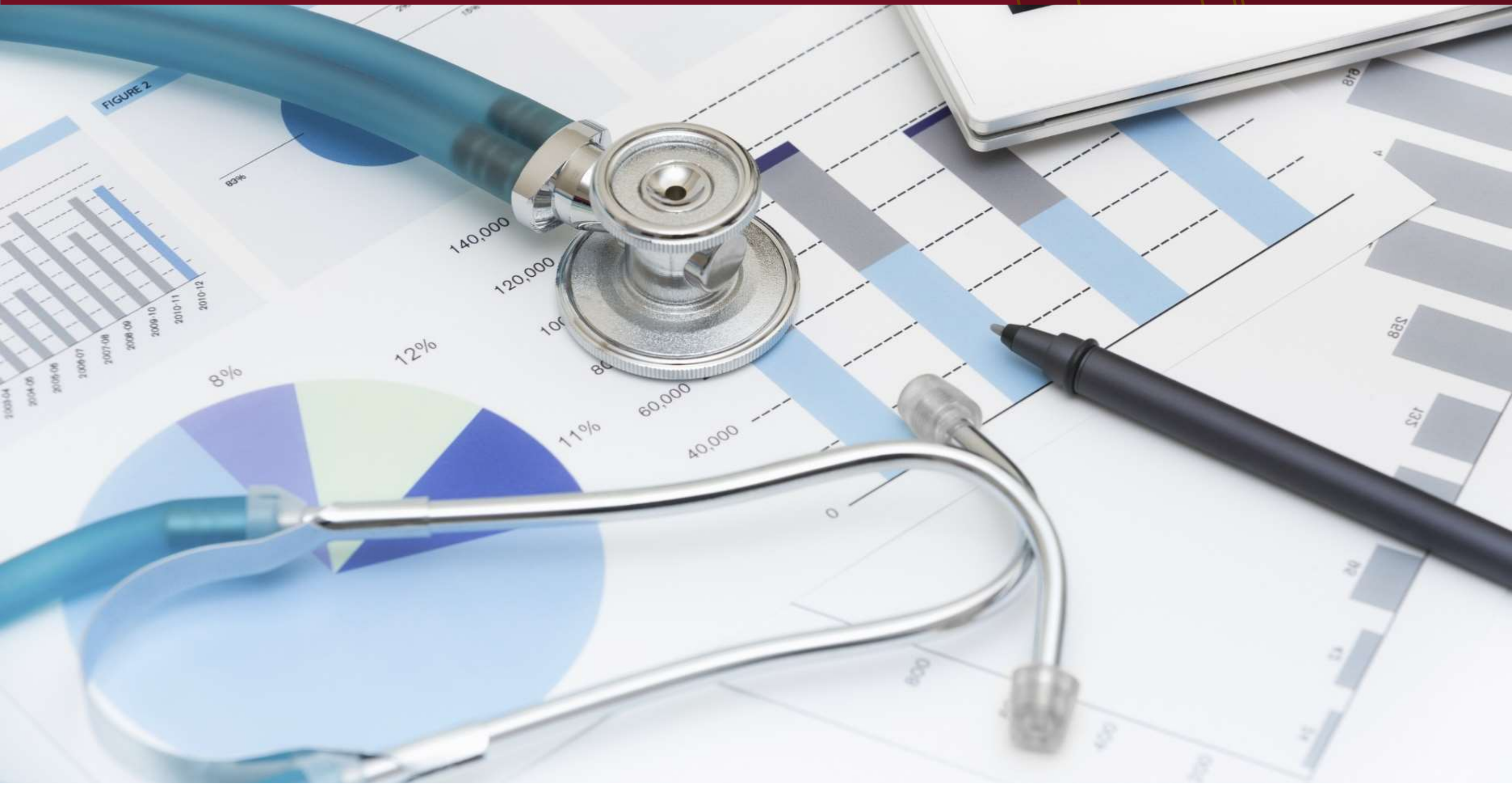
Appendix H: CMS Medicare PSI 90 Conceptual Framework



MIDS Patient Safety Measure Development and Maintenance Project

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Authors
Patrick Romano, UC Davis
Meghan Weyrich, UC Davis

Submitted To
Annese Abdullah-Mclaughlin
Yuling Li

Centers for Medicare & Medicaid Services (CMS)
Center for Clinical Standards and Quality (CCSQ)

7500 Security Boulevard
Baltimore, MD 21244-1850

IMPAQ International, LLC
10420 Little Patuxent Parkway, Suite 300
Columbia, MD 21044
(443) 259-5000

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1. Background

1.1 INTRODUCTION

CMS Patient Safety Indicator (PSI) 90, also known as the Patient Safety and Adverse Events Composite, combines information about 10 common patient safety problems that may occur to hospitalized patients. Each Patent Safety Indicator (PSI) was developed with the goal of identifying injuries that can often be prevented, after accounting for the patient's condition and/or risk of treatment.[1] The PSIs (hence CMS PSI 90) are based on inexpensive and readily available administrative hospital data or claims.

Scoring of CMS PSI 90 uses a pre-determined weighting methodology to produce a single actionable score. The safety composite score is the weighted average of the reliability-adjusted, risk-standardized ratios of 10 component indicators. The weights are comprised of a harm score and frequency of the complication, which results in an overall potential harm adjusted composite. Whereas a score of less than one indicates that the hospital had fewer selected patient safety events than expected based on its case mix, a score of greater than one indicates that the hospital had more selected patient safety events than expected. Very small hospitals may be assigned a PSI 90 score of one because of insufficient data to support a finding of either fewer events or more events than expected.

Components of CMS PSI 90 include:

- PSI 03 Pressure Ulcer Rate
- PSI 06 Iatrogenic Pneumothorax Rate
- PSI 08 Postoperative Hip Fracture Rate
- PSI 09 Postoperative Hemorrhage or Hematoma Rate
- PSI 10 Postoperative Physiologic and Metabolic Derangement Rate
- PSI 11 Postoperative Respiratory Failure Rate
- PSI 12 Postoperative Pulmonary Embolism or Deep Vein Thrombosis Rate
- PSI 13 Postoperative Sepsis Rate
- PSI 14 Postoperative Wound Dehiscence Rate
- PSI 15 Accidental Puncture or Laceration Rate

1.2 PURPOSE OF THE CMS MEDICARE PSI 90 COMPOSITE SCORE

The original purpose of the PSI 90 composite score was to provide a simple and transparent single metric that can be used to better understand, communicate, and track patient safety in US hospitals. As described in the Composite Measure Work Group Final Report,[2] the development effort was stimulated by requests from users of the AHRQ Quality Indicators and the Healthcare Cost and Utilization Project (HCUP) data sets, with the aim of "monitoring performance over time or across regions and populations using a methodology that could be applied at the national, regional, State, or provider/area levels." This composite was described for a lay audience in the Hospital Quality Model Report as summarizing "how often adult patients experience the following complications, either after an operation or as a result of other care provided in the hospital."

1.3 CONCEPTUAL MODEL

Potential benefits of composite measures include the ability to: (1) summarize quality across multiple indicators to simplify interpretation and decision-making, (2) more reliably detect differences among providers or groups, (3) identify important domains and drivers of quality, (4) prioritize action for quality improvement, (5) make current decisions about future (unknown) health care needs (i.e., selecting a preferred hospital), and (6) avoid flawed heuristics (also known as cognitive "shortcuts" that result in incorrectly weighting different sources of information).

Figure 1. Formative Composite Model

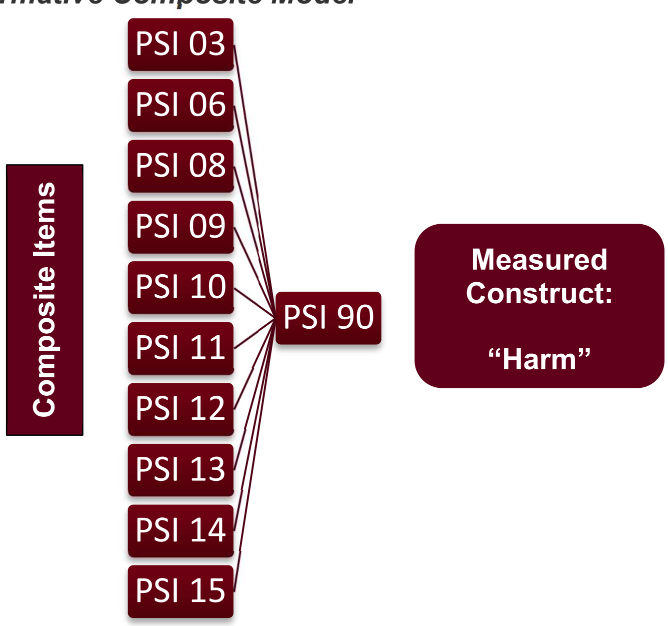

Figure 1 above illustrates the formative design of PSI 90, in which the composite measure is “formed from” a set of components that assess different harms or aspects of patient safety. Formative composites require deliberate selection of weights that best support the decision-making purpose of the composite. Composite measures typically provide a more valid signal if more "important" components are weighted more heavily than less "important" components. Commonly used weighting methods include:

1. Weighting all components equally, which is convenient and easy, but has little theoretical or empirical support;

2. Weighting each component according to the number of “opportunities” that it provides to provide the optimal process of care or experience the optimal outcome (based on the concept that relatively rare events become more important to the extent that more patients are at risk of experiencing them);

3. Soliciting patients’ or clinicians’ judgments about the relative importance of each component (based on the concept that some events are more important, from the clinical or public health perspective, than others of equal frequency);

4. Using more complex statistical and empirical methods such as regression or structural equation modeling to estimate the relative importance of each component (based on the concept that relative importance can be estimated from a causal model in which adverse events are a final common pathway leading to death, prolonged hospital stay, or other undesirable outcomes).

In response to prior feedback from NQF and other stakeholders, AHRQ and CMS redesigned the PSI 90 composite by shifting from approach (2) to approach (4), and this approach was re-endorsed by the National Quality Forum (NQF) in 2015. At that time, two general approaches to this challenge were considered: retaining a “formative” construct, with weighting based on empirical estimates of importance, versus switching to a “reflective” construct based on an underlying unobserved construct of patient safety. AHRQ and its Standing Work Group agreed that the former approach is preferable, because (1) it is historically consistent with how the PSIs were developed and how PSI 90 was conceived; (2) it retains the conceptual advantages of a single composite, whereas applying item response theory might require division into multiple composites; (3) it is driven by stronger theory; i.e., decision-making by providers, consumers, and other stakeholders should be driven by the objective of reducing net harm and increasing utility.

In the framework that CMS and AHRQ adopted, summarized in the Table 1 below, a Level I composite is a combination of two or more component measures in a manner intended primarily to support better decision-making by increasing statistical precision or reliability. This is the approach taken in constructing, for example, composite measures of patient experience from Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey items. In a Level II composite such as CMS PSI 90, the composite is designed in a manner that not only enhances reliability, but also reflects competing importance for specific cohorts of patients.

In other words, some patients are at risk for iatrogenic pneumothorax, but are not at risk for postoperative respiratory failure, and vice versa. The goal of the Level II composite is to assess and improve safety (freedom from harm) for a population that may be at risk for a variety of different adverse events, each of which may have different causes and potential mechanisms. The Level II composite must balance the competing risks of these different events, based (in the case of CMS PSI 90) on the perspective of patients who experience inpatient care. Finally, the goal of a Level III composite, such as AHRQ's Inpatient Quality Indicator composites of mortality for selected conditions and procedures, is to assess and improve outcomes for a specific population when the health states relevant to the population (e.g., stroke, pneumonia, heart failure) are unknown at the time of the decision.

Table 1. Types of Composite Measures

Level	What	Why	How	Components
I	Measuring a latent construct ("reflective")	Improve statistical precision	Weighted average based on shared signal variance or loadings on a common factor	Structure, process, outcome measures
II	Maximizing patient or societal utility ('formative")	Handle multiple outcomes of competing importance (e.g., death, complications) while improving statistical precision	Weighted average based on discounting (i.e., making component indicators equivalent in the current decision context using measures of patient utility or harm; e.g., mortality, morbidity, hospital days, QALYs)	Level I Composites or individual process/ outcome measures
III	Maximizing patient or societal utility ("formative")	Handle multiple outcomes of uncertain importance (conditioned on unknown health state) (e.g., AMI, pneumonia, stroke) while improving statistical precision	Weighted average based on state probabilities (i.e., probability of a patient entering each state, such as MI, heart failure, pneumonia, stroke)	Level II Composites or individual process/ outcome measures

2. Composite Weighting Methods

The CMS PSI 90 weights reflect a potential harm-based approach and are based on three components: 1) excess harm associated with the component PSI, 2) the estimated preferences for health states reflected by these harms, and 3) the frequency of the component PSI complication. Below we describe the methods used to quantify each portion of the harm-based weights and the calculation method for the weights.

2.1 DATA

To estimate excess harms for deriving the weights we used the following CMS datasets: the 2012 and 2013 CMS Limited Dataset (LDS) Inpatient Standard Analytic File (SAF), the LDS Outpatient SAF (Base Claims File and Revenue Center File), the LDS Skilled Nursing Facility SAF, and the LDS Denominator SAF (2012 only). These datasets include all inpatient and outpatient final action claims for the Medicare Fee- For-Service population. The files contain diagnoses (ICD-9-CM), procedure codes (ICD-9-CM or HCPCS), dates of service, cost and revenue codes, provider identifiers and beneficiary information. Data from 2012 were used to identify index admissions and the 2013 data were used solely to identify harms subsequent to those index admissions.

We included a subset of hospital claims to limit the sample to community hospitals, mirroring the HCUP dataset described above. To do so, we eliminated any claims associated with non-community hospitals, such as rehabilitation, psychiatric or specialty hospitals. Non-Community Hospitals were identified using the American Hospital Association (AHA) Annual Survey Database. The data include hospitals and providers paid both under the Inpatient Prospective Payment System and other payment mechanisms.

The inpatient dataset was used to identify individuals qualifying for any PSI indicator. The outpatient and skilled nursing facility datasets were used to track outcomes for these individuals following hospital discharge. The denominator dataset was used to gather demographic variables for individuals. The final dataset included 6,529,709 individuals, 4,705 hospitals, and 10,552,935 hospital stays. Numbers by PSI indicator are shown below.

Table 2. Patient, Hospital and Discharge Counts, by Indicator in CMS Data Used to Estimate Excess Harm

PSI	Title	Individuals	Hospitals	Stays
03	Pressure Ulcer	2,367,595	4,615	3,153,68
06	Iatrogenic Pneumothorax	6,252,940	4,702	9,947,20
08	Postoperative Hip Fracture	1,343,305	4,117	1,531,04
09	Perioperative Hemorrhage or Hematoma	2,226,409	4,154	2,532,61
10	Postoperative Physiologic and Metabolic Derangement	1,330,871	3,886	1,449,50
11	Postoperative Respiratory Failure	1,066,909	3,863	1,151,96

12	Perioperative Pulmonary Embolism or Deep Vein Thrombosis	2,393,597	4,167	2,746,25
13	Postoperative Sepsis	284,142	3,580	296,483
14	Postoperative Wound Dehiscence	296,139	3,798	315,973
15	Accidental Puncture or Laceration	383,362	3,835	410,698

Source data: 2012 and 2013 CMS Limited Dataset (LDS) Inpatient Standard Analytic File (SAF); LDS Outpatient SAF (Base Claims File and Revenue Center File); LDS Skilled Nursing Facility SAF; the LDS Denominator SAF (2012 only).

The data sets used to estimate PSI event rates are fully described in the NQF Composite Measure Testing Form.

2.2 DETERMINING EXCESS HARM

Identifying Potential Harms

Excess harms associated with each of the PSIs used in the harm-based weights were based on a conceptual model using information from the clinical literature, research associated with the PSIs, and clinical judgment. Physicians and nurses within the development team identified harms that represent the potential outcomes and/or results associated with the PSI event or treatment thereof. These unintentional harms may be temporary (such as the pain from a chest tube insertion) to permanent (such as anoxic brain damage or the need for long-term dialysis due to permanent renal failure). Each individual harm event was further defined using data elements available in CMS Standard Analytic Files. Specific data elements include diagnosis and procedure codes; service counts such as the number of readmissions, outpatient visits or Emergency Department encounters; revenue codes; length of stay; presence of an intensive care unit admission; and disposition codes.

Estimating the Excess Frequency of Outcomes (Harm Models):

Once the harms were identified and specified, the CMS SAF were used to estimate the average excess number of harmful outcomes associated with the occurrence of a PSI event. A separate cohort sample was defined for each component indicator based on the sample of 2012 patient records who were “at risk” (i.e. in the denominator) for the component PSI indicator. Index events were identified as patient discharges in 2012 with an eligible PSI component event. The comparison group was composed of “at risk” patients (as defined by the component PSI specification) who did not experience the PSI event. The 2013 data were used solely to provide follow-up information.

Propensity Score

Confounding may arise if factors associated with the probability of experiencing a component PSI event are also related to the probability of experiencing a consequence (outcome) from the PSI event. To account for potential confounding in these analyses, for each component indicator, we used a propensity score weighting approach. The propensity score (PS) was the predicted value from the component PSI risk adjustment model, which accounted for age and sex as well as pre-existing diagnoses and comorbidities.

To further balance observed covariates in the CMS data between the patients with and without safety events, we refined the PS from the risk adjustment model using a logistic regression with the following predictors: log [PS/(1-PS)], age, sex, race, and Medicare eligibility category. Note that these covariates were only used to balance the groups of patients with and without safety events to better estimate excess harms. We did not alter the component PSI risk adjustment model.

We used an inverse probability of treatment weighting (IPTW) approach to balance confounders between patients with and without component PSI events. We used a version of IPTW suitable for estimating the average treatment effect on the treated (ATT). In other words, we estimated the effect of the safety event on harms among patients who suffered the safety event. Patient stays with the safety event (PSI=1) received a weight of 1 and at-risk patient stays without a safety event (PSI=0) received a weight of PS/(1-PS).

Follow-up Timeline

The baseline time (t_0) was the discharge date of the at-risk inpatient stay. The follow-up period was up to 12 months from t_0.

Independent Variable

The independent variable was the component PSI event indicator.

Dependent Variable

Separate models were fit for each harm outcome. Outcomes varied among the component PSIs. Example outcomes included all-cause 30-day and 180-day mortality, hospital readmissions within 30 days, condition-specific complications, and total length of hospital stay (potentially including the postoperative period during the index admission plus all qualifying readmissions within the ascertainment window). The selection of outcomes relied on the underlying conceptual model for the component indicator, the available data elements in the CMS data, and the availability of a meaningful utility weight.

Regression Model

For binary outcomes such as mortality, readmission indicators, and complication indicators, we fit a linear probability model to estimate the excess probability of the outcome associated with the safety event. We also fit a linear model for length of stay (LOS). We fit all models using SAS® PROC GENMOD employing generalized estimating equations (GEE) to account for hospital clustering and using the IPTW weights described earlier. These models included only intercept terms and a dummy variable for each PSI event.

For the binary outcomes we specified a binomial distribution with an identity link function for the linear probability model. We also fit a logistic regression (logit link function). However, the point estimates from the logistic regression were the same as those generated by the linear probability model and the linear probability model produced coefficients directly interpretable as excess harm with suitably- calculated standard errors. For LOS we specified a normal distribution with an identity link function. While LOS was not normally distributed, our samples were very large, justifying this use of the normal distribution.

Utility Scoring of Harms

To assign a relative value for decrements to the quality of life as a result of each PSI event and its sequelae, we adopted the utility scale. A health utility refers to an individual's preference for a specific health state on a scale of 0 to 1, where 0 is equivalent to death and 1 denotes perfect health. These utility values weight different health states according to their relative valuation. They are widely used in health economic analysis (e.g., calculation of quality-of life years saved by a treatment) because they represent stable and assessable population values.[3]

Utilities of many different health states are available from the literature. Various approaches to utility assessment exist, with the common step of defining and describing each health state to be valued. The utility value for a given health state can be derived by surveying patients who have experienced that health state about their quality of life. Alternatively, the general public can respond to a description of the health state and undergo an elicitation technique to assess their preference on the utility scale.

Utility elicitation techniques include time tradeoff, standard gamble, and category scaling. These methods produce somewhat different estimates, though similar preference ordering.[4,5]

For CMS PSI 90, the critical need is for accurate relative utility values that reflect patient experiences. The challenges to achieving this goal are:

1. No patients have experienced all the PSI-related harms, making it impossible to determine ranking within one population;
2. Even among different populations of patients, the literature does not report utility values for all PSI events and their sequelae;
3. For utility values that have been reported, some are derived from the general public as opposed to patients who have experienced the PSI-related harm; and

4. For some health states, estimates differ as a function of the method employed or the population assessed.

To address these challenges, we used multiple data sources and fit these to what is known from a utility perspective about patients' experiences of PSI-related harms. Literature values provide patients' and the general public's assessment of some PSI-related harms.[3,6-9] Because not all health states are reported in the literature, we developed a ranking exercise to assess relative quality of life across all PSI-related harms. We conducted the ranking task with clinicians, including physicians and nurses, across several academic institutions. Using clinicians from diverse disciplines (i.e., general internal medicine, nephrology, pediatrics, hospital medicine, surgery, critical care nursing, home care nursing), we were able to assess PSI-related harms from a variety of perspectives. In addition, we were able to benefit from shared professional understanding of the implications of these PSI-related harms. For example, it is difficult without first-hand experience with multiple patients to estimate the average disutility of having a thoracostomy tube to evacuate an iatrogenic pneumothorax or a flap graft procedure to cover a stage IV pressure ulcer. Each of the PSI-related harms has a spectrum of severity that experienced clinicians can assess (albeit subject to the well-known availability heuristic).

The clinicians were shown the detailed specification used to identify patients who experience each of the 38 PSI-related harms. We asked the clinicians (n=8) to review these descriptions, and rank order them from worst to best, with ties allowed. Specifically, they were asked to think of the "average patient" in the group identified and consider their own preference for enduring the health state experienced by this average patient relative to the other PSI-related harm health states (again the "average patient" in each harm state). Implicit to the task, the raters had to imagine themselves experiencing each harm state for its average duration, as well as its average severity. They were also instructed to ignore any harms from a given health state that were included in another health state (e.g., treatment for iatrogenic pneumothorax during a readmission for pneumothorax since the chest tube placement would be valued separately). Each clinician provided a rank ordered list of the 38 distinct health states (those that relate to one or more of the 11 PSI events).

The average rankings by participating clinicians were calibrated to the available literature values (patient and public derived) to interpolate the relative utility value of harm states not available in the literature. The calibration was done based on a best fit of the clinician-derived values for those health states with available patient/public-derived values. A cubic function resulted in the best fit for the calibration curve and was applied to estimate the remaining values. As a result, the ranking follows the average of the clinician's assessments, scaled to patient-derived assessments for the PSI-related harms for which such assessments are available.

The advantage of the utility approach is that it adopts a commonly used scale from 0-1 that can be converted to a harm scale (1-utility) to weight the relative quality of life effect on patients of a diverse set of PSI-related harms. Insignificant events to a patient are not given any weight since there is no disutility. Finally, average utility values represent a relative preference for one health state versus another at a group level, the appropriate analytic level for a quality indicator composite. Relative rankings of utilities are robust at the population level, regardless of the utility assessment method chosen.

2.3 CALCULATION OF CMS MEDICARE PSI 90 WEIGHTS

Each component PSI indicator, q, that is part of CMS PSI 90 receives a weight defined by:

$$weight_q = \frac{volume_q \sum_{h=1}^{H} harm_{qh}\ disutility_{qh}}{\sum_{q=1}^{Q} volume_q \sum_{h=1}^{H} harm_{qh}\ disutility_{qh}}$$

Where:

- Q is the total number of component quality indicators, q=10, in CMS PSI 90.
- H is the total number of outcome types (harms), h, related to each component indicator.
- volume is the numerator count, or the number of total PSI events within the component indicator in the reference population.
- harm is the excess risk (risk difference) of each type of outcome (i.e. harm) within each component indicator estimated from a model comparing people with PSI events to those without PSI events in an “at risk” cohort.
- disutility is the complement of a utility weight (1-utility_wt) assigned to each excess occurrence of each type of outcome within each component indicator.

For each component indicator in the CMS PSI 90 composite, two sets of values need to be computed or estimated. The first is the excess risk of the outcomes (risk difference) that may occur as a result of the indicator patient safety event. The second is the set of numerator weights, which are calculated from the volume (count) of component events in the Medicare Fee-for-Service reference population.

2.4 SUMMARY OF STRENGTHS AND LIMITATIONS

In the original version of PSI 90, endorsed by NQF in 2009 and updated in 2013, component weights in the Patient Safety Composite were based entirely on the relative frequency of the PSI events, after risk-adjustment (by indirect standardization) and reliability adjustment (by shrinkage to a "prior probability estimate" for each hospital). In other words, if PSI A had twice as many occurrences in the entire HCUP reference population as PSI B, then PSI A would have received twice the weight of PSI B (holding risk-adjustment and reliability-adjustment constant). One implication of this weighting scheme is that all PSIs were assumed to be equally serious, from the perspective of the average patient in the reference population. A consequence of this approach is that users of the composite were implicitly encouraged to focus their quality improvement and evaluation efforts on the PSIs that occur most often in the reference population. Through extensive experience in a variety of settings, several limitations of this approach became apparent:

1. Some PSIs have greater consequences and implications for affected individuals than others. For example, most "iatrogenic pneumothoraxes" (PSI 06) are identified within 24 hours and rapidly corrected. By contrast, postoperative respiratory failure (PSI 11) may lead to chronic ventilator dependence and postoperative renal failure (PSI 10) may lead to chronic hemodialysis. In other words, the number of occurrences of a safety-related event is a very limited proxy for the impact of that event on population health.

2. Minor events are often easier to "prevent" than major events. AHRQ's earlier approach gave equal credit to hospitals that "prevented" 20% of "accidental punctures or lacerations" (PSI 15) and hospitals that "prevented" 20% of postoperative renal failure (PSI 10). However, in practice, hospitals were able to "prevent" 20% of PSI 15 events simply by changing their coding practices and/or implementing pre-billing clinical review programs. From the population health perspective, this could be considered misallocation of professional effort. By contrast, preventing 20% of PSI 10 events requires careful attention to processes of care and would likely have significant implications for long-term health outcomes and health care expenditures.

3. Approximately 75% of the total weight in the original PSI 90 composite rested on two component variables: PSI 15 and postoperative venous thrombosis (PSI 12). Even after re- incorporating three additional PSIs (PSI 09, Perioperative Hemorrhage or Hematoma; PSI 10, Postoperative Renal Failure; and PSI 11, Postoperative Respiratory Failure) into the composite with non-zero weights, 48% of the total weight still rested on PSIs 12 and 15. This approach sent a potentially misleading "signal" to healthcare providers and consumers that these two events are particularly important, relative to other safety-related events.

With the encouragement of NQF and other stakeholders, in 2015 AHRQ and CMS reconceptualized the PSI 90 component weighting scheme to focus on the potential harms that result from each PSI, and thus the relative population health impact of the PSIs. The population health impact of each PSI is expressed as the sum of the products of the marginal likelihood of various health outcomes after that PSI (e.g., death, transfer to a skilled nursing facility, reoperation) and the average marginal disutility associated with that health outcome. As a result, component indicators are weighted more heavily when PSI-attributable harms are either more frequent or more burdensome to the patients who experience them. This approach has several important advantages:

1. The total weight is more evenly balanced across PSIs; no single indicator carries more than 30% of that total weight.

2. PSI events with worse health consequences, such as PSI 11 (Postoperative Respiratory Failure) and PSI 13 (Postoperative Sepsis) are now weighted more heavily than in the original composite.

3. PSI events that are easy to "prevent" by changes in coding practice, such as PSI 15, are no longer weighted more heavily than events that require careful attention to complex processes of care to achieve the same relative reduction in frequency.

4. To the extent that some of the PSIs have false positive rates that approach 25%, these false positives (i.e., events that were reported but did not actually happen, according to accepted clinical definitions) reduce the component weights on these PSIs. For example, postoperative respiratory failure ascertained by diagnosis codes, without procedure codes to indicate prolonged mechanical ventilation or re-intubation, has a relatively weak association with subsequent harms (relative to PSI 11 cases ascertained using procedure codes for prolonged mechanical ventilation). The higher a PSI's false positive rate, the more that PSI is effectively down-weighted because the false positive events have zero marginal risk of post-event harms (by definition).

5. CMS PSI 90, as re-specified, is now better aligned with the concept of patient safety, or freedom from harm occurring in the process of inpatient medical care, as that concept has been described by the Institute of Medicine and operationalized through a variety of public and private initiatives.

In summary, the more recent approach as endorsed by NQF in 2015 represents a clear and important advance over previous approaches to weighting component indicators in PSI 90. CMS and AHRQ believe that "signaling errors" leading to misallocation of effort under the original approach are now corrected. CMS and AHRQ welcome input from NQF and from all stakeholders to continue the cycle of quality improvement while advancing the science of quality measurement nationwide.

3. Evidence Table: PSI Events Association with Health System Structures and Processes of Care, Potential Downstream Harms

For evidence review methods and detailed results, see the individual measure evidence forms, included in the supplemental files packet.

Indicator	Structures/ Processes of Care Associated with Lower PSI Rates	Potential Downstream Harms Associated with PSI Event
PSI 03	*<u>Processes of Care</u>* • Skin assessments performed at admission and daily, with particular attention to bony prominences and skin adjacent to external/medical devices[10-14] • Complete documentation of all skin lesions/pressure ulcers along with staging (including location, tissue type, shape, size, presence of sinus tracts/tunneling, undermining, exudate amount and type, presence/absence of infection, and wound edges). • Documentation of skin inspections in the medical record, including skin temperature, skin color, skin texture/ turgor, skin integrity, and moisture status.[10-13,15] • Pressure ulcer risk assessments performed at admission and daily (using a validated tool such as the Braden Scale) with results documented in the patient's chart.[16] • Repositioning of patients every 1 to 2 hours. [16,17] • Promoting the patient's highest level of mobility. • Development and implementation of evidence- based guidelines, care paths, or protocols that cover the full continuum of care for the prevention of pressure ulcers, within the local hospital context. • Placement of at-risk patients on a pressure- reducing surface rather than a standard hospital mattress.[10-13,15,18] • Special attention to mattress type and preventive care for patients in holding areas such as the Emergency Department and perioperative care units.[12]	• Hospital-acquired pressure ulcer complications have been associated with up to 60,000 deaths each year in the US.[25] • Using the 2000 HCUP NIS database, patients with a PSI 03 event (compared to propensity-matched eligible patients without an event) had excess length of stay of 4.0 days, excess hospital charges of $10,845, and excess inpatient mortality of 7.2% (all p<0.001).[26] • Using the 2001 Patient Treatment File from the VA, patients with a PSI 03 event (compared to propensity-matched or multivariable regression-adjusted eligible patients without an event) had excess length of stay of 3.7-5.2 days, excess hospital costs of $5,552-6,713, and excess inpatient mortality of 6.8- 10.8% (all p<0.001).[Error! Reference source not found.] • PSI 03 events may extend the typical hospital stay from 5 to 14 days and costs between $16,755 and $20,430, depending on the circumstances.[13] • Pressure ulcers can be painful and severely limit mobility, leading to admission to a

	• For patients at risk, performing a nutritional assessment at entry to a new health care setting and whenever the patient's status changes.[11,12,13,15] • Education directed toward patients, families, and caregivers on how to prevent and treat pressure ulcers.[12,16] *Structures of care* • Initial and ongoing comprehensive staff education on how to: (1) undertake a comprehensive skin assessment that includes the techniques for identifying blanching response, localized heat, edema, and induration,111516 [16,17,22] (2) prevent pressure ulcers, (3) perform pressure ulcer risk assessments, and (4) treat pressure ulcers. • Hospitals with stronger emphasis on safety have been shown to have lower pressure ulcer rates.[19] • Higher RN tenure,2021[24,25] higher RN hours per patient per day,2022[24-26] higher RN job satisfaction,21[25] and increased percentages of RNs with baccalaureate or higher degrees[22,23] have been some shown to be correlated with lower pressure ulcer rates in select populations and unit types; whereas high RN or nurse manager turnover24[28] have been shown to have the opposite effect. • Ongoing surveillance and performance improvement activities to prevent pressure ulcers and to detect pressure ulcers early to prevent progression.	nursing home or other type of institutional care due to loss of functional independence or other increased care needs.[17] • Short-term and long-term medical complications of pressure ulcers include: cellulitis, pyoderma, bacteremia, sepsis, osteomyelitis, septic arthritis, necrotizing fasciitis, and gas gangrene/gangrene, and or flap failure. These complications often require intensive care[27]). • Surgical procedures associated with pressure ulcer development include wound debridement and skin graft or flap.[17]
PSI 08	*Processes of care* • Development of an evidence-based hospital fall protocol to identify patients at risk for post- operative falls.[28] • Careful attention to postoperative medication management that includes: developing a systematic and standardized approach for detailed medication reconciliation upon admission, avoidance of polypharmacy (more than 4-5 medications per day can double a patient's risk for falling), and a systematic and standardized approach for team members to evaluate a patient's medication regimen postoperatively.[28-34] • Limit concurrent use of narcotics, sedatives, and diuretics, which are associated with increased fall risk.[28,31,32,34]	• Patients suffering from a postoperative hip fracture are more likely to suffer in the short-term from: acute myocardial infarction, pneumonia, venous thrombosis event, sepsis/septic shock, and surgical site bleeding. • Long-term complications include: mechanical complications related to the orthopedic device, implant, and or graft; peri-prosthetic joint infection/wound infection, osteomyelitis, and avascular necrosis. • Many patients with hip fracture require post-acute care hospitalization and or home care.

	• Development of a systematic and standardized practice for postoperative fall prevention that includes assessing and addressing the aforementioned risks;[28,35-39] ○ Familiarize the patient with the environment. ○ Have the patient demonstrate call light use and keep within reach. ○ Keep patient personal possessions within the patient's reach. ○ Have sturdy handrails in patient bathrooms, room and hallway. ○ Place the hospital bed in a low position and keep brakes locked. ○ Keep non-slip, well-fitting footwear on patient. ○ Utilize a night light or supplemental lighting. ○ Keep floor surfaces clean and dry. Clean up all spills promptly. ○ Keep patient care areas uncluttered. ○ Communicate patient fall risk to all caregivers. ○ Offer assistance to bathroom/ commode or use bedpan hourly while awake. ○ Multifactorial education such as bed posters, patient education handouts, fall risk alert cards, and exercise programs.[40,41] *Structures of care* • Fall rates may be improved on units with low RN staffing levels by improving the direct RN hours per patient day.[42] • Environmental adjuncts associated with lower fall rates include: sturdy handrails in patient bathrooms, room and hallway; adjustable and lockable beds; availability of non-slip footwear, hip protectors [43] and shock-absorbing flooring[4445]; improved lighting; and multimedia education materials. • Educate staff at time of hire, annually and when protocols are changed. • Track compliance with elements of established practices by using checklists, appropriate documentation, etc. • Evaluate effectiveness of new processes, determine gaps, modify processes as needed, and implement practices. • Mandate that all personnel follow the safety practices related to preventing postoperative hip fracture and falls and develop a plan of action for staff in noncompliance.	• Additionally, direct and indirect medical costs are significantly increased due to increased length of stay, additional hospitalizations/ treatment, and long- term institutional care[32,46-49] • Using the 2000 HCUP NIS database, patients with a PSI 08 event (compared to propensity-matched eligible patients without an event) had excess length of stay of 5.2 days, excess hospital charges of $13,441, and excess inpatient mortality of 4.5% (all $p<0.001$).[26]

	• Provide feedback to all stakeholders (physician, pharmacy, nursing, and ancillary staff; senior medical staff; and executive leadership) on level of compliance with processes and postoperative fall rates.	
PSI 09	*Processes of care* • Postoperative hemorrhage and hematoma events may be related to the technical skill and judgment of the surgeon, especially when the hemorrhage is not recognized during the initial procedure and requires reoperation on a subsequent day. • Steps to decrease PSI 09 rates include addressing and avoiding technical errors such as: inadequate ligation, cauterization, clipping, or stapling of blood vessels; failure to recognize transection of a minor vessel; or a defect in a vascular anastomosis. • Additional processes related to intra- and peri- operative management also can contribute: excessive anticoagulation; inadequate correction or reversal of coagulopathy; failure to replace clotting factors in cases involving large-volume blood loss; and hypothermia. • The best way to reduce the risk of hemorrhage is to identify and correct potential causes of coagulopathy preoperatively as well as postoperatively[54]. Medication management should include a process for obtaining a thorough history of medication use prior to surgery that includes over-the-counter medications and prescribed medications that impair clotting function. *Structures of care* • Engage key preoperative/ perioperative/ procedure personnel, including nurses, physicians, technicians, and representatives from the quality improvement department to develop evidence- based protocols for care of the patient preoperatively, intraoperatively, and postoperatively to prevent postoperative hemorrhage or hematoma. • Develop a process and protocol for determining if discontinuation of antiplatelet/anticoagulant medications prior to procedure or surgery is appropriate based on individual risk factors and current evidence-based guidelines for surgery type.[50-53] This process should include standardized documentation in the patient's medical record that is available to all care providers.	• Patients suffering a PSI 09 event are at increased risk of developing postoperative infection and hypovolemic or hemorrhagic shock (leading to end- organ damage or dysfunction such as respiratory failure, renal failure, and brain anoxia). These complications often require intensive care [27]). • Using the 2000 HCUP NIS database, patients with a PSI 09 event (compared to propensity-matched eligible patients without an event) had excess length of stay of 3.9 days, excess hospital charges of $21,431, and excess mortality of 3.0% (all p<0.001).[26] • Using the 2001 Patient Treatment File from the VA, patients with a PSI 09 event (compared to propensity-matched or multivariable regression-adjusted eligible patients without an event) had excess length of stay of 3.9-4.7 days, excess hospital costs of $7,863-10,012, and excess inpatient mortality of 5.1- 8.1% (all p<0.001).[Error! Reference source not found.] • These patients are also at risk for being re-hospitalized for recurrent wound complications. In a Veteran's Administration study, the adjusted odds of readmission after a PSI 09 event was 60% higher than among those without an event (18.8% vs. 11.3%).[58] Using all- payer data

	• Consider developing an early warning tool based a standard set of criteria (e.g., common early warning signs of hemorrhage can include but are not limited to: restlessness and anxiety, frank bleeding and bruising, tachycardia, diminished cardiac output and dropping central venous pressure, reductions in urine output, swelling and discoloration of the extremities) to trigger notification of the responsible surgeon of possible postoperative bleeding. • Establish a policy to empower nurses to rapidly escalate up the chain of authority to reach the responsible surgeon (limit time to 5-minute wait after initial page before notifying next higher level of authority). • Plan and provide education on protocols to physician, nursing, and all other staff involved in operative, procedural cases and the care of patients postoperatively. Education should occur upon hire, annually, and when protocols are changed or added.	from 7 states, PSI 09 was associated with an adjusted odds of 1.03 (NS) for inpatient death, 1.10 (NS) for 30-day readmission, and 1.18 (p<0.01) for 90-day readmission.[Error! Reference source not found.]
PSI 10	*Processes of care* • Avoid use of nephrotoxins or use with caution (e.g. ACE inhibitors, aminoglycosides, amphotericin, aspirin, cisplatin, cyclosporin, low molecular weight dextran, NSAID, radioactive dyes, etc.), especially in patients with known renal insufficiency.[68,69] • Careful thought to using laparoscopic versus open surgical technique in select cases (such as in patients undergoing bariatric surgery, appendectomy or lung resection) [55,57,58]. • Limit increases in abdominal pressure. Intra- abdominal pressure increases can be due to bleeding, intestinal distension, peritonitis, paralytic ileus and ascites. • Use volume expansion, vasodilators, and inotropes cautiously and avoid hypovolemia. • Ongoing assessment of condition of patients in hospital including use of early warning scores and monitoring for oliguria [56]. • Monitoring and preventing deterioration in patients with or at high risk of AKI[56] • Use of electronic clinical decision support systems (CDSS) • Consultation with pharmacist • Temporarily stopping ACE inhibitors and ARBs	• Using the 2000 HCUP NIS database, patients with a PSI 10 event (compared to propensity-matched eligible patients without an event) had excess length of stay of 8.9 days, excess hospital charges of $54,818, and excess inpatient mortality of 19.8% (all p<0.001)[26]. • More recent studies also support increased mean adjusted LOS in patients with a PSI 10 event,[59,60] with significantly increased costs[49,61] estimated at $11,797 by Encinosa and Hellinger (2009). • These patients are also at risk for being re-hospitalized for dialysis-related needs or complications. In a Veteran's Administration study, the adjusted odds of readmission after a PSI 10 event was 53% higher than among those without an event (23.8% vs. 11.4%)[54].

	<u>Structures of care</u> • Plan and provide education on protocols to physician, nursing, and all other staff involved in operative, procedural cases and the care of patients postoperatively. Education should occur upon hire, annually, and when protocols are changed or added. • Targeted quality improvement related activities and surveillance.	• Using all-payer data from 7 states, PSI 10 was associated with an adjusted odd of 3.73 ($p<0.01$) for inpatient death, 1.09 (NS) for 30-day readmission, and 1.30 ($p<0.05$) for 90-day readmission. • 30-day [57,58,62,63,64] and 90-day[60,61] mortality has been repeatedly shown to be higher in patients with a PSI 10 event than in otherwise similar patients. • In addition, patients with renal failure requiring dialysis may suffer from permanent renal damage requiring long-term dialysis and possible renal transplant. • Other frequent complications include: respiratory failure requiring intubation and mechanical ventilation[55], uremic syndrome, fluid or electrolyte abnormalities, and cardiovascular events. These complications often require intensive care [27]).
PSI 13	*<u>Processes of care</u>* *Preoperatively*[65] • Steps to decrease PSI 13 events include: nutritional repletion and smoking cessation and consideration of ICU or intermediate care unit admission for high risk patients [66]. • Consider chlorohexidine bathing preoperatively. • If removing hair prior to surgery, avoid use of razors, by using one of following appropriate techniques: hair removal with clippers, depilatory, or no hair removal at all. • Prophylactic antibiotics should be administered within 1 hour prior to surgical incision. • Administer appropriate antibiotic selection based on evidence-based guidelines *Intra-operatively* • Reduce the amount of staff traffic in and out of the operating room	• Using the 2000 HCUP NIS database, patients with a PSI 13 event (compared to propensity-matched eligible patients without an event) had excess length of stay of 10.9 days, excess hospital charges of $57,727, and excess inpatient mortality of 21.9% (all $p<0.001$)[26]. • Using the 2001 Patient Treatment File from the VA, patients with a PSI 13 event (compared to propensity-matched or multivariable regression-adjusted eligible patients without an event) had excess length of stay of 5.7-18.8 days, excess hospital costs of $13,395-31,264, and excess

	• When possible/appropriate: use regional instead of general anesthesia; avoid central intravenous line insertion, and if necessary, employ the current guidelines and using checklists; avoiding hypotension and resultant bacterial translocation; minimizing blood product transfusions; maintain glycemic control while avoiding hypoglycemia;, avoid diathermy for skin incision; leave contaminated wounds open; place surgical drains through separate incisions; and minimize the duration of surgery as able. • Use appropriate wound dressings determined by the type of closure: o Primary: Dry, sterile cover dressing for 24-48 hours o Secondary and chronic: Dressings that provide a moist wound healing environment while preventing it from becoming too wet. *Postoperatively* • Stop prophylaxis with antibiotics within 24 h after the procedure for all procedures except cardiac surgery (stopped within 48 h) • Perform routine pain assessments to ensure early identification of delayed wound healing. • Early diagnosis, source control, prompt and appropriate antibiotic treatment, maintaining appropriate intravascular fluid balance, maintaining adequate blood pressure and tissue perfusion and oxygen delivery. • Incorporate the "Surviving Sepsis Campaign" evidence-based guidelines, including the 3-hour resuscitation and 6-hour care bundles, into the sepsis management protocol and/or procedures. • Administer recommended vaccinations after splenectomy. • Early mobilization, physiotherapy, pain control, and preventing hospital-acquired infections using guidelines to prevent ventilator-associated pneumonia (VAP) and catheter-associated blood stream infections (CABSIs); appropriate glucose control maintaining glucose <200 mg/dl) while avoiding hypoglycemia. • Maintain local immunity, particularly the maintenance of gut integrity, by starting enteral feeding as early as possible after surgery. *<u>Structures of care</u>*	inpatient mortality of 30.2- 35.7% (all p<0.001)[Error! Reference source not found.] • Infection in the postoperative patient may be due to infection at the surgical site/or adjacent anatomical areas (e.g., intra-abdominal/subphrenic abscesses wound infection and infected seromas) or may be due to infection at a non- surgical site. Common severe non- surgical site infections include: pneumonia, intravenous catheter or implant infections, and urinary tract infection. These complications often require intensive care[27]). • Patients with postoperative sepsis are more likely to readmitted for infection and complications as well as suffer from acute and chronic end organ damage (such as renal failure, respiratory failure, cerebral anoxia, critical illness myopathy and polyneuropathy, disseminated intravascular coagulopathy syndrome, encephalopathy, hepatic failure, septic shock, and amputation). In a Veteran's Administration study, the adjusted odds of readmission after a PSI 13 event was 32% higher than among those without an event (19.2% vs 13.0%)54. Using all-payer data from 7 states, PSI 13 was associated with an adjusted odds of 4.70 (p<0.01) for inpatient death, 0.99 for 30- day readmission, and 1.26 (p<0.01) for 90-day readmission[Error! Reference source not found.]. • Patients with end-organ damage are more likely to require post-hospital care ranging

	• Restrict surgeries to higher volume facilities for select procedures. Increased procedure volume for open and endovascular repair of non-ruptured abdominal aortic aneurysm is associated with lower rates of PSI 13[67]. By redirecting AAA repairs in this single study from low to high volume hospitals may have prevented 111 cases of sepsis at an extra change of $6.7 million dollars for those repaired using endovascular approach and $15.1 million for cases repaired with an open procedure. • Maintaining a high RN to patient care hours based on two out of three studies that support lower rates of PSI 13 in hospitals with higher RN to patient hours[68,69]. • Employ systems to avoid surgical delay. Surgical delays in three high volume elective major surgical procedures (coronary artery bypass graft, colon resection and lung resection) has been associated with an increase in sepsis ($p<0.0001$)[70]. • Implement the AHRQ toolkit for Postoperative Sepsis. In a study by Hussey et. al., one hospital was able to decrease their PSI13 rates from 18.5 per 1000 pre-intervention to 11.8 per 1000 post-intervention.[71] • Convene a multidisciplinary team that includes different professions and service lines to develop an organization wide sepsis management protocol that integrates evidence-based guidelines into clinical practice. • Develop order sets, preferably electronic, for non-severe sepsis and for severe sepsis/septic shock. • Develop a system wide antibiotic policy and/or procedure that include: antibiotic type, dosing, initiation, timing, and compatibility. • Use a process for screening patients for sepsis, such as a paper or electronic screening tool that is 1 page and will take 2-3 minutes to complete. Also consider use of the rapid-response team for screening. • Provide continuous quality improvement activities related to sepsis that includes surveillance, measurement, and feedback. • Education should occur upon hire, annually, and when this protocol is added to job responsibilities.	from sub-acute to rehabilitation to skilled nursing/institutional care.

PSI 14	*<u>Processes of care</u>* • Avoid departure from the standards of care. Patients with wound dehiscence are three-times more likely to have received care that departed from professionally recognized standards (when adjusted for patient demographic and hospital factors). (4.3% versus 1.7%).[72] • Address modifiable risk such as nutritional status and decreasing surgical error. • Avoid inadequate undermining of the wound during surgery; excessive tension on the wound edges caused by lifting, straining, or excessive wound length; or the wound being located on a highly mobile or high-tension area. • A well-planned incision should provide ready access to anticipated pathology and provide adequate exposure but allow for extension if the scope of operation needs to be expanded. • The incision should interfere minimally with function by preserving important structures and heal with adequate strength to reduce the risk of wound disruption. • A major cause of wound separation is failure of suture to remain anchored in the fascia, suture breakage, knot failure, and excessive stitch interval which allows protrusion of viscera. Sutures should be about 1 cm from the wound edge and about 1 cm from the adjacent suture to ensure that the tissue is strong enough to hold the suture. For continuous closure, the total length of the suture should be approximately four times the length of the incision. To minimize the risk of incisional hernia, elective midline abdominal closure (first operation or reoperation) should be performed with continuous, slowly absorbable sutures. • Additional postoperative processes that can help prevent dehiscence include: control of diabetes and the avoidance of medications that may delay wound healing. • Perform routine pain assessments to ensure early identification of delayed wound healing.	• After postoperative wound dehiscence, patients face an increased risk of additional procedures and operations to repair the dehiscence, as well as complications of those operations. These complications often require intensive care.[27] • Using the 2000 HCUP NIS database, patients with a PSI 14 event (compared to propensity-matched eligible patients without an event) had excess length of stay of 9.4 days, excess hospital charges of $40,323, and excess inpatient mortality of 9.6% (all p<0.001).[26] • Using the 2001 Patient Treatment File from the VA, patients with a PSI 14 event (compared to propensity-matched or multivariable regression-adjusted eligible patients without an event) had excess length of stay of 8.3-11.7 days, excess hospital costs of $17,281-18,905, and excess inpatient mortality of 11.7- 17.2% (all p<0.001).[Error! Reference source not found.] • 40% higher costs are also seen in cancer patients with PSI 14 events compared to those without in 4 of the 6 types of cancer resection patients studied (p<0.001). [49] • These patients are also at risk for being re-hospitalized for recurrent wound complications. In a Veteran's Administration study, the adjusted odds of readmission after a PSI 14 event was 61% higher than among those without an event (20.0% vs 11.5%).[27,54,73]

		• Using all-payer data from 7 states, PSI 14 was associated with an adjusted odds of 1.57 ($p<0.05$) for inpatient death, 1.24 for 30- day readmission, and 1.56 ($p<0.01$) for 90-day readmission.[Error! Reference source not found.] • Major wound dehiscence is associated with significant risk of mortality between 14% and 50%. [72]
PSI 15	*Processes of care* • Engage key nurses, physicians, and surgical technicians from the operating room; and representatives from quality improvement, radiology, and information services to develop time-sequenced guidelines, care paths, or protocols for the full continuum of care. • Use appropriate equipment selection methods, including scalpel blades with safety blades; mechanical/instrument tissue retraction; blunt surgical instruments (when possible); and alternative cutting methods (e.g., cautery, harmonic scalpel). • Keep used needles on the sterile field in a disposable puncture-resistant needle container. • Adopt a hands-free technique of passing suture needles and sharps between perioperative team members. • Use a one-handed or instrument-assisted suturing technique to avoid finger contact with needles. • Use control-release or pop-off needles. • Double glove. • Do not bend, break, or recap contaminated needles. • Use closable orange or red, leak-proof puncture- resistant disposable container, placed close to the point of use. Empty routinely and do not overfill. Use mounted, upright containers, either floor or wall. *Structures of care* • Plan and provide education on protocols and standing orders to physician, nurses, and all other staff involved in accidental puncture and laceration prevention and care. Education should occur upon hire, annually, and when this protocol is added to job responsibilities.	• Using the 2000 HCUP NIS database, patients with a PSI 15 event (compared to propensity-matched eligible patients without an event) had excess length of stay of 1.3 days, excess hospital charges of $8,271, and excess inpatient mortality of 2.2% (all $p<0.001$)[26] • Using the 2001 Patient Treatment File from the VA, patients with a PSI 15 event (compared to propensity-matched or multivariable regression-adjusted eligible patients without an event) had excess length of stay of 1.4-3.1 days, excess hospital costs of $3,359-6,880, and excess inpatient mortality of 3.2- 3.9% (all $p<0.001$)[Error! Reference source not found.] • These patients were not at significantly increased risk of readmission in a Veteran's Administration study (adjusted odds of readmission 1.07, 95% confidence interval 0.99-1.15).[54] However, using all-payer data from 7 states, PSI 15 was associated with an adjusted odds of 1.52 ($p<0.01$) for inpatient death, 1.25 ($p<0.01$) for 30-day readmission, and 1.16 ($p<0.01$) for 90- day readmission.[Error! Reference source not found.]

	Education should include simulation training for technically complex laparoscopic procedures. • Track compliance with elements of established protocol steps. • Evaluate effectiveness of new processes, determine gaps, modify processes as needed, and re- implement. • Mandate that all personnel follow the protocol and develop a plan of action for staff in noncompliance. • Provide feedback to all stakeholders (physician, nursing, and ancillary staff; senior medical staff; and executive leadership) on level of compliance with process.	

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