NATIONAL QUALITY FORUM

TO: NQF Members and public

FR: NQF staff

RE: Pre-voting review for National Voluntary Consensus Standards for Patient Safety Measures, Second Report: A Consensus Report (Supplemental Comment Period)

DA: August 26, 2011

This first report of the patient safety measures project presents the evaluation results of several healthcare-associated infections (HAI) measures. A Steering Committee of 21 individuals representing the range of stakeholder perspectives reviewed and considered for endorsement five HAI candidate standards. All five measures, including two surgical site infection (SSI) measures, were recommended for endorsement as voluntary consensus standards.

The report was initially presented for NQF Member and public comment in November 2010. Following that initial comment period, the Centers for Disease Control and Prevention (CDC) and the American College of Surgeons (ACS) worked together to harmonize their originally submitted SSI measures. The harmonized measure, PSM-002-10 (ACS-CDC Harmonized Procedure Specific SSI Outcome measure) is now available for comment. During this period, the CDC also significantly revised two additional measures, PSM-001-10 NHSN (Central line-associated bloodstream infection (CLABSI) outcome measure) and PSM-003-10 (NHSN Catheter-associated urinary tract infection (CAUTI) outcome measure). These three modified measures are being posted for a supplemental comment period, to allow NQF Members and the public an opportunity to provide feedback on the revised specifications.

The draft document, *National Voluntary Consensus Standards for Patient Safety Measures, Second Report*, is also posted on the NQF website, http://www.qualityforum.org/projects/patient_safety_measures.aspx, along with the following additional information:

- measure evaluations; and
- additional technical information, if applicable.

Pursuant to section II.A of the Consensus Development Process v. 1.8, this draft document, along with the accompanying material, is being provided to you at this time for purposes of review and comment only—not voting. You may post your comments and view the comments of others on the NQF website.

Please note that there is one deadline for both NQF Member and public comments. All comments must be submitted no later than 6:00 pm ET, September 14, 2011.

Thank you for your interest in the NQF's work. We look forward to your review and comments.

NATIONAL QUALITY FORUM

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PATIENT SAFETY MEASURES, FIRST REPORT: A CONSENSUS REPORT

DRAFT REPORT FOR SUPPLEMENTAL COMMENT

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EXECUTIVE SUMMARY

Healthcare-associated infections (HAIs) remain a significant public health issue in the United States. In hospitals alone, the incidence of HAIs is estimated at 1.7 million infections, with 99,000 associated deaths. Urinary tract infections (UTIs), surgical site infections (SSIs), pneumonia, and bloodstream infections account for 83 percent of all HAIs. The estimated direct cost of these infections to the healthcare system is nearly $4.5 billion. In 2009, the American Recovery and Reinvestment Act (ARRA) authorized $50 million in funding for states to engage in HAI planning and other activities in support of the Department of Health and Human Services (HHS) Action Plan to Prevent Healthcare-Associated Infections. Preventing HAIs has become a national priority for public health and patient safety.

The National Quality Forum (NQF) inventory of endorsed measures includes more than 100 measures related to patient safety. Several of these measures focus specifically on HAIs, addressing UTIs, SSIs, pneumonia, and bloodstream infections. Similarly, the measures recommended for endorsement in this first report of patient safety measures include updated versions of previously HAI endorsed measures. Ultimately, the endorsement of these national standards for HAI measurement will provide states and other organizations with valuable resources for implementing comparable standards and will enable consumers to gain access to uniformly reported data that are reliable and useful for decision making.

Under this initial phase of NQF's most recent Patient Safety Measures project, five HAI measures are recommended for endorsement. These measures were submitted by the Centers for Disease Control and Prevention (CDC) and the American College of Surgeons (ACS) and are listed below:

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RECOMMENDATIONS FOR ENDORSEMENT AVAILABLE FOR COMMENT AUGUST 24-SEPTEMBER9.*

- PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated bloodstream infection (CLABSI) outcome measure (CDC)
- PSM-003-10: National Healthcare Safety Network (NHSN) catheter-associated urinary tract infection (CAUTI) Outcome (CDC)
- PSM-002-10: American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure

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- **RECOMMENDATIONS FOR ENDORSEMENT PREVIOUSLY AVAILABLE FOR COMMENT**
- PSM-007-10: Risk adjusted urinary tract infection outcome measure (ACS)

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<#>PSM-006-10: Risk adjusted surgical site infection outcome measure (ACS)¶
<#>PSM-003-10: National Healthcare Safety Network (NHSN) catheter-associated urinary tract infection (CAUTI) Outcome (CDC) ¶

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*Following Member and public Comment in November 2010, the Centers for Disease Control and Prevention (CDC) and the American College of Surgeons (ACS) worked together to harmonize their two surgical site infection measures, PSM-002-10 (National Healthcare Safety Network [NHSN] surgical site infection outcome measure) and PSM-006-10 (Risk-adjusted surgical site infection outcome measure). The harmonized measure, PSM-002-10 (American College of Surgeons – Centers for Disease Control and Prevention [ACS-CDC] Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure) is now available for Member and public comment. In addition, the CDC updated PSM-001-10 and PSM-003-10. These three modified measures are being posted for a supplemental comment period, to allow NQF Members and the public an opportunity to provide feedback on the revised specifications. Please note that the comment period for NQF Members and the public will be two weeks.

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NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PATIENT SAFETY, FIRST REPORT: A CONSENSUS REPORT

BACKGROUND

Healthcare-associated infections (HAIs) remain a significant public health issue in the United States. In hospitals alone, the incidence of HAI is estimated at 1.7 million infections, with 99,000 associated deaths.[1] Urinary tract infections (UTIs), surgical site infections (SSIs), pneumonia, and bloodstream infections account for 83 percent of HAIs[1]. In 1992, the estimated direct cost of these infections on the healthcare system was $4.5 billion in 1992 dollars; adjusting for inflation, this cost rose to $6.65 billion in 2007.[2]

Consumer, provider, purchaser, and regulatory and accreditation organizations are growing increasingly interested in HAIs.[3] Many of the stakeholders in healthcare have focused increased attention on both surveillance and public reporting of HAIs. From 1970 to the present, the Centers for Disease Control and Prevention (CDC) collected voluntary data on HAIs, clinical practices known to prevent HAIs, as well as information about multidrug-resistant organisms and other adverse events. Twenty-seven states are now requiring public reporting of certain HAIs.[4] Preventing HAIs has become a public health and patient safety priority issue. In 2009, the American Recovery and Reinvestment Act (ARRA) authorized $50 million in funding for states to engage in HAI planning and other activities in support of the HHS Action Plan to Prevent Healthcare-Associated Infections.[5] In October 2008, Medicare reduced reimbursement to facilities not collecting data on particular HAIs including catheter-associated urinary tract infection (CAUTI), central line-associated bloodstream infection (CLABSI), and SSI. The Patient Protection Affordable Care Act (PPAC) will extend these payment reductions to Medicaid providers in 2011. Beginning in 2013, hospitals' annual Medicare payment updates will be tied to submission of infection data, including CLABSIs and SSIs.[6]

Though HAI data have been collected for many years, use of the data for comparison of infection rates between hospitals and other healthcare facilities requires uniform measurement standards.

Because methods for diagnosis and data collection on HAIs vary among institutions, the validity of data comparisons between facilities or across geographic areas is questionable. Endorsement of national standards for HAI measurement allows states and other organizations to gain a valuable resource for implementing nationally comparable standards rather than going forward with separate, potentially discordant measurement efforts. Ultimately, consumers gain access to standardized data that are reliable and useful for decision making.

STRATEGIC DIRECTIONS FOR NQF

NQF's mission includes three parts: 1) setting national priorities and goals for performance improvement, 2) endorsing national consensus standards for measuring and publicly reporting on performance, and 3) promoting the attainment of national goals through education and outreach programs. As greater numbers of quality measures are developed and brought to NQF for consideration of endorsement, it is incumbent on NQF to assist stakeholders to "measure what makes a difference" and address what is important to achieve the best outcomes for patients and populations. For more information see www.qualityforum.org.

Several strategic issues have been identified to guide consideration of candidate consensus standards:

DRIVE TOWARD HIGH PERFORMANCE. Over time, the bar of performance expectations should be raised to encourage the achievement of higher levels of system performance.

EMPHASIZE COMPOSITES. Composite measures provide much needed summary information pertaining to multiple dimensions of performance and are more comprehensible to patients and consumers.

MOVE TOWARD OUTCOME MEASUREMENT. Outcome measures provide information of keen interest to consumers and purchasers, and when coupled with healthcare process measures, they provide useful and actionable information to providers. Outcome measures also focus attention on much needed system-level improvements, because achieving the best patient outcomes often requires carefully designed care processes, teamwork, and coordinated action on the part of many providers.

CONSIDER DISPARITIES IN ALL THAT WE DO. Some of the greatest performance gaps relate to care of minority populations. Particular attention should be focused on the most relevant race/ethnicity/language/socioeconomic strata to identify relevant measures for reporting.

NATIONAL PRIORITIES PARTNERSHIP

NQF seeks to endorse measures that address the National Priorities and Goals of the National Priorities Partnership.[7] The National Priorities Partnership represents those who receive, pay for, provide, and evaluate healthcare. The National Priorities and Goals focus on these areas:

- patient and family engagement,
- population health,
- safety,
- care coordination,
- palliative and end-of-life care,
- overuse,
- equitable access, and
- infrastructure support.

NQF'S CONSENSUS DEVELOPMENT PROCESS (CDP)

Patient Safety Measures Project[8]

The National Quality Forum's National Voluntary Consensus Standards for Patient Safety Measures project seeks to endorse patient safety-related measures that address healthcare-associated infections (HAIs), medication safety, and other areas. Potential consensus standards focus on a broad range of areas including but not limited to safety risk assessment and/or risk identification, hospital standardized mortality rates, reporting and follow-up or critical test results, and leadership and culture of safety. Additionally, the project will identify gaps in patient safety measures.

This report does not represent the entire scope of NQF work relevant to patient safety. NQF has endorsed over 100 measures related to patient safety through the National Voluntary Consensus

Standards for Medication Management project[9], the National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data[10] and other projects. In addition the Safe Practices for Better Healthcare: 2010 Update[11] provides evidence based strategies to increase patient safety.

The full constellation of consensus standards, along with those presented in this report, provide a growing number of NQF-endorsed® voluntary consensus standards that directly reflect the importance of measuring and improving the quality of care provided to patients. Organizations that adopt these consensus standards will promote the delivery of safer and higher-quality care for patients.

Evaluating Potential Consensus Standards

Candidate standards were solicited though an open "Call for Measures" in January 2010 and were actively sought by NQF staff through literature reviews, a search of the National Quality Measures Clearinghouse, NQF Member websites, and an environmental scan. The measures were evaluated using NQF's standard evaluation criteria[12]. The HAI Technical Advisory Panel (TAP) rated the subcriteria for each candidate consensus standard and identified strengths and weaknesses to assist the project Steering Committee (Committee) in making recommendations. For this first report, the 21-member, multi-stakeholder Committee provided final evaluations of the four main criteria: importance to measure and report, scientific acceptability of the measure properties, usability, and feasibility. Measure developers participated in the TAP and Committee discussions to respond to questions and clarify any issues or concerns.

RECOMMENDATIONS FOR ENDORSEMENT

This first report of the Patient Safety Measures project presents the evaluation results of four HAI measures considered under NQF's Consensus Development Process. All four measures are recommended for endorsement as voluntary consensus standards suitable for public reporting and quality improvement.

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Candidate Consensus Standards Recommended for Endorsement

PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated bloodstream infection (CLABSI) outcome measure (CDC)

Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) will be calculated among patients in the following patient care locations:

- *Intensive Care Units (ICUs)*
- *Specialty Care Areas (SCAs) - adult and pediatric: long term acute care, bone marrow transplant, acute dialysis, hematology/oncology, and solid organ transplant locations*
- *Other inpatient locations. (Data from these locations are reported from acute care general hospitals (including specialty hospitals), freestanding long term acute care hospitals, rehabilitation hospitals, and behavioral health hospitals. Only locations where patients reside overnight are included, i.e., inpatient locations.*

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Deleted: *This measure applies a standardized infection ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) among patients in intensive care units (ICUs) and neonatal intensive care units (NICUs).PSM-001-10 is intended as a replacement for NQF-endorsed measure #0139 - Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients.*

This measure was designed to capitalize on increased reporting to the National Healthcare Safety Network (NHSN), a voluntary, nationwide HAI surveillance system managed by the Centers for Disease Control and Prevention (CDC). Hospitals and other healthcare providers use standardized definitions and protocols to report HAI data to the NHSN regularly, allowing the CDC to estimate the prevalence of HAIs, recognize trends, and assist healthcare facilities in quality improvement activities. The measure uses a standardized infection ratio (SIR) to compare a given healthcare facility's observed CLABSI rate to that facility's expected CLABSI rate. The expected rate is based on standardized rates that account for length of stay, length of central line use, patient care location, and other factors.

During the course of this project, PSM-001-10 was modified by its developer to extend the measure's scope of coverage beyond intensive care units (ICUs) and acute care hospitals to include non-ICU locations, acute care general hospitals, free standing long-term acute care

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hospitals, rehabilitation hospitals and behavioral health hospitals where patients reside overnight. CMS has requested measures in these domains for the Inpatient Prospective Payment System (IPPS) reporting requirements. The measure developer noted that the measures are currently in use in non-ICU locations, acute care hospitals and inpatient and long-term care facilities.

This measure addresses a high impact area; the CDC estimates that 248,000 bloodstream infections occur in U.S. hospitals each year, and that a large proportion of these are central line-related. CLABSIs are associated with significant increases in mortality and healthcare costs.[13] Moreover, evidence-based interventions have shown significant reductions in CLABSI rates and improved health outcomes. For these reasons, the Committee agreed that this expanded measure strongly meets the criteria of importance to measure and report.

While the Committee appreciated the detail within the measure specifications, members expressed concern about the absence of a risk adjustment model or specific exclusions that consider the variability of disease severity from unit to unit or within units. Committee members also requested clarification on the measure developer's unit type classifications. The developer explained that as part of the NHSN enrollment process, facilities must map internal location to pre-defined locations in the NHSN Patient Safety Manual. The criteria or unit designation are included in the Manual. Although the measure is based on unit experience and not patient-level data, there are mechanisms to stratify patients by risk. Units with increased risk related to disease severity are identified as "special care areas" separate from critical care units or intensive care units (ICUs). The developer noted that patient-level analysis would add to the data collection and manual calculation burden. The developer added that data could be stratified on several levels including by hospital type (i.e. teaching versus non-teaching hospital). Ultimately, the Committee and the developer acknowledged the inevitable variability from patient to patient that might be missed with this type of unit-based analysis. Following its conference call to review the updated specifications, the Steering Committee agreed that the expanded measure meets the scientific acceptability criterion.

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The Committee raised several questions about how data are reported within the NHSN-- specifically, the level of granularity used to report organism types and the specific reporting time period (i.e., whether reporting is cumulative, ongoing, annual, or quarterly). For public reporting, bloodstream infections are grouped together regardless of pathogen type. The developer stated that pathogen-specific data are captured on CLABSI events when available, and that appropriate exclusionary rules are applied to those events. Although annual data are published in the *American Journal of Infection Control*, the NHSN application also houses aggregate data, which provides facilities an opportunity to compare their performance with the national aggregate over specific time intervals. The developer acknowledged that they have not explored all potential issues associated with quarterly public reporting. The Committee recommended that the developer define a specific reporting timeframe, especially if the metric is adopted by a regulatory agency that requires quarterly reporting. No clarification has been received from the developer yet. The expanded measure retains the same reporting structure. The developer noted that in SCAs, because of differing infection risks, the number of patients with temporary central lines and those with permanent central lines is collected daily, at the same time each day, during the month. If a patient had both a temporary and permanent central line, the day would be counted only as a temporary central line day.

On the issue of feasibility, the Committee voiced concerns about reporting a SIR rather than a rate, since several states already mandate the reporting of CLABSI rates. The Committee questioned the usability outside NHSN participation and believed that a SIR may also lead to increased manual data collection and entry. The measure developer stated that using the SIR creates significant added value by enabling comparisons of observed HAIs to expected HAIs based on nationally aggregated data.

This outcome measure replaces NQF-endorsed measure #0139 (Central line catheter-associated blood stream infections rate for ICU and high-risk nursery (HRN) patients) and addresses the National Priority area of safety.

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Harmonization of SSI Measures

The CDC and the ACS submitted two surgical site infection measures – PSM-002-10 (NHSN surgical site infection outcome measure) and PSM-006-10 (Risk adjusted surgical site infection outcome measure), respectively. The Committee compared the two SSI measures to determine if one measure could be considered best-in-class. The Committee noted that both measures capture similar information using different data sources. Steering Committee members acknowledged that each measure may offer benefits for quality improvement because they assess populations differently. Both measures are currently in use in the NSQIP and NHSN surveillance systems; however, it was difficult for the Committee to compare these measures, where the advantages and disadvantages of one measure may be offset by those of a competing measure without additional evidence from the field on their use. Committee members also discussed the possibility of harmonization.[14] In addition, there were a significant number of public comments on the report expressing concern about the recommendation of two potentially competing SSI measures. Ultimately, the Committee recommended both measures for endorsement, independently, with the following suggestions:

- Harmonization of both measures should be complete by the first maintenance review; and
- The developers should conduct focus groups with current NSQIP and NSHN participating facilities to assess how both surveillance programs are working, with regard to feasibility and usability.

At that time, the CDC and the ACS requested time to harmonize the measures, and it was agreed that this effort should be supported. The following, the newly-submitted SSI measure, represents the results of their harmonization efforts.

PSM-002-10: American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure. *Prototype measure for the facility adjusted Standardized Infection Ratio (SIR) of deep incisional and organ/space Surgical Site Infections (SSI) at the primary incision site among*

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adult patients aged >= 18 years as reported through the ACS National Surgical Quality Improvement Program (ACS-NSQIP) or CDC National Health and Safety Network (NHSN). Prototype also includes a systematic, retrospective sampling of operative procedures in healthcare facilities. This prototype measure is intended for time-limited use and is proposed as a first step toward a more comprehensive SSI measure or set of SSI measures that include additional surgical procedure categories and expanded SSI risk-adjustment by procedure type. This single prototype measure is applied to two operative procedures, colon surgeries and abdominal hysterectomies, and the measure yields separate SIRs for each procedure.

This surgical site infection outcome measure focuses on two procedures: colon surgeries and abdominal hysterectomies. It is specified using ICD-9-CM procedure codes for NHSN operative procedure categories, with additional CPT mappings to those categories for use in NSQIP. The target population is inpatients over 18 years old with deep incisional and organ/space SSIs. The measure will use separate Standardized Infection Ratios (SIRs) for the two operative procedure categories, and risk adjustment will be based on age and the American Society of Anesthesiology (ASA) Physical Status Classification system. For hospitals performing more than 42 colon surgeries per year, SIRs will be calculated using a sample based on the first colon surgery per 8-day cycle for hospitals. For hospitals performing over 200 abdominal hysterectomies per year, SIRs will be calculated using a sample of the first 5 abdominal hysterectomies per 8-day cycle. Data collected and reported to the ACS National Surgical Quality Improvement Program (NSQIP) would be available for data transfer to NHSN. Follow-up will occur within 30 days using admission, readmission, and post-discharge surveillance. This measure is the first in a planned larger set of measures focused on surgical procedure categories with additional risk factors incorporated.

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The measure addresses a high impact area. Each year, approximately 11 percent of all deaths in ICUs are associated with SSIs, resulting in up to 20,000 deaths and $2 billion in additional costs.[2] Moreover, evidence-based interventions have shown significant reductions in SSI rates and improved health outcomes.

The Steering Committee discussed the newly-harmonized measure in a supplemental conference call, reviewing the relevant changes, while also receiving clarification from the developers on several issues. Committee members inquired as to why these two particular measures had been chosen, and asked for clarification on the plan for public reporting. The developer explained that the Centers for Medicare & Medicaid Services (CMS) inpatient prospective reporting system (IPPS) requirements released on August 1, 2011, call for abdominal hysterectomies and colon surgeries to be reported by the CDC to CMS. The NHSN will serve as the single reporting system for CMS-required reporting. However, facilities may choose which calculations of performance on the measure can be accomplished using either the NHSN or NSQIP data system. The measure developer acknowledged that for hospitals participating in both systems, there could be duplication.

The Steering Committee questioned why both organ space and deep incisional infections were included in the measure. The developer described the approach as a long standing precedent and stated that superficial infections are considered trivial events and therefore not included. However, organ space infections that drain through the incisions are classified as deep incisional infections. The combination of organ space and deep incisional infections are considered a clinically coherent grouping.

The Committee expressed their appreciation for the developers' efforts at harmonization, and agreed that the measure continues to meet the four major evaluation criteria. The Steering Committee recommended this measure for endorsement in a unanimous vote.

This outcome measure replaces NQF-endorsed measure #0299 (Surgical Site Infection Rate) and addresses the National Priority area of safety.

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This measure captures deep incisional and organ/space surgical site infections and is currently used in the NHSN surveillance system. The selected procedure categories closely correspond with the Centers for Medicare and Medicaid Services' (CMS') SCIP quality reporting initiative and were included in the NHSN because they focus on higher risk and higher volume procedures. Consideration was also given to procedures with strong evidence-based data on care practices and related outcomes.

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Similar to the CDC's CLABSI outcome measure, data for this measure are published in NHSN reports as a standardized infection ratio (SIR). The SIR calculation considers the total number of observed SSI events and the expected number using the national aggregate rates within the NHSN system. Because several states mandate rate-based SSI reporting, TAP and Committee members debated the feasibility of calculating a SIR for facilities not participating in the NHSN. The measure developer acknowledged the concern, yet believed that the utility of a SIR as an indirect standardization of cumulative SSI experiences across several stratified groups of data, specifically procedure categories, provides significant added value. ¶
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Similar to measure #PSM-002-10, this measure counts the number of SSIs associated with a subset of procedures used in the American College of Surgeons (ACS) National Surgical Quality
… [2]

PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated urinary tract Infection (CAUTI) outcome measure (CDC). *Standardized Infection Ratio (SIR) of healthcare-associated, catheter-associated urinary tract infections (CAUTI) will be calculated among patients in the following patient care locations:*

- *Intensive Care Units (ICUs) (excluding patients in neonatal ICUs [NICUs: Level II/III and Level III nurseries])*
- *Specialty Care Areas (SCAs) - adult and pediatric: long term acute care, bone marrow transplant, acute dialysis, hematology/oncology, and solid organ transplant locations*
- *Other inpatient locations (excluding Level I and Level II nurseries).*

Data from these locations are reported from acute care general hospitals (including specialty hospitals), freestanding long term acute care hospitals, rehabilitation hospitals, and behavioral health hospitals. Only locations where patients reside overnight are included, i.e., inpatient locations.

Urinary tract infections are estimated to be the most frequently-occurring HAIs, accounting for approximately 36 percent of HAIs in U.S. hospitals.[15] UTIs can cause significant increases in morbidity, mortality, and costs. The Steering Committee agreed that this measure strongly meets the criteria for importance to measure and report.

During the course of this project, PSM-003-10 was modified by its developer to extend the measure's scope of coverage beyond intensive care units (ICUs) and acute care hospitals to include non-ICU locations, acute care general hospitals, free standing long-term acute care hospitals, rehabilitation hospitals and behavioral health hospitals where patients reside overnight. CMS has requested measures in these domains for IPPS reporting requirements. The measure developer noted that the measures are currently in use in non-ICU locations, acute care hospitals and inpatient and long-term care facilities.

Similar to the CDC's CLABSI and SSI outcome measures, this measure uses a SIR to compare a given healthcare facility's observed CAUTI rate to that facility's expected CAUTI rate. The expected rate is based on standardized rates that account for length of stay, length of urinary

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The Committee compared the two SSI measures, measure #PSM-002-10 and measure #PSM-006-10, to determine if one measure could be considered best-in-class. The Committee noted that both measures capture similar information using different data sources. Steering Committee members acknowledged that each measure may offer benefits for quality improvement because they assess populations differently. Both measures are currently in use in the NSQIP and NHSN surveillance systems; however, it was difficult for the Committee to compare these measures, where the advantages and disadvantages of one measure may be offset by those of a competing measure without additional evidence from the field on their use. Committee members also discussed the possibility of harmonization.[14] The developers are collaborating to harmonize both measures in the very near future. Ultimately, the Committee recommended both measures for endorsement, independently, with the following suggestions:¶
<#>Harmonization of both measures should be complete by the first maintenance review; and ¶
The developers should conduct focus groups with current NSQIP and NSHN participating facilities to assess how both surveillance programs are working, with regard to feasibility and usability. . ¶

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catheterization, patient care location, and other factors. As with previous discussions about the CDC's CLABSI and SSI measures, the Committee questioned the usability outside NHSN participation and believed that a SIR may also lead to increased manual data collection and entry. The developer reiterated the benefits of utilizing an indirect standardization of cumulative SSI experiences across several stratified groups of data.

Measure development in this topic area has generally focused on specific sites and/or settings like nursing homes. The Committee discussed the benefits of developing more cross-cutting measures and suggested broader application beyond the ICU (i.e., to long term care settings across the whole continuum of care) in the future. The CDC's subsequent update to PSM-003-10 expanded application of the measure to Specialty Care Areas and other inpatient locations (excluding Level I and Level II nurseries). Following its conference call to review the updated specifications, the Steering Committee agreed that the expanded measure continues to meet the major evaluation criteria.

This outcome measure replaces NQF-endorsed measure #0138 (Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients) and addresses the National Priority area of safety.

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PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure (ACS) *This is a risk adjusted, case mix adjusted urinary tract infection outcome measure of adults 18+ years after surgical procedure.*

This measure is currently used in the ACS NSQIP surveillance system. The developer reiterated that the measure assesses UTIs within 30 days of surgical procedure and it is not catheter-specific. Nonetheless, urinary catheterizations account for the vast majority of UTIs. In a recent study of 36,000 major surgery patients, 86 percent of the study cohort had perioperative urinary catheters. Patients who had indwelling catheters for longer than two days postoperative, were twice as likely to develop a catheter associated urinary tract infection (CAUTI).[16] In monetary terms, UTIs contribute to approximately $340-450 million in additional health care costs

annually.[17] For these reasons, the Steering Committee agreed that this measure strongly meets the criteria for importance to measure and report.

Both TAP and Committee members were concerned that reliability and validity testing have only been conducted through modeling. The developer noted that inter-rater reliability is tested regularly. The Committee observed that, based on the model's estimates, a minimum case load of approximately 300 patients is required to achieve adequate reliability. Some members were concerned that the data collection associated with this requirement could impose a burden on providers

The 30-day patient follow-up, specifically the clinical expertise needed to identify and differentiate infections and all associated financial costs, were cited by TAP and Committee members as a barrier to data collection and implementation.

The Committee also discussed the benefits of developing more cross-cutting measures and suggested broader application beyond the surgical population.

This outcome measure addresses the National Priority area of safety.

Head-to-Head Comparison of UTI measures (#PSM-003-10 and #PSM-007-10)

The Steering Committee evaluated the benefits of potential harmonization between proposed measures #PSM-003-10 and #PSM-007-10. Although both measures address UTIs, the Committee noted that there are substantial differences between the targeted populations and data sources of the measures. Even with the subsequent expansion of #PSM-003-10, the Committee agreed that there would still be value in having both measures. Therefore, the Committee did not think that it was necessary to make a determination on best-in-class or render a recommendation for harmonization.

Additional Recommendations

Steering Committee members presented the following recommendations for further research and measure development:

Increasing opportunities to harmonize would relieve some of the current reporting burden. In some cases, harmonization would be prudent and useful. However, it is important to note that harmonization may not be feasible in all circumstances. Therefore, clustering measures into meaningful topic categories that creates a suite of tools might assist the healthcare industry with evaluating measures at multiple levels. For example, in the case of urinary tract infections, a cluster of measures could be identified that uses any one of the following: lab results, physician diagnosis from empirical symptoms, a transfer diagnosis from hospital to long-term care, patient qualitative report, device usage patterns, or physician antibiotic orders. Defining the numerators and denominators would vary depending on the source and use of the data. The selection of the right measure would depend on the users' intentions.

As clinical information technologies become fully deployed throughout the healthcare system, antibiotics or lab result data may be useful from a surveillance perspective for public accountability, while clinical judgment and empirical symptoms may be more useful for improved patient care. Further discussion about this issue is needed to more clearly define the usability characteristics of each measure in relationship to other similar measures. Only by clustering the measures into groups can in-depth analysis of the similarities and the differences be obtained. From there, more thoughtful dialogue on the "value" of each measure can be assessed.

NOTES

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9. http://www.qualityforum.org/Publications/2010/05/National_Voluntary_Consensus_Standards_for_Medication_Management.aspx. Last accessed October 2010.
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14. Harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.
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NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PATIENT SAFETY MEAURES: A CONSENSUS REPORT
APPENDIX A: MEASURE SPECIFICATIONS

The following table presents the detailed specifications for the National Quality Forum (NQF)-endorsed® *National Voluntary Consensus Standards for Patient Safety*. All information presented has been derived directly from measure sources/developers without modifications or alteration (except when the measure developer agreed to such modifications during the NQF Consensus Development Process) and is current as of August 29, 2010. All NQF-endorsed voluntary consensus standards are open source, meaning they are fully accessible and disclosed. Measures were developed by the Centers for Disease Control and Prevention, and the American College of Surgeons.

Measure Numbers	Measure Title	Measure Steward	Measure Description	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PSM-001-10	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure	Centers for Disease Control and Prevention	Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) ~~among patients in intensive care units (ICUs) and Neonatal Intensive Care Units (NICUs)~~ will be calculated among patients in the following patient care locations: • Intensive	Total number of observed healthcare-associated CLABSI among patients in ICUs~~, and~~ NICUs, SCAs and other acute care hospital locations where patients reside overnight.	Total number of expected CLABSIs, calculated by multiplying the number of central line device days for each location under surveillance for CLABSI during the period by the CLABSI rate for the same types of locations obtained from the standard population. Central line device-day denominator data that are collected differ according to the location of the patients being monitored. See 2a.8.	1. Pacemaker wires and other nonlumened devices inserted into central blood vessels or the heart are excluded as central lines 2. Peripheral intravenous lines are excluded from this measure	Electronic clinical data; Electronic Health/ Medical Record; Lab data; Paper medical record/ flow-sheet; Special or unique data	Population: states; Facility/ Agency; Population: national

				Care Units (ICUs) • Specialty Care Areas (SCAs) - adult and pediatric: long term acute care, bone marrow transplant, acute dialysis, hematology/oncology, and solid organ transplant locations • other inpatient locations. (Data from these locations are reported from acute care general hospitals (including specialty hospitals), freestanding long term acute care hospitals, rehabilitation hospitals, and					

				behavioral health hospitals. Only locations where patients reside overnight are included, i.e., inpatient locations.					

Measure Numbers	Measure Title	Measure Steward	Measure Description	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PSM-002-10	~~National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure~~ American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	American College of Surgeons- Centers for Disease Control and Prevention (ACS-CDC)	~~Standardized Infection Ratio (SIR) of deep incisional and organ/space Surgical Site Infections (SSI) at the primary incision site among patients undergoing selected inpatient operative procedure categories.~~ Prototype measure for the facility adjusted Standardized Infection Ratio (SIR) of deep incisional and organ/space Surgical Site Infections (SSI) at the primary incision site among adult patients aged >= 18 years as	~~Total number of observed deep incisional primary (DIP) and organ/space SSIs detected during admission or readmission among patients who have undergone the following inpatient NHSN operative procedure categories:~~ ~~1. Abdominal Aortic Aneurysm Repair (AAA)~~ ~~2. Coronary Artery Bypass Graft with both chest and donor site incisions (CBGB); only SSI from the chest (primary site) are included~~ ~~3. Coronary Artery Bypass Graft with chest incision only (CBGC)~~ ~~4. Colon surgery (COLO)~~ ~~5. Hip Arthroplasty (HPRO)~~ ~~6. Abdominal Hysterectomy (HYST)~~ ~~7. Knee Arthroplasty (KPRO)~~ ~~8. Peripheral Vascular Bypass surgery (PVBY)~~ ~~9. Rectal surgery (REC)~~ ~~10. Vaginal Hysterectomy (VHYS)~~ Deep incisional primary	~~Using multivariable procedure specific logistic regression models, the expected number of SSIs is obtained. These expected numbers are summed across strata (e.g., procedure categories, surgeons, etc) and used as the denominator of this measure (see also 2a.8).~~ Using multivariable logistic regression models for colon surgeries and abdominal hysterectomies, the expected number of SSIs is obtained. These expected numbers are summed by facility and surgical procedure and used as the denominator of this measure (see also 2a.8).	~~None~~ Persons under the age of 18, those having a procedure performed on an outpatient basis, those with ASA Class VI (6) are excluded. In the NHSN, patients without primary closure of the surgical incision are not considered eligible cases and are excluded- the NSQIP will match this practice for this measure, although this is not standard practice within the NSQIP.	Electronic clinical data; Electronic Health/ Medical Record; Lab data; Paper medical record/ flow-sheet; Special or unique data	Facility/ Agency; Population: national; Population: states

Measure Numbers		Measure Title	Measure Steward	Measure Description	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
				reported through the ACS National Surgical Quality Improvement Program (ACS-NSQIP) or CDC National Health and Safety Network (NHSN). Prototype also includes a systematic, retrospective sampling of operative procedures in healthcare facilities. This prototype measure is intended for time-limited use and is proposed as a first step toward a more comprehensive SSI measure or	(DIP) and organ/space SSIs during the 30-day postoperative period among patients = 18 years of age, who undergo inpatient colon surgeries or abdominal hysterectomies. SSIs will be identified before discharge from the hospital, upon readmission to the same hospital, or during outpatient care or admission to another hospital (post-discharge surveillance). Case accrual will be guided by sampling algorithms as described below.				

Measure Numbers		Measure Title	Measure Steward	Measure Description	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
				set of SSI measures that include additional surgical procedure categories and expanded SSI risk-adjustment by procedure type. This single prototype measure is applied to two operative procedures, colon surgeries and abdominal hysterectomies, and the measure yields separate SIRs for each procedure.					

Measure Numbers	Measure Title	Measure Steward	Measure Description	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PSM 006 10	Risk Adjusted Surgical Site Infection Outcome Measure	American College of Surgeons	This is a hospital based, risk adjusted, case mix adjusted surgical site infection measure of adults 18 years of age and over.	The outcome of interest is a hospital specific risk adjusted Deep Incisional Surgical Site Infection (SSI) or Organ/Space SSI as defined by American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP), occurring within 30 days of any of the listed CPT surgical procedures. The list of eligible CPT codes is attached.	Patients undergoing any of the specified list of eligible CPT surgical procedure codes. See separate attached list of eligible CPT codes.	Major trauma and transplant surgeries are excluded as are surgeries not on the supplied CPT list as eligible for selection. Patients who are ASA 6 (brain death organ donor) are not eligible surgical cases. A patient who has a second surgical procedure performed within 30 days after an index procedure cannot be accrued into the measure as a new (second) index procedure since the measure is based on 30 day outcomes.	Documentation of original self assessment; Paper medical record/ flow sheet; Pharmacy data; Electronic clinical data; Electronic Health/ Medical Record; Lab data; Management data	Facility/ Agency; Population: national; Population: regional/ network; Population: states

Measure Numbers	Measure Title	Measure Steward	Measure Description	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PSM-003-10	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	Centers for Disease Control and Prevention	Standardized Infection Ratio (SIR) of healthcare-associated, catheter-associated urinary tract infections (CAUTI) ~~among patients in intensive care units (ICUs), excluding patients in neonatal ICUs (NICUs)~~ will be calculated among patients in the following patient care locations: • Intensive Care Units (ICUs) (excluding patients in neonatal ICUs	Total number of observed healthcare-associated CAUTI among patients in ICUs (excluding patients in NICUs), SCAs, and other inpatient locations (excluding Level I and Level II nurseries).	Total number of expected CAUTIs, which is calculated by multiplying the number of urinary catheter days for each location under surveillance for CAUTI during the period by the CAUTI rate for the same types of locations obtained from the standard population. These expected numbers are summed across locations and used as the denominator of this measure (see also 2a.8).	Non-indwelling catheters by NHSN definitions: 1.Suprapubic catheters 2.Condom catheters 3.“In and out” catheterizations	Electronic clinical data; Electronic Health/ Medical Record; Lab data; Paper medical record/ flow-sheet; Special or unique data	Population: states; Population: national; Facility/ Agency

				[NICUs: Level II/III and Level III nurseries]) • Specialty Care Areas (SCAs) - adult and pediatric: long term acute care, bone marrow transplant, acute dialysis, hematology/oncology, and solid organ transplant locations • other inpatient locations (excluding Level I and Level II nurseries). Data from these locations are reported from acute care general hospitals (including specialty					

				hospitals), freestanding long term acute care hospitals, rehabilitation hospitals, and behavioral health hospitals. Only locations where patients reside overnight are included, i.e., inpatient locations.					

Measure Numbers	Measure Title	Measure Steward	Measure Description	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PSM-007-10	Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery	American College of Surgeons	Risk adjusted, case mix adjusted urinary tract infection outcome measure of adults 18+ years after surgical procedure.	The outcome of interest is a hospital-specific assessment of risk-adjusted Urinary Tract Infection (UTI: as defined by American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP)defined below) within 30 days of any listed (CPT) surgical procedure: the list of eligible CPT codes is attached separately.	Patients undergoing any of the listed (CPT) surgical procedures-list is attached separately. Specifically excluded are certain CPTs involving the urinary tract (excluded: 50220, 50545, 50400, 50205, 51040, 54640, 53852, 55866, 52450, 52234). See attached submitted list of eligible CPT codes.	Major trauma and transplant surgeries are excluded as are surgeries not on the supplied CPT list as eligible for selection. Patients who are ASA 6 (brain-death organ donor) are not eligible surgical cases. A patient who has a second surgical procedure performed within 30 days after an index procedure cannot be accrued into the measure as a new (second) index procedure since the measure is based on 30 day outcomes.	Documentation of original self-assessment; Paper medical record/ flow-sheet; Pharmacy data; Electronic clinical data; Electronic Health/ Medical Record; Lab data; Management data	Facility/ Agency; Population: national; Population: regional/ network; Population: states

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NQF-endorsed® Healthcare-associated Infections Measures

Measure# 0138: Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients	
Steward	Centers for Disease Control and Prevention
Description	Percentage of intensive care unit patients with urinary catheter-associated urinary tract infections
Numerator	Number of indwelling urinary catheter-associated UTIs (defined by CDC case definitions of symptomatic UTI or asymptomatic bacteriuria, excludes other infections of the urinary tract) x 1,000
Denominator	Number of indwelling urinary catheter days for ICU patients ?Reported by type of ICU (coronary, cardiothoracic, medical, medical-surgical (major teaching and all others), neurosurgical, pediatric, surgical, trauma, burn, and respiratory)
Exclusions	
Risk Adjustment	Comparisons are made among ICUs of similar type: Coronary, Cardiothoracic, medical, medical-surgical (major teaching and all others), Neurosurgical, Pediatric, Surgical, Trauma, Burn and Respiratory
Data Source	Electronic Clinical Database
Level	Facility (e.g., hospital, nursing home)
Setting	Hospital
Measure# 0139: Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients	
Steward	Centers for Disease Control and Prevention
Description	Percentage of ICU and high-risk nursery patients, who over a certain amount of days acquired a central line catheter-associated blood stream infections over a specified amount of line-days
Numerator	Number of central line-associated blood stream infections (laboratory-confirmed bloodstream infection or clinical sepsis) x 1,000 Number of umbilical and central line-associated blood stream infections (laboratory-confirmed bloodstream infection or clinical sepsis) x 1,000
Denominator	Number of central line-days for ICU patients. Reported by type of ICU (coronary, cardiothoracic, medical, medical-surgical (major teaching and all others), neurosurgical, pediatric, surgical, trauma, burn, and respiratory) Number of central-line days for HRN patients ?Reported for HRNs by birth weight category (<1,000, 1,001-1,500, 1,501-2,500, and >2,500g)
Exclusions	
Risk Adjustment	The measure is reported stratified by ICU-type, and the denominator as stated per 1,000 line days adjusts for the increased risk over time after a central line is inserted
Data Source	Electronic Clinical Database
Level	Facility (e.g., hospital, nursing home)
Setting	Hospital

Measure# 0140: Ventilator-associated pneumonia for ICU and high-risk nursery (HRN) patients	
Steward	Centers for Disease Control and Prevention
Description	Percentage of ICU and HRN patients who over a certain amoint of days have ventilator-associated pneumonia
Numerator	Number of ventilator-associated pneumonias x 1,000
Denominator	Number of ventilator-days for ICU patients: Reported by type of ICU (coronary, cardiothoracic, medical, medical-surgical (major teaching and all others), neurosurgical, pediatric, surgical, trauma, burn, and respiratory) Number of ventilator days for HRN patients: Reported for HRNs by birth weight category (<1,000, 1,001-1,500, 1,501-2,500, and >2,500g)
Exclusions	
Risk Adjustment	Risk Adjustment: This measure of ventilator-associated pneumonias per ventilator days is adjusted for the major risk factor, which is use of catheters, as well as length of stay.
Data Source	Electronic Clinical Database
Level	Facility (e.g., hospital, nursing home)
Setting	Hospital
Measure# 0196: Residents with a urinary tract infection	
Steward	Centers for Medicare & Medicaid Services
Description	Percentage of residents on most recent assessment with a urinary tract infection
Numerator	Residents with urinary tract infection on target assessment. (I2j = checked)
Denominator	All residents with a valid target assessment.
Exclusions	Exclusions: Residents satisfying any of the following conditions: 1. The target assessment is an admission (AA8a = 01) assessment. 2. I2j is missing on the target assessment.
Risk Adjustment	
Data Source	Standardized clinical instrument
Level	Facility (e.g., hospital, nursing home)
Setting	Nursing home/ Skilled Nursing Facility (SNF)
Measure# 0299: Surgical Site Infection Rate	
Steward	Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services
Description	Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place or with one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time
Numerator	Number of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place or with one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure. Infections are identified on original admission or upon readmission to the facility of original operative procedure within the relevant time frame (30 days for no implants; within 1 year for implants). Two types of CDC-defined SSIs are included: (1) A deep incisional SSI must meet the following criteria: • Infection occurs within 30 days after the operative procedure if no implant is left or within one year if implant is in place and the infection appears to be related to the operative procedure and • involves deep soft tissues (e.g., fascial and muscle layers) of the incision and • patient has at least one of the following: a) purulent drainage from the deep incision but not from the organ/space component of the surgical site b) a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured when the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness. A culture-negative finding does not meet this criterion.

	c) an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination d) diagnosis of a deep incisional SSI by a surgeon or attending physician. Note: There are two specific types of deep incisional SSIs: 1) Deep Incisional Primary (DIP) – a deep incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CABG) 2) Deep Incisional Secondary (DIS) - a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site [leg] incision for CBGB) (2) An organ/space SSI must meet the following critieria: • Infection occurs within 30 days after the operative procedure if no implant is left or within one year if implant is in place and the infection appears to be related to the operative procedure and • infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure and • patient has at least one of the following: a). purulent drainage from a drain that is placed through a stab wound into the organ/space b). organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space c). an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination d) diagnosis of an organ/space SSI by a surgeon or attending physician. Specific sites of an organ/space SSI may be identified11
Denominator	Number of NHSN operative procedures performed during a specified time period stratified by: • Type of NHSN operative procedure and • NNIS SSI risk index: Every patient having the selected procedure is assigned one (1) risk point for each of the following three factors: o Surgical wound classification = clean contaminated or dirty o American Society of Anesthesiologists (ASA) preoperative severity of illness score = 3, 4, or 5 o Duration of operation >t hours, where t varies by type of NHSN operative procedure and is the approximate 75th percentile of the duration of the procedure rounded to the nearest whole number of hours. Note: For operative procedures performed using lapyroscopes and endoscopes the use of a lapyroscope is an additional factor that modifies the risk index.
Exclusions	Exclude Procedures Not Included Under The Definition Of NHSN Operative Procedure And Excludes Superficial SSI.
Risk Adjustment	
Data Source	Paper Medical Record
Level	Facility (e.g., hospital, nursing home)
Setting	Hospital