**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite Measure Number)

**Measure Title**: PSI 03 Pressure Ulcer Rate (Component Measure)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If

the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

* Use of a pressure care bundle
* Frequent repositioning
* Proper skin care
* Specialized cushions or beds
* Increased monitoring, including risk and skin assessments

Decrease incidence of pressure injuries

Decrease risk of additional patient harm:

* Local infection, osteomyelitis, anemia, sepsis
* Depression, pain, discomfort
* Additional hospital length of stay

Pressure injuries, also called pressure ulcers, are serious events and one of the most common patient harms. Pressure ulcers can be prevented by addressing modifiable risk factors such as friction, humidity, temperature, continence, medication, shearing forces, unrelieved pressure, and poor nutrition. One approach that has been very successful in decreasing hospital associated pressure ulcer includes the use of a pressure ulcer care bundle based on best practices and tailored to individual hospital settings. Critical components of the pressure ulcer care bundle include: use of a comprehensive skin assessment and standardized pressure ulcer risk assessment along with structured interventions to address areas of risk (such as the use of mechanical loading and support surfaces).

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

### *Association with Process of Care*

To prevent hospital-acquired pressure ulcers, evidence-based guidelines1-4 and systematic reviews5 recommend that skin assessments be performed at admission and daily during the inpatient stay, with particular attention to bony prominences and skin adjacent to external/medical devices. These assessments should include complete documentation of all skin lesions and 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 in the medical record should include skin temperature, skin color, skin texture/turgor, skin integrity, and moisture status. In addition, evidence-based guidelines2,6 and systematic reviews5 recommend that nutritional assessments be performed at entry to new health care settings and whenever patient status changes.

Evidence-based guidelines and systematic reviews also recommend that at-risk patients are placed on a pressure-reducing surface rather than a standard hospital mattress.1-3,5,7 In a systematic review of 120 studies reporting on pressure ulcer risk assessment and prevention, Chou and colleagues examined the effectiveness of various interventions for reducing pressure ulcers for hospitalized patients.8 They concluded that fair-quality randomized trials consistently found that in higher risk patients, advanced static support surfaces were associated with lower risk of pressure ulcers compared to standard mattresses (relative risk range, 0.20 to 0.60), with no clear differences among different advanced static support surfaces. Evidence on the comparative effectiveness of more advanced dynamic support surfaces was limited; some trials showed no significant differences between dynamic and static support surfaces. In lower risk populations of patients undergoing surgery, two trials found use of a foam overlay associated with a higher risk of pressure ulcers compared with a standard operating room mattress. Evidence on the effectiveness of other preventive interventions (e.g., nutritional supplementation; repositioning; pads and dressings; lotions, creams, and cleansers; corticotrophin injections; polarized light therapy; and intraoperative warming therapy) was sparse and insufficient to reach reliable conclusions. In a systematic review of 25 studies reporting on pressure ulcer prevention strategies in the ICU, meta-analyses found a statistically significant effect of silicone foam dressing in reducing sacral HAPUs in critically ill patients (effect size, 0.12; p<0.00001). Evidence on the effectiveness of other strategies (nutrition, skin care, position/repositioning, support surfaces) was limited and insufficient to reach reliable conclusions.9 A 2020 Cochrane review of eight trials concluded that there is an absence of high-quality evidence to evaluating the effectiveness of repositioning frequency and positioning for pressure ulcer prevention.10 Another 2020 systematic review including both trial and observational studies assessing the effects of different repositioning regimens concluded that there is low-certainty evidence that more frequent repositioning (every 2-3 hours versus 4-6 hours; OR, 0.75; 95% CI, 0.61-0.90, p=0.03) and use of a turning team (OR, 0.49; 95% CI, 0.27-0.86, p=0.01) can reduce pressure ulcer incidence in at-risk adult patients.11 A 2018 Cochrane review including six trials comparing silicone dressings with no dressings found low-certainty evidence that silicone dressings reduce HAPUs (RR, 0.25; 90% CI, 0.16-0.41).12 An observational cohort study conducted in 38 acute care hospitals between 2010 and 2015 found that adoption of a prophylactic foam sacral dressing as part of a HAPU prevention protocol resulted in reduced HAPU rates; the average hospital experienced one fewer HAPU per quarter following implementation of the dressing.13 Elsabrout et al. found that a hospital-wide mattress switch-out program resulted in a 66.6% decrease in Stage III and IV HAPUs and a cost savings of $714,724.14

### *Association with hospital and health system characteristics*

Two studies have showed thatlow-volume hospitals have higher rates of pressure ulcers than higher volume hospitals.In an analysis of Diagnosis Procedure Combination/per-diem payment system (DPC/PDPS) data from 1,383,872 patients discharged from 188 hospitals in Japan (2008-2010), Kitazawa and colleagues found that low-volume hospitals (< 33rd percentile by volume) had higher rates (8.0 per 1,000 discharges; 95% CI 5.1 to 10.09) of pressure ulcers (PSI 03, version 4.2) than mid-volume (4.5 per 1,000 discharges; 95% CI 3.5 to 5.5) and high volume hospitals (3.8 per 1,000 discharges; 95% CI 3.0 to 4.6) (p < 0.05).15 Likewise, in an analysis of Medicare claims data for patients undergoing any of six types of cancer resection in 2005-2009, Short et al. found that the pressure ulcer rate was higher (0.78%) at low-volume hospitals than at high volume hospitals (0.59%), but not different between teaching and non-teaching hospitals.16Seemingly at odds with these findings, a cross-sectional study by Choi et al. using 2009 unit-level data from the National Database of Nursing Quality Indicators (NDNQI) linked with the NDNQI RN Survey found the odds of hospital-acquired pressure ulcer (HAPU) were higher (OR 1.27; p < .05) in hospitals with 300 or more beds compared to hospitals with <300 beds.17 However, these associations were not consistent across unit types.

The impact of Magnet-hospital designation was assessed by three different studies.In an analysis of quarterly unit-level data from the NDNQI (2008-2010), including 10,935 unit-quarter observations (2,294 adult units in 465 hospitals from 47 U.S. states), Park et al found that hospital magnet status was significantly associated with lower unit-acquired pressure ulcer (UAPU) rates (OR 0.84; p =0.049). In a cross-sectional study using 2009 unit-level data from the NDNQI linked with the NDNQI RN Survey, Choi et al found17 the odds of HAPU occurrence were lower in Magnet hospitals (OR 0.81; p < .05) than in non-Magnet hospitals. However, these associations were not consistent across unit types. Magnet status was significantly associated with the UAPU rate in step-down (OR 0.76; p < .05) and medical units (OR 0.64; p < .001), but not in critical care units, rehabilitation units, surgical units and combined medical-surgical units. Mills & Gillespie, however, found conflicting results using five years (2001-2005) of data from the Health Care Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS), merged with annual surveys conducted by the American Hospital Association. They found no differences in HAPU rates between 80 Magnet hospitals and 80 non-Magnet hospitals (p > .05).18

Rosen and colleagues **used PSI 03 (version 3.1a) to explore associations between safety climate, as measured through 9,309 responses to the Patient Safety Climate in Healthcare Organizations survey, and hospital safety performance in 2005-2006. Among the 30 Veterans Health Administration (VA) hospitals that participated in the survey,** “greater fear of blame and punishment for making mistakes” was significantly associated with higher rates of pressure ulcer (p < .05), stronger endorsement of “overall emphasis on safety” was significantly associated with lower rates of pressure ulcer (p < .05), and greater endorsement of “unit safety norms” was associated with lower rates of pressure ulcer (p < 0.1), in models adjusting for hospital teaching status, metropolitan area, and nurse-staffing ratio.19 A different study by Rosen et al. (2006) used VA Patient Treatment File (PTF) data to examine risk-adjusted PSIs (version 2.1) for acute care VA hospitals for fiscal years 2001 to 2004.20 The PSIs were assessed to characterize adverse patient safety events, determine trends in PSIs over time, and evaluate potential predictors of hospital safety. This study did not find PSI 03 to be significantly associated with any single hospital characteristic (e.g. bed size, teaching status, location).

Since 1991, the VA system has used risk-adjusted pressure ulcer rates as a system-wide outcome to monitor hospital performance and also supported research to explore best practices targeting pressure ulcer prevention in the inpatient setting. To assess the impact of this work, Chen et al. compared PSI 03 rates among 266,203 veteran dual users who were hospitalized in both VA facilities and private sector facilities between 2002 and 2007 using AHRQ PSI software (version 3.1a).21 Rates of pressure ulcer among these dual users were significantly lower in VA hospitals than in private sector hospitals: 25.9 versus 44.4 per 1,000 population. After adjustment for age, sex and 27 comorbidities, the pressure ulcer rate among VA hospitalizations was 20.4 per 1,000 discharges (95% CI 19.9 to 21.0) while among Medicare hospitalizations, the rate was 27.8 per 1,000 discharges (95% CI 27.3 to 28.3). Among veteran dual users, the odds of experiencing a PSI 03 event was 35% lower in the VA versus in the private sector (OR 0.65, 95% CI 0.63 to 0.68).

### *Associations with nursing staff characteristics*

Multiple studies have examined the association between pressure ulcers and hospital nurse staffing characteristics, including registered nurse (RNs) turnover, hours, and education level. In a longitudinal study of 23 nursing units in two hospitals from October 2009 through December 2011, Warashawsky et al found that patients on units with nurse manager turnover (OR 3.16; 95% CI 1.49 to 6.70) were more likely to develop pressure ulcers than patients on other units.22 In an analysis of quarterly unit-level data from the NDNQI (2008-2010), including 10,935 unit-quarter observations (2,294 adult units in 465 hospitals from 47 U.S. states), Park et al found a significant lagged effect of RN turnover on HAPU rates, but not a concurrent effect.23 For every 10 percentage-point increase in RN turnover in a quarter, the odds of a patient having a pressure ulcer increased by 4% in the next quarter (p = 0.038). Similarly, in a cross-sectional study using 2009 unit-level data from the NDNQI linked with the NDNQI RN Survey of 77,826 nurse respondents on 3,329 units at 561 different hospitals, Choi et al found that longer RN tenure on the current unit was related to lower HAPU rates among older adult patients (OR 0.97; p < .05), although when examined by unit type, this relationship only remained significant for step-down units (OR 0.97; p < .05).17

Choi et al also found17 that UAPU rates were associated with both RN job satisfaction and hours per patient day. RN workgroup job satisfaction was significantly and inversely associated (OR 0.98; p < .001) with the odds of UAPU after adjusting for other unit (nurse staffing, RN education level, and RN unit tenure) and hospital (bed size, teaching status, and Magnet status) characteristics. However, the association between RN job satisfaction and UAPU rates varied by unit type: Higher job satisfaction among RN workgroups was significantly associated with lower UAPU rates among older adults on critical care (OR 0.97; p < .001), medical (OR 0.98; p < .05), and rehabilitation units (OR 0.97; p < .05), but no significant relationship was found in step-down, surgical, and medical-surgical units. In the model with all sample units, RN hours per patient day and licensed practical nurse (LPN) hours per patient day were also significantly related to UAPU rates, but in the opposite direction of what was expected: the odds of UAPU occurrence increased for each additional RN hour per patient day (OR 1.05; p < .05) and additional LPN hour per patient day (OR 1.14; p < .05). In the unit-specific model, this relationship between increased hour per patient day and increased HAPU rates only remained significant in step-down units for additional RN hours per patient day (OR 1.07; p < .05). Park et al., however, found the opposite: more RN hours per patient day were associated with lower UAPU rates, controlling for other variables (unit type, non-RN staffing, hospital magnet status, hospital size, case mix index), (OR 0.952; p = 0.11). The significant effect of RN staffing on UAPUs remained without including the RN turnover variables as predictors (OR 0.950; p = .009).23

In a cross-sectional study using 2005 data from 21 University Health System Consortium hospitals, Blegen et al. found that hospitals with higher percentages of RNs with baccalaureate or higher degrees had lower rates of hospital-acquired pressure ulcers (Pearson r = 0.500; p < 0.05), as measured by PSI 03 (version 3.1).24 The effect of nursing education was stronger than the effect of nurse staffing (as measured by hours of direct patient care by RN, licensed practical nurse [LPN] or nursing assistant [NA] per patient day). Results were similar when using a regression model to adjust for nurse staffing, Medicare case mix index (CMI), and Hospital Technology and Safety Net status; there was a trend towards lower pressure ulcer rates in general hospital units and in intensive care units when the proportion of baccalaureate -prepared RNs was higher (p < 0.10). Using NDNQI data, Boyle et al found that hospitals employing certified wound, ostomy, and continence (WOC) specialty nurses had lower HAPU rates, as well as better pressure injury risk assessment and prevention practices. The study found that the prevalence of stage III and IV pressure ulcers at hospitals employing specialty certified nurses was much lower (0.27%) than at hospitals that did not employ specialty nurses (0.51%).25 Another study using longitudinal data from NDNQI found that HAPU rates decreased after nurse practitioners took on the role of wound care consultants (OR, 0.20; 95% CI, 0.15-0.27).26

Finally, Aydin et al. used data from a convenience sample of 789 medical-surgical units from 215 hospitals from CALNOC, a nursing-sensitive benchmarking registry, to model the predictive power of nursing staff characteristics on HAPU prevalence.27 The percent of patients with HAPUs decreased as total nursing hours per patient day (HPPD) increased, the years of RN experience increased, and percent of hours provided by contract staff decreased. Thus, at 5 HPPD, with 6 years of mean experience and 10 percent of hours provided by contact staff, HAPUs affected 5.2% of patients, versus only 2.2% when RNs had 16 years of experience and no contract staff hours were used.

### *Association with other outcomes*

Pressure ulcers commonly lead to further patient harm, including local infection, osteomyelitis, anemia, and sepsis, cellulitis, pyoderma, bacteremia, septic arthritis, necrotizing fasciitis, and gas gangrene/gangrene, and or flap failure;28-31 these complications often require intensive care or surgical procedures including wound debridement and skin graft or flap.32 Pressure ulcers can also lead to significant depression, pain, and discomfort to patients.28-30

Multiple studies in adult populations have found that the occurrence of pressure ulcers is associated with longer length of stay in the hospital and greater costs. Brito et al conducted a multicenter, cross-sectional study of 473 adults admitted to hospitals in different geographic regions of Brazil (2009-2011).33 In multivariable analyses, the presence of pressure ulcers was directly associated with length of stay of more than 8 days (OR 3.85; 95% CI 1.53 to 9.73). Using data on Medicare fee-for-service patient discharges (n=51,842) in 50 U.S. states over a two-year period (2006 –2007), Moore found that patients with a HAPU had a statistically significant longer length of stay than those without a HAPU (11.6±10.1 days vs 4.9±5.2 days, p<0.001).34 In a cross-sectional study using the 2008 NIS, Lee et al analyzed 10,660 hospitalizations with head and neck cancers who underwent radical neck dissections.35 Using multivariable linear regression analysis (controlling for patient age, sex, race, comorbidities, insurance, type of radical neck dissection, hospital region and hospital teaching status), the authors found that patients who experienced pressure ulcers stayed 5.6 extra days in the hospital (p < 0.0001) and incurred $49,153 in extra hospitalization charges (p = 0.003), compared with patients who did not. In an analysis of Medicare claims data for patients undergoing any of six types of cancer resection in 2005-2009, Short et al found that after adjusting for patient (age, sex, race, income), hospital (hospital volume, surgeon volume, surgeon specialty designation, hospital resources, patient characteristics) and tumor factors (tumor stage, site), costs increased by 28% to 60% after a pressure ulcer (p < 0.001).16 In an analysis of 3,466,596 inpatient visits in the year 2009 from the Premier Hospital Database, Mallow et al found that the prevalence of in-hospital pressure ulcer in this general population sample was 18.3 per 1000 visits, the median cost associated with pressure ulcers was $1,017, and the total cost of pressure ulcers was $478,501,000 for 2009.36 Zhan and Miller used AHRQ PSI software on 7.45 million discharges in the HCUP NIS (2000) and found that patients who experienced a PSI 03 event had a higher mean (SD) unadjusted length of stay (160.32 [0.09] vs. 90.79 [0.006]), charges ($45,987 [375] vs. $28,100 [29]), and mortality (130.85 [0.17] vs. 40.01 [0.01]) than patients who did not.37 However, statistical differences of these comparisons were not reported. Ramanathan et al. retroactively examined data on surgical patients hospitalized between 2011 and 2012 at an academic medical center and found that hospitalizations that included pressure ulcers (PSI 03, version 3.1) were associated with a 48.0 day mean hospital LOS, 80% included an intensive care unit stay, and 33.3% died in hospital.31 Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 03 event were associated with an additional 2.26 hospital days compared to patients without a PSI 03 event (p<0.001).38 Using HCUP NIS data for 2008 to 2012, Bauer et al. identified statistically significant differences in median length of stay between patients with and without pressure ulcers (7 days versus 3 days) and significant differences in total cost ($36,500 versus $17,000).39 Bath et al. used Medicare data (MedPAR) from 2009 to 2012 and found that the likelihood of 30-day readmission among patients undergoing abdominal aortic aneurysm repair was greater among patients with a pressure ulcer event (OR=2.88, p<0.001).40

### *Population group disparities*

### Table 3 presents population group disparities for component measure PSI 03 Pressure Ulcer Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims data from July 1, 2017 to June 30, 2018.

**Table 3. PSI 03 Pressure Ulcer Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 66766 | 0.509 | 0.461 |
| White | 5399715 | 0.564 | 0.572 |
| Black | 879228 | 0.954 | 0.781 |
| Other | 86037 | 0.628 | 0.480 |
| Asian | 100197 | 0.659 | 0.498 |
| Hispanic | 155142 | 0.535 | 0.458 |
| North American Native | 49801 | 1.024 | 0.803 |
| **Gender** |  |  |  |
| Female | 3642129 | 0.512 | 0.614 |
| Male | 3094757 | 0.745 | 0.588 |
| **Age** |  |  |  |
| <50 | 383026 | 0.509 | 0.587 |
| 50-54 | 209771 | 0.682 | 0.636 |
| 55-59 | 319073 | 0.787 | 0.647 |
| 60-64 | 402353 | 0.833 | 0.635 |
| 65-69 | 1070923 | 0.660 | 0.601 |
| 70-74 | 1078841 | 0.608 | 0.579 |
| 75-79 | 1005215 | 0.652 | 0.584 |
| 80-84 | 899429 | 0.609 | 0.599 |
| 85-89 | 759021 | 0.506 | 0.578 |
| 90 plus | 609234 | 0.486 | 0.623 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

### For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review presented below constitute the most recent update, conducted in August 2020. Search terms included relevant MeSH terms (pressure ulcer) and keywords (pressure ulcer, decubitus ulcer, pressure sore, skin ulcer). Studies focused on long-term care settings or obstetric care were excluded. We combined this clinical search string with MeSH terms (patient admission) and keywords (hospitals, patient admission, inpatient, patient safety, quality, indicator, epidemiologic, statistic, AHRQ, prevalence, incidence, or utilization) to identify studies examining inpatient care and quality measurement. Search was limited to English publications. We also tested more inclusive search strings. To provide the most up-to-date evidence, we summarize below the most recent evidence.

# 1a.4.3. Provide the citation(s) for the evidence.

1. Black JM, Cuddigan JE, Walko MA, Didier LA, Lander MJ, Kelpe MR. Medical device related pressure ulcers in hospitalized patients. *Int Wound J.* 2010;7(5):358-365.

2. WOCN 2016 Guideline for Prevention and Management of Pressure Injuries (Ulcers): An Executive Summary. *J Wound Ostomy Continence Nurs.* 2017;44(3):241-246.

3. Registered Nurses’ Association of Ontario. *Risk assessment and prevention of pressure ulcers (Revised).* Toronto, Canada: Registered Nurses’ Association of Ontario;2005.

4. Institute for Clinical Systems Improvement (ICSI). Health Care Protocol: Pressure Ulcer Prevention and Treatment Protocol. http://lnx.mednemo.it/wp-content/uploads/2010/11/febb7157.pdf. Published January 2012. Accessed August 17, 2020.

5. Reddy M, Gill SS, Rochon PA. Preventing pressure ulcers: a systematic review. *Jama.* 2006;296(8):974-984.

6. Posthauer ME, Banks M, Dorner B, Schols JM. The role of nutrition for pressure ulcer management: national pressure ulcer advisory panel, European pressure ulcer advisory panel, and pan pacific pressure injury alliance white paper. *Adv Skin Wound Care.* 2015;28(4):175-188; quiz 189-190.

7. Chou R, Dana T, Bougatsos C, et al. Pressure ulcer risk assessment and prevention: a systematic comparative effectiveness review. *Ann Intern Med.* 2013;159(1):28-38.

8. Chou R, Dana T, Bougatsos C, et al. AHRQ Comparative Effectiveness Reviews. In: *Pressure Ulcer Risk Assessment and Prevention: Comparative Effectiveness.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2013.

9. Tayyib N, Coyer F. Effectiveness of Pressure Ulcer Prevention Strategies for Adult Patients in Intensive Care Units: A Systematic Review. *Worldviews Evid Based Nurs.* 2016;13(6):432-444.

10. Gillespie BM, Walker RM, Latimer SL, et al. Repositioning for pressure injury prevention in adults. *Cochrane Database Syst Rev.* 2020;6(6):Cd009958.

11. Avsar P, Moore Z, Patton D, O'Connor T, Budri AM, Nuget L. Repositioning for preventing pressure ulcers: a systematic review and meta-analysis. *J Wound Care.* 2020;29(9):496-508.

12. Moore ZE, Webster J. Dressings and topical agents for preventing pressure ulcers. *Cochrane Database Syst Rev.* 2018;12(12):Cd009362.

13. Padula WV. Effectiveness and Value of Prophylactic 5-Layer Foam Sacral Dressings to Prevent Hospital-Acquired Pressure Injuries in Acute Care Hospitals: An Observational Cohort Study. *J Wound Ostomy Continence Nurs.* 2017;44(5):413-419.

14. Elsabrout K, Orbacz E, McMahon LA, Apold S. Large-Scale Hospital Mattress Switch-Out Leads to Reduction Hospital-Acquired Pressure Ulcers: Operationalization of a Multidisciplinary Task Force. *Worldviews Evid Based Nurs.* 2018;15(3):161-169.

15. Kitazawa T, Matsumoto K, Fujita S, et al. Perioperative patient safety indicators and hospital surgical volumes. *BMC research notes.* 2014;7:117.

16. Short MN, Aloia TA, Ho V. The influence of complications on the costs of complex cancer surgery. *Cancer.* 2014;120(7):1035-1041.

17. Choi J, Bergquist-Beringer S, Staggs VS. Linking RN workgroup job satisfaction to pressure ulcers among older adults on acute care hospital units. *Res Nurs Health.* 2013;36(2):181-190.

18. Mills AC, Gillespie KN. Effect of Magnet hospital recognition on 2 patient outcomes. *J Nurs Care Qual.* 2013;28(1):17-23.

19. Rosen AK, Singer S, Zhao S, Shokeen P, Meterko M, Gaba D. Hospital Safety Climate and Safety Outcomes: Is There a Relationship in the VA? *Medical Care Research and Review.* 2010;67(590).

20. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Med Care.* 2006;44(9):850-861.

21. Chen Q, Hanchate A, Shwartz M, et al. Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicator Rates Among Veteran Dual Users. *Am J Med Qual.* 2013;29(4):335-343.

22. Warshawsky N, Rayens MK, Stefaniak K, Rahman R. The effect of nurse manager turnover on patient fall and pressure ulcer rates. *J Nurs Manag.* 2013;21(5):725-732.

23. Park SH, Boyle DK, Bergquist-Beringer S, Staggs VS, Dunton NE. Concurrent and lagged effects of registered nurse turnover and staffing on unit-acquired pressure ulcers. *Health Serv Res.* 2014;49(4):1205-1225.

24. Blegen MA, Goode CJ, Park SH, Vaughn T, Spetz J. Baccalaureate education in nursing and patient outcomes. *J Nurs Adm.* 2013;43(2):89-94.

25. Boyle DK, Bergquist-Beringer S, Cramer E. Relationship of Wound, Ostomy, and Continence Certified Nurses and Healthcare-Acquired Conditions in Acute Care Hospitals. *J Wound Ostomy Continence Nurs.* 2017;44(3):283-292.

26. Irvin C, Sedlak E, Walton C, Collier S, Bernhofer EI. Hospital-acquired pressure injuries: The significance of the advanced practice registered nurse's role in a community hospital. *J Am Assoc Nurse Pract.* 2017;29(4):203-208.

27. Aydin C, Donaldson N, Stotts NA, Fridman M, Brown DS. Modeling hospital-acquired pressure ulcer prevalence on medical-surgical units: nurse workload, expertise, and clinical processes of care. *Health Serv Res.* 2015;50(2):351-373.

28. Brem H, Maggi J, Nierman D, et al. High cost of stage IV pressure ulcers. *Am J Surg.* 2010;200(4):473-477.

29. National Pressure Ulcer Advisory Panel (NPUAP). NPUAP Pressure Injury Stages. https://npiap.com/page/PressureInjuryStages. Published 2016. Accessed August 17, 2020.

30. Gunningberg L, Donaldson N, Aydin C, Idvall E. Exploring variation in pressure ulcer prevalence in Sweden and the USA: benchmarking in action. *J Eval Clin Pract.* 2012;18(4):904-910.

31. Ramanathan R, Leavell P, Wolfe LG, Duane TM. Agency for Healthcare Research and Quality patient safety indicators and mortality in surgical patients. *Am Surg.* 2014;80(8):801-804.

32. Berry M, Kiel D. Falls: Prevention in nursing care facilities and the hospital setting. In: Post T, ed. *UpToDate.* Waltham, MA2020.

33. Brito PA, de Vasconcelos Generoso S, Correia MI. Prevalence of pressure ulcers in hospitals in Brazil and association with nutritional status--a multicenter, cross-sectional study. *Nutrition (Burbank, Los Angeles County, Calif).* 2013;29(4):646-649.

34. Moore Z. US Medicare data show incidence of hospital-acquired pressure ulcers is 4.5%, and they are associated with longer hospital stay and higher risk of death. *Evidence-based nursing.* 2013;16(4):118-119.

35. Lee MK, Dodson TB, Karimbux NY, Nalliah RP, Allareddy V. Effect of occurrence of infection-related never events on length of stay and hospital charges in patients undergoing radical neck dissection for head and neck cancer. *Oral surgery, oral medicine, oral pathology and oral radiology.* 2013;116(2):147-158.

36. Mallow PJ, Pandya B, Horblyuk R, Kaplan HS. Prevalence and cost of hospital medical errors in the general and elderly United States populations. *Journal of medical economics.* 2013;16(12):1367-1378.

37. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Quality & safety in health care.* 2003;12 Suppl 2:ii58-63.

38. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *Am J Med Qual.* 2017;32(6):583-590.

39. Bauer K, Rock K, Nazzal M, Jones O, Qu W. Pressure Ulcers in the United States' Inpatient Population From 2008 to 2012: Results of a Retrospective Nationwide Study. *Ostomy Wound Manage.* 2016;62(11):30-38.

40. Bath J, Dombrovskiy VY, Vogel TR. Impact of Patient Safety Indicators on readmission after abdominal aortic surgery. *J Vasc Nurs.* 2018;36(4):189-195.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite Measure)

**Measure Title**: PSI 06 Iatrogenic Pneumothorax Rate (Component Measure)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

PSI 06 targets iatrogenic pneumothorax/pneumothoraces caused by diagnostic and therapeutic interventional-based procedures in the hospitalized patient. The most common procedures associated with iatrogenic pneumothoraces (as targeted by this indicator) include central line placement, pacemaker placement or manipulation, barotrauma from positive pressure ventilation, feeding tube placement, and other procedures close to the thoracic cavity. Operator technical skill and experience has been shown to be inversely related to the rate of iatrogenic pneumothorax. Use of ultrasound guidance during central venous catheter placement and judicious site selection (such as use of the internal jugular vein) are associated with lower indicator rates.

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

### *Association with process of care*

Two studies have shown that implementation of guidelines (American College of Surgeons and UK National Institute for Clinical Excellence)1,2 is associated with a substantial reduction in the incidence of procedure-associated iatrogenic pneumothorax (i.e., 0 of 1,978 procedures in Cavanna’s series, and 0 of 169 procedures in Wigmore’s series).3,4

Several studies have focused on the potential to prevent iatrogenic pneumothorax. Research findings summarized in a narrative review by Wrightson et al (2010) recommend that the use of a lateral approach (versus posterior approach) to thoracentesis and use of blunt dissection (versus trocar use) for chest tube insertion can reduce the risk of pneumothorax. A meta-analysis of 6 randomized trials with 579 participants showed that the risk of any procedural complication, including pneumothorax, is reduced when internal jugular (IJ) venous catheters are inserted with real-time ultrasound guidance (relative risk [RR] = 0.43; 95% confidence interval [CI] = 0.22-0.87).5 A subsequent randomized trial that involved 450 critically ill adults who underwent real-time ultrasound-guided cannulation of the IJ vein and 450 comparison patients for whom the landmark technique was used confirmed that ultrasound reduces the risk of pneumothorax (ie, from 2.4% to 0%, P < .001) and other complications.6 More recently, a meta-analysis of 24 studies (of which only two were randomized trials) reported pneumothorax rates following 6,605 unique thoracentesis procedures.7 Of the 6 comparative studies that reported pneumothorax rates with and without ultrasonography guidance, ultrasonography-guided thoracentesis was associated with a significantly lower risk of pneumothorax than unguided thoracentesis (OR 0.3, 95% CI 0.2-0.7). Among these studies, two randomized controlled trials found a similar effect size, but the difference was not significant (OR 0.3, 95% CI 0.0-2.8). A more recent retrospective study of 394 ICU patients at a single tertiary referral center found that the use of real-time ultrasound guidance was associated with a lower rate of iatrogenic pneumothorax compared to ultrasound-marked procedures (0.63% vs. 4.43%; p=0.02).8

Buckley et al. measured the rate of iatrogenic pneumothorax to evaluate quality improvement efforts based on a Plan-Do-Study-Act (PDSA) methodology to improve clinical outcomes at a single institution.9 Beginning in 2005, the PDSA intervention consisted of providing quality improvement education to residents and fellows in the medical intensive care unit (MICU) and providing training on central venous catheter insertion techniques known to reduce iatrogenic pneumothorax rates. Iatrogenic pneumothorax rates decreased from 0.31% at the beginning of the intervention to 0.17% approximately 3 years after the intervention was first implemented (chi-square with Yates correction, p < 0.001). Beginning in 2007, other improvements and areas of evaluation included expanding ultrasound catheter insertion guidance to fellows and residents and advocating for the use of peripheral rather than central catheters.

### *Association with hospital and health system characteristics*

Several studies have explored the association between health system characteristics and the prevalence of **iatrogenic pneumothorax. For example, in 2010, Rivard and colleagues compared the relationship between** Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicators (PSIs) **rates, including PSI6 (version 2.1), and various hospital characteristics in VA vs. community non-Federal hospitals.10 Using VA and Nationwide Inpatient Sample (NIS) data from 2003 through 2004 (n=116 VA hospitals, n=992 community non-Federal hospitals from NIS), they found that the risk-adjusted rate iatrogenic pneumothorax was 1.34 per 1000 (95% CI 1.14 to 1.53) in VA hospitals and 0.78 per 1000 (95% CI 0.72 to 0.83) in non-VA hospitals (from the NIS dataset). In both VA and non-VA (NIS) hospitals, rates of PSI 06 were significantly higher in major teaching hospitals than in nonteaching hospitals [(VA OR 2.51, 95% CI 1.30 to 4.86) (NIS OR 1.59, 95% CI 1.33 to 1.91)]. Rates of this indicator were significantly associated with nurse staffing hours in VA hospitals only (OR 1.03, 95% CI 1.00 to 1.07).**

Using fiscal year 2004 data from the Veterans Health Administration (VA) and calendar year 2003 Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS), Rivard and co-authors (2008) used the AHRQ PSIs (version 2.1, rev. 3a) to compare the rates of adverse patient safety events between federal (VA) and nonfederal (NIS) hospitals and between teaching and nonteaching hospitals.11 They found that risk-adjusted rate of PSI 06 overall was higher in federal hospitals than nonfederal hospitals [(VA 1.3 cases per 1,000 discharges) (NIS 0.8 cases per 1,000 discharges)], though the results were not significant. These findings were consistent across major teaching hospitals [(VA 1.4 cases per 1,000 discharges, 99% CI 1.1 to 1.7) (NIS 1.2 cases per 1,000 discharges, 99% CI 1.0 to 1.4)], minor teaching hospitals [(VA 1.3 cases per 1,000 discharges, 99% CI 0.8 to 1.9) (NIS 0.8 cases per 1,000 discharges, 99% CI 0.7 to 1.0)], and nonteaching hospitals [(VA 0.7 cases per 1,000 discharges, 99% CI 0.2 to 1.1) (NIS 0.6 cases per 1,000 discharges, 99% CI 0.6 to 0.7)]. Among both federal and nonfederal teaching and non-teaching hospitals, major teaching hospitals had higher risk-adjusted PSI 06 rates than nonteaching hospitals; however, the difference was only significant in nonfederal hospitals. The rate of PSI6 was significantly greater in nonfederal major teaching hospitals compared to nonfederal nonteaching hospitals (OR 1.45, 99% CI 1.13 to 1.85, p<0.01). The rate of PSI6 was greater in federal major teaching hospitals than in federal nonteaching hospitals, although this relationship was not significant (OR 1.63, 99% CI 0.59 to 4.51).

Chen et al. analyzed rates of PSI 06 (version 3.1a) among veteran dual users (i.e., those with hospitalizations in both the Veterans Health Administration [VA] and the private sector through Medicare fee-for-service coverage) during 2002 to 2007 and found the risk-adjusted rate of PSI 06 in the VA (0.8; 95% CI 0.7 to 0.9) to be significantly higher than in the private sector (0.5; 95% CI 0.5 to 0.6), however when risk-adjusted PSI rates for Medicare hospitalizations were recalculated using VA expected rates, risk-adjusted rates for PSI 06 were no longer significantly different across the two settings.12 This study found no significant differences in the risk-adjusted odds among dual users of developing PSI 06 between those hospitalized in the VA and those hospitalized in the private sector.

One study by Li et al. compared rates of several PSIs (version 3.0) in Iowa hospitals between 1997 to 2004.13 The authors examined the difference in PSI rates between critical access hospitals (CAHs) and Rural Prospective Payment System (PPS) hospitals and found that CAHs had significantly better performance than rural PPS hospitals for PSI 06 in 2001, 2003, and 2004 (p<0.05). In 2001, the PSI 06 rate was 0.07 cases per 1,000 discharges for CAHs and 0.21 cases per 1,000 discharges for PPS hospitals (p<0.05). In 2003, the PSI 06 rate was 0.26 cases per 1,000 discharges for CAHs and 0.46 cases per 1,000 discharges for PPS hospitals (p<0.05). In 2004 the PSI 06 rate was 0.14 cases per 1,000 discharges for CAHs and 0.29 cases per 1,000 discharges for PPS hospitals (p<0.05). Further analyses found that the odds of poor performance on PSI 06 were significantly lower among CAHs compared to PPS hospitals (OR 0.29, 95% CI 0.15 to 0.56). To examine the effect of CAH conversion on patient safety, Li et al. also compared PSIs within-hospitals before and after conversion from a PPS hospital to a CAH. Conversion from a PPS hospital to a CAH was associated with non-significant improved risk-adjusted rates of iatrogenic pneumothorax. The PSI rate of PPS hospitals decreased by an average of 0.090 cases per 1,000 discharges when they converted to CAHs (p=0.34). Of the 66 hospitals that converted, 18 had better performance on PSI 06 after conversion compared to 8 that had worse performance. In adjusted analyses controlling for comorbidities, selection bias and history bias, the odds ratios of poor performance in CAH hospitals compared with rural PPS hospitals was 0.30 (95% CI 0.14 to 0.64).

In an analysis of patient-level Medicare claims data for patients undergoing any of 6 cancer resections for the years 2005-2009, Short et al. found that the iatrogenic pneumothorax rate was lower at high procedure volume hospitals than at low-volume hospitals (0.67% vs 0.76%), at rural hospitals than urban hospitals (0.27% vs 0.69%), and at non-teaching hospitals than teaching hospitals (0.65% vs 0.71%) (statistical values not provided).14

**In another study, Rosen et al. (2010) used PSI 06 (version 3.1a), to explore the potential relationship between safety climate, as measured through more than 4500 responses to the Patient Safety Climate in Healthcare Organizations survey, and hospital safety performance, and found that among the 30 Veteran’s Health Administration hospitals that participated in the survey, the rate of iatrogenic pneumothorax was only marginally associated with the overall 11 dimensions of patient safety culture included in the analysis (p>0.05).15 Analyses were adjusted for major teaching status, metropolitan area and nurse-staffing ratio. The relationship between the indicator rate and patient safety culture dimensions remained non-significant when senior managers and frontline staff were analyzed separately.** An additional study by Rosen et al. (2006) used VA Patient Treatment File (PTF) data, to examine risk-adjusted PSIs (version 2.1, revision 2) for acute care VA hospitals for fiscal years 2001 to 2004.16 The PSIs were assessed to characterize adverse patient safety events, determine trends in PSIs over time, and evaluate potential predictors of hospital safety. The only hospital characteristic (e.g. bed size, teaching status) they found to be associated with PSI 06 rates was a measure of hospital leadership, a component of a quality improvement score given to hospitals.

A study by Anhang Price et al compared patient safety events in VA versus matched non-VA hospitals and did not identify a significant difference in PSI 06 rates (p=0.177).17 Using NIS data from 2000 to 2012, John et al found that the incidence of iatrogenic pneumothorax was higher in teaching hospitals compared to non-teaching hospitals.18

### *Association with other outcomes*

Numerous studies have examined the relationship between **iatrogenic pneumothorax** and outcomes including length of stay in the hospital, costs, mortality, and readmissions. Rosen et al. (2013), examined whether PSI events, experienced within index hospitalizations, increased the likelihood of readmission within Veterans Health Administration (VA) hospitals.19 They found that iatrogenic pneumothorax resulted in significantly higher rates of all-cause readmissions (18.0%) compared to those hospitalizations without an event (14.3%; p<0.0001). In a multivariate analysis using AHRQ comorbidity software (version 3.5) - controlling for age, sex, comorbidities, and other PSI events - hospitalizations with a PSI 06 event were 22% more likely to result in subsequent readmissions (OR 1.22; 95% CI 1.03 to 1.45).

In an analysis of patient-level Medicare claims data for patients undergoing any of 6 cancer resections for the years 2005-2009, Short et al. found that after adjusting for patient (age, sex, race, income), hospital (hospital volume, surgeon volume, surgeon specialty designation, hospital resources, patient characteristics) and tumor factors (tumor stage, site), costs increased significantly with iatrogenic pneumothorax among 3 of the 6 types of cancer resection patients (p<0.01).14

Based on an analysis of the 501,908 hospitalizations involving a brain tumor in the NIS between 2002 and 2010, Rahman et al. found that patients with iatrogenic pneumothorax had significantly longer LOS (p < 0.0001) than patients without iatrogenic pneumothorax.20 Finally, Ramanathan et al. retroactively examined data on surgical patients hospitalized between 2011 and 2012 at an academic medical center and found that hospitalizations that included iatrogenic pneumothorax (PSI 06, version 3.1) were associated with a 13.0 day mean hospital LOS, 0% included an intensive care unit stay, and 0% died in hospital.21

Zhan and Miller used AHRQ PSI software on 7.45 million discharges in the HCUP Nationwide Inpatient Sample (NIS, 2000) and found that compared to those that did not experienced a PSI 06 event, those that did had a higher mean (SD) unadjusted length of stay (130.78 [0.25] vs. 40.59 [0.003]), charges ($55,286 [1454] vs. $13,384 [11]), and percent mortality (160.11 [0.59] vs. 20.56 [0.006]).22 However, statistical differences of these comparisons were not reported. The overall rate of iatrogenic pneumothorax was 0.67 per 1000 discharges at risk.

Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 06 event were associated with an additional 1.41 hospital days compared to patients without an event (p=0.006) and an increased risk of 30-day unplanned readmissions (OR=3.30, p<0.001).23

### *Population group disparities*

**Table 4** presents population group disparities for PSI 06 Iatrogenic Pneumothorax Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims data from July 1, 2017 to June 30, 2018.

**Table 4. PSI 06 Iatrogenic** **Pneumothorax Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| Population-Based Disparity Factor | N(beneficiaries) | Observed Rate per 1,000 | Adjusted Rate per 1,000 |
| Race |  |  |  |
| Unknown | 94976 | 0.211 | 0.250 |
| White | 7138286 | 0.253 | 0.235 |
| Black | 1150073 | 0.202 | 0.240 |
| Other | 111270 | 0.270 | 0.252 |
| Asian | 127710 | 0.211 | 0.177 |
| Hispanic | 201697 | 0.159 | 0.188 |
| North American Native | 67236 | 0.134 | 0.153 |
| Gender |  |  |  |
| Female | 4782258 | 0.269 | 0.232 |
| Male | 4108990 | 0.211 | 0.237 |
| Age |  |  |  |
| <50 | 533851 | 0.103 | 0.227 |
| 50-54 | 286839 | 0.129 | 0.235 |
| 55-59 | 427643 | 0.124 | 0.201 |
| 60-64 | 528012 | 0.155 | 0.233 |
| 65-69 | 1498806 | 0.221 | 0.246 |
| 70-74 | 1468061 | 0.217 | 0.229 |
| 75-79 | 1318805 | 0.291 | 0.243 |
| 80-84 | 1146640 | 0.328 | 0.227 |
| 85-89 | 940204 | 0.333 | 0.240 |
| 90 plus | 742387 | 0.273 | 0.222 |

### Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

### For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review results presented below constitute the most recent update, conducted in August 2020. Search terms included relevant MeSH terms (pneumothorax, iatrogenic disease) We combined this clinical search string with a MeSH term (postoperative complications) to identify complications following surgery. Search was limited to English publications. We also tested more inclusive search strings. To provide the most up-to-date evidence, we summarize below the most recent evidence.

# 1a.4.3. Provide the citation(s) for the evidence.

1. American College of Surgeons. Revised Statement on Recommendations for Use of Real-Time Ultrasound Guidance for Placement of Central Venous Catheters. http://www.facs.org/fellows\_info/statements/st-60.html Published 2011. Accessed March 4, 2015.

2. National Institute for Clinical Excellence. *Guidance on the Use of Ultrasound Locating Devices for Placing Central Venous Catheters.* London, UK: National Institute for Clinical Excellence,;2002.

3. Cavanna L, Civardi G, Vallisa D, et al. Ultrasound-guided central venous catheterization in cancer patients improves the success rate of cannulation and reduces mechanical complications: a prospective observational study of 1,978 consecutive catheterizations. *World journal of surgical oncology.* 2010;8:91.

4. Wigmore TJ, Smythe JF, Hacking MB, Raobaikady R, MacCallum NS. Effect of the implementation of NICE guidelines for ultrasound guidance on the complication rates associated with central venous catheter placement in patients presenting for routine surgery in a tertiary referral centre. *British journal of anaesthesia.* 2007;99(5):662-665.

5. Hind D, Calvert N, McWilliams R, et al. Ultrasonic locating devices for central venous cannulation: meta-analysis. *Bmj.* 2003;327(7411):361.

6. Karakitsos D, Labropoulos N, De Groot E, et al. Real-time ultrasound-guided catheterisation of the internal jugular vein: a prospective comparison with the landmark technique in critical care patients. *Crit Care.* 2006;10(6):R162.

7. Gordon CE, Feller-Kopman D, Balk EM, Smetana GW. Pneumothorax following thoracentesis: a systematic review and meta-analysis. *Archives of internal medicine.* 2010;170(4):332-339.

8. Helgeson SA, Fritz AV, Tatari MM, Daniels CE, Diaz-Gomez JL. Reducing Iatrogenic Pneumothoraces: Using Real-Time Ultrasound Guidance for Pleural Procedures. *Crit Care Med.* 2019;47(7):903-909.

9. Buckley JD, Joyce B, Garcia AJ, Jordan J, Scher E. Linking residency training effectiveness to clinical outcomes: a quality improvement approach. *Jt Comm J Qual Patient Saf.* 2010;36(5):203-208.

10. Rivard PE, Elixhauser A, Christiansen CL, Shibei Z, Rosen AK. Testing the association between patient safety indicators and hospital structural characteristics in VA and nonfederal hospitals. *Medical care research and review : MCRR.* 2010;67(3):321-341.

11. Rivard PE, Christiansen CL, Zhao S, Elixhauser A, Rosen AK. Is There an Association Between Patient Safety Indicators and Hospital Teaching Status? In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 2: Culture and Redesign).* Rockville (MD)2008.

12. Chen Q, Hanchate A, Shwartz M, et al. Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicator Rates Among Veteran Dual Users. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2013;29(4):335-343.

13. Li P, Schneider JE, Ward MM. Effect of critical access hospital conversion on patient safety. *Health Serv Res.* 2007;42(6 Pt 1):2089-2108; discussion 2294-2323.

14. Short MN, Aloia TA, Ho V. The influence of complications on the costs of complex cancer surgery. *Cancer.* 2014;120(7):1035-1041.

15. Rosen AK, Singer S, Shibei Z, Shokeen P, Meterko M, Gaba D. Hospital safety climate and safety outcomes: is there a relationship in the VA? *Medical care research and review : MCRR.* 2010;67(5):590-608.

16. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Medical care.* 2006;44(9):850-861.

17. Anhang Price R, Sloss EM, Cefalu M, Farmer CM, Hussey PS. Comparing Quality of Care in Veterans Affairs and Non-Veterans Affairs Settings. *J Gen Intern Med.* 2018;33(10):1631-1638.

18. John J, Seifi A. Incidence of iatrogenic pneumothorax in the United States in teaching vs. non-teaching hospitals from 2000 to 2012. *J Crit Care.* 2016;34:66-68.

19. Rosen AK, Loveland S, Shin M, et al. Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Medical care.* 2013;51(1):37-44.

20. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

21. Ramanathan R, Leavell P, Wolfe LG, Duane TM. Agency for Healthcare Research and Quality patient safety indicators and mortality in surgical patients. *Am Surg.* 2014;80(8):801-804.

22. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Quality & safety in health care.* 2003;12 Suppl 2:ii58-63.

23. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2017;32(6):583-590.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite Measure)

**Measure Title**: PSI 08 In-Hospital Fall with Fracture Rate (Component Measure)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Falls leading to hip fracture among hospitalized patients can be prevented by identifying patients at high risk for falling and taking appropriate preventive actions. Interventions that have been shown to decrease the risk of falls in institutional settings include: use of adaptive equipment such as mobility aids; use of safety devices such as bed alarms, call lights and hip protectors; engaging the patient and family in safety; frequent toileting; attention to postoperative medication management (especially polypharmacy and use of select medications); and implementation of a standardized fall prevention protocol. Structural inventions at the hospital level include making the environment safer through use of handrails, no-slip bathing surfaces, improved lighting, and the provision of no-slip footwear.

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

***Association with processes of care***

Inpatient hip fractures can be prevented by reducing falls during hospital stays, particularly among elderly patients. Accordingly, several studies have examined the effect of interventions aimed at either preventing in-hospital falls or decreasing the severity of injuries from falls. According to a meta-analysis by Cameron et al., multifactorial interventions reduce fall rates (rate ratio 0.69; 95% CI 0.49 to 0.96; 4 trials, 6478 participants) and the risk of falling (risk ratio 0.73; 95% CI 0.56 to 0.96; 3 trials, 4824 participants) in hospitals.1 Several other recent studies have reported on interventions that significantly reduced the risk of falls during hospital stays.2-6 These interventions included bed posters, patient education handouts, plans of care, fall risk alert cards with informational brochures, exercise programs, education programs, hip protectors, and pre-printed care plans for patients identified as at risk of falling. All intervention groups reported a significant reduction in the risk of falling in-hospital compared with the control groups. One non-blinded cluster randomized trial by Drahota et al. in eight hospitals in the United Kingdom between 2010 and 2011 estimated the impact of shock-absorbing flooring and found fewer injuries from falls in the intervention group (22.9%) than in the control group (42.4%) [injury incident rate ratio (IRR) 0.58; 95% CI 0.18 to 1.91].7 In this study, there were no moderate to major injuries in the intervention group, compared with six in the control group [IRR 1.07; 95% CI 0.64 to 1.81].

Falls can also be prevented through careful attention to postoperative medication management and avoidance of polypharmacy. Two cross-sectional studies of older patients (one conducted in Taiwan and the other in the Netherlands) found that polypharmacy (daily use of >4 or 5 medications) is a significant risk factor for falling, and the risk increases with the number of medications used.8,9

Pierce et al. conducted univariable and multivariable analyses based on the medical records of patients in a 435-bed university hospital in New Mexico who fell in-hospital in 2010.10 They found that 25% of falls were associated with injury and 4% were associated with serious injury. Furthermore, patients who reported hitting their head, patients with pre-fall confusion, and patients who received narcotics within 24 hours before falling were more likely to suffer injury than those who did not (OR 6.04, 2.00, and 5.12 respectively). Using multivariable analysis, they confirmed that receiving a narcotic prior to falling was the strongest clinical predictor of fall-related injury (OR 5.38; 95% CI 2.07 to 13.98, p < 0.001).

Other studies have examined the cost effectiveness of interventions aimed at preventing in-hospital falls and hip fractures. Stollenwerk et al. conducted a cost effectiveness analysis on the use of hip protectors for hospitalized patients in Germany.11 They found that hip protectors could prevent 45.4% (95% CI 35.1% to 51.4%) of in-hospital hip fractures and save hospitals €52.2 ($72.60) per patient screened to be at risk of falling. Latimer et al. estimated the cost-effectiveness of a shock-absorbing floor intervention aimed at preventing serious injuries from falls among elderly patients in eight United Kingdom hospitals.12 They found the shock-absorbing floor to be associated with an £843 cost saving per patient, but a quality-adjusted life year (QALY) loss of 0.006, yielding an incremental cost-effectiveness ratio of £134,903. A third study conducted in two Australian hospitals (n=1,206) by Haines et al. evaluated the cost-effectiveness of two different patient education models for the prevention of in-hospital falls.3 One model included multimedia patient education materials, while the other combined these materials with a trained health professional follow-up. A control group received usual care and no patient education materials. There was no significant difference in fall rates between the control group and the group with only patient education materials. However, the patients who received multimedia educational materials as well as a healthcare provider follow-up had a significantly lower fall rate (8.72 vs. 4.01 falls per 1,000 patient days, adjusted hazard ratio = 0.43) and lower odds of falling (30 fallers and 280 non-fallers in control group vs. 20 fallers and 260 non-fallers in complete program, adjusted odds ratio = 0.51). If the percent of patients on a hospital ward who fall is 4% or greater, then the complete program of multimedia materials and professional follow-ups is cost-effective and likely to prevent falls and reduce future costs.

***Association with hospital and health system characteristics***

Several studies have examined the association between PSI 08 and hospital factors, such as staffing and assistance with falls. Staggs et al. conducted a cross-sectional analysis using data from the National Database of Nursing Quality Indicators (NDNQI) to compare assisted falls (falls for which a staff member was present to ease the patient’s descent) and unassisted falls that occurred in-hospital.13 Out of 166,883 falls (3.44 per 1,000 patient-days), 85.5% were unassisted, and unassisted falls had a higher odds of injury (adjusted odds ratio [aOR] 1.39; 95% CI 1.32 to 1.46) than assisted falls. Staggs and Dunton separately analyzed the rate of unassisted falls per inpatient hospital day in 1391 US hospitals in 2011 using data from the NDNQI. In medical-surgical units, each additional registered nurse (RN) hour per patient-day was weakly associated with a 2% (95% CI 0 to 3%) decrease in average fall rate.14 In step-down and medical units, fall rates depended on the level of staffing: at low staffing levels, fall rates increased as staffing increased, but at moderate to high levels of staffing, the fall rate decreased as staffing increased. Higher levels of non-RN staffing were generally associated with higher fall rates.

Using fiscal year 2004 data from the Veterans Health Administration (VA) and calendar year 2003 data from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS), Rivard and co-authors (2008)6 found that the overall risk-adjusted rate of PSI 08 (version 2.1) was similar (0.3 per 1,000 discharges) between the VA and the NIS. Chen et al. analyzed rates of PSI 08 (version 3.1a) among veteran dual users (i.e., those with hospitalizations in both the Veterans Health Administration [VA] and private sector hospitals through Medicare) during 2002-2007 and found observed and risk-adjusted rates of PSI 08 in the VA (0.8 and 0.6 respectively; 95% CI 0.5 to 0.7) to be significantly lower than in the private sector (0.7 and 0.4 respectively; 95% CI 0.3 to 0.5).15 However, they found no significant differences in the adjusted odds of developing PSI 08 between VA and private sector hospitalizations, among dual users (OR 1.20; 95% CI 0.80 to 1.81). Rosen et al. (2006) used VA Patient Treatment File (PTF) data to examine risk-adjusted PSI rates (version 2.1) across acute care VA hospitals for fiscal years 2001 to 2004;16 the only hospital characteristic (e.g. bed size, teaching status) associated with PSI 08 rates was hospital location (i.e., metropolitan status) (p < 0.01). Finally**, Rosen et al. (2010) used PSI 08 (version 3.1a) to explore associations between safety climate, as measured through more than 4,500 responses to the Patient Safety Climate in Healthcare Organizations survey, and hospital safety performance. Among the 30 VA hospitals that participated in the survey, the rate of postoperative hip fractures was not significantly associated with the 11 dimensions of patient safety culture included in the analysis.17**

Analyzing NIS data on all hospitalizations between 2002 and 2010 involving coiling or clipping unruptured cerebral aneurysms, Fargen et al found hospital type (teaching vs nonteaching) and hospital bed size were not associated with PSI 08 incidence in this sample.18 In an analysis of Medicare claims data for patients undergoing any of 6 cancer resections in 2005-2009, Short et al. found that the postoperative hip fracture rate was higher at high procedure volume hospitals than at low-volume hospitals (0.01% vs 0%), at urban hospitals than rural hospitals (0.01% vs 0%), and at non-teaching hospitals than teaching hospitals (0.02% vs 0.01%) (statistical values not provided).19

***Association with other outcomes***

Zapatero et al. analyzed clinical data (n=2,134,363) from the Basic Minimum Data Set (BMDS) which is part of the Spanish National Health Service. A total of 1127 (0.057%) patients were coded using the AHRQ PSI (version 4.3) for an in-hospital hip fracture.20 Patients with an in-hospital hip fracture had a higher mortality rate (27.9% vs 9.4%, p <0.001) and a longer mean length of stay (20.7 days vs 9.8 days, p<0.001) than those who did not experience a hip fracture. Costs were also higher for patients who experienced PSI 08 than for patients who did not (6927€ versus 3730€). Murray et al. studied 2003 data on Australian patients with hip fractures and found that several outcome measures were worse after hospital-acquired hip fractures than after hip fractures in the community.21 These outcomes included higher in-hospital mortality (28% vs 9%, p=0.03), higher prevalence of discharge to nursing homes (33% vs 12%, p=0.02), lower prevalence of discharge back into the community (23% vs. 72%, p <0.001), lower prevalence of return to preadmission activities of daily living (ADL) (9% vs 56%, p <0.001), and higher median length of stay after fracture (46 versus 32 days, p<0.01). Based on an analysis of the 501,908 hospitalizations involving a brain tumor in the NIS between 2002 and 2010, Rahman et al found that patients with postoperative hip fractures had significantly longer stays than patients without postoperative hip fractures (7.6 vs 6.5 day mean length of stay, respectively; p < 0.0001).22

In an analysis of Medicare claims data for patients undergoing any of 6 cancer resections for the years 2005-2009, Short et al. found that after adjusting for patient (age, sex, race, income), hospital (hospital volume, surgeon volume, surgeon specialty designation, hospital resources, patient characteristics) and tumor factors (tumor stage, site), costs increased significantly with postoperative hip fracture among 2 of the 6 types of cancer resection patients (p < 0.01).19 Zhan and Miller used AHRQ PSI software on 7.45 million discharges in the HCUP NIS (2000) and found that compared to those that did not experienced a PSI 08 event, those that did had a higher mean (SD) unadjusted length of stay (160.37 [0.58] vs. 50.39 [0.007]), charges $52,224 [1784] vs. $24,594 [35]), and percent mortality (90.93 [0.92] vs. 10.70 [0.01]).23 Finally, Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 08 event were associated with an additional 3.46 hospital days compared to patients without a PSI 03 event (p<0.001).24

***Population group disparities***

**Table 5** presents population group disparities for PSI 08 In-Hospital Fall with Fracture Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims datafrom July 1, 2017 to June 30, 2018.

**Table 5. PSI 08 In-Hospital Fall with Fracture Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 84356 | 0.083 | 0.117 |
| White | 6266488 | 0.120 | 0.115 |
| Black | 1015824 | 0.040 | 0.050 |
| Other | 98333 | 0.102 | 0.109 |
| Asian | 112160 | 0.054 | 0.055 |
| Hispanic | 180702 | 0.066 | 0.083 |
| North American Native | 60503 | 0.066 | 0.080 |
| **Gender** |  |  |  |
| Female | 4168509 | 0.125 | 0.103 |
| Male | 3649857 | 0.085 | 0.114 |
| **Age** |  |  |  |
| <50 | 459025 | 0.037 | 0.112 |
| 50-54 | 255344 | 0.086 | 0.149 |
| 55-59 | 383777 | 0.050 | 0.085 |
| 60-64 | 476589 | 0.076 | 0.097 |
| 65-69 | 1352972 | 0.070 | 0.105 |
| 70-74 | 1318953 | 0.090 | 0.113 |
| 75-79 | 1166006 | 0.121 | 0.097 |
| 80-84 | 989580 | 0.145 | 0.113 |
| 85-89 | 793387 | 0.187 | 0.116 |
| 90 plus | 622733 | 0.148 | 0.095 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review results presented below constitute the most recent update, conducted in August 2020. Search terms included relevant MeSH terms (accidental falls, hip fracture) and keywords (inpatient falls). We combined this clinical search string with MeSH terms (patient admission) and keywords (hospitals, patient admission, inpatient, patient safety, or quality) to identify studies examining inpatient care. Search was limited to English publications. We also tested more inclusive search strings. To provide the most up-to-date evidence, we summarize below the most recent evidence.

# 1a.4.3. Provide the citation(s) for the evidence.

1. Cameron ID, Gillespie LD, Robertson MC, et al. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database Syst Rev.* 2012;12:CD005465.

2. Dykes PC, Carroll DL, Hurley A, et al. Fall prevention in acute care hospitals: a randomized trial. *Jama.* 2010;304(17):1912-1918.

3. Haines TP, Hill AM, Hill KD, et al. Cost effectiveness of patient education for the prevention of falls in hospital: economic evaluation from a randomized controlled trial. *BMC Med.* 2013;11:135.

4. Haines TP, Bennell KL, Osborne RH, Hill KD. Effectiveness of targeted falls prevention programme in subacute hospital setting: randomised controlled trial. *Bmj.* 2004;328(7441):676.

5. Healey F, Monro A, Cockram A, Adams V, Heseltine D. Using targeted risk factor reduction to prevent falls in older in-patients: a randomised controlled trial. *Age Ageing.* 2004;33(4):390-395.

6. Miake-Lye IM, Hempel S, Ganz DA, Shekelle PG. Inpatient fall prevention programs as a patient safety strategy: a systematic review. *Ann Intern Med.* 2013;158(5 Pt 2):390-396.

7. Drahota AK, Ward D, Udell JE, et al. Pilot cluster randomised controlled trial of flooring to reduce injuries from falls in wards for older people. *Age Ageing.* 2013;42(5):633-640.

8. Lai SW, Liao KF, Liao CC, Muo CH, Liu CS, Sung FC. Polypharmacy correlates with increased risk for hip fracture in the elderly: a population-based study. *Medicine (Baltimore).* 2010;89(5):295-299.

9. Ziere G, Dieleman JP, Hofman A, Pols HA, van der Cammen TJ, Stricker BH. Polypharmacy and falls in the middle age and elderly population. *Br J Clin Pharmacol.* 2006;61(2):218-223.

10. Pierce JR, Jr., Shirley M, Johnson EF, Kang H. Narcotic administration and fall-related injury in the hospital: implications for patient safety programs and providers. *The International journal of risk & safety in medicine.* 2013;25(4):229-234.

11. Stollenwerk B, Waldeyer R, Klein-Meding C, Müller D, Stock S. Cost effectiveness of external hip protectors in the hospital setting: a modeling study. *Nurs Econ.* 2014;32(2):89-98.

12. Latimer N, Dixon S, Drahota AK, Severs M. Cost--utility analysis of a shock-absorbing floor intervention to prevent injuries from falls in hospital wards for older people. *Age Ageing.* 2013;42(5):641-645.

13. Staggs VS, Mion LC, Shorr RI. Assisted and unassisted falls: different events, different outcomes, different implications for quality of hospital care. *Jt Comm J Qual Patient Saf.* 2014;40(8):358-364.

14. Staggs VS, Dunton N. Associations between rates of unassisted inpatient falls and levels of registered and non-registered nurse staffing. *Int J Qual Health Care.* 2014;26(1):87-92.

15. Chen Q, Hanchate A, Shwartz M, et al. Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicator Rates Among Veteran Dual Users. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2013;29(4):335-343.

16. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Medical care.* 2006;44(9):850-861.

17. Rosen AK, Singer S, Shibei Z, Shokeen P, Meterko M, Gaba D. Hospital safety climate and safety outcomes: is there a relationship in the VA? *Med Care Res Rev.* 2010;67(5):590-608.

18. Fargen KM, Rahman M, Neal D, Hoh BL. Prevalence of patient safety indicators and hospital-acquired conditions in those treated for unruptured cerebral aneurysms: establishing standard performance measures using the Nationwide Inpatient Sample database. *J Neurosurg.* 2013;119(4):966-973.

19. Short MN, Aloia TA, Ho V. The influence of complications on the costs of complex cancer surgery. *Cancer.* 2014;120(7):1035-1041.

20. Zapatero A, Barba R, Canora J, et al. Hip fracture in hospitalized medical patients. *BMC Musculoskelet Disord.* 2013;14:15.

21. Murray GR, Cameron ID, Cumming RG. The consequences of falls in acute and subacute hospitals in Australia that cause proximal femoral fractures. *Journal of the American Geriatrics Society.* 2007;55(4):577-582.

22. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

23. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Quality & safety in health care.* 2003;12 Suppl 2:ii58-63.

24. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2017;32(6):583-590.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite Measure)

**Measure Title**: PSI 09 Perioperative Hemorrhage and Hematoma Rate (Component Measure)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:**  Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

PSI 09 is intended to capture preventable and significant perioperative hemorrhage or hematoma events that are in excess of what is expected for the surgery type. The intent is to capture bleeding-related events that are severe or involve a delay in diagnosis or treatment requiring reoperation, as these events are associated with a significant increase in risk to the patient. Such events are often associated with 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. Best practices to prevent perioperative hemorrhage and hematoma include taking steps to address and avoid technical errors such as inadequate ligation, cauterization, clipping, or stapling of blood vessels; failure to recognize transection of a minor vessel; or defects in vascular anastomoses. Additional patient management processes that can contribute to PSI 09 events include excessive anticoagulation; inadequate correction or reversal of coagulopathy; failure to replace clotting factors in cases involving large-volume blood loss; and intraoperative hypothermia.

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

***Association with processes of care***

Several studies have identified variation in postoperative bleeding rates based on the operative approach chosen by the surgeon, including the use of transcervical arterial ligation for transoral robotic surgery,1 robotic distal pancreatectomy,2 and percutaneous approach for trans-femoral transcatheter aortic valve implantation.3 A Cochrane review assessed the comparative effects of three anti-fibrinolytic drugs (aprotinin, tranexamic acid (TXA), and epsilon aminocaproic acid [EACA]) on blood loss during surgery, the need for red blood cell (RBC) transfusion, and other adverse events. The review concluded that aprotinin and EACA significantly reduced the need for reoperation due to bleeding, but that TXA did not.4 Wiegmann et al analyzed claims data from 2007 through 2017 (22 million covered lives) found that patients preoperatively prescribed antithrombotic agents were 2.3 times more likely to develop postoperative bleeding complications (p<0.0001).5

Spertus et al. (2015) used percutaneous coronary intervention data from 9 US hospitals to compare the use of bleeding avoidance strategies and bleeding rates before and after implementation of a validated risk model to determine individual patient risk of bleeding [developed by the American College of Cardiology’s National Cardiovascular Data Registry (NCDR) Catheterization PCI Registry]. They compared 7408 pre-intervention procedures with 3529 post-intervention procedures and found that the use of the risk stratification protocol was also associated with lower bleeding rates compared to non-interventional sites (1.0% v 1.7%; odds ratio 0.56, 0.40 to 0.78; 0.62, 0.44 to 0.87), after adjustment.6

A limited number of older studies evaluated the actual occurrence of process failures in association with PSI 09 events. In a case control study involving 1,025 Medicare discharges from acute-care hospitals in California and Connecticut in 1994, nurse-identified process of care failures were relatively frequent among major surgical cases with postprocedural hemorrhage or hematoma (29/44=66%), after excluding patients who had hemorrhage or hematoma at admission.7 Specifically, “problems with technical care during a procedure were present in 12 of 17 surgical… cases of postprocedural hemorrhage or hematoma”.8 Physician reviewers identified potential quality problems in 37% of major surgery patients with this event, versus 2% of unflagged controls.8 However, cases flagged on this indicator and unflagged controls did not differ significantly on a composite of 17 generic process criteria, confirming previous findings in elderly Medicare beneficiaries from Massachusetts, Alabama, Iowa, and New York.9

***Association with hospital and health system characteristics***

**Studies** examining the impact of health system characteristics such as teaching status, safety climate, bed size, and nurse staffing hours on PSI 09 rates have been inconclusive**.10-13 Before mandatory present on admission (POA) reporting, rates were significantly higher at major teaching hospitals than at nonteaching hospitals in the Nationwide Inpatient Sample (OR 1.20 [95% CI 1.01 to 1.42]), but not in the Veterans Health Administration.** Chen et al. analyzed rates of PSI 09 (version 3.1a) among veteran dual users (i.e., those with hospitalizations in both the VA and the private sector with Medicare coverage) during 2002 to 2007 and found the risk-adjusted rate of PSI 09 in the VA (3.3; 95% CI 3.0-3.6) to be significantly higher than in the private sector (2.1; 95% CI 1.9-2.4); dual users hospitalized in the VA had 1.73 times higher odds of PSI 09 than those hospitalized in the private sector (95% CI 1.48-2.03).12 Rivard et al. (2010) examined over 4500 responses to the Patient Safety Climate in Healthcare Organizations survey **and found that the PSI 09 rate was not significantly associated with any of the 11 dimensions of patient safety culture, adjusting for major teaching status, metropolitan area, and nurse-staffing ratio (p>0.10 for all comparisons).10** A study using the national inpatient data from the Japanese Diagnosis Procedure Combination database reported postoperative bleeding and perforation in 331 (4.4%) and 13 patients (0.2%) who underwent colorectal endoscopic submucosal dissections (n=7567). “Multivariable logistic regression analysis showed that the very high hospital volume group had a significantly lower proportion of severe postoperative bleeding than the very low hospital volume group (OR = 0.48 [95 % CI, 0.27-0.83]; p = 0.009)”.14

***Association with other outcomes***

PSI 09 events are associated with a number of important and significant patient harms such as increased postoperative infection, hypovolemic or hemorrhagic shock, reoperation, complications from blood transfusion (such as transfusion-related acute cardiac overload [TACO] and transfusion-related lung injury [TRALI]), mortality and resource use.11,15-25

**Research has established associations between PSI 09 and other outcomes, including hospital readmissions,** costs, length of stay, and mortality.17-20,26 Cases from the 2000 Nationwide Inpatient Sample that were flagged by this PSI had 3.0% excess mortality, 3.9 days of excess hospitalization, and $21,431 in excess hospital charges, relative to carefully matched controls that were not flagged.19 This finding was confirmed in the Veterans Health Administration system, where cases that were flagged by this PSI in 2001 had 5.1-8.0% excess mortality, 3.9-4.7 days of excess hospitalization, and $7,863-10,012 in excess hospital costs, relative to propensity-matched or multivariable regression-adjusted controls that were eligible but not flagged.11 In another study based on State Inpatient Databases from seven states that permit linkage of serial hospitalizations, PSI 09 was associated with risk ratios of 1.03 (NS) for inpatient death, 1.18 (p<0.01) for readmission within three months, and 1.10 (NS) for readmission within one month, after adjusting for age, gender, payer, comorbidities, specific surgical DRGs, and APR-DRG severity levels.21 Similarly, in a multivariable analysis of Veterans Health Administration data, hospitalizations with PSI 09 were 60% more likely to result in a readmission within 30 days than eligible hospitalizations without PSI 09 (18.8% versus 11.3%; OR=1.60, 95% CI 1.40 to 1.83), after adjusting for age, sex, comorbidities, and other PSI events (Rosen et al., 2013).17 Ramanathan et al. (2014) retroactively examined data on surgical patients hospitalized between 2011 and 2012 at a single academic medical center and found that hospitalizations with PSI 09 (version 3.1) were associated with a mean hospital LOS of 22.1 days, 64.5% included an intensive care unit stay, and 3.2% died in hospital.22 Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 09 event were associated with an additional 2.23 hospital days compared to patients without a PSI 03 event (p<0.001).27

Several other studies have focused on narrower clinical cohorts. In an analysis of patient-level Medicare claims data for patients undergoing any of 6 cancer resections in 2005-2009, Short et al. found that after adjusting for patient factors (age, sex, race, income), hospital factors (hospital volume, surgeon volume, surgeon specialty designation, hospital resources, patient characteristics) and tumor factors (tumor stage, site), costs increased significantly in association with postoperative hemorrhage or hematoma for four of the six types of cancer resection patients (p<0.001).18 Based on an analysis of the 501,908 hospitalizations involving a brain tumor in the NIS between 2002 and 2010, Rahman et al. (2013) found that patients with postoperative hemorrhage or hematoma had significantly longer length-of-stay (LOS) (13.1 days vs 6.5 days; p < 0.0001), on average, than patients without this complication.20 In another NIS-based study limited to patients with breast cancer hospitalized for a mastectomy in 2011, Nwaogu et al. (2015) reported a 1.3 day increase in the mean length of stay (P < 0.0001), a $5495 increase in the mean cost per hospital stay (P < 0.0001), and a reoperation rate of 2.5% (42 of 201) associated with a bleeding complication (as defined by ICD-9-CM codes 998.11, 998.12, 39.98, and 86.04).16 De la Garza-Ramos and colleagues (2016) estimated the incidence of in-hospital morbidity and mortality following surgery for malignant brain tumors using the NIS from 2002 to 2011; patients who had experienced a hemorrhage/hematoma complication (based on an expanded list of ICD-9-CM codes [998.1–998.13] compared to PSI 09) had 3.3 times higher odds of mortality (95% CI 1.6–6.6) than those who did not experience that surgical complication.23 Finally, Ang and colleagues (2015) used 2013 data from the Florida Agency for Health Care Administration to evaluate trauma mortality using the AHRQ PSIs. Of the 939 PSI 09 events (version 4.5) in 50,596 trauma patients, there were 101 deaths. With an adjusted “failure to prevent” observed-to-expected ratio of 3.53, PSI 09 had the strongest influence on trauma mortality among the 10 PSIs reviewed.28

***Population group disparities***

**Table 6** presents population group disparities for PSI 09 Perioperative Hemorrhage and Hematoma Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims data from July 1, 2017 to June 30, 2018.

**Table 6. PSI 09 Perioperative Hemorrhage and Hematoma Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 35227 | 2.498 | 2.642 |
| White | 1990623 | 2.396 | 2.579 |
| Black | 216349 | 3.480 | 2.921 |
| Other | 28434 | 3.622 | 3.352 |
| Asian | 26454 | 3.553 | 3.235 |
| Hispanic | 42594 | 2.676 | 2.315 |
| North American Native | 16747 | 2.986 | 2.917 |
| **Gender** |  |  |  |
| Female | 1240467 | 2.102 | 2.636 |
| Male | 1115961 | 3.015 | 2.633 |
| **Age** |  |  |  |
| <50 | 99339 | 3.755 | 2.697 |
| 50-54 | 65309 | 3.491 | 2.854 |
| 55-59 | 102184 | 3.269 | 2.678 |
| 60-64 | 131922 | 2.903 | 2.582 |
| 65-69 | 554705 | 2.331 | 2.618 |
| 70-74 | 497712 | 2.429 | 2.608 |
| 75-79 | 384242 | 2.800 | 2.718 |
| 80-84 | 263996 | 2.379 | 2.540 |
| 85-89 | 165309 | 2.057 | 2.587 |
| 90 plus | 91710 | 1.178 | 2.476 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review results presented below constitute the most recent update, conducted in August 2020. Search terms included relevant MeSH terms (hematoma, hemorrhage, hypovolemic shock, postoperative, perioperative, or surgical complications). We combined this clinical search string with MeSH terms (hospitals, patient admission, inpatient, indicator, epidemiol\*, statistic, patient safety, AHRQ, prevalence, incidence, or utilization) to identify studies examining quality of inpatient care. The search was limited to English-language publications. For completeness we also tested more inclusive search strings. Below we have provided a summary of the most up-to-date evidence.

# 1a.4.3. Provide the citation(s) for the evidence.

1. Sharbel DD, Abkemeier M, Sullivan J, et al. Transcervical arterial ligation for prevention of postoperative hemorrhage in transoral oropharyngectomy: Systematic review and meta-analysis. *Head Neck.* 2020.

2. Lyu Y, Cheng Y, Wang B, Zhao S, Chen L. Comparison of 3 Minimally Invasive Methods Versus Open Distal Pancreatectomy: A Systematic Review and Network Meta-Analysis. *Surg Laparosc Endosc Percutan Tech.* 2020.

3. Abdelaziz HK, Megaly M, Debski M, et al. Meta-Analysis Comparing Percutaneous to Surgical Access in Trans-Femoral Transcatheter Aortic Valve Implantation. *Am J Cardiol.* 2020;125(8):1239-1248.

4. Henry DA, Carless PA, Moxey AJ, et al. Anti-fibrinolytic use for minimising perioperative allogeneic blood transfusion. *Cochrane Database Syst Rev.* 2011(3):CD001886.

5. Wiegmann AL, Khalid SI, Coogan AC, et al. Antithrombotic prescriptions for many general surgery patients significantly increases the likelihood of post-operative bleeding complications. *Am J Surg.* 2020;219(3):453-459.

6. Spertus JA, Decker C, Gialde E, et al. Precision medicine to improve use of bleeding avoidance strategies and reduce bleeding in patients undergoing percutaneous coronary intervention: prospective cohort study before and after implementation of personalized bleeding risks. *Bmj.* 2015;350:h1302.

7. Iezzoni LI, Davis RB, Palmer RH, et al. Does the Complications Screening Program flag cases with process of care problems? Using explicit criteria to judge processes. *Int J Qual Health Care.* 1999;11(2):107-118.

8. Weingart SN, Iezzoni LI, Davis RB, et al. Use of administrative data to find substandard care: validation of the complications screening program. *Med Care.* 2000;38(8):796-806.

9. Iezzoni LI, Lawthers A, Peterson L, McCarthy E, Palmer RH, Cahalane M. *Project to validate the Complications Screening Program: Health Care Financing Administration.* 1998. HCFA Contract 500-94-0055.

10. Rivard PE, Elixhauser A, Christiansen CL, Shibei Z, Rosen AK. Testing the association between patient safety indicators and hospital structural characteristics in VA and nonfederal hospitals. *Med Care Res Rev.* 2010;67(3):321-341.

11. Rivard PE, Christiansen CL, Zhao S, Elixhauser A, Rosen AK. Advances in Patient Safety: Is There an Association Between Patient Safety Indicators and Hospital Teaching Status? In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 2: Culture and Redesign).* Rockville (MD)2008.

12. Chen Q, Hanchate A, Shwartz M, et al. Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicator Rates Among Veteran Dual Users. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2013;29(4):335-343.

13. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Medical care.* 2006;44(9):850-861.

14. Odagiri H, Yasunaga H, Matsui H, Fushimi K, Iizuka T, Kaise M. Hospital volume and the occurrence of bleeding and perforation after colorectal endoscopic submucosal dissection: analysis of a national administrative database in Japan. *Dis Colon Rectum.* 2015;58(6):597-603.

15. In: *WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives.* Geneva2009.

16. Nwaogu IY, Bommarito K, Olsen MA, Margenthaler JA. Economic impact of bleeding complications after mastectomy. *J Surg Res.* 2015;199(1):77-83.

17. Rosen AK, Loveland S, Shin M, et al. Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Med Care.* 2013;51(1):37-44.

18. Short MN, Aloia TA, Ho V. The influence of complications on the costs of complex cancer surgery. *Cancer.* 2014;120(7):1035-1041.

19. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Quality & safety in health care.* 2003;12 Suppl 2:ii58-63.

20. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

21. Friedman B, Encinosa W, Jiang HJ, Mutter R. Do patient safety events increase readmissions? *Med Care.* 2009;47(5):583-590.

22. Ramanathan R, Leavell P, Wolfe LG, Duane TM. Agency for Healthcare Research and Quality patient safety indicators and mortality in surgical patients. *Am Surg.* 2014;80(8):801-804.

23. De la Garza-Ramos R, Kerezoudis P, Tamargo RJ, Brem H, Huang J, Bydon M. Surgical complications following malignant brain tumor surgery: An analysis of 2002-2011 data. *Clin Neurol Neurosurg.* 2016;140:6-10.

24. Mulholland MW, Doherty GM. *Complications in Surgery.* Philadelphia, PA: Lippincott, Williams & Wilkins; 2011.

25. Brunicardi F, Andersen D, Billiar T. *Schwartz's Principles of Surgery, 10e.* Columbus, OH: McGraw-Hill Education; 2015.

26. Ramanathan R, Leavell P, Stockslager G, Mays C, Harvey D, Duane TM. Validity of Agency for Healthcare Research and Quality Patient Safety Indicators at an academic medical center. *Am Surg.* 2013;79(6):578-582.

27. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2017;32(6):583-590.

28. Ang D, McKenney M, Norwood S, et al. Benchmarking statewide trauma mortality using Agency for Healthcare Research and Quality's patient safety indicators. *J Surg Res.* 2015;198(1):34-40.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite Measure)

**Measure Title**: PSI 10 Postoperative Acute Kidney Injury Requiring Dialysis Rate (Component)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

PSI 10 focuses on patients without severe chronic kidney disease at baseline who undergo an elective surgical procedure and then develop acute kidney failure (also referred to as acute kidney injury [AKI] or acute renal failure [ARF]) severe enough to require dialysis as a postoperative complication. It is thought that through better perioperative care, many of these events are preventable. Best practices to prevent postoperative kidney failure include identifying patients at risk (e.g. older age, hypovolemia, infection, etc.); avoiding nephrotoxic medications or using them with caution (e.g. ACE inhibitors, aminoglycosides, NSAIDs, intravenous contrast, etc.); and using volume expansion, vasodilators, and inotropes as needed to avoid hypovolemia and hypotension.

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

### *Association with process of care*

Several studies have identified variation in AKI rates based on the operative approach chosen by the surgeon, including laparoscopic vs. open bariatric surgery (0.94% versus 3.87%; p < .01),1 non-gastric vs. gastric bypass (0.82% versus 1.54%; p< .01)1 and laparoscopic vs. open abdominal procedures (aRR 0.52 [95% CI 0.47 to 0.58]).2 Among patients who underwent lung resection surgery in a tertiary care academic center (2006-2010; n=1129), postoperative AKI was associated with preoperative use of angiotensin II receptor blockers (OR 2.2, 95% CI: 1.1-4.4), intraoperative hydroxyethyl starch administration (OR 1.5, 95% CI: 1.1-2.1), and thoracoscopic (versus open) procedures (OR 0.37, 95% CI: 0.15-0.90). AKI in this study was also associated with increased rates of tracheal reintubation (12% vs 2%, P < 0.001) and postoperative mechanical ventilation (15% vs 3%, P < 0.001), suggesting that AKI may precede or occur concurrently with postoperative respiratory failure. 3 In a study of 119 cases flagged by PSI 10 (v3.1) from 28 acute care hospitals in the Veterans Health Administration, there were 73 true positives with AKI, of whom 37% died and 26% were discharged on dialysis. AKI was most commonly attributed to perioperative renal hypoperfusion (84% of true positives), followed by nephrotoxins (33%) including contrast (11%).23 A recent systematic review including one randomized trial and four observational studies (n=10,468) concluded that preoperative aspirin (at any dose) is associated with reduced incidence of postoperative AKI (OR 0.68, 95% CI, 0.51-0.91, p=0.008).4

Studies examining the association between PSI 10 and patient or clinical characteristics found that strong predictors of AKI include male gender, hypertension, higher body mass index, ascites, preoperative sepsis, active congestive heart failure, renal insufficiency, peripheral vascular disease, increased age, Medicare payer, alcohol abuse, chronic lung disease, diabetes, smoking, schizophrenia, functional dependence, ventilator dependence, myocardial infarction, bleeding disorders, hematocrit, chronic steroid use, and cancer.1-3,5-9

### *Association with hospital and health system characteristics*

Various hospital and health system characteristics have been shown to be associated with **postoperative acute kidney injury (AKI). Using 2000-2010 NIS data,** Spolverate et al found acute renal **f**ailure (ARF) occurred in 4.2% of patients who underwent liver resection for malignancy and was less common in high-volume hospitals than in low or intermediate volume hospitals (3.3% versus 4.7% and 5.0%, respectively).10 In an analysis of Medicare claims data for patients undergoing any of six types of cancer resection (2005-2009), Short et al. found that the rate of **postoperative AKI** was lower at high procedure volume hospitals than at low-volume hospitals (0.06 vs 0.09), at rural hospitals than at urban hospitals (0 vs 0.09), and at non-teaching hospitals than at teaching hospitals (0.07 vs 0.10) (statistical values not provided).11 **Rivard et al. (2010) examined the relationship between PSI 10 (V2.1) and hospital characteristics in Veterans Health Administration (VHA) and nonfederal community hospitals, using data from the VA and the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS, 2003-2004). Rates of this indicator were not significantly associated with bed size, nurse staffing hours, or teaching status in either VA or NIS hospitals.12** Using the NIS database (2006 to 2008), Masoomi et al analyzed **cl**inical data from morbidly obese patients who underwent bariatric surgery and also found no significant effect for teaching status of the hospital on the rate of ARF.1

Rosen et al. (2006) did not find risk-adjusted PSI 10 rates (version 2.1) to be significantly associated with any single hospital characteristic (e.g. bed size, teaching status, location) in the 2001-2004 VA Patient Treatment File (PTF).13 **In another study, Rosen et al. used the PSIs, including PSI 10 (version 3.1), to explore the potential relationship between safety climate, as measured through more than 4500 responses to the Patient Safety Climate in Healthcare Organizations survey, and hospital safety performance. They found that among the 30 VA hospitals that participated in the survey, the PSI 10 rate was not significantly associated with any of the 11 dimensions of patient safety culture (p>0.10 for all comparisons). The authors note that due to the small sample size, the relatively low rate of PSIs among VA hospitals, and narrow variation across hospitals in patient safety culture, statistical power to detect associations was limited for most PSIs, including PSI 10.14**

Finally, a study by Hawkins et al, drawing on NSQIP data (2005-2010) for patients undergoing repairs of ruptured abdominal aortic aneurysms, found that after risk adjustment for factors including age, sex, and method of repair, the odds of renal insufficiency or failure (OR 0.54; 95% CI 0.31 to 0.95; p = .034) were significantly less for those operated on by vascular surgeons than for those who were operated on by general surgeons.15

### *Association with other outcomes*

Cases from the 2000 Nationwide Inpatient Sample that were flagged by this PSI had 19.8% excess mortality, 8.9 days of excess hospitalization, and $54,818 in excess hospital charges, relative to carefully matched controls that were not flagged (Zhan and Miller, 2003).16 More recent studies have confirmed these findings, as summarized below, separately for each outcome.

AKI is associated with significantly increased mortality following a variety of surgical procedures. Ricciardi et al. analyzed NSQIP data (2005-2008) for patients undergoing colorectal surgery and found that patients who experienced postoperative kidney failure had 2.7 times higher odds of 30-day mortality than those who did not (95% CI 1.3 to 5.5).17 Using the NIS database (2006-2008), Masoomi et al. studied morbidly obese patients who underwent bariatric surgery and found that patients with acute kidney failure had significantly greater in-hospital mortality than those without it (5.69% versus 0.04%, p< .01).1 Similarly, Bensley et al.’s multivariable regression analysis of 450 NSQIP (2005-2010) patients who underwent open surgical repair of thoracoabdominal aortic aneurysms (TAAA) showed that postoperative kidney failure was a strong predictor of perioperative (30-day) mortality (OR=8.4; 95% CI 3.41 to 20.56).18 Based on data on 15 intra-abdominal general surgery procedure categories (n = 457,656) in the NSQIP database (2005-2010), Kim et al. found that after adjusting for comorbidities and operative factors, perioperative AKI was associated with a 3.5-fold increase in the risk of 30-day mortality (aRR, 3.51, 95% CI 3.29 to 3.74).2 Similarly, using NSQIP (2005-2006) data, Kheterpal et al. found that all-cause 30-day mortality among patients who developed AKI after general surgery was 42% vs 8.6% for matched cohorts who did not develop AKI (hazard ratio 7.5; 95% CI 5.2–10.8).8 Corredor et al. conducted a systematic review and meta–analysis based on 9 observational studies with long-term follow-up of 35,021 cardiac surgery patients. Postoperative AKI was associated with a significantly increased risk of long-term mortality (HR 1.68, 95% CI, 1.45-1.95 based on 8 studies). Hobson et al. found that risk-adjusted 90-day mortality was 6.5% for patients with AKI compared to 4.4% for patients without AKI (risk-adjusted rate ratio 1.65, 95% CI 1.48 to 1.84) in a single-center cohort of 50,314 adult surgical patients undergoing major inpatient surgery.19 In-hospital mortality was also significantly higher in the AKI group (4.2% vs. 2.1%, adjusted risk ratio 2.38, 95% CI 2.00-2.84). Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 10 event were associated with an additional 6.37 hospital days compared to hospitalizations without a PSI 10 event (p<0.001), as well as a significantly increased risk of in-hospital mortality (OR=168.91; p<0.001).20

In a study based on State Inpatient Databases from seven states that permit linkage of serial hospitalizations, PSI 10 was associated with risk ratios of 1.30 for readmission within three months, and 1.09 for readmission within one month, after adjusting for age, gender, payer, comorbidities, specific surgical DRGs, and APR-DRG severity levels).21 Similarly, in a multivariable analysis of Veterans Health Administration data, hospitalizations with a PSI 10 event had 53% higher odds of resulting in a readmission within 30 days (OR 1.53; 95% CI 1.26 to 1.86), after adjusting for age, sex, comorbidities, and other PSI events (Rosen et al., 2013).22 In a sample of over 2,000 coronary artery or valve surgery patients from seven hospitals (2008-2010), Brown et. al. found that patients without postoperative AKI had a 30-day readmission rate of 9.3% compared to 16.1%, 21.8%, and 28.6% among patients developing stage 1, 2, and 3 AKI, respectively (p < 0.001).23 Adjusted odds ratios showed a similar progression of risk, with odds ratios of 1.81 (95% CI 1.35 to 2.44), 2.39 (95% CI 1.38 to 4.14), and 3.47 (95% CI 1.85 to 6.50) for patients developing stage 1, 2, and 3 AKI, compared to those without AKI. Among 501,908 hospitalizations with brain tumors in the 2002-2010 NIS, patients with a PSI 10 AKI event had significantly longer LOS (7.6 days vs 6.5 days; p < 0.0001) than patients without postoperative AKI.24 Bath et al. used Medicare data (MedPAR) from 2009 to 2012 and found that the likelihood of 30-day readmission among patients undergoing abdominal aortic aneurysm repair was greater among patients with postoperative AKI requiring dialysis (OR=1.88, p=0.0001).25

In a single-center cohort of 50,314 adult surgical patients, Hobson et al. used regression models to estimate the effect of postoperative AKI on hospital costs.19 The risk-adjusted average cost of care was $42,600 for patients with any AKI compared with $26,700 for patients without AKI, but the average cost per patient rose to $62,600 for those in the failure (F) category. Short et al. found that after adjusting for patient (age, sex, race, income), hospital (hospital volume, surgeon volume, surgeon specialty designation, hospital resources, patient characteristics) and tumor factors (tumor stage, site), costs increased significantly with PSI 10 among patients with three of six types of cancer resection (p < 0.001).11

***Population group disparities***

**Table 7** presents population group disparities for PSI 10 Postoperative AKI Requiring Dialysis Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims datafrom July 1, 2017 to June 30, 2018.

**Table 7: PSI 10 Postoperative AKI Requiring Dialysis Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 22980 | 1.480 | 1.678 |
| White | 1141162 | 1.332 | 1.339 |
| Black | 94263 | 1.772 | 1.422 |
| Other | 14517 | 0.896 | 0.730 |
| Asian | 11784 | 1.697 | 1.289 |
| Hispanic | 16533 | 1.391 | 1.224 |
| North American Native | 7416 | 1.753 | 1.581 |
| **Gender** |  |  |  |
| Female | 708991 | 0.990 | 1.351 |
| Male | 599664 | 1.814 | 1.337 |
| **Age** |  |  |  |
| <50 | 40893 | 0.954 | 1.374 |
| 50-54 | 30371 | 0.823 | 1.086 |
| 55-59 | 49802 | 0.944 | 1.339 |
| 60-64 | 66518 | 1.443 | 1.414 |
| 65-69 | 362055 | 1.190 | 1.395 |
| 70-74 | 319420 | 1.406 | 1.386 |
| 75-79 | 230198 | 1.672 | 1.280 |
| 80-84 | 131561 | 1.703 | 1.338 |
| 85-89 | 59900 | 1.336 | 1.218 |
| 90 plus | 17937 | 0.781 | 1.124 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review was conducted in August 2020. Search terms included relevant MeSH terms (Acute kidney injury or failure, or acute renal failure or insufficiency, or kidney tubular necrosis) and MeSH terms (hospitals, patient admission, inpatient, patient safety, quality, and perioperative, postoperative, or surgical complications, and indicator, epidemiol\*, statistic, patient safety, AHRQ, prevalence, incidence, or utilization) to identify studies examining quality of inpatient care. The search was limited to English publications.

# 1a.4.3. Provide the citation(s) for the evidence.

1. Masoomi H, Reavis KM, Smith BR, Kim H, Stamos MJ, Nguyen NT. Risk factors for acute respiratory failure in bariatric surgery: data from the Nationwide Inpatient Sample, 2006-2008. *Surg Obes Relat Dis.* 2013;9(2):277-281.

2. Kim M, Brady JE, Li G. Variations in the risk of acute kidney injury across intraabdominal surgery procedures. *Anesth Analg.* 2014;119(5):1121-1132.

3. Ishikawa S, Griesdale DE, Lohser J. Acute kidney injury after lung resection surgery: incidence and perioperative risk factors. *Anesth Analg.* 2012;114(6):1256-1262.

4. Aboul-Hassan SS, Stankowski T, Marczak J, et al. The use of preoperative aspirin in cardiac surgery: A systematic review and meta-analysis. *J Card Surg.* 2017;32(12):758-774.

5. Liao CC, Shen WW, Chang CC, Chang H, Chen TL. Surgical adverse outcomes in patients with schizophrenia: a population-based study. *Ann Surg.* 2013;257(3):433-438.

6. Gupta H, Ramanan B, Gupta PK, et al. Impact of COPD on postoperative outcomes: results from a national database. *Chest.* 2013;143(6):1599-1606.

7. Ponce BA, Oladeji LO, Raley JA, Menendez ME. Analysis of perioperative morbidity and mortality in shoulder arthroplasty patients with preexisting alcohol use disorders. *Journal of shoulder and elbow surgery / American Shoulder and Elbow Surgeons [et al].* 2014.

8. Kheterpal S, Tremper KK, Heung M, et al. Development and validation of an acute kidney injury risk index for patients undergoing general surgery: results from a national data set. *Anesthesiology* 2009;110(3):505-515.

9. Zhou X, Zhang Y, Teng Y, et al. Predictors of postoperative acute kidney injury in patients undergoing hip fracture surgery: A systematic review and meta-analysis. *Injury.* 2020.

10. Spolverato G, Ejaz A, Hyder O, Kim Y, Pawlik TM. Failure to rescue as a source of variation in hospital mortality after hepatic surgery. *The British journal of surgery.* 2014;101(7):836-846.

11. Short MN, Aloia TA, Ho V. The influence of complications on the costs of complex cancer surgery. *Cancer.* 2014;120(7):1035-1041.

12. Rivard PE, Elixhauser A, Christiansen CL, Shibei Z, Rosen AK. Testing the association between patient safety indicators and hospital structural characteristics in VA and nonfederal hospitals. *Medical care research and review : MCRR.* 2010;67(3):321-341.

13. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Medical care.* 2006;44(9):850-861.

14. Rosen AK, Singer S, Shibei Z, Shokeen P, Meterko M, Gaba D. Hospital safety climate and safety outcomes: is there a relationship in the VA? *Medical care research and review : MCRR.* 2010;67(5):590-608.

15. Hawkins AT, Smith AD, Schaumeier MJ, de Vos MS, Hevelone ND, Nguyen LL. The effect of surgeon specialization on outcomes after ruptured abdominal aortic aneurysm repair. *J Vasc Surg.* 2014;60(3):590-596.

16. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Quality & safety in health care.* 2003;12 Suppl 2:ii58-63.

17. Ricciardi R, Roberts PL, Read TE, Hall JF, Marcello PW, Schoetz DJ. Which adverse events are associated with mortality and prolonged length of stay following colorectal surgery? *J Gastrointest Surg.* 2013;17(8):1485-1493.

18. Bensley RP, Curran T, Hurks R, et al. Open repair of intact thoracoabdominal aortic aneurysms in the American College of Surgeons National Surgical Quality Improvement Program. *J Vasc Surg.* 2013;58(4):894-900.

19. Hobson C, Ozrazgat-Baslanti T, Kuxhausen A, et al. Cost and Mortality Associated With Postoperative Acute Kidney Injury. *Ann Surg.* 2014.

20. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2017;32(6):583-590.

21. Friedman B, Encinosa W, Jiang HJ, Mutter R. Do patient safety events increase readmissions? *Medical care.* 2009;47(5):583-590.

22. Rosen AK, Loveland S, Shin M, et al. Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Medical care.* 2013;51(1):37-44.

23. Brown JR, Parikh CR, Ross CS, et al. Impact of perioperative acute kidney injury as a severity index for thirty-day readmission after cardiac surgery. *The Annals of thoracic surgery.* 2014;97(1):111-117.

24. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

25. Bath J, Dombrovskiy VY, Vogel TR. Impact of Patient Safety Indicators on readmission after abdominal aortic surgery. *J Vasc Nurs.* 2018;36(4):189-195.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite Measure)

**Measure Title**: PSI 11 Postoperative Respiratory Failure Rate (Component Measure)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Respiratory failure—usually defined as unplanned intubation or prolonged ventilation—is considered to be the most serious of the postoperative respiratory complications because it represents the “end stage” of several types of pulmonary complications (e.g., pneumonia, aspiration, pulmonary edema, ARDS) and it often results in prolonged morbidity, mortality, and associated costs. Healthcare facilities can decrease postoperative respiratory failure rates by adopting and following guidelines for assessing perioperative pulmonary risk and implementing recommended preventive strategies for high-risk patients. Careful management of blood products and fluid resuscitation in the perioperative setting may reduce the risk of postoperative respiratory failure due to adult respiratory distress syndrome (ARDS).

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

### *Association with process of care*

Numerous studies have identified associations between specific intraoperative risk factors and postoperative respiratory failure.1-5 Analyzing data on 50,367 patient admissions for common adult surgical procedures using an anesthesia information system between 2004 and 2009, Blum et al. identified intraoperative risk factors associated with respiratory failure among patients with similar preoperative risk: ventilator drive pressure (OR=1.17), fraction inspired oxygen (OR=1.02), erythrocyte transfusion (OR=5.36), and crystalloid administration in liters (OR=1.37).1 Hughes et al. identified intraoperative risk factors for the postoperative development of ARDS among 89 patients admitted to the ICU with postoperative respiratory failure. In this study, patients who received more than 20mL/kg/h fluid resuscitation in the operating room had a higher chance of developing ARDS than those who received less than 10mL/kg/h (OR=3.8, p=0.04). Those who received between 10 and 20mL/kg/h had a non-significant odds ratio of 2.4 (p=0.14).2 In multivariable analysis of the National Surgical Quality Improvement Program (NSQIP) database of adult inpatients who underwent neurosurgery under general anesthesia (2005-2010), Shalev and co-authors found that operative time exceeding 3 hours was associated with increased risk of reintubation (OR 2.9; 95%CI 1.8–4.8).3 Blum et al. found that among 50,367 patient admissions for common adult surgical procedures between 2004 and 2009, the number of different anesthetics administered during the admission was associated with higher risk of ARDS (OR=1.37).1 In a retrospective time-matched cohort study, Attaallah et al. found that operative-specific risk factors including ASA status, elective case type, and surgical duration were significantly associated with postoperative respiratory failure.4 A recent matched case-control study conducted across five academic medical centers (n=638) found greater intraoperative ventilator volume and pressure and 24-hour fluid balance to be potentially modifiable factors associated with postoperative respiratory failure (personal communication; manuscript under review).

Two studies describe quality improvement interventions that resulted in decreased rates of acute respiratory failure.6,7 In a one-year, prospective cohort intervention study involving 13,743 patients in a large academic medical center, Braddock et al. found that, adjusting for patient characteristics, implementation of a multifaceted, microsystem intervention utilizing in situ simulation training (TRANSFORM) was associated with a significantly decreased rate of ARF.6 Multivariable logistic regression showed reduced odds of ARF following the intervention (OR 0.58, 95% CI 0.35 to 0.96). In a pre-post intervention study of 250 patients at an academic safety net hospital, Cassidy et al. found a trend towards fewer unplanned intubations following the I COUGH intervention, which emphasized incentive spirometry, coughing and deep breathing, oral care, patient and family education, head-of-bed elevation, and promoting mobilization.7 The incidence of unplanned intubations declined from 2.0% to 1.2% in the intervention group (p = 0.09), but remained relatively stable at comparable NSQIP hospitals (1.4% to 1.6%). Risk-adjusted NSQIP data showed that unplanned intubations fell from an observed-to-expected (OE) ratio of 2.10 (95% CI 1.42 to 2.98) before I COUGH to an OE ratio of 1.31 (95% CI, 0.87 to 1.97) after the intervention; however, the authors did not report the statistical significance of this difference.

A systematic review of incentive spirometry after upper abdominal surgery found no evidence that this intervention is effective in preventing pulmonary complications, include acute respiratory inadequacy.8 However, another systematic review by Lawrence et al evaluated all interventions to prevent postoperative pulmonary complications after non-cardiothoracic surgery. These authors identified good evidence suggesting that lung expansion therapy (for example, incentive spirometry, deep breathing exercises, and continuous positive airway pressure) reduces postoperative pulmonary risk after abdominal surgery and fair evidence suggesting that nasogastric tube decompression after abdominal surgery reduces risk. Fair evidence also suggests that short-acting neuromuscular blocking agents result in lower rates of residual neuromuscular blockade and may reduce risk for pulmonary complications.9

### *Association with hospital and health system characteristics*

Several studies have examined the association between postoperative respiratory failure and hospital or health system characteristics. In a multivariable analysis of Nationwide Inpatient Sample (NIS) data from the Healthcare Cost and Utilization Project (HCUP), Rahman et al. found that postoperative respiratory failure was less likely in patients admitted to nonteaching hospitals than those admitted to teaching hospitals (OR 0.89, 95% CI 0.846 to 0.926).10 The odds of developing postoperative respiratory failure increased by 6% for each level increase in hospital size from small to large (OR 1.06, 95% CI 1.03 to 1.09). Using VA and NIS data from 2003 through 2004 (n=116 VA hospitals, n=992 community non-Federal hospitals), Rivard et al. reported lower risk-adjusted rates of postoperative respiratory failure in VA hospitals (3.86 per 1,000, 95% CI 2.83 to 4.88) than in the NIS (4.87 per 1,000, 95% CI 3.92 to 5.81).11 Another study involving 4,581 staff surveys from 30 VA hospitals (2005-2006) by Rosen et al. found that there was no association between hospital safety climate (overall or for various climate dimensions) and individual hospital-level PSIs, including postoperative respiratory failure.12

### *Association with other outcomes*

Several studies found that postoperative respiratory failure is associated with longer length of stay.10,13-15 In a multivariable analysis of NIS data from 2002-2010, Rahman et al. found that length of stay was significantly longer for patients with postoperative respiratory failure (median 8.0 days) compared to those without respiratory failure (median 4.0 days, p<0.0001).10 Using NSQIP data, Gajdos et al. found that failure to wean from ventilator and reintubation were associated with longer postsurgical length of stay in all age groups compared with participants not having these complications (median length of stay ≥19 days with complications; p<0.001).14 In a smaller study (n=178), Marda et al. found that mean duration of intensive care unit (ICU) and hospital stay after surgery was significantly longer in patients who had postoperative pulmonary complications (PPCs), including respiratory failure, as compared to patients without PPCs (9.5 ± 14.8 days vs. 2.7 ± 1.8 days, [p < 0.001]; 22.6 ± 16.8 days vs. 7.6 ± 2.8 days [p < 0.001], respectively).15

Several studies also found that that postoperative respiratory failure is associated with higher 30-day readmission rates.13,16,17 In three studies included in a recent literature review by Sabate et al., the estimated increased costs in U.S. dollars associated with postoperative respiratory failure ranged from $5,983 to $7,109 per procedure (for complications not requiring ventilation) to $118,841 to $120,579 (for complications requiring tracheostomy), in part due to more readmissions.13 In a cross-sectional analysis of VA patient treatment files, including 1,807,488 index hospitalizations and 262,026 readmissions, Rosen et al. found that 30-day readmission rates after surgical hospitalizations with a PSI 11 event (17.8%) were significantly higher than after surgical hospitalizations without a PSI 11 event (9.9%) (p<0.0001),17 with an adjusted odds ratio of 1.39 (95% CI 1.25 to 1.54). In a cohort study of NSQIP data from the American College of Surgeons (ACS) and Medicare inpatient claims (n =90,932), the rate of unplanned intubation within 30 days of an index procedure was significantly higher among patients with a 30-day readmission (4.1%) than among those without a 30-day readmission (1.8%, p<0.001).16 Likewise, prolonged ventilation was more frequent among readmitted patients (4.4%) than among patients who were not readmitted (2.7%, p<0.001). Bath et al. used Medicare data (MedPAR) from 2009 to 2012 and found that the odds of 30-day readmission among patients undergoing abdominal aortic aneurysm repair were increased among patients with postoperative respiratory failure (OR=1.44, p<0.0001).18

Four different population-based studies have demonstrated that postoperative respiratory failure is independently associated with mortality. Based on NIS data of morbidly obese patients who underwent bariatric surgery, Masoomi et al. found that patients who developed acute respiratory failure had significantly greater in-hospital mortality than those who did not develop this complication (5.69% versus 0.04%, p<0.01).19 Based on an analysis of data from 165,600 senior patients undergoing non-emergent major general surgeries from the ACS NSQIP dataset, Gajdos et al. found that reintubation had one of the highest failure-to-rescue rates among all postoperative complications (25.6%).14 In multivariable analysis of 5,318 adults undergoing cardiothoracic surgery at a single institution, the risk of perioperative mortality was significantly increased among patients with a respiratory failure complication (OR 3.2, 95% CI 2.2 to 4.9).20 Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 11 event were associated with an additional 3.78 hospital days, compared to hospitalizations without a PSI 11 event (p<0.001), as well as a significantly increased risk of in-hospital mortality (OR=248.93; p<0.001).21 One small study (n = 450) of patients from the ACS NSQIP database undergoing thoracoabdominal aortic aneurysm (TAAA) repair did not find such an association between reintubation and mortality.22

***Population group disparities***

**Table 8** presents population group disparities for PSI 11 Postoperative Respiratory Failure Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims datafrom July 1, 2017 to June 30, 2018.

**Table 8. PSI 11 Postoperative Respiratory Failure Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 19662 | 4.781 | 5.820 |
| White | 920041 | 5.507 | 5.198 |
| Black | 78549 | 8.453 | 6.046 |
| Other | 11585 | 5.697 | 4.831 |
| Asian | 9340 | 5.782 | 4.749 |
| Hispanic | 14199 | 7.465 | 5.687 |
| North American Native | 6124 | 7.348 | 5.748 |
| **Gender** |  |  |  |
| Female | 605665 | 5.006 | 5.197 |
| Male | 453835 | 6.751 | 5.386 |
| **Age** |  |  |  |
| <50 | 39287 | 7.865 | 5.757 |
| 50-54 | 27247 | 7.487 | 5.417 |
| 55-59 | 42943 | 7.778 | 5.431 |
| 60-64 | 55682 | 7.669 | 5.192 |
| 65-69 | 307397 | 4.447 | 5.242 |
| 70-74 | 262105 | 5.135 | 5.305 |
| 75-79 | 180021 | 5.916 | 5.212 |
| 80-84 | 95877 | 6.394 | 5.217 |
| 85-89 | 39029 | 8.840 | 5.424 |
| 90 plus | 9912 | 8.676 | 4.986 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review results presented below constitute the most recent update, conducted in August 2020. Search terms included relevant MeSH terms (respiratory distress syndrome, adult) and keywords (post-operative respiratory failure, postoperative respiratory failure, postoperative acute respiratory, acute respiratory failure, respiratory distress syndrome, ARDS, reintubation, prolonged intubation, delayed extubation). Studies focused on early extubation or immediate extubation were excluded, as were those focused on obstetric, peripartum or neonatal care. We combined this clinical search string with MeSH terms (patient admission) and keywords (hospitals, patient admission, inpatient) to identify studies examining inpatient care. Search was limited to English publications. We also tested more inclusive search strings. To provide the most up-to-date evidence, we summarize below the most recent evidence.

# 1a.4.3. Provide the citation(s) for the evidence.

1. Blum JM, Stentz MJ, Dechert R, et al. Preoperative and intraoperative predictors of postoperative acute respiratory distress syndrome in a general surgical population. *Anesthesiology.* 2013;118(1):19-29.

2. Hughes CG, Weavind L, Banerjee A, Mercaldo ND, Schildcrout JS, Pandharipande PP. Intraoperative risk factors for acute respiratory distress syndrome in critically ill patients. *Anesth Analg.* 2010;111(2):464-467.

3. Shalev D, Kamel H. Risk of Reintubation in Neurosurgical Patients. *Neurocritical care.* 2014.

4. Attaallah AF, Vallejo MC, Elzamzamy OM, Mueller MG, Eller WS. Perioperative risk factors for postoperative respiratory failure. *J Perioper Pract.* 2019;29(3):49-53.

5. Chandler D, Mosieri C, Kallurkar A, et al. Perioperative strategies for the reduction of postoperative pulmonary complications. *Best Pract Res Clin Anaesthesiol.* 2020;34(2):153-166.

6. Braddock CH, 3rd, Szaflarski N, Forsey L, Abel L, Hernandez-Boussard T, Morton J. The TRANSFORM Patient Safety Project: A Microsystem Approach to Improving Outcomes on Inpatient Units. *J Gen Intern Med.* 2014.

7. Cassidy MR, Rosenkranz P, McCabe K, Rosen JE, McAneny D. I COUGH: reducing postoperative pulmonary complications with a multidisciplinary patient care program. *JAMA surgery.* 2013;148(8):740-745.

8. Guimaraes MM, El Dib R, Smith AF, Matos D. Incentive spirometry for prevention of postoperative pulmonary complications in upper abdominal surgery. *Cochrane Database Syst Rev.* 2009(3):CD006058.

9. Lawrence VA, Cornell JE, Smetana GW. Strategies to reduce postoperative pulmonary complications after noncardiothoracic surgery: systematic review for the American College of Physicians. *Ann Intern Med.* 2006;144(8):596-608.

10. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

11. Rivard PE, Elixhauser A, Christiansen CL, Shibei Z, Rosen AK. Testing the association between patient safety indicators and hospital structural characteristics in VA and nonfederal hospitals. *Medical care research and review : MCRR.* 2010;67(3):321-341.

12. Rosen AK, Singer S, Shibei Z, Shokeen P, Meterko M, Gaba D. Hospital safety climate and safety outcomes: is there a relationship in the VA? *Medical care research and review : MCRR.* 2010;67(5):590-608.

13. Sabate S, Mazo V, Canet J. Predicting postoperative pulmonary complications: implications for outcomes and costs. *Case reports in anesthesiology.* 2014;27(2):201-209.

14. Gajdos C, Kile D, Hawn MT, Finlayson E, Henderson WG, Robinson TN. Advancing age and 30-day adverse outcomes after nonemergent general surgeries. *J Am Geriatr Soc.* 2013;61(9):1608-1614.

15. Marda M, Pandia MP, Rath GP, Bithal PK, Dash HH. Post-operative pulmonary complications in patients undergoing transoral odontoidectomy and posterior fixation for craniovertebral junction anomalies. *Journal of anaesthesiology, clinical pharmacology.* 2013;29(2):200-204.

16. Lawson EH, Hall BL, Louie R, et al. Association between occurrence of a postoperative complication and readmission: implications for quality improvement and cost savings. *Ann Surg.* 2013;258(1):10-18.

17. Rosen AK, Loveland S, Shin M, et al. Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Medical care.* 2013;51(1):37-44.

18. Bath J, Dombrovskiy VY, Vogel TR. Impact of Patient Safety Indicators on readmission after abdominal aortic surgery. *J Vasc Nurs.* 2018;36(4):189-195.

19. Masoomi H, Reavis KM, Smith BR, Kim H, Stamos MJ, Nguyen NT. Risk factors for acute respiratory failure in bariatric surgery: data from the Nationwide Inpatient Sample, 2006-2008. *Surg Obes Relat Dis.* 2013;9(2):277-281.

20. Rahmanian PB, Kroner A, Langebartels G, Ozel O, Wippermann J, Wahlers T. Impact of major non-cardiac complications on outcome following cardiac surgery procedures: logistic regression analysis in a very recent patient cohort. *Interactive cardiovascular and thoracic surgery.* 2013;17(2):319-326; discussion 326-317.

21. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2017;32(6):583-590.

22. Bensley RP, Curran T, Hurks R, et al. Open repair of intact thoracoabdominal aortic aneurysms in the American College of Surgeons National Surgical Quality Improvement Program. *Journal of vascular surgery.* 2013;58(4):894-900.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite Measure)

**Measure Title**: PSI 12 Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate (Component)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If

the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Deep vein thrombosis (DVT) is the formation of a blood clot in a deep vein—usually in the leg or pelvic veins. The most serious complication of a DVT is that the clot dislodges and travels to the lungs, becoming a pulmonary embolus (PE). Venous thromboembolism (VTE), which encompasses both DVT and PE, is common in the perioperative setting, especially after high-risk operations, and can be deadly. Clinical trials have demonstrated that mechanical and pharmacologic interventions can substantially reduce the risk of perioperative VTE among moderate and high-risk surgical patients, especially when these interventions are initiated before or immediately after surgery and continued until or after discharge. Case control studies have demonstrated that early ambulation after surgery can further reduce the risk of perioperative VTE among high-risk surgical patients who receive appropriate mechanical or pharmacologic prophylaxis. Effective and safe prophylactic measures are now available for most high-risk patients, and numerous evidence-based guidelines have been published for the prevention of VTE (most notably by the American College of Chest Physicians and the American Academy of Orthopedic Surgeons).

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

### *Association with process of care*

A recent systematic review including 19 studies of 11,430 patients concluded that primary prophylaxis in ambulatory cancer patients can significantly reduce the risk of VTE.1 Several recent studies examined the impact of efforts to improve VTE prophylaxis adherence, tracking changes in incidence over time as processes improved. Most of these studies reported favorable results, with the notable exception of cancer patients. For example, implementation of "mandated risk assessment" with computerized DVT prophylaxis order entry at a tertiary cancer center increased use of prophylaxis without reducing VTE incidence,2 whereas similar protocols reduced the incidence of postoperative VTE on an vascular surgery service from 1.49% to 0.38%,3 at a large Russian medical center from 0.88% to 0.42%,4 and at a large medical center in Abu Dhabi from 0.9-3.1% to 0.1-0.2%.5 Nelson et al. (2015) analyzed 2006-2011 surgical registry data on colorectal surgery from Washington and reported that use of in-hospital postoperative VTE chemoprophylaxis increased from 59.6% to 91.4%, but 90-day VTE rates did not decrease.6 Heslin et al. reported that among 12 surgical services in a single institution the most common contributing factor for PSI 12 was “failure to follow protocol,” but they did not report the impact of improved adherence on PSI 12.7 Hussey et al tested an alpha version of the AHRQ QI Toolkit in a one-year quality improvement initiative at an academic medical center. After the electronic medical record was revised so that DVT prophylaxis would be a mandatory part of the order set, PSI 12 rates decreased from 20.7 to 15.9.8 A similar clinical decision support intervention at the University of Pennsylvania was associated with increased use of “recommended” prophylaxis (from 32.3% to 60.0%) and a concurrent drop in PSI 12 rates from 21.8 to 17.3.9 The University of California recently reported that a five-campus collaborative effort to improve VTE risk stratification and prophylaxis achieved a 23.8% relative reduction in the incidence of PSI 12 in 2014 relative to 2011.10 A similar program at Boston Medical Center, which also included an emphasis on early ambulation, was associated with an 84% decrease in DVT incidence (from 1.9% to 0.3%) and a 55% decrease in PE incidence (from 1.1% to 0.5%), lowering the observed-to-expected VTE ratio from 3.41 to 0.94.

In a series of studies from The John Hopkins, use of risk-appropriate VTE prophylaxis in surgical patients increased from 26% (42 of 161) at baseline to 68% (178 of 262) within 12 months, and to 85% after implementation of computer-based "smart order sets."14 A retrospective review of 92 patients diagnosed with hospital-acquired VTE found that only 43 (47%) received defect-free care, while 49 (53%) had potentially preventable VTE.11 On the trauma service, 56.0% of residents prescribed “optimal, risk-appropriate” VTE prophylaxis, while attending physicians had a compliance rate of 74.2% (interquartile range, 72.6%-77.3%), indicating that resident practice variation may be an important contributor to VTE events at teaching hospitals.12 Lau et al. (2015) reported that a performance feedback scorecard with individual peer-to-peer coaching increased the percentage of these residents providing defect-free care from 45% to 78% and reduced the incidence of postoperative VTE from 0.81% to 0.38-0.39%.12

AHRQ’s Evidence-based Practice Review on Patient Safety summarized the state of the field: “Evidence generally finds that the use of aspirin following these surgical procedures – either as the sole prophylaxis in combination with other pharmacologic agents or in conjunction with mechanical prophylaxis – is equivalent to other agents or has a better safety profile.”13 An older report from the AHRQ’s Evidence-based Practice Review on Patient Safety noted that many hospitalized patients are not given risk-appropriate VTE prophylaxis. A 2008 study across 32 countries found that only 59% of at-risk surgical and 40% of at-risk medical patients received guideline-recommended VTE prophylaxis, and a 2004 United States registry study found that only 42% of patients diagnosed with DVT during a hospitalization had received prophylaxis…”14 Similar findings have been reported from Europe15 and from 28 Veterans Health Administration hospitals, where “accounting for contraindications and early VTE occurrence, a total of 78% of cases [with PSI 12] and 80% of controls [without PSI 12] were appropriately managed.”16

*Delayed Ambulation*

Based on observational data from case control studies and longitudinal intervention studies, delayed ambulation is an independent risk factor for VTE after orthopedic surgery, even accounting for appropriate pharmacologic prophylaxis. In a case-control study of patients undergoing total knee arthroplasty (TKA) in 15 teaching hospitals, among PSI 12 cases with an objectively documented acute VTE within 9 days of surgery (N=130) and randomly selected controls (N=463), only 68% ambulated on day 1 or 2 after surgery despite allpatients receiving thromboprophylaxis (pharmacologic in 80%, mechanical alone in 20%). Factors significantly associated with VTE (after adjusting for age, sex, history of VTE, and BMI) were bilateral TKA (OR=4.2; 95% CI: 1.9-9.1), receipt of pharmacological prophylaxis (OR=0.5; 95% CI: 0.3-0.8), and ambulation by postoperative day 2 (OR=0.3; 95% CI: 0.1-0.9).17 In an earlier case control study based on a sampling frame with 25,388 Medicare fee-for-service beneficiaries who underwent unilateral total hip arthroplasty (THA) in any nonfederal hospital in California, White et al. compared processes of care between 297 randomly selected cases with VTE within 3 months after surgery and 592 randomly selected controls. Factors independently associated with VTE included initial ambulation before day 2 after surgery (OR=0.7; 95% CI 0.5–0.9), use of pneumatic compression (among patients with body-mass index <25; OR=0.3; 95% CI 0.2–0.6), and use of warfarin after discharge (OR=0.6; 95% CI 0.4–1.0).18 These studies suggest a population fraction of post-arthroplasty VTE attributable to delayed ambulation of at least 10% and perhaps over 40%.

Two studies have reported single-center results of prospectively implementing early ambulation postoperative care protocols. Chandrasekaran et al. found that getting patients out of bed or walking for at least 15–30 minutes twice on the first day after TKA significantly reduced the odds of asymptomatic or symptomatic VTE (OR=0.35; 95% CI: 0.13-0.94) compared with the previous practice of confining patients to bed on that day.19 Similarly, Pearse et al. implemented a treatment protocol that involved showering and walking up to 30 meters within 24 hours after TKA, and observed a substantial reduction in the odds of asymptomatic or symptomatic DVT (OR=0.04; 95% CI 0.004-0.30).20 These findings are supported by several cohort studies summarized in a recent structured review.21

*Patient and Clinical Risk Factors*

Studies have shown variation in PE/DVT by procedure type, suggesting the importance of risk adjustment.22-25 Total operative time is also associated with increased VTE risk. Kim et al. (2015) reported that the risk of VTE in NSQIP data increased in a stepwise manner with the procedure standardized duration of general anesthesia time.26 These findings were confirmed by Daley et al. (2015), using a measure of whether total operative time exceeded the upper 95% confidence limit of its expected value.27

Several studies have examined the association between patient characteristics and rates of pulmonary embolism and deep vein thrombosis. Associations between PSI 12 and patient characteristics have been found for black race (for post-surgical DVT but not PE),28 gender,23,12 age,9,29 obesity,14 and select comorbidities (postoperative infection or stroke,8 disseminated cancer,8 dependent functional status,8 return to operating room,8 preoperative hyponatremia,13 irritable bowel disease,15 and congestive heart failure and cancer.9 Other preoperative risk factors for VTE were identified in studies included: age, ASA risk classification (for colorectal surgery), white race (for esophageal surgery), body mass index (for hysterectomy and colorectal and bariatric surgery), cancer (for craniotomy and hysterectomy) and disseminated cancer (for colorectal surgery), chronic steroid use, emergent or non-elective surgery, open (versus laparoscopic) surgery (for colorectal and bariatric surgery), duration of pre-surgical hospitalization, preoperative sepsis, previous cardiac surgery, weight loss, hypoalbuminemia (for colorectal surgery), history of prior VTE, operation for inflammatory disease (for colorectal surgery), transfer from acute care hospital (for craniotomy), dependent functional status (for craniotomy), or individual comorbidities such as peripheral vascular disease and prior stroke (for craniotomy).6,30-39 Risk models have been developed and validated for VTE; Obi et al. (2015) and Hachey et al. (2016) validated the Caprini VTE risk assessment model among critically ill surgical patients and after lung cancer resection.40,41

Some of the identified risk factors are at least partially under providers’ control, and may account for some of the observed hospital-level variation in PSI 12 rates (e.g., pre-surgical days, duration of general anesthesia or surgery, open versus laparoscopic approach, and postoperative complications such as prolonged mechanical ventilation and unplanned reintubation). Surgical duration is an especially noteworthy factor because of its association with resident involvement in surgery.

### *Association with hospital and health system characteristics*

Several studies have examined the influence of various hospital and health system characteristics on the rate of postoperative PE and DVT. One study demonstrated that hospitals with higher percentages of registered nurses with baccalaureate or higher degrees had lower rates of PSI 12,42 while studies **were inconclusive** regarding the impact of hospital factors such as being within the VA healthcare system,**43-45** teaching status**,**44,46 **bed size,46 location,46 nurse staffing hours,43 safety climate47 and the** implementation of duty-hour regulations.48Another study found lower rates of postoperative PE and DVT at low procedure volume hospitals (compared to high-volume hospitals), rural hospitals (compared to urban hospitals), and non-teaching hospitals (compared to teaching hospitals), but statistical test values were not provided.19

### *Association with other outcomes*

Cases from the HCUP Nationwide Inpatient Sample that were flagged by this PSI in 2000 had 6.6% excess mortality, 5.4 days of excess hospitalization, and $21,709 in excess hospital charges, relative to carefully matched controls that were not flagged.49 This finding was confirmed in the Veterans Affairs hospital system, where cases that were flagged by this PSI in 2001 had 6.1% excess mortality, 4.5-5.5 days of excess hospitalization, and $7,205-9,064 in excess hospital costs, relative to carefully matched controls that were not flagged43. Carey and Stefos re-estimated the financial impact of each PSI 12 event in the VA system in 2007 as $17,453-18,935, using more sophisticated cost accounting and econometric methods.50 In another study based on HCUP SID from seven states in 2004 that permit linkage of serial hospitalizations, this indicator was associated with risk ratios of 1.35 for inpatient death, 1.28 for readmission within three months, and 1.25 for readmission within one month (after adjusting for age, gender, payer, comorbidities, specific surgical DRGs, and APR-DRG severity levels).51 Similarly, in a multivariable analysis of Veterans Health Administration data from 2003-2007, hospitalizations with a PSI 12 event were 33% more likely to result in a readmission within 30 days (OR 1.33; 95% CI 1.23-1.44), after adjusting for age, sex, comorbidities, and other PSI events.52

Several other studies have focused on narrower clinical cohorts, with similar results. Bohensky et al. examined cost and length of stay (LOS) following complications in 139,031 knee arthroscopy cases in the Victorian Admitted Episodes Dataset (2000 to 2009).53 VTE events were the most common complication (0.3%) and the cumulative excess 30-day cost of VTE was $3227 (95% CI $3211-3244). Patients who experienced VTE also had longer median LOS (6 days vs. 1 day, p<0.01) than those without VTE. Ramanan et al. used 2007-2009 National Surgical Quality Improvement Program (NSQIP) data on patients undergoing vascular surgery to show that VTE events increased overall mortality risk among patients with DVT (1.5% to 6.2%) or PE (1.5% to 5.7%), compared to those without VTE.22 Using data from the NSQIP Semi Annual Reports for 197 US and Canadian hospitals (2007-2008), Borgi et al. demonstrated that VTE events were positively and statistically significantly associated with postoperative mortality (regression slope 0.393; 95% CI 0.235 to 0.551, p<0.0001).54 In an analysis of Medicare claims data for patients undergoing any of 6 cancer resections in 2005-2009, Short et al. found that after adjusting for patient factors (age, sex, race, income), hospital factors (hospital volume, surgeon volume, surgeon specialty designation, hospital resources, patient characteristics) and tumor factors (tumor stage, site), costs increased significantly in association with postoperative VTE for all six types of surgery (p<0.001).55 Based on an analysis of the 501,908 hospitalizations involving a brain tumor in the NIS between 2002 and 2010, Rahman et al. (2013) found that patients with postoperative DVT or PE had significantly longer length-of-stay, on average, than patients without these complications (10.4 vs 6.3 days and 8.8 vs. 6.4 days, respectively; p < 0.0001 for both).29 Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 12 event were associated with an additional 2.83 hospital days compared to patients without a PSI 12 event (p<0.001).56

***Population group disparities***

**Table 9** presents population group disparities for PSI 12 Perioperative PE or DVT Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims datafrom July 1, 2017 to June 30, 2018.

**Table 9. PSI 12 Perioperative PE or DVT Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 37392 | 3.370 | 3.612 |
| White | 2122522 | 3.526 | 3.509 |
| Black | 233166 | 5.237 | 4.980 |
| Other | 30971 | 3.390 | 3.252 |
| Asian | 29215 | 2.909 | 2.760 |
| Hispanic | 46115 | 3.643 | 3.797 |
| North American Native | 18093 | 2.542 | 2.418 |
| **Gender** |  |  |  |
| Female | 1307262 | 3.593 | 3.635 |
| Male | 1210212 | 3.750 | 3.639 |
| **Age** |  |  |  |
| <50 | 107216 | 3.516 | 3.911 |
| 50-54 | 70230 | 3.303 | 3.646 |
| 55-59 | 109865 | 3.632 | 3.904 |
| 60-64 | 142036 | 3.816 | 3.880 |
| 65-69 | 586155 | 3.337 | 3.582 |
| 70-74 | 528720 | 3.567 | 3.555 |
| 75-79 | 411071 | 3.985 | 3.673 |
| 80-84 | 284379 | 3.847 | 3.646 |
| 85-89 | 178740 | 3.989 | 3.476 |
| 90 plus | 99062 | 4.018 | 3.632 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review was conducted in August 2020. Search terms included relevant MeSH terms (Venous Thromboembolism or VTE, Pulmonary embolus (PE) or embolism, DVT or Thrombosis) with MeSH terms (patient admission, hospitals, inpatient, patient safety, AHRQ) to identify studies examining quality of inpatient care. The search was limited to English-language publications.

# 1a.4.3. Provide the citation(s) for the evidence.

1. Xin Z, Liu F, Du Y, et al. Primary prophylaxis for venous thromboembolism in ambulatory cancer patients: a systematic review and network meta-analysis. *Ann Palliat Med.* 2020.

2. Kukar M, Asaro J, Aquino A, Groman A, Skitzki J, Kane JM. Incidence of Venous Thromboembolic Events in Mandated Risk Assessment versus Optional DVT Prophylaxis Era at a Large Tertiary Cancer Center. *Am Surg.* 2015;81(9):893-898.

3. Durinka JB, Hecht TE, Layne AJ, et al. Aggressive venous thromboembolism prophylaxis reduces VTE events in vascular surgery patients. *Vascular.* 2016;24(3):233-240.

4. Nazarenko GI, Kleymenova EB, Payushik SA, Otdelenov VA, Sychev DA, Yashina LP. Decision support systems in clinical practice: The case of venous thromboembolism prevention. *The International journal of risk & safety in medicine.* 2015;27 Suppl 1:S104-105.

5. Nimeri AA, Gamaleldin MM, McKenna KL, Turrin NP, Mustafa BO. Reduction of Venous Thromboembolism in Surgical Patients Using a Mandatory Risk-Scoring System: 5-Year Follow-Up of an American College of Surgeons National Surgical Quality Improvement Program. *Clin Appl Thromb Hemost.* 2017;23(4):392-396.

6. Nelson DW, Simianu VV, Bastawrous AL, et al. Thromboembolic Complications and Prophylaxis Patterns in Colorectal Surgery. *JAMA surgery.* 2015;150(8):712-720.

7. Heslin MJ, Taylor B, Hawn MT, et al. A 100% departmental mortality review improves observed-to-expected mortality ratios and University HealthSystem Consortium rankings. *J Am Coll Surg.* 2014;218(4):554-562.

8. Hussey PS, Burns RM, Weinick RM, Mayer L, Cerese J, Farley DO. Using a hospital quality improvement toolkit to improve performance on the AHRQ quality indicators. *Jt Comm J Qual Patient Saf.* 2013;39(4):177-184.

9. Umscheid CA, Hanish A, Chittams J, Weiner MG, Hecht TEH. Effectiveness of a novel and scalable clinical decision support intervention to improve venous thromboembolism prophylaxis: a quasi-experimental study. *BMC Medical Informatics and Decision Making.* 2012;12(1):92.

10. UC Center for Health Quality and Innovation (CHQI). Report: UC Center for Health Quality and Innovation. Review and Assessment of Grant Impact to Date. https://www.universityofcalifornia.edu/sites/default/files/uc\_chqi\_report\_8.27.14.pdf Published 2014. Accessed September 17, 2020.

11. Haut ER, Lau BD, Kraus PS, et al. Preventability of Hospital-Acquired Venous Thromboembolism. *JAMA surgery.* 2015;150(9):912-915.

12. Lau BD, Streiff MB, Pronovost PJ, Haider AH, Efron DT, Haut ER. Attending Physician Performance Measure Scores and Resident Physicians' Ordering Practices. *JAMA surgery.* 2015;150(8):813-814.

13. Hall KK, Shoemaker-Hunt S, Hoffman L, et al. In: *Making Healthcare Safer III: A Critical Analysis of Existing and Emerging Patient Safety Practices.* Rockville (MD): Agency for Healthcare Research and Quality (US); 2020.

14. Shekelle PG, Wachter RM, Pronovost PJ, et al. Making health care safer II: an updated critical analysis of the evidence for patient safety practices. *Evid Rep Technol Assess (Full Rep).* 2013(211):1-945.

15. Markovic-Denic L, Zivkovic K, Lesic A, Bumbasirevic V, Dubljanin-Raspopovic E, Bumbasirevic M. Risk factors and distribution of symptomatic venous thromboembolism in total hip and knee replacements: prospective study. *Int Orthop.* 2012;36(6):1299-1305.

16. Borzecki AM, Cowan AJ, Cevasco M, et al. Is development of postoperative venous thromboembolism related to thromboprophylaxis use? A case-control study in the Veterans Health Administration. *Jt Comm J Qual Patient Saf.* 2012;38(8):348-358.

17. Sadeghi B, Romano PS, Maynard G, et al. Mechanical and suboptimal pharmacologic prophylaxis and delayed mobilization but not morbid obesity are associated with venous thromboembolism after total knee arthroplasty: a case-control study. *J Hosp Med.* 2012;7(9):665-671.

18. White RH, Gettner S, Newman JM, Trauner KB, Romano PS. Predictors of rehospitalization for symptomatic venous thromboembolism after total hip arthroplasty. *N Engl J Med.* 2000;343(24):1758-1764.

19. Chandrasekaran S, Ariaretnam SK, Tsung J, Dickison D. Early mobilization after total knee replacement reduces the incidence of deep venous thrombosis. *ANZ J Surg.* 2009;79(7-8):526-529.

20. Pearse EO, Caldwell BF, Lockwood RJ, Hollard J. Early mobilisation after conventional knee replacement may reduce the risk of postoperative venous thromboembolism. *J Bone Joint Surg Br.* 2007;89(3):316-322.

21. Zhang ZH, Shen B, Yang J, Zhou ZK, Kang PD, Pei FX. Risk factors for venous thromboembolism of total hip arthroplasty and total knee arthroplasty: a systematic review of evidences in ten years. *BMC Musculoskelet Disord.* 2015;16:24.

22. Ramanan B, Gupta PK, Sundaram A, et al. In-hospital and postdischarge venous thromboembolism after vascular surgery. *J Vasc Surg.* 2013;57(6):1589-1596.

23. Assareh H, Chen J, Ou L, Hollis SJ, Hillman K, Flabouris A. Rate of venous thromboembolism among surgical patients in Australian hospitals: a multicentre retrospective cohort study. *BMJ Open.* 2014;4(10):e005502.

24. White RH, Zhou H, Romano PS. Incidence of symptomatic venous thromboembolism after different elective or urgent surgical procedures. *Thromb Haemost.* 2003;90(3):446-455.

25. Aziz F, Patel M, Ortenzi G, Reed AB. Incidence of Postoperative Deep Venous Thrombosis Is Higher among Cardiac and Vascular Surgery Patients as Compared with General Surgery Patients. *Ann Vasc Surg.* 2015;29(4):661-669.

26. Kim HK, Jung H, Cho J, Huh S, Lee JM, Kim YW. Therapeutic outcomes and thromboembolic events after treatment of acute arterial thromboembolism of the upper extremity. *Ann Vasc Surg.* 2015;29(2):303-310.

27. Daley BJ, Cecil W, Clarke PC, Cofer JB, Guillamondegui OD. How slow is too slow? Correlation of operative time to complications: an analysis from the Tennessee Surgical Quality Collaborative. *J Am Coll Surg.* 2015;220(4):550-558.

28. Adelani MA, Archer KR, Song Y, Holt GE. Immediate complications following hip and knee arthroplasty: does race matter? *J Arthroplasty.* 2013;28(5):732-735.

29. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

30. Jamal MH, Corcelles R, Shimizu H, et al. Thromboembolic events in bariatric surgery: a large multi-institutional referral center experience. *Surg Endosc.* 2015;29(2):376-380.

31. Moghadamyeghaneh Z, Hanna MH, Carmichael JC, Nguyen NT, Stamos MJ. A nationwide analysis of postoperative deep vein thrombosis and pulmonary embolism in colon and rectal surgery. *J Gastrointest Surg.* 2014;18(12):2169-2177.

32. Martin JT, Mahan AL, Ferraris VA, et al. Identifying Esophagectomy Patients at Risk for Predischarge Versus Postdischarge Venous Thromboembolism. *The Annals of thoracic surgery.* 2015;100(3):932-938; discussion 938.

33. Kimmell KT, Jahromi BS. Clinical factors associated with venous thromboembolism risk in patients undergoing craniotomy. *J Neurosurg.* 2015;122(5):1004-1011.

34. Hoh DJ, Rahman M, Fargen KM, Neal D, Hoh BL. Establishing standard hospital performance measures for cervical spinal trauma: a Nationwide In-patient Sample study. *Spinal Cord.* 2016;54(4):306-313.

35. Bekelis K, Kalakoti P, Nanda A, Missios S. A Predictive Model of Unfavorable Outcomes After Benign Intracranial Tumor Resection. *World Neurosurg.* 2015;84(1):82-89.

36. Swenson CW, Berger MB, Kamdar NS, Campbell DA, Jr., Morgan DM. Risk factors for venous thromboembolism after hysterectomy. *Obstet Gynecol.* 2015;125(5):1139-1144.

37. Wang L, Pryor AD, Altieri MS, et al. Perioperative rates of deep vein thrombosis and pulmonary embolism in normal weight vs obese and morbidly obese surgical patients in the era post venous thromboembolism prophylaxis guidelines. *Am J Surg.* 2015;210(5):859-863.

38. Greaves SW, Holubar SD. Preoperative Hospitalization Is Independently Associated With Increased Risk for Venous Thromboembolism in Patients Undergoing Colorectal Surgery: A National Surgical Quality Improvement Program Database Study. *Dis Colon Rectum.* 2015;58(8):782-791.

39. Zhang L, Cao H, Chen Y, Jiao G. Risk factors for venous thromboembolism following spinal surgery: A meta-analysis. *Medicine (Baltimore).* 2020;99(29):e20954.

40. Obi AT, Pannucci CJ, Nackashi A, et al. Validation of the Caprini Venous Thromboembolism Risk Assessment Model in Critically Ill Surgical Patients. *JAMA surgery.* 2015;150(10):941-948.

41. Hachey KJ, Hewes PD, Porter LP, et al. Caprini venous thromboembolism risk assessment permits selection for postdischarge prophylactic anticoagulation in patients with resectable lung cancer. *J Thorac Cardiovasc Surg.* 2016;151(1):37-44.e31.

42. Blegen MA, Goode CJ, Park SH, Vaughn T, Spetz J. Baccalaureate education in nursing and patient outcomes. *J Nurs Adm.* 2013;43(2):89-94.

43. Rivard PE, Elixhauser A, Christiansen CL, Shibei Z, Rosen AK. Testing the association between patient safety indicators and hospital structural characteristics in VA and nonfederal hospitals. *Med Care Res Rev.* 2010;67(3):321-341.

44. Rivard PE, Christiansen CL, Zhao S, Elixhauser A, Rosen AK. Advances in Patient Safety: Is There an Association Between Patient Safety Indicators and Hospital Teaching Status? In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 2: Culture and Redesign).* Rockville (MD)2008.

45. Chen Q, Hanchate A, Shwartz M, et al. Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicator Rates Among Veteran Dual Users. *Am J Med Qual.* 2013;29(4):335-343.

46. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Med Care.* 2006;44(9):850-861.

47. Rosen AK, Singer S, Shibei Z, Shokeen P, Meterko M, Gaba D. Hospital safety climate and safety outcomes: is there a relationship in the VA? *Med Care Res Rev.* 2010;67(5):590-608.

48. Shelton J, Kummerow K, Phillips S, et al. Patient safety in the era of the 80-hour workweek. *J Surg Educ.* 2014;71(4):551-559.

49. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Qual Saf Health Care.* 2003;12 Suppl 2(Suppl 2):ii58-63.

50. Carey K, Stefos T. Measuring the cost of hospital adverse patient safety events. *Health Econ.* 2011;20(12):1417-1430.

51. Friedman B, Encinosa W, Jiang HJ, Mutter R. Do patient safety events increase readmissions? *Med Care.* 2009;47(5):583-590.

52. Rosen AK, Loveland S, Shin M, et al. Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Med Care.* 2013;51(1):37-44.

53. Bohensky MA, Ademi Z, deSteiger R, et al. Quantifying the excess cost and resource utilisation for patients with complications associated with elective knee arthroscopy: a retrospective cohort study. *The Knee.* 2014;21(2):491-496.

54. Borgi J, Rubinfeld I, Ritz J, Jordan J, Velanovich V. The differential effects of intermediate complications with postoperative mortality. *Am Surg.* 2013;79(3):261-266.

55. Short MN, Aloia TA, Ho V. The influence of complications on the costs of complex cancer surgery. *Cancer.* 2014;120(7):1035-1041.

56. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *Am J Med Qual.* 2017;32(6):583-590.

57. Kaafarani HM, A.M. B, K.M. I, et al. Validity of selected Patient Safety Indicators: opportunities and concerns. *J Am Coll Surg* 2011;212(6):924-934.

58. Mull HJ, Borzecki AM, Loveland S, et al. Detecting adverse events in surgery: comparing events detected by the Veterans Health Administration Surgical Quality Improvement Program and the Patient Safety Indicators. *Am J Surg.* 2014;207(4):584-595.

59. Cima RR, Lackore K, Nehring S, et al. How best to measure surgical quality? Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicators (AHRQ-PSI) and the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) postoperative adverse events at a single institution. *Surgery.* 2011;150(5):943-949.

60. Koch CG, Li L, Hixson E, Tang A, Phillips S, Henderson JM. What are the real rates of postoperative complications: elucidating inconsistencies between administrative and clinical data sources. *Journal of the American College of Surgeons.* 2012;214(5):798-805.

61. Sadeghi B, White RH, Maynard G, et al. Improved Coding of Postoperative Deep Vein Thrombosis and Pulmonary Embolism in Administrative Data (AHRQ Patient Safety Indicator 12) After Introduction of New ICD-9-CM Diagnosis Codes. *Med Care.* 2013.

62. Bilimoria KY, Chung J, Ju MH, et al. Evaluation of surveillance bias and the validity of the venous thromboembolism quality measure. *Jama.* 2013;310(14):1482-1489.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite)

**Measure Title**: PSI 13 Postoperative Sepsis Rate (Component)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Prevention of postoperative sepsis requires consideration of patient level risk factors along with review of process measures aimed at neutralizing the threat of bacterial, viral and fungal contamination posed by healthcare staff, the operating room environment and the patient's endogenous skin flora. Appropriate interventions include preoperative disinfection, clipping instead of shaving of hair, use of appropriate surgical attire, skin preparation of both patient and surgeon, timely prophylactic antibiotic therapy as appropriate based on surgery type, and the maintenance of gut function. Other important aspects of care include monitoring for early signs of infection, maintaining normal blood glucose levels in patients with diabetes, limiting operative traffic, and temperature control (patient and operating room). In combination, these processes can decrease the size of the pathogen innoculum at the surgical site and/or alter the operative site so it is less hospitable to the growth of bacteria and other pathogens. By reducing the incidence of surgical site infections, these processes also help to prevent postoperative sepsis.

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

### *Association with process of care*

A recent systematic review including 193 studies and over 30 million patients identified several surgery-specific risk factors for post-operative sepsis, including emergency surgery (OR, 3.38, 95% CI, 2.29-4.98, p<0.001), peri-operative blood transfusion (OR, 1.90, 95% CI, 1.57-2.05, p<0.001), delay of surgery (OR, 1.50, 95% CI, 1.25-1.79, p<0.001), inpatient hospital stay (OR, 2.31, 95% CI, 1.27-4.20, p<0.001) and open surgery (OR, 1.80, 95% CI, 1.57-2.05, p<0.001).1Studies have examined the association between postoperative sepsis andhospital safety climate and processes of care. Vogel et al examined NIS data (2003-2007) on patients who developed postoperative infectious complications following three high volume elective major surgical procedures (coronary artery bypass graft, colon resections and lung resections).2 Using multivariable analysis, they found that surgical delay (as measured by time from admission to elective surgery in days) was associated with sepsis after all three procedures (p < 0.0001). In another study, Rosen et al. used the PSIs, including PSI 13 (version 3.1a), to explore the potential relationship between safety climate, as measured through more than 4500 responses to the Patient Safety Climate in Healthcare Organizations survey, and hospital safety performance.3 Among the 30 VA hospitals that participated in the survey, postoperative sepsis was not significantly associated with any of the 11 dimensions of patient safety culture (p>0.10 for all comparisons). The authors noted that due to the small sample size, the relatively low rate of PSIs among VA hospitals, and narrow variation across hospitals in patient safety culture, statistical power to detect associations was limited for most PSIs, including PSI 13.

### *Association with hospital and health system characteristics*

Multiple studies have explored the association between postoperative sepsis and health system characteristics, such as hospital teaching status, magnet designation, and public versus private status. A recent systematic review by Plaeke et al. identified an association between large-sized hospitals (OR 1.38, 95% CI, 1.12-1.70, p=0.003) and postoperative sepsis.1 For example, three studies examined the relationship between nursing staff characteristics and postoperative sepsis. Based on data from the 2005 University HealthSystems Consortium (UHC) operational and clinical databases, Goode and colleagues found that registered nurse staff mix was significantly associated with lower PSI 13 rates after adjusting for nurse staffing hours and hospital case mix (p<0.05).4 Surprisingly, PSI 13 rates were higher at designated Magnet hospitals than at non-Magnet hospitals (observed-to-expected ratio 1.83 versus 1.20; p<0.05).4 Using VA and Nationwide Inpatient Sample (NIS) data from 2003 through 2004, Rivard and colleagues found that rates of PSI 13 (version 2.1) were not significantly associated with nurse staffing hours in either VA or NIS hospitals.5 Unruh and Zhang used latent growth curve models to examine the relationship between changes in registered nurse (RN) full-time employees (FTEs), registered nurses per adjusted patient day (RN/APD), and PSIs (version 2.1) in Florida hospitals from 1996 through 2004.6 Postoperative sepsis had strong evidence of sensitivity to nursing care, in that higher baseline RN FTE levels were significantly associated with lower levels of postoperative sepsis. Increases over time in RN/APD were associated with decreased rates of postoperative sepsis.

Multiple studies havealso assessed the impact of hospital volume and bed size on PSI 13. Analyzing NIS data on all hospitalizations between 2002 and 2010 that involved coiling or clipping cerebral aneurysms, two studies found that hospital bed size was not associated with PSI 13.7,8 Likewise, using VA and NIS data from 2003 through 2004, Rivard and colleagues found that rates of PSI 13 (version 2.1) were not significantly associated with bed size in either VA or NIS hospitals.5 Using the VA Patient Treatment File data, Rosen et al. examined risk-adjusted PSIs (version 2.1) for acute care VA hospitals for fiscal years 2001 to 2004 and found that hospital volume was positively associated with PSI 13 rate (1.90, 95% CI 0.26 to 3.54)(model R2 0.11).9 Vogel et al found the opposite relationship between PSI 13 and hospital volume when analyzing CMS data (2005-2007) on Medicare beneficiaries aged 65 years and older with non-ruptured abdominal aortic aneurysms who underwent elective endovascular aortic aneurysm repair (EVAR) or open aortic repair (OAR).10 Patients in low volume (LV) centers were more likely to develop sepsis than patients in high volume (HV) centers after both EVAR (OR 1.45; 95**%** CI 1.04 to 2.03) and OAR (OR 1.36; 95**%** CI 1.11 to 1.68). After adjusting for patient age, gender, race, and comorbidities, the likelihood of developing postoperative sepsis remained significantly greater in LV hospitals than in HV centers for both EVAR (OR 1.44; 95**%** CI 1.03 to 2.01) and OAR (OR 1.33; 95**%** CI 1.07 to 1.64). The authors estimated that 111 cases of sepsis (36 after EVAR and 75 after OAR) may have been avoided if all patients were treated at HV hospitals, and that these potentially preventable cases of postoperative sepsis accounted for $6.7 million in extra hospital charges after EVAR and $15.1 million in extra charges after OAR surgery.

### *Association with other outcomes*

Several studies have examined the relationship between postoperative sepsis and subsequent outcomes, including length of stay in the hospital, mortality, and readmissions. For example, Ramanathan et al. examined data on surgical patients hospitalized between 2011 and 2012 at an academic medical center and found that hospitalizations with PSI 13 (version 3.1) were associated with a 33.3 day mean hospital length of stay, 100% included an intensive care unit (ICU) stay, and 38.5% died in hospital.11 Rosen et al.12 reported that hospitalizations with postoperative sepsis had a significantly higher all-cause readmission rate (19.2%) than hospitalizations without PSI 13 (13.0%; p < 0.0001). In a multivariable analysis controlling for age, sex, comorbidities, and other PSI events, hospitalizations with a PSI 13 event had 32% higher odds of having a subsequent readmission (OR 1.32; 95% CI 1.12 to 1.57). In another study based on an analysis of the 501,908 hospitalizations involving a brain tumor in the NIS between 2002 and 2010, Rahman et al found that patients with postoperative sepsis had significantly longer lengths of stay (p < 0.0001) than similar patients without postoperative sepsis.13

Zhan and Miller used AHRQ PSI software on 7.45 million discharges in the HCUP NIS (2000) and found that patients who experienced PSI 13 had higher mean (SD) unadjusted length of stay (250.10 [0.48] vs. 70.20 [0.01]), mean charges $113,708 [2486] vs. $32,328 [72]), and mortality (240.87 [0.85] vs. 10.12 [0.02]) than patients who did not experience a PSI 13 event.14 However, statistical differences of these comparisons were not reported. Liu and colleagues analyzed NIS (2003-2007) data on patients hospitalized with and without sepsis to examine the association between sepsis and patient health.15 They found that nearly all PSI (version 4.2) rates were higher among patients with sepsis compared with patients without sepsis, and that among those with sepsis, most PSI rates increased as sepsis severity increased.

Bath et al. used Medicare data (MedPAR) from 2009 to 2012 and found that the likelihood of 30-day readmission among patients undergoing abdominal aortic aneurysm repair was greater among patients with postoperative sepsis (OR=1.53, p<0.001).16 Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 13 event were associated with an additional 2.42 hospital days compared to patients without a PSI 13 event (p<0.001), as well as a significantly increased risk of in-hospital mortality (OR=6.62; p<0.001).17 A study by Rhee et al compared 11,534 hospitalizations with hospital-onset sepsis and 83,620 hospitalizations with community-onset sepsis occurring across 136 hospitals from 2009 to 2015, and found that patients with hospital-onset sepsis had longer hospital length of stay (19 days vs. 8 days), were admitted to the ICU more often (60.7% vs. 44.1%), had longer ICU length of stay (6 vs. 4 days) and were at greater risk for in-hospital mortality (odds ratio, 2.5).18

***Population group disparities***

**Table 10** presents population group disparities for PSI 13 Postoperative Sepsis Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims datafrom July 1, 2017 to June 30, 2018.

**Table 10. PSI 13 Postoperative Sepsis Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 22762 | 3.207 | 3.661 |
| White | 1110970 | 4.482 | 4.539 |
| Black | 93991 | 6.830 | 5.267 |
| Other | 14386 | 8.272 | 6.837 |
| Asian | 11960 | 7.860 | 5.898 |
| Hispanic | 16582 | 6.513 | 5.188 |
| North American Native | 7090 | 6.065 | 5.571 |
| **Gender** |  |  |  |
| Female | 689453 | 3.664 | 4.759 |
| Male | 588287 | 6.004 | 4.698 |
| **Age** |  |  |  |
| <50 | 40869 | 6.288 | 4.674 |
| 50-54 | 29493 | 5.900 | 4.744 |
| 55-59 | 48271 | 6.691 | 5.472 |
| 60-64 | 64626 | 5.663 | 4.715 |
| 65-69 | 353019 | 3.782 | 4.708 |
| 70-74 | 312064 | 4.332 | 4.625 |
| 75-79 | 225227 | 4.844 | 4.428 |
| 80-84 | 128745 | 5.491 | 4.630 |
| 85-89 | 58281 | 6.228 | 4.680 |
| 90 plus | 17145 | 5.249 | 4.517 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review results presented below constitute the most recent update, conducted in August 2020. Search terms included relevant MeSH terms (sepsis) and keywords (sepsis, SIRS, septic). We combined this clinical search string with MeSH terms (postoperative complications, iatrogenic disease, quality indicators) to identify studies examining postoperative complications or quality measures. Search was limited to English publications. We also tested more inclusive search strings. To provide the most up-to-date evidence, we summarize below the most recent evidence.

# 1a.4.3. Provide the citation(s) for the evidence.

1. Plaeke P, De Man JG, Coenen S, Jorens PG, De Winter BY, Hubens G. Clinical- and surgery-specific risk factors for post-operative sepsis: a systematic review and meta-analysis of over 30 million patients. *Surg Today.* 2020;50(5):427-439.

2. Vogel TR, Dombrovskiy VY, Lowry SF. In-hospital delay of elective surgery for high volume procedures: the impact on infectious complications. *J Am Coll Surg.* 2010;211(6):784-790.

3. Rosen AK, Singer S, Shibei Z, Shokeen P, Meterko M, Gaba D. Hospital safety climate and safety outcomes: is there a relationship in the VA? *Med Care Res Rev.* 2010;67(5):590-608.

4. Goode CJ, Blegen MA, Park SH, Vaughn T, Spetz J. Comparison of patient outcomes in Magnet(R) and non-Magnet hospitals. *J Nurs Adm.* 2011;41(12):517-523.

5. Rivard PE, Elixhauser A, Christiansen CL, Shibei Z, Rosen AK. Testing the association between patient safety indicators and hospital structural characteristics in VA and nonfederal hospitals. *Med Care Res Rev.* 2010;67(3):321-341.

6. Unruh LY, Zhang NJ. Nurse staffing and patient safety in hospitals: new variable and longitudinal approaches. *Nurs Res.* 2012;61(1):3-12.

7. Fargen KM, Neal D, Rahman M, Hoh BL. The prevalence of patient safety indicators and hospital-acquired conditions in patients with ruptured cerebral aneurysms: establishing standard performance measures using the Nationwide Inpatient Sample database. *J Neurosurg.* 2013;119(6):1633-1640.

8. Fargen KM, Rahman M, Neal D, Hoh BL. Prevalence of patient safety indicators and hospital-acquired conditions in those treated for unruptured cerebral aneurysms: establishing standard performance measures using the Nationwide Inpatient Sample database. *J Neurosurg.* 2013;119(4):966-973.

9. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Med Care.* 2006;44(9):850-861.

10. Vogel TR, Dombrovskiy VY, Graham AM, Lowry SF. The impact of hospital volume on the development of infectious complications after elective abdominal aortic surgery in the Medicare population. *Vasc Endovascular Surg.* 2011;45(4):317-324.

11. Ramanathan R, Leavell P, Wolfe LG, Duane TM. Agency for Healthcare Research and Quality patient safety indicators and mortality in surgical patients. *Am Surg.* 2014;80(8):801-804.

12. Rosen AK, Loveland S, Shin M, et al. Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Med Care.* 2013;51(1):37-44.

13. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

14. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Quality & safety in health care.* 2003;12 Suppl 2:ii58-63.

15. Liu V, Turk BJ, Rizk NW, Kipnis P, Escobar GJ. The association between sepsis and potential medical injury among hospitalized patients. *Chest.* 2012;142(3):606-613.

16. Bath J, Dombrovskiy VY, Vogel TR. Impact of Patient Safety Indicators on readmission after abdominal aortic surgery. *J Vasc Nurs.* 2018;36(4):189-195.

17. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *Am J Med Qual.* 2017;32(6):583-590.

18. Rhee C, Wang R, Zhang Z, Fram D, Kadri SS, Klompas M. Epidemiology of Hospital-Onset Versus Community-Onset Sepsis in U.S. Hospitals and Association With Mortality: A Retrospective Analysis Using Electronic Clinical Data. *Crit Care Med.* 2019;47(9):1169-1176.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite)

**Measure Title**: PSI 14 Postoperative Wound Dehiscence Rate (Component)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Wound dehiscence can be caused by 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. Prevention of wound dehiscence focuses primarily on control of patient level factors and technical factors under the control of the surgeon. Technical factors may be associated with surgical technique, incisional factors, and those associated with suture. 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. Additional postoperative processes that can help prevent dehiscence include: preventing undue stress on the wound edges and facilitating healing through adequate nutrition, control of diabetes, and the avoidance of medications that may delay wound healing.

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

### *Association with process of care*

During the preoperative workup, patients should be evaluated for risk for factors for postoperative wound dehiscence using a validated tool.1,2 Patients with wound dehiscence are more likely to have received care that departed from professionally recognized standards. For example, Hannan et al. reported that cases with a secondary diagnosis of wound disruption were 3.0 times more likely to have received care that departed from professionally recognized standards than cases without that code (4.3% versus 1.7%), after adjusting for patient demographic, geographic, and hospital characteristics.1 In the case of abdominal wound dehiscence, in the majority of cases (up to 95 percent),2-4 the sutures and knots are intact, but the suture has pulled through the fascia. This is usually the result of fascial necrosis from the surgeon placing the sutures too close to the edge or from the wound being under too much tension.

Two additional studies examined the association between postoperative wound dehiscence **and** hospital safety climate and processes of care. Rosen et al. (2010) used the PSIs, including PSI 14 (version 3.1a), to explore the potential relationship between safety climate, as measured through more than 4500 responses to the Patient Safety Climate in Healthcare Organizations survey, and hospital safety performance.3 They found that among the 30 Veteran’s Health Administration hospitals that participated in the survey, the rate of postoperative wound dehiscence was not significantly associated with any of the 11 dimensions of patient safety culture included in the analysis (p>0.10 for all comparisons) after adjusting for major teaching status, metropolitan area and nurse-staffing ratio. The relationship between the indicator rate and patient safety culture dimensions remained non-significant when senior managers and frontline staff were analyzed separately. The authors note that due to the small sample size, the relatively low rate of PSIs among VA hospitals, and narrow variation across hospitals in patient safety culture, statistical power to detect associations was limited for most PSIs, including PSI 14. Chen et al. (2013a) reviewed PSI 14 (version 3.1a), in relation to hospital processes of care. Using VA data, 28 out of 158 VA hospitals were selected for a stratified sample based upon observed-to-expected PSI 14 cases.4 The study found differences in the surgical techniques (incision type and closure techniques), however physician review suggested that the techniques were not an indication of poor quality of care. Overall, postoperative wound dehiscence cases were not determined to be indicative of examined hospital processes of care, though it should be noted that about 25% of the cases and controls were missing data from their charts.

### *Association with hospital and health system characteristics*

Multiple studies have explored the association between health system characteristics and the prevalence of postoperative wound dehiscence**.** Using fiscal year 2004 data from the Veterans Health Administration (VA) and calendar year 2003 data from the Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS) (n=116 VA hospitals, n=992 community non-Federal hospitals), Rivard and colleagues5 found that the risk-adjusted rate of PSI 14 was 4.80 per 1000 (95% CI 3.41 to 6.19) in VA hospitals and 1.55 per 1000 (95% CI 1.19 to 1.90) in non-VA hospitals PSI 14 rates were not significantly associated with nurse staffing hours in either VA or NIS hospitals. Among VA hospitals, both major and minor teaching hospitals had lower risk-adjusted PSI 14 rates than nonteaching hospitals (major OR 0.53, 99% CI 0.19 to 1.51; minor OR 0.55, 99% CI 0.18-1.67). Among nonfederal hospitals, both major and minor teaching hospitals had higher risk-adjusted PSI 14 rates than nonteaching hospitals (major OR 1.58, 99% CI 1.01 to 2.48; minor OR 1.40, 95% 0.96 to 2.05). None of these findings, however, was statistically significant. The same authors6 confirmed that PSI 14 rates across NIS hospitals, but not across VA hospitals, were significantly higher in minor (OR 1.35, 95% CI 1.02 to 1.79) and major (OR 1.41, 95% CI 1.02 to 1.95) teaching hospitals than in nonteaching hospitals. Rates of this indicator were significantly lower at large hospitals (OR 0.70, 95% CI 0.53 to 0.94) than at small hospitals in the NIS, but not in the VA system. A contemporaneous VA study using a longer period of data (2001-2004) reported that after adjusting for hospital and patient characteristics using a generalized linear model, hospital bed size (-2.90, 95% CI -5.71 to -0.10, p<0.05) and mean quality improvement implementation score (-15.54, 95% CI -28.38 to -2.70, p<0.05) were negatively associated with PSI 14 (version 2.1) rates (model R2 0.12).7

In 2013, Chen et al. (2013b) compared PSI 14 rates (version 3.1a) among veteran dual users (who were treated in both VA and private sector hospitals) over the period 2002-2007 and found that the odds of experiencing PSI 14 were significantly higher for veteran dual users hospitalized in the VA than in the private sector through Medicare (OR 2.23; 95% CI 1.60 to 3.10).8 After adjustment for age, sex and 27 comorbidities, the PSI 14 rate among VA hospitalizations was 4.4 per 1000 (95% CI 3.8 to 4.9) versus 1.8 per 1,000 in the private sector (95% CI 1.3 to 2.3).

In an analysis of patient-level Medicare claims data for patients undergoing any of 6 cancer resections for the years 2005-2009, Short et al. found that the postoperative wound dehiscence rate was higher at high procedure volume hospitals than at low-volume hospitals (0.25% vs 0.22%), at rural hospitals than urban hospitals (0.39% vs 0.26%), and at non-teaching hospitals than teaching hospitals (0.30% vs 0.23%) (statistical values not provided).9

### *Association with other outcomes*

Other studies have examined the relationship between postoperative wound dehiscence and outcomes including length of stay in the hospital, mortality, and readmissions. For example, Rosen et al. (2013), examined whether PSI events, experienced within index hospitalizations, increased the likelihood of readmission within VA hospitals.10 Of the 1,807,488 index medical and surgical hospitalizations, there were a total of 262,026 readmissions. Postoperative wound dehiscence resulted in significantly higher rates of all-cause readmissions (20.0%) compared to those hospitalizations without an event (11.5%; p<0.0001). In a multivariate analysis using AHRQ comorbidity software (version 3.5) - controlling for age, sex, comorbidities, and other PSI events - hospitalizations with a PSI 14 event were 61% more likely to result in subsequent readmissions (OR 1.61; 95% CI 1.27 to 2.05).

Ramanathan et al (2014) retroactively examined data on surgical patients hospitalized between 2011 and 2012 at an academic medical center and found that hospitalizations that included a postoperative wound dehiscence (PSI 14, version 3.1) were associated with a 108.5 day mean hospital length of stay; 100% included an intensive care unit stay, and 0% died in hospital.11 Of those with an ICU stay, the mean ICU length of stay was 24.0 days.

Chen et al. (2013a) reviewed PSI 14 (version 3.1a) in relation to hospital processes of care using VA hospital Patient Treatment Files for 28 VA hospitals and found that length of stay (LOS) was significantly longer for cases than controls (cases mean LOS 41 days, standard deviation [SD] 43.2; controls LOS 24, SD 36.2; p<0.01).4 Another study by Zhan and Miller used AHRQ PSI software on 7.45 million discharges in the HCUP NIS for the year 2000 and report that those with PSI 14 had a higher mean (SD) unadjusted length of stay (220.32 [0.61] vs. 60.72 [0.014]), charges ($93,022 [3,336] vs. $22,623 [75]), and percent mortality (330.66 [10.16] vs. 160.53 [0.026]) than those who did not experience a PSI 14 event.12 However, statistical significance was not reported. The findings related to length of stay from these two studies conflict with those of another study of 501,908 hospitalizations involving a brain tumor in the NIS (2002-2010) by Rahman et al, which reported no association between postoperative wound dehiscence and length of stay.13

In an analysis of patient-level Medicare claims data for patients undergoing any of 6 cancer resections for the years 2005-2009, Short et al. found that after adjusting for patient (age, sex, race, income), hospital (hospital volume, surgeon volume, surgeon specialty designation, hospital resources, patient characteristics) and tumor factors (tumor stage, site), costs increased significantly, by more than 40%, for postoperative wound dehiscence among 4 of the 6 types of cancer resection patients (p < 0.001).9

Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations with a PSI 14 event were associated with an additional 3.09 hospital days compared to patients without a PSI 14 event (p<0.001), as well as a significantly increased risk of in-hospital mortality (OR=72.56; p<0.001).14

***Population group disparities***

**Table 11** presents population group disparities for PSI 14 Postoperative Wound Dehiscence Rate for 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims datafrom July 1, 2017 to June 30, 2018.

**Table 11. PSI 14 Postoperative Wound Dehiscence Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 7925 | 0.379 | 0.342 |
| White | 457827 | 0.867 | 0.806 |
| Black | 50179 | 0.917 | 0.877 |
| Other | 7339 | 1.090 | 1.275 |
| Asian | 7080 | 0.847 | 1.045 |
| Hispanic | 11377 | 0.791 | 1.070 |
| North American Native | 3985 | 0.502 | 0.475 |
| **Gender** |  |  |  |
| Female | 286226 | 0.528 | 0.795 |
| Male | 259486 | 1.233 | 0.824 |
| **Age** |  |  |  |
| <50 | 26871 | 0.558 | 0.751 |
| 50-54 | 16277 | 0.922 | 0.647 |
| 55-59 | 24677 | 0.851 | 0.769 |
| 60-64 | 30726 | 1.497 | 0.961 |
| 65-69 | 131633 | 0.858 | 0.847 |
| 70-74 | 115036 | 0.861 | 0.776 |
| 75-79 | 87627 | 0.890 | 0.851 |
| 80-84 | 59928 | 0.734 | 0.736 |
| 85-89 | 35746 | 0.671 | 0.747 |
| 90 plus | 17191 | 0.931 | 1.032 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review results presented below constitute the most recent update, conducted in August 2020. Search terms included relevant MeSH terms (surgical wound dehiscence). We combined this clinical search string with MeSH terms (postoperative complications) and keywords (patient safety) to identify studies examining inpatient care. Search was limited to English publications. We also tested more inclusive search strings.

# 1a.4.3. Provide the citation(s) for the evidence.

1. van Ramshorst GH, Nieuwenhuizen J, Hop WC, et al. Abdominal wound dehiscence in adults: development and validation of a risk model. *World J Surg.* 2010;34(1):20-27.

2. Kenig J, Richter P, Lasek A, Zbierska K, Zurawska S. The efficacy of risk scores for predicting abdominal wound dehiscence: a case-controlled validation study. *BMC Surg.* 2014;14:65.

3. Rosen AK, Singer S, Shibei Z, Shokeen P, Meterko M, Gaba D. Hospital safety climate and safety outcomes: is there a relationship in the VA? *Medical care research and review : MCRR.* 2010;67(5):590-608.

4. Chen Q, Borzecki AM, Cevasco M, et al. Examining the relationship between processes of care and selected AHRQ patient safety indicators postoperative wound dehiscence and accidental puncture or laceration using the VA electronic medical record. *Am J Med Qual.* 2013;28(3):206-213.

5. Rivard PE, Christiansen CL, Zhao S, Elixhauser A, Rosen AK. Advances in Patient Safety

Is There an Association Between Patient Safety Indicators and Hospital Teaching Status? In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 2: Culture and Redesign).* Rockville (MD): Agency for Healthcare Research and Quality (US); 2008.

6. Rivard PE, Elixhauser A, Christiansen CL, Shibei Z, Rosen AK. Testing the association between patient safety indicators and hospital structural characteristics in VA and nonfederal hospitals. *Medical care research and review : MCRR.* 2010;67(3):321-341.

7. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Medical care.* 2006;44(9):850-861.

8. Chen Q, Hanchate A, Shwartz M, et al. Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicator Rates Among Veteran Dual Users. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2013;29(4):335-343.

9. Short MN, Aloia TA, Ho V. The influence of complications on the costs of complex cancer surgery. *Cancer.* 2014;120(7):1035-1041.

10. Rosen AK, Loveland S, Shin M, et al. Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Medical care.* 2013;51(1):37-44.

11. Ramanathan R, Leavell P, Wolfe LG, Duane TM. Agency for Healthcare Research and Quality patient safety indicators and mortality in surgical patients. *Am Surg.* 2014;80(8):801-804.

12. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Quality & safety in health care.* 2003;12 Suppl 2:ii58-63.

13. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

14. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2017;32(6):583-590.

**NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0531 (Composite)

**Measure Title**: PSI 15 Unrecognized Abdominopelvic Accidental Puncture or Laceration Rate (Component)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Patient Safety and Adverse Events Composite (PSI 90; NQF #0531)

**Date of Submission**: 10/28/2020

**Instructions**

* *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
* *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*
* *For composite performance measures:*
  + *A separate evidence form is required for each component measure unless several components were studied together.*
  + *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
* All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
* If you are unable to check a box, please highlight or shade the box for your response.
* Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage.](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx)

### Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.

**1a. Evidence to Support the Measure Focus**

The measure focus is evidence-based, demonstrated as follows:

* Outcome: [**3**](#_bookmark0)Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
* Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured intermediate clinical outcome leads to a desired health outcome.
* Process: [**5**](#_bookmark2)a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured process leads to a desired health outcome.
* Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#_bookmark1)that the measured structure leads to a desired health outcome.
* Efficiency: [**6**](#_bookmark3)evidence not required for the resource use component.
* For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
* Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

### Notes

1. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
2. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/) and/or modified GRADE.
3. Clinical care processes typically include multiple steps: assess  identify problem/potential problem  choose/plan intervention (with patient input)  provide intervention  evaluate impact on health status. If the measure focus is one

step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework:](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [Evaluating Efficiency Across Episodes of Care;](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx) [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)).

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*) Outcome

Outcome: Click here to name the health outcome

☐Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health- related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

□ Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

* Process: Click here to name what is being measured

□ Appropriate use measure: Click here to name what is being measured

* Structure: Click here to name the structure
* Composite: Click here to name what is being measured

**1a.2 LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

This measure identifies surgical injuries to an abdominopelvic organ (e.g., bowel, bladder, liver, spleen, diaphragm, kidney) that were unintended and presumptively not recognized and treated at the time of occurrence. This definition would be met if, for example, a surgeon errantly creates a full-thickness injury of the small intestine with a cautery device or scissors while dissecting adhesions AND does not recognize the injury until reoperation a few days later for intra-abdominal sepsis. The rationale for this measure is that these injuries have major adverse consequences for patients and are usually preventable. Physicians can prevent these injuries either by avoiding the accidental puncture or laceration with more careful technique or, if that is not possible, by promptly identifying and treating the accidental puncture or laceration at the time it occurs.

**1a.3 Value and Meaningfulness: IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

NA

# \*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\*

**1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

NA

**1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the**

**evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

NA

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

## ☐Clinical Practice Guideline recommendation (with evidence review)

☐US Preventive Services Task Force Recommendation

☐Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

## ☐Other

|  |  |
| --- | --- |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** |  |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. |  |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade |  |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation**  with definition of the grade |  |
| Provide all other grades and definitions from the recommendation grading system |  |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? |  |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

Much of the available literature regarding PSI 15 concerns the pre-2015 version of the indicator, rather than the reformulated version, which focuses on abdominopelvic injuries that were not treated at the time of occurrence. Although the literature summarized below may provide some relevant information, reviewers should be cognizant that the current version of PSI 15 focuses on a more homogeneous and consequential subset of events.

### *Association with process of care*

Two studies examined the association between hospital safety climate and accidental puncture and laceration. Rosen et al. used PSI 15 (version 3.1a), to explore the potential relationship between safety climate, as measured through more than 4500 responses to the Patient Safety Climate in Healthcare Organizations survey, and hospital safety performance.1 Among the 30 VA hospitals that participated in the survey, the rate of accidental puncture or laceration was not significantly associated with any of the 11 dimensions of patient safety culture included in the analysis (p>0.10 for all comparisons). Analyses were adjusted for major teaching status, metropolitan area and nurse-staffing ratio. The relationship between PSI 15 rates and patient safety culture dimensions remained non-significant when senior managers and frontline staff were analyzed separately. The authors note that due to the small sample size, the relatively low rate of PSIs among VA hospitals, and narrow variation across hospitals in patient safety culture, statistical power to detect associations was limited.

In a study testing construct validity using an implicit process measure of quality created through the hospital accreditation review process, smoothed rates of PSI 15 among 2,116 hospitals surveyed by The Joint Commission were significantly (p<0.01) associated with summary evaluation scores, in the expected direction.2 Chen et al. reviewed PSI 15 (version 3.1a) in relation to hospital processes of care using data from 28 VA hospitals, but was unable to confirm any significant associations between examined processes of care and incidence of PSI 15 (although the study was likely underpowered, as it included only 112 PSI 15 events).3

Other studies have examined the role played by factors such as procedure timing, physician ranking, and duty-hour regulations. For example, Shelton et al., analyzed 376 million patient discharges from NIS between 1998-2007 to evaluate the effect of the 2003 U.S. implementation of duty-hour regulations, limiting resident work hours to 80 per week, within teaching and non-teaching hospitals; non-teaching hospitals served as the control group.4 They found that the rates of accidental puncture or laceration prior to implementation were 30.27 and 42.27, per 10,000 discharges, in non-teaching and teaching hospitals, respectively. Rates of accidental puncture or laceration were not significantly altered after the implementation of the duty-hour regulations (non-teaching 28.62, teaching 24.65 per 10,000 discharges). Another study by Chen and colleagues (2013a) examined whether PSI 15 events are affected by hospital processes of care such as timing of procedure and physician ranking.5 Using VA administrative data from October 2002-September 2007, AHRQ PSI software (version 3.1a), and medical chart review, the authors identified 95 matched case-control pairs for PSI 15. There were no significant differences found for operating room procedures performed during the weekend (n=3, 3.9%; n=4, 4.4%) or at night (n=3, 3.9%; n=7, 7.8%) between cases and controls, respectively. The authors also found no association between physician rank and PSI 15 within the matched pairs – attending physicians (cases n=33, 42.3%, controls n=33, 36.7%) and trainees (cases n=41, 52.6%; controls n=53, 58.9%) had similar rates of PSI 15 events.

### *Association with hospital and health system characteristics*

Multiple studies have explored the association between health system characteristics and the occurrence of accidental punctures or lacerations. In 2010, Rivard and colleagues compared the relationship between PSI 15 (version 2.1) rates and various hospital characteristics in Veteran’s Health Association (VA) vs. community non-Federal hospitals.6 Using VA and Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS) data from 2003 through 2004 (n=116 VA hospitals, n=992 community non-Federal hospitals), they found that the risk-adjusted rate of PSI 15 was 3.93 per 1000 (95% CI 3.31 to 4.54) in VA hospitals and 3.29 per 1000 (95% CI 3.03 to 3.56) in non-VA hospitals (from the NIS dataset). Rates were significantly higher among minor teaching hospitals, compared to nonteaching hospitals, in both samples (VA OR 2.12, 95% CI 1.11 to 4.08; NIS OR 1.23, 95% CI 1.04 to 1.47). Compared to nonteaching status, major teaching status was significantly associated with higher rates of accidental puncture and laceration, compared to nonteaching hospitals, in NIS hospitals only (OR 1.36, 95% CI 1.11 to 1.66). Another study using fiscal year 2004 data from the VA and calendar year 2003 NIS (PSI version 2.1)7 reported that for both VA and NIS data, PSI 15 rates were lower in non-teaching hospitals than in either major or minor teaching hospitals. However, a contemporaneous VA study using a longer period of data (2001-2004) found no hospital characteristics (e.g. bed size, teaching status, location) that were associated with PSI 15 (version 2.1) across acute care VA hospitals.8

Chen et al (2013b) compared PSI 15 (version 3.1a) rates among 266,203 veteran dual users (who were treated in both VA and private sector hospitals) over the period 2002-2007 and found that the odds of experiencing PSI 15 were significantly higher for veteran dual users hospitalized in the VA than in the private sector through Medicare (OR 1.30, 95% CI 1.20 to 1.42).5 After adjustment for age, sex and 27 comorbidities, the PSI 15 rate among VA hospitalizations was 5.6 per 1000 (95% CI 5.3 to 5.8) versus 3.9 per 1000 among Medicare hospitalizations (95% CI 3.7 to 4.1).

Basu & Friedman analyzed the HCUP database focusing on 3,481,086 senior Medicare patients in Florida hospitals and found that Health Maintenance Organization (HMO) patients had more PSI 15 events than Fee for Service (FFS) patients (OR = 1.155, p<0.05).9 In an analysis of Medicare claims data for patients undergoing any of 6 cancer resections in 2005-2009, Short et al. found that the accidental puncture or laceration rate was higher at high procedure volume hospitals than at low-volume hospitals (2.17% vs 2.10%), at urban hospitals than rural hospitals (2.11% vs 1.89%), and at teaching hospitals than non-teaching hospitals (2.22% vs 1.98%).10

### *Association with other outcomes*

Multiple studies have examined the relationship between PSI 15 and outcomes including readmissions and cost.Rosen et al., examined whether PSI events, experienced within index hospitalizations, increased the likelihood of readmission within VA hospitals.11 Of the 1,807,488 index medical and surgical hospitalizations, there were a total of 262,026 readmissions. Accidental puncture or laceration resulted in significantly higher rates of all-cause readmissions (15.3%) compared to those hospitalizations without an event (14.6%; p<0.0001). In a multivariate analysis using AHRQ comorbidity software (version 3.5) - controlling for age, sex, comorbidities, and other PSI events - hospitalizations with a PSI 15 event were not significantly more likely to result in subsequent readmissions (OR 1.07; 95% CI 0.99 to 1.15).By contrast, an earlier study of 1,409,547 adults from about 1,080 hospitals in 7 geographically dispersed states (California, Florida, Missouri, New York, Tennessee, Utah, and Virginia) for surgical procedures in 2004, assembled from the State Inpatient Databases (SID) of the Healthcare Cost and Utilization Project, reported that PSI 15 events were independently and significantly (p<0.01) associated with inpatient deaths, 90-day readmissions, and 30-day readmissions (odds ratios 1. 52, 1. 16, and 1. 25, respectively).12 These results were adjusted through multinomial logistic regression for age, gender, severity levels in the All Patient Refined DRG classification system from 3M Health Information Systems, coding system, payer group, presence of specific comorbid conditions, and specific surgical DRGs. It is not clear why the VA and SID results differed, but under-ascertainment of readmissions in VA data (because of the availability of non-VA hospitals) represents one possibility.

Analyses of financial outcomes such as length of stay and costs (or charges) have been more consistent. Cases from the 2000 Nationwide Inpatient Sample that were flagged by PSI 15 had 2.2% excess mortality (p<0.001), 1.34 days of excess hospitalization (p<0.001), and $8,271 in excess hospital charges (p<0.001), relative to carefully matched controls that were not flagged. These differences were robust to the specific adjustment approach that was used (i.e., propensity matching versus multivariable logistic modeling), but they exceeded corresponding estimates without adjustment.13 This finding was confirmed in the Veterans Affairs hospital system, where cases that were flagged by this PSI had 3.2% excess mortality, 1.4-3.1 days of excess hospitalization, and $3,359-6,880 in excess hospital costs, relative to carefully matched controls that were not flagged.14

In an analysis of patient-level Medicare claims data for patients undergoing any of 6 cancer resections for the years 2005-2009, Short et al. found that after adjusting for patient (age, sex, race, income), hospital (hospital volume, surgeon volume, surgeon specialty designation, hospital resources, patient characteristics) and tumor factors (tumor stage, site), costs increased significantly, by 15% to 21% for accidental puncture or laceration among 5 of the 6 types of cancer resection patients (p<0.001).10

Based on an analysis of the 501,908 hospitalizations involving a brain tumor in the NIS between 2002 and 2010, Rahman et al found that patients with accidental punctures or lacerations had significantly longer length of stay (LOS) (p < 0.0001) than patients without this indicator.15 Ramanathan et al retroactively examined data on surgical patients hospitalized between 2011 and 2012 at an academic medical center and found that those hospitalizations that included an accidental puncture or laceration (PSI 15, version 3.1) were associated with a 17.4 day mean hospital LOS, 45.6% included an intensive care unit stay, and 5.9% died in hospital.16 Of those with an ICU stay, the mean intensive care unit (ICU) LOS was 9.5 days.

In a retrospective study using data collected from a single-hospital department of colorectal surgery, Kin et al. found that accidental puncture or laceration cases had more diagnoses of enterocutaneous fistula (11% vs 2%, p < 0.001), reoperative cases (91% vs 61%, p < 0.001), open surgery (96% vs 77%, p < 0.001), longer operative times (186 vs 146 minutes, p = 0.001), and increased length of stay (10 vs 7 days, p = 0.002).17

Bath et al. used Medicare data (MedPAR) from 2009 to 2012 and found that the likelihood of 30-day readmission among patients undergoing abdominal aortic aneurysm repair was greater among patients with unrecognized abdominopelvic puncture or laceration (OR=1.40, p=0.009).18 Gray et al. retrospectively examined 57,000 inpatient discharges at six hospitals between July 2012 and June 2014 and found that hospitalizations involving an accidental puncture or laceration were associated with an additional 1.35 hospital days compared to patients without an event (p<0.001), as well as a significantly increased risk of 30-day readmission (OR=4.29; p<0.001) and in-hospital mortality (OR=2.59; p<0.001).19 Bohnen et al used ACS-NSQIP data from 2007 to 2012 and found that in multivariable analyses, PSI 15 events were independently associated with increased 30-day mortality (OR=3.19; p=0.002), 30-day morbidity (OR=2.68; p<0.001) and prolonged postoperative length of stay (OR=1.85; p=0.001).20 Using the same dataset, Nandan et al found that in multivariable analyses, PSI 15 events were associated with an increase in readmission rates (OR=2.17; p=0.008).

***Population group disparities***

**Table 12** presents population group disparities for PSI 15 Unrecognized Abdominopelvic Accidental Puncture or Laceration Rate from 3,254 measured entities by applying the CMS PSI v10.0 software to a full year of Medicare FFS claims datafrom July 1, 2017 to June 30, 2018.

**Table 12: PSI 15 Rate Disparities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Population-Based Disparity Factor** | **N**  **(beneficiaries)** | **Observed Rate per 1,000** | **Adjusted Rate per 1,000** |
| **Race** |  |  |  |
| Unknown | 20076 | 1.295 | 1.280 |
| White | 1251324 | 1.199 | 1.152 |
| Black | 196235 | 1.289 | 1.517 |
| Other | 23021 | 1.651 | 1.822 |
| Asian | 25219 | 1.546 | 1.832 |
| Hispanic | 38350 | 1.173 | 1.495 |
| North American Native | 11197 | 1.429 | 1.431 |
| **Gender** |  |  |  |
| Female | 782040 | 1.362 | 1.215 |
| Male | 783382 | 1.088 | 1.224 |
| **Age** |  |  |  |
| <50 | 91024 | 1.077 | 1.335 |
| 50-54 | 50348 | 1.231 | 1.124 |
| 55-59 | 75367 | 0.942 | 1.083 |
| 60-64 | 94531 | 1.164 | 1.173 |
| 65-69 | 312823 | 1.260 | 1.172 |
| 70-74 | 289356 | 1.369 | 1.297 |
| 75-79 | 244653 | 1.328 | 1.204 |
| 80-84 | 191918 | 1.230 | 1.159 |
| 85-89 | 136689 | 1.192 | 1.356 |
| 90 plus | 78713 | 0.788 | 1.269 |

Source: CMS Medicare Fee-for-Service Data, 7/2017 – 6/2018

For additional information on disparities see the PSI 90 Composite (NQF #0531) Measure Information Form Section 1b.4.

# 1a.4.2 What process was used to identify the evidence?

Formal environmental scans of the literature, including routine PubMed searches are performed to continually update evidence. The current evidence review results presented below constitute the most recent update, conducted in August 2020. Search terms included relevant keywords (accidental puncture, laceration). Search was limited to English publications. We also tested more inclusive search strings.

# 1a.4.3. Provide the citation(s) for the evidence.

1. Rosen AK, Singer S, Shibei Z, Shokeen P, Meterko M, Gaba D. Hospital safety climate and safety outcomes: is there a relationship in the VA? *Medical care research and review : MCRR.* 2010;67(5):590-608.

2. Miller MR, Pronovost P, Donithan M, et al. Relationship between performance measurement and accreditation: implications for quality of care and patient safety. *Am J Med Qual.* 2005;20(5):239-252.

3. Chen Q, Borzecki AM, Cevasco M, et al. Examining the relationship between processes of care and selected AHRQ patient safety indicators postoperative wound dehiscence and accidental puncture or laceration using the VA electronic medical record. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2013;28(3):206-213.

4. Shelton J, Kummerow K, Phillips S, et al. Patient safety in the era of the 80-hour workweek. *Journal of surgical education.* 2014;71(4):551-559.

5. Chen Q, Hanchate A, Shwartz M, et al. Comparison of the Agency for Healthcare Research and Quality Patient Safety Indicator Rates Among Veteran Dual Users. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2013;29(4):335-343.

6. Rivard PE, Elixhauser A, Christiansen CL, Shibei Z, Rosen AK. Testing the association between patient safety indicators and hospital structural characteristics in VA and nonfederal hospitals. *Medical care research and review : MCRR.* 2010;67(3):321-341.

7. Rivard PE, Christiansen CL, Zhao S, Elixhauser A, Rosen AK. Advances in Patient Safety: Is There an Association Between Patient Safety Indicators and Hospital Teaching Status? In: Henriksen K, Battles JB, Keyes MA, Grady ML, eds. *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 2: Culture and Redesign).* Rockville (MD)2008.

8. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: lessons from the Veterans Administration. *Medical care.* 2006;44(9):850-861.

9. Basu J, Friedman B. Adverse events for hospitalized medicare patients: is there a difference between HMO and FFS enrollees? *Social work in public health.* 2013;28(7):639-651.

10. Short MN, Aloia TA, Ho V. The influence of complications on the costs of complex cancer surgery. *Cancer.* 2014;120(7):1035-1041.

11. Rosen AK, Loveland S, Shin M, et al. Examining the impact of the AHRQ Patient Safety Indicators (PSIs) on the Veterans Health Administration: the case of readmissions. *Medical care.* 2013;51(1):37-44.

12. Friedman B, Encinosa W, Jiang HJ, Mutter R. Do patient safety events increase readmissions? *Medical care.* 2009;47(5):583-590.

13. Zhan C, Miller MR. Administrative data based patient safety research: a critical review. *Quality & safety in health care.* 2003;12 Suppl 2:ii58-63.

14. Rivard PE, Luther SL, Christiansen CL, et al. Using Patient Safety Indicators to Estimate the Impact of Potential Adverse Events on Outcomes. *Medical Care Research and Review.* 2008;65(1):67-87.

15. Rahman M, Neal D, Fargen KM, Hoh BL. Establishing standard performance measures for adult brain tumor patients: a Nationwide Inpatient Sample database study. *Neuro Oncol.* 2013;15(11):1580-1588.

16. Ramanathan R, Leavell P, Wolfe LG, Duane TM. Agency for Healthcare Research and Quality patient safety indicators and mortality in surgical patients. *Am Surg.* 2014;80(8):801-804.

17. Kin C, Snyder K, Kiran RP, Remzi FH, Vogel JD. Accidental puncture or laceration in colorectal surgery: a quality indicator or a complexity measure? *Dis Colon Rectum.* 2013;56(2):219-225.

18. Bath J, Dombrovskiy VY, Vogel TR. Impact of Patient Safety Indicators on readmission after abdominal aortic surgery. *J Vasc Nurs.* 2018;36(4):189-195.

19. Gray DM, 2nd, Hefner JL, Nguyen MC, Eiferman D, Moffatt-Bruce SD. The Link Between Clinically Validated Patient Safety Indicators and Clinical Outcomes. *American journal of medical quality : the official journal of the American College of Medical Quality.* 2017;32(6):583-590.

20. Bohnen JD, Mavros MN, Ramly EP, et al. Intraoperative Adverse Events in Abdominal Surgery: What Happens in the Operating Room Does Not Stay in the Operating Room. *Ann Surg.* 2017;265(6):1119-1125.