness (2004) Issue 28: Infection Control Related Sentinel Events (2003) Issue 25: Preventing Ventilator-Related Deaths & Injuries (2002)			Surgical Complications	PSI 1: Complications of Anesthesia (see also CM1) PSI 7 & PDI 12: Selected Infections Due to Medical Care PSI 8: Postoperative Hip Fracture PSI 9 & PDI 8: Postoperative Hemorrhage or Hematoma (See also CM8) PSI 10: Postoperative Physiologic & Metabolic Derangements (See also CM8) PSI 11 & PDI 9: Postoperative Respiratory Failure (see also CM8) PSI 12: Postoperative Pulmonary Embolism or Deep Vein Thrombosis (See also CM8) PSI 13 & PDI 10: Postoperative Sepsis PSI 14: Postoperative Wound Dehiscence in Abdominopelvic Surgical Patients PDI 11: Postoperative Wound Dehiscence PDI 6: Pediatric Heart Surgery Mortality PDI 7: Pediatric Heart Surgery Volume PSI 2: Death in Low Mortality DRGs PSI 6: Iatrogenic Pneumothorax PDI 4: Iatrogenic Pneumothorax in Neonates at Risk PDI 5: Iatrogenic Pneumothorax in Non-neonates (See also CM8)

HPI Safety Event Category	NQF Serious Event[2]	Joint Commission Voluntary Reportable Events[4]	Joint Commission Sentinel Event Alerts[4]	DoD Safety Center Safety Alert[5]	VA National Center for Patient Safety SAC Matrix[6]	Harvard Risk Foundation High Risk Areas[3]	AHRQ PSI Indicator[1]
PD: PRODUCT OR DEVICE							
PD1: Contaminated Drugs, Devices or Biologics	Patient death or serious disability associated with use of contaminated drugs, devices, or biologics provided by the health care facility		Issue 20: Exposure to Creutzfeldt-Jakob Disease (2001)				
PD2: Device Malfunction or Use Not as Intended	Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended		Issue 15: Infusion Pumps – Preventing Future Adverse Events (2000) Issue 36: Tubing Misconnections – a Persistent & Potentially Deadly Occurrence (2006)	Issue 6: Stryker EZ-Pro R4 Ambulance Cot (2005)			
PD3: Intravascular Air Embolism	Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility						
CE: CRIMINAL							
CE1: Non-Licensed Individual Orders Care	Any instance of care ordered or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider						
CE2: Abduction	Abduction of a patient of any age		Issue 9: Infant Abductions – Preventing Future Occurrences (1999)		Infant abduction		
CE3: Sexual Assault	Sexual assault on a patient within or on the grounds of the healthcare facility	Rape in a continuous care setting			Rape		
CE4: Physical Assault	Death or significant injury of a patient or staff member resulting from a physical assault (i.e. battery) that occurs within or on the grounds of the healthcare facility				Death or major permanent loss of function that is the result of an assault or other crime		

Sources Cited

[1] **AHRQ Quality Indicators:** www.qualityindicators.ahrq.govwww.qualitymeausures.ahrq.gov (Last Accessed February 12, 2007)

- Used by hospitals to identify potential adverse events that may need further study
- Provides opportunity to assess the incidence of adverse events and in hospital complications using administrative data found in typical discharge record
- Standardized methodology and algorithm software that can be downloaded from AHRQ website at no cost
- National aggregate comparative (benchmark) results available on AHRQ website
- PDI (pediatric) and PSI (adult) indicators

[2] **National Quality Forum Endorsed Serious Reportable Events in Healthcare** (2006) www.qualityforum.org (Last Accessed February 13, 2007)

[3] **Harvard Risk Foundation High Risk Areas**: http://www.rmf.harvard.edu/high-risk-areas/index.aspx (Last Accessed February 18, 2007)

- **Missed, delayed, or incorrect diagnoses** account for approximately one-quarter of all malpractice cases naming CRICO/RMF-insured providers. Colorectal and breast cancer cases are the most common type filed.
- While the frequency of **obstetrical** malpractice claims has remained relatively stable among those insured by CRICO/RMF, the severity of claims and potential for large pay-outs has risen.
- Selecting, ordering, preparing, administering, and monitoring **medications** is a complex, ongoing process and remains a high priority area.
- **Surgery-related** claims are the second highest category of cases asserted against CRICO-insured providers over the past 10 years

[4] **The Joint Commission Sentinel Event Alert:** www.jointcommission.org/SentinelEvents/SentinalEventAlert/ (Last Accessed February 06, 2009)
Sentinel Event defined as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a person or persons, not related to the natural course of the patient's illness. These sentinel events specifically include loss of limb or gross motor function, and any event for which a recurrence would carry a risk of serious adverse outcome. Sentinel events also include the following, even if the outcome was not death or major permanent loss of function:

- Infant abduction or discharge to the wrong family
- Unexpected death of a full term infant
- Sever neonatal jaundice (bilirubin over 30 milligrams/deciliter)
- Surgery on the wrong individual or wrong body part
- Surgical instrument or object left in a patient after surgery or another procedure
- Rape in a continuous care setting
- Suicide in a continuous care setting, or within 72 hours of discharge
- Hemolytic transfusion reaction due to blood group incompatibilities
- Radiation therapy to the wrong body region or 25% above the planned dose

Sentinel Event Alerts # 1-5 *not included in harmonization matrix; these reflect Joint Commission operational processes and hospital related accountabilities.* ***Sentinel Event Alert # 13*** *(Making an Impact on Health Care) also not included;* ***Sentinel Event Alert #40*** *(Behaviors that Undermine a Patient of Safety) is overarching as behavior reflects how an individual may or may not act within their safety culture).****Sentinel Event Alert # 42*** *(Safely Implementing Health Information and Conversing Technologies) not specifically included – the outcome of problems in this area may relate to numerous event-related outcomes (e.g. Care Management categories)*

[5] **US Department of Defense Patient Safety Program**. DoD Patient Safety Center –Safety Alerts. www.patientsafety.satx.disa/nil (Last Accessed February 12, 2007)

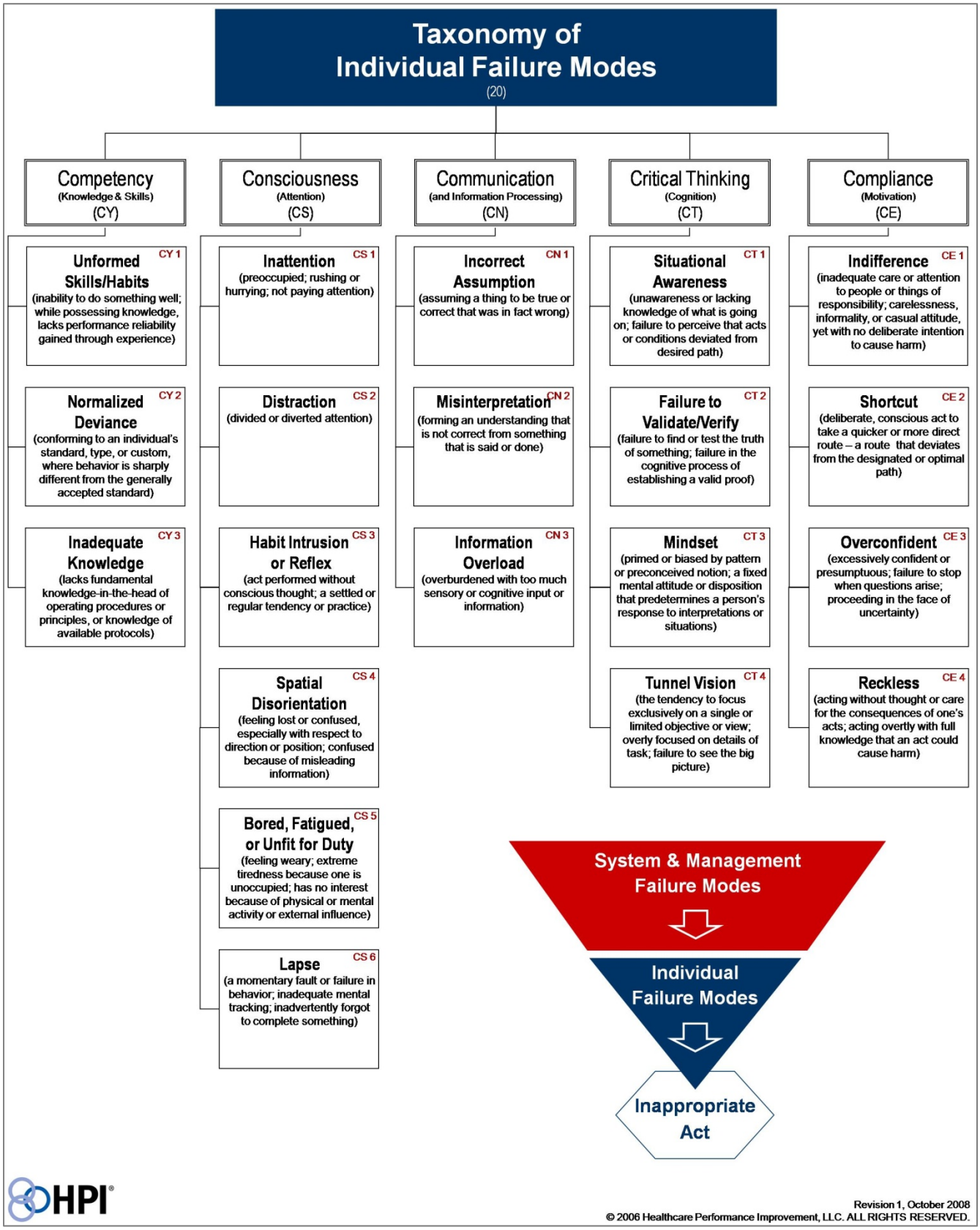
[6] **US Department of Veteran Affairs. National Center for Patient Safety**. Safety Assessment Code (SAC) Matrix) www.va.gov/NCPS/ (Last Accessed February 12, 2007)
SAC Matrix pairs a severity category with a probability category for either an actual event or close call. These ranks (1 = lowest risk to 3 = highest risk) can then be used for comparative analysis. Categories include Catastrophic; Major; Moderate; and Minor *(Both Catastrophic and Major are included in this harmonization matrix).*
Catastrophic category includes:

- Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission) OR Death or major permanent loss of function that is the direct result or a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the results of an assault or other crime
- Suicide
- Rape
- Surgery/procedure on the wrong patient or wrong body part
- Infant abduction or infant discharge to the wrong family

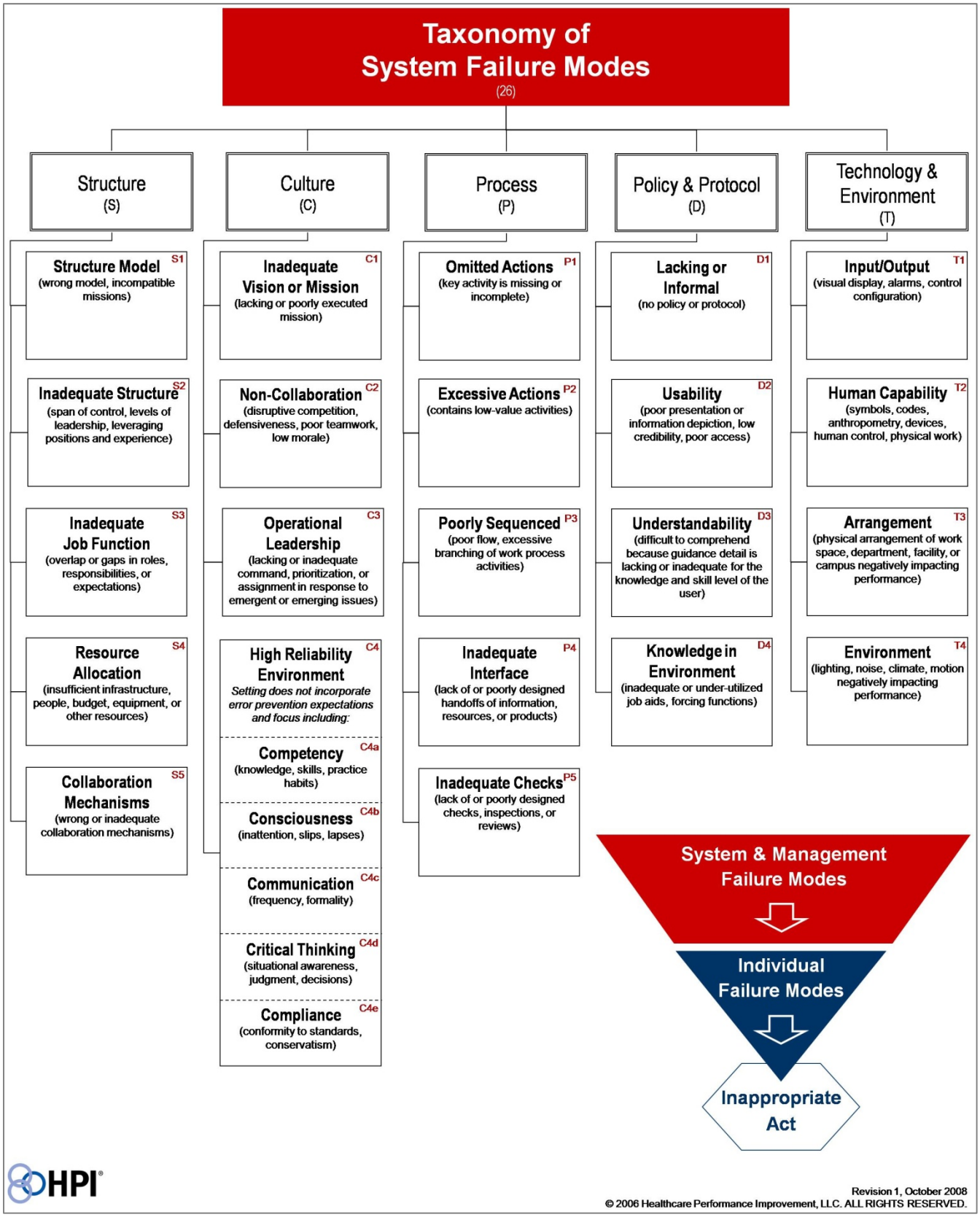
Major category includes:

- Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e. acts of commission or omission)
- Disfigurement requiring surgical intervention
- Increased length of stay (more than three patients)
- Increased level of care (more than three patients)

Appendix C-1



Appendix C-2



Appendix D

HPI Safety Event Classification[SM] (SEC) Levels of Harm

Safety Event classification applies if a deviation from Generally Accepted Performance Standards (GAPS) causes, or results in, the event

	Code	Level of Harm	Description
Serious Safety Event	SSE 1	Death	A deviation in GAPS resulting in death
	SSE 2	Severe Permanent Harm	A deviation in GAPS resulting in critical, life-changing harm with no expected change in clinical status; includes events resulting in permanent loss of organ, limb, or vital physiologic or neurologic function Example - Wrong site procedure resulting in removal of healthy limb - Missed diagnosis of stroke resulting in permanent impairment - Uterine rupture resulting in loss of uterus - Anoxic brain injury resulting in permanent brain damage - Incorrect radiologic contrast dosing resulting in need for permanent dialysis
	SSE 3	Moderate Permanent Harm	A deviation in GAPS resulting in significant harm with no expected change in clinical condition yet not sufficiently severe to impact activities of daily living or business functioning; includes events that result in permanent reduction in physiologic reserve, disfigurement, and impaired or aided sense or function Examples - Incorrect radiology contrast dosing resulting in reduced renal function - Inadvertent injury to spleen during abdominal surgery requiring removal of the spleen - Delay in treatment of limb ischemia requiring fasciotomy that results in minimal loss of function but disfiguring scars - Inappropriate intra-arterial medication injection resulting in loss of a finger, other than the thumb or 2nd finger which may qualify the event as SSE 2
	SSE 4	Severe Temporary Harm	A deviation in GAPS resulting in critical, potentially life-threatening harm yet lasting for a limited time with no permanent residual; requires prolonged transfer to a higher level of care/monitoring, transfer to a higher level of care for a life-threatening condition, or an additional major surgery, procedure, or treatment to resolve the condition Examples - Induced condition that requires resuscitation - Unrecognized fluid overload that progresses to pulmonary edema requiring transfer to the ICU for treatment - Failure to diagnose respiratory insufficiency resulting in temporary intubation where earlier recognition of the condition would have avoided the intubation - Preventable fall with hip fracture that requires surgical repair - Retained object that requires return to the operating room
	SSE 5	Moderate Temporary Harm	A deviation in GAPS resulting in significant harm lasting for a limited time; requires a higher level of care/monitoring or an additional minor procedure or treatment to resolve the condition Examples - Failure to treat a low potassium level that results in an arrhythmia requiring administration of intravenous anti-arrythmic drug, but with continued arrhythmia requiring extended monitoring and a higher intensity of care - Incorrect dose of dilaudid for pain resulting in over-sedation and requiring transfer to ICU for treatment and monitoring after narcan was ineffective in treating - Failure to routinely assess IV site resulting in an infection at IV site or (septic phlebitis) requiring extensive surgical incision and drainage to resolve - Incision made on the right knee instead of the left knee during an schedule knee replacement surgery

	Code	Level of Harm	Description
Precursor Safety Event	PSE 1	Minimal Permanent Harm	A deviation in GAPS resulting in minor harm with no expected change in clinical status; requires little or no intervention Examples - Inadequate protection of ulnar nerve during an operation resulting in numbness of 4th and 5th fingers - Excess radiation therapy resulting in skin color change in non-critical cosmetic area
	PSE 2	Minimal Temporary Harm	A deviation in GAPS resulting in minor harm lasting for a limited time only; requires little or no intervention Examples - Failure to assess IV site resulting in bruising or swelling - Retained sponge in vaginal cavity found and removed during office exam and resulting in no or minor infection - Administration of low dose insulin to a non-diabetic patient requiring only a glucose check and drink of orange juice - Incorrect dose of dilaudid for pain resulting in over-sedation and narcan resuscitation with immediate resolution - An anesthetic nerve block was performed on the right knee instead of the left knee in a scheduled knee replacement surgery before it was realized the wrong side had been anesthetized
	PSE 3	No Detectable Harm	A deviation in GAPS that reaches the patient yet without ability to determine the existence or fact of harm, yet harm may exist; includes events where the onset of harm may occur later in time Example - Procedure performed with un-sterile instruments with no detectable post-procedure complications or infection - Inappropriate technique resulting in losing coronary artery stent into systemic circulation with no evidence of limb or organ ischemia
	PSE 4	No Harm	A deviation in GAPS that reaches the patient yet results in no harm, with sufficient information available to determine that no harm occurred Example - Transfusion of blood intended for another patient yet of the correct blood type - Administration of an adult dose of vitamin K to a full term newborn infant with no resulting damage
Near Miss Event	NME 1	Unplanned Barrier Catch	A deviation in GAPS that passes through all error detection barriers and does not reach the patient because it is caught by chance or a barrier not designed into the system Example - 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 patient's nurse who ensures medication administration
	NME 2	Last Strong Barrier Catch	A deviation in GAPS that passes through early error detection barriers and is caught by a last strong error detection barrier designed into the system Example - Medication error caught by nurse performing "5 Rights" prior to administration - Wrong patient brought to the OR and identified during the team time out
	NME 3	Early Barrier Catch	A deviation in GAPS that is caught by an early error detection barrier designed into the system's defense in depth Example - Medication error identified when a contraindication alert fires in the pharmacy 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

Appendix E

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

This crosswalk aligns the HPI SEC Levels of Harm with the NCC MERP Severity Index Coding and is based on information published and available as of March 2009.

	HPI SEC Levels of Harm Healthcare Performance Improvement *Safety Event classification applies if a deviation from Generally Accepted Performance Standards (GAPS) causes, or results in, the event*		NCC MERP Severity Index Coding National Coordinating Council for Medication Error Reporting and Prevention (from *NCC MERP Index for Categorizing Medication Errors*, Copyright 2001)	
	Code	Description	Code	Description
Serious Safety Event	SSE 1 Death	A deviation in GAPS resulting in death	I	An error occurred that may have contributed to or resulted in the patient's death
	SSE 2 Severe Permanent Harm	A deviation in GAPS resulting in critical, life-changing harm with no expected change in clinical status; includes events resulting in permanent loss of organ, limb, or vital physiologic or neurologic function	H Also Consider SSE 4	An error occurred that required intervention necessary to sustain life
			G Also Consider SSE 3 PSE1	An error occurred that may have contributed to or resulted in permanent patient harm
	SSE 3 Moderate Permanent Harm	A deviation in GAPS resulting in significant harm with no expected change in clinical condition yet not sufficiently severe to impact activities of daily living or business functioning; includes events that result in permanent reduction in physiologic reserve, disfigurement, and impaired or aided sense or function	G Also Consider SSE 2 PSE 1	An error occurred that may have contributed to or resulted in permanent patient harm
	SSE 4 Severe Temporary Harm	A deviation in GAPS resulting in critical, potentially life-threatening harm yet lasting for a limited time with no permanent residual; requires prolonged transfer to a higher level of care/monitoring, transfer to a higher level of care for a life-threatening condition, or an additional major surgery, procedure, or treatment to resolve the condition	H Also Consider SSE 2	An error occurred that required intervention necessary to sustain life
			E Also Consider SSE 5 PSE 2	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
	SSE 5 Moderate Temporary Harm	A deviation in GAPS resulting in significant harm lasting for a limited time; requires a higher level of care/monitoring or an additional minor procedure or treatment to resolve the condition	F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
			E Also Consider SSE 4 PSE 2	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention

	HPI SEC Levels of Harm Healthcare Performance Improvement *Safety Event classification applies if a deviation from* *Generally Accepted Performance Standards (GAPS) causes, or results in, the event*		NCC MERP Severity Index Coding National Coordinating Council for Medication Error Reporting and Prevention (from *NCC MERP Index for Categorizing Medication Errors*, Copyright 2001)	
	Code	Description	Code	Description
Precursor Safety Event	PSE 1 Minimal Permanent Harm	A deviation in GAPS resulting in minor harm with no expected change in clinical status; requires little or no intervention	G Also Consider SSE 2 SSE 3	An error occurred that may have contributed to or resulted in permanent patient harm
	PSE 2 Minimal Temporary Harm	A deviation in GAPS resulting in minor harm lasting for a limited time only; requires little or no intervention	E Also Consider SSE 4 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	A deviation in GAPS that reaches the patient yet without ability to determine the existence or fact of harm, yet harm may exist; includes events where the onset of harm may occur later in time	D Also Consider PSE 2	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 4 No Harm	A deviation in GAPS that reaches the patient yet results in no harm, with 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 GAPS that passes through all error detection barriers and does not reach the patient because it is caught by chance or a barrier not designed 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 GAPS that passes through early error detection barriers and is caught by a last strong error detection barrier designed into the system	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)
	NME 3 Early Barrier Catch	A deviation in GAPS that is caught by an early error detection barrier 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)

Appendix F

HPI Safety Event Classification[SM] (SEC) Case Studies

Case #1

A 72-year-old female, admitted to the critical care unit with congestive heart failure, 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 needs immediate intervention for acute myocardial infarction was performed, there was a significant delay in treatment.
SEC Classification	SSE
Level of Harm	SSE1: Death
Safety Event Type	CM8: Delay in Diagnosis or Treatment

Case #2

A patient presents to the Emergency Department complaining of chest pain and is admitted to rule out myocardial infarction (MI). A CT scan is performed in which there is 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. After acute MI has been ruled out, the patient is discharged home without confirmation and/or treatment for the atrial thrombus. Two weeks later, the patient presents to the Emergency Department 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 necessary information needed to diagnose and treat the patient was available at the time of the initial hospitalization, yet the condition was not adequately assessed or appropriately treated.
SEC Classification	SSE
Level of Harm	SSE2: Severe Permanent Harm (delay in treatment resulted in loss of function of one kidney)
Safety Event Type	CM8: Delay in Diagnosis or Treatment

Case #3

An elderly patient is admitted with congestive heart failure and is on multiple medications including sedative agents. The patient, evaluated for fall risk per policy, is determined to be high risk. The fall protocol calls for bed alarms and leg alarms to be applied, along with educating the patient about the need to call for help before getting up for any reason. None of these interventions are completed. The next day, the patient falls and is found by a respiratory therapist on the floor. She is complaining of intense hip and leg pain. Evaluation determines that she has a hip fracture as a result of this fall, requiring surgical repair.

Deviation from GAPS?	Yes. Although the patient was assessed as high-risk for a fall, the protocol-defined interventions to prevent this occurrence were not implemented.
SEC Classification	SSE
Level of Harm	SSE4: Severe Temporary Harm (hip fracture requires surgical repair)
Safety Event Type	EE3: Fall

Case #4

A 75-year-old is admitted for treatment of pneumonia. Admitting orders from a different patient are entered on this patient's medical record inadvertently, one order of which is "Lorazepam 1mg by mouth three times daily." The patient receives six doses of Lorazepam. He becomes confused, requires a foley catheter, and then pulls it out due to his confusion. This requires a urological procedure to correct the urethral damage.

Deviation from GAPS?	Yes. The patient received multiple doses of a medication intended for another patient.
SEC Classification	SSE
Level of Harm	SSE4: Severe Temporary Harm (serious adverse drug event requiring an additional intervention and unanticipated surgical intervention)
Safety Event Type	CM1: Medication Error

Case #5

A 65-year-old patient with chronic renal insufficiency is given contrast for a CT scan in error. The physician had ordered a CT scan without contrast, but the radiologist requested use of contrast without checking the patient's renal status. The patient's creatinine increases from 1.6 to 4.5, BUN is 89, potassium is 5.9, and he suffers fluid overload. After adequate trial with diuretics, the patient requires transfer to another facility for dialysis due to contrast media-induced renal failure. The patient's renal function eventually returns to baseline.

Deviation from GAPS?	Yes. The information regarding the patient's renal status was available but not considered by the radiologist in the decision making process. The patient subsequently developed contrast media induced renal failure.
SEC Classification	SSE
Level of Harm	SSE4: Severe Temporary Harm (contrast media-induced renal failure requiring hemodialysis to correct)
Safety Event Type	CM1: Medication Error

Case #6

A frail 82-year-old patient – admitted with a history of chronic respiratory disease (COPD) – is found on the floor. The side rails are in the up position, and the patient's call light is found tangled in the bedding. X-rays reveal a fractured left hip requiring surgical pinning. Two days postoperatively, the patient develops increasing oxygen desaturation and respiratory distress resulting in transfer to the ICU. Chest x-rays reveal pneumonia which does not respond well to treatment. Despite aggressive therapy, the patient expires three days after transfer to the ICU. Subsequent medical staff peer review determines that the pneumonia was not hospital-acquired and patient death could not have been prevented.

Deviation from GAPS?	Yes. Given the patient was at a high-risk for falls, an evaluation of fall prevention strategies would have been warranted including close observation and monitoring which does not appear to have been implemented.
SEC Classification	SSE
Level of Harm	SSE4: Severe Temporary Harm (fall with serious injury requiring a surgical procedure)
Safety Event Type	EE3: Fall

Case #7

The physician orders methadone for pain control for a 7-year-old patient status post surgical intervention for treatment of rhabdomyosarcoma. The nurse double-checks the medication calculation with another RN but does not request verification of the medication infusion pump setting as per hospital policy. The patient subsequently receives a 10-fold dose and experiences signs of respiratory compromise. The nurse realizing the setting error, immediately stops the pump, contacts the physician, and closely monitors the patient. A reversal agent is ordered and administered, and the patient is moved to the ICU for 24 hours for continuous monitoring. No further intervention is required.

Deviation from GAPS?	Yes. The medication infusion pump setting was not double-checked by another RN according to hospital policy.
SEC Classification	SSE
Level of Harm	SSE5: Moderate Temporary Harm (respiratory compromise required a reversal agent and more intense monitoring)
Safety Event Type	CM1: Medication Error

Case #8

A healthy 26-year-old 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 boy 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. Subsequent peer review of this unexpected death determines that the care and treatment were appropriate and that this death could not have been prevented.

Deviation from GAPS?	No
SEC Classification	This is not classified as a Safety Event. Despite the fact that a healthy mother expired post delivery, clinical review of the case determined that the patient died of an amniotic fluid embolism, which according to literature is an extremely rare, but known, complication with a mortality rate of 80% or greater. There was no deviation in generally accepted performance standards that led to the death.
Level of Harm	NA
Safety Event Type	NA

Case #9

A 56-year-old male is being treated in the Cardiac Progressive Care Unit with a heparin lock in place. As part of the routine hep-lock care, the nurse administers what she thinks is the usual hep-lock flush solution from an unlabeled syringe she previously placed at the bedside. The unlabeled syringe contains Cardizem, which she administers to the patient. The patient experiences an immediate hypotensive reaction, which quickly resolves without further incident.

Deviation from GAPS?	Yes. The nurse did not follow medication labeling requirements or medication verification procedures prior to medication administration.
SEC Classification	PSE
Level of Harm	PSE2: Minimal Temporary Harm (no apparent harm beyond the initial hypotensive reaction)
Safety Event Type	CM1: Medication Error

Case #10
A 52-year-old male admitted with severe anemia requires a blood transfusion. Another patient admitted to the same hematology unit with severe anemia also requires a blood transfusion. The 52-year-old with Type O blood is transfused with 2 units of Type A+ blood intended for the other patient. The patient receiving the wrong transfusion suffers 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. Verifications prior to blood administration were either not performed or not performed effectively.
SEC Classification	PSE
Level of Harm	PSE3: No Detectable Harm (no apparent harm at the time, though patient may have a suppressed reaction with another transfusion)
Safety Event Type	CM1: Medication Error

Case #11
A 47-year-old patient is admitted to a general medicine floor for treatment of diabetic ketoacidosis. The Maintenance Department is contacted to evaluate an equipment problem requiring repair. The technician utilizes a cleaning solution of diluted hydrogen peroxide during the repair process and draws a small amount of the solution in a syringe with a label for normal saline flush. The technician unintentionally leaves the syringe with cleaning solution at the bedside. A nurse enters the room to administer a medication requiring a saline flush and uses the syringe filled with cleaning solution. The technician later returns to complete the repairs, realizes the cleaning solution-filled syringe is missing, and finds the nurse. They notify the attending physicians, retrieve the MSDS forms, and the patient is monitored appropriately with no apparent harm from receiving the cleaning solution intravenously.

Deviation from GAPS?	Yes. Inappropriate supplies were used for the equipment repair process, and there was a lack of appropriate validation and verification of the syringe lying on the bed.
SEC Classification	PSE
Level of Harm	PSE3: No Detectable Harm
Safety Event Type	CM1: Medication Error

Case #12
A 60-year-old female undergoing a laparoscopic hysterectomy is discharged post-operatively without complications, with discharge instructions for a follow-up visit which is already scheduled. During this follow-up visit, the surgeon discovers and removes a surgical sponge retained in the vaginal space.

Deviation from GAPS?	Yes. The sponge count procedure was either not performed or not performed effectively.
SEC Classification	PSE
Level of Harm	PSE4: No Harm (sponge was removed during a routine examination with no additional surgical intervention)
Safety Event Type	PR4: Unintended Retention of a Foreign Object

Case #13
The physician treating an 85-year-old patient with Coumadin therapy prescribes new orders based on most recent laboratory results. The pharmacist preparing the medication does not seek clarification from the physician regarding this order and sent the MAR to the floor reflecting both the old and new dose. The nurse does not question the two doses and administers both the old and new dose. Scheduled laboratory results the next day show and elevated PT/INR, requiring another dose adjustment. The patient is monitored yet suffers no bleeding or long term harm from the error.

Deviation from GAPS?	Yes. The physician did not discontinue the prior dose, and neither the pharmacist nor the nurse questioned the two doses.
SEC Classification	PSE
Level of Harm	PSE2: Minimal Temporary No Harm (induced condition of over-thinned blood requiring a Coumadin dose adjustment and monitoring)
Safety Event Type	CM1: Medication Error

Case #14
A 55-year-old female with a very complex medical condition is admitted for a femoral artery bypass graft and subsequently transferred to the ICU post procedure with an arterial line in place. Due to an incomplete transfer assessment, the patient's arterial line is not connected to a monitor as required. The arterial line remains disconnected from the monitoring device for greater than 12 hours and is noticed at shift change by the nurse assuming care of the patient. While the patient remains unstable during much of the recovery period, no harm results from the period that the arterial line was not attached to the monitor.

Deviation from GAPS?	Yes. The nurse failed to complete a full transfer assessment and did not notice the unconnected arterial line.
SEC Classification	PSE
Level of Harm	PSE4: No Harm
Safety Event Type	CM10: Other Care Management

Case #15
Baby Boy A and Baby Boy B are scheduled for circumcisions on the same day. The pediatrician performs a circumcision on Baby Boy B after verbally confirming with the nursery nurse that this is the correct patient. Post procedure, the pediatrician discovers while documenting in the medical record that she performed the procedure on the Baby Boy B rather than Baby Boy A. The pediatrician informs the family of Baby Boy B of the mix-up and that the circumcision on their baby will be performed later that day.

Deviation from GAPS?	Yes. Pre-procedure record review and a complete time-out procedure were not performed.
SEC Classification	PSE
Level of Harm	PSE4: No Harm
Safety Event Type	PR2: Wrong Patient

Case #16
Breast feedings are prescribed for a baby in the NICU. The nurse reaches for donor milk without verifying the identification label and gives the milk to the baby. The parents are informed of the error, and subsequent follow-up testing reveals no adversity to the infant.

Deviation from GAPS?	Yes. The "5 rights" were not performed prior to feeding donor milk.
SEC Classification	PSE
Level of Harm	PSE4: No Harm
Safety Event Type	CM1: Medication Error

Case #17
The circulating nurse discovers post procedure that a laparoscopic procedure was performed on a patient in which the sterile processing biologic showed that the instrument may not have been thoroughly cleaned. The surgeon is informed immediately. The patient is monitored for possible infection over the next 30 days, with no subsequent harm.

Deviation from GAPS?	Yes. An instrument with a questionable sterile processing biologic was used during a laparoscopic procedure.
SEC Classification	PSE
Level of Harm	PSE4: No Harm (patient was monitored and suffered no infection)
Safety Event Type	PD1: Contaminated Drugs, Devices, or Biologics

Case #18
A 9-year-old male is admitted from the pediatrician's office with severe cellulitis from a dog bite requiring three days of IV antibiotic therapy prior to a 10 day outpatient antibiotic course of therapy. The pediatrician contacts the admitting physician by phone ahead of the patient's arrival. Based on this clinical information and initial nursing assessment, the admitting physician writes orders for IV Unasyn (penicillin and sulbactam). The patient's mother has communicated to both the admitting physician and nurse that her son is allergic to penicillin and Ancef. These medication allergies are clearly documented on the patient's medical record. The pharmacist overrides the allergy alert thinking that the physician is aware of the allergy and wants the patient to receive this medication. The nurse brings the medication to the bedside to begin IV administration. The mother states, "I just want to remind you that my son has had severe reactions to penicillin and Ancef." The nurse then realizes that Unasyn is a penicillin derivative, asks the mother for more information about her son's reactions (clarified as anaphylaxis) when these medications have been administered and contacts the physician to alter the order prior to administration.

Deviation from GAPS?	Yes. The admitting physician missed the allergy to penicillin, and the pharmacist did not verify the contraindicated order.
SEC Classification	NME
Level of Harm	NME1: Unplanned Barrier Catch (nurse responded to the mother's reinforcement of her son's allergies)
Safety Event Type	NA

Case #19
Two patients with the same name are admitted to the same unit. Patient A's clinical treatment is to include administration of blood. The unit secretary enters the blood order on the wrong patient, Patient B. The nurse draws the pre-transfusion blood specimen on Patient B instead of Patient A. After the blood work had been drawn, the patient questions the nurse regarding why this specimen was taken. When informed this is to type and cross-match blood for his upcoming transfusion, the patient informs the nurse that he is not supposed to receive any blood transfusion. Upon further investigation, the nurse identifies that there had been a mix-up in patients due to the same name and the transfusion is not administered.

Deviation from GAPS?	Yes. The unit secretary selected the wrong patient when entering the order, and the nurse did not check the order against orders in the medical record before drawing the specimen.
SEC Classification	NME
Level of Harm	NME1: Unplanned Barrier Catch (condition is identified when following up on concern voiced by patient)
Safety Event Type	NA

Case #20

A nurse is preparing to administer Zosyn to a patient. She notices on the Medication Administration Record (MAR) that the patient has an allergy to penicillin. She calls the physician to clarify whether the patient should receive this medication. The physician recognizes that she did not note the allergy when prescribing the Zosyn. The physician and the nurse clarify with the patient that she has a history of hives and difficulty breathing the last time she received penicillin two years ago. The order is changed and the patient does not receive the Zosyn. The nurse contacts the pharmacy to assure that the allergy is entered in the pharmacy computer.

Deviation from GAPS?	Yes. The physician did not consider the patient's medication allergies when writing the initial order.
SEC Classification	NME
Level of Harm	NME2: Last Strong Barrier Catch (condition is identified by a last defensive barrier in the medication administration process)
Safety Event Type	NA

Case #21

A physician writes an order for an inappropriately high dose of Heparin. The receiving pharmacist entering the order notes the dose and is concerned. The pharmacist calls the ordering physician to clarify the order. A correction is made, and the error does not reach the patient.

Deviation from GAPS?	Yes. The physician wrote an incorrect medication dose.
SEC Classification	NME
Level of Harm	NME3: Early Barrier Catch (error is detected early within a well-functioning safety net of detection barriers)
Safety Event Type	NA

Case #22

A 27-year-old male is admitted to an inpatient psychiatric unit. He is assessed as high risk for suicide, is dressed in a gown with snaps, and 15-minute checks are initiated. When conducting the routine checks as scheduled, a nurse finds the patient behind the bathroom door, having just dropped from a noose made from a partially torn strip of sheet (still attached to main sheet) and hung over the door. The nurse calls for assistance and immediately cuts the sheet, releasing the patient. The patient is assessed by the Code team and found in stable condition with no apparent harm.

Deviation from GAPS?	No. The patient had been appropriately assessed, appropriate suicide precautions were in place, and the 15 minute checks were being conducted routinely.
SEC Classification	Not a Safety Event (while a serious event, this is not a Safety Event as there was no deviation from GAPS)
Level of Harm	NA
Safety Event Type	NA