

## Measure Comment Report for Patient Safety Measures

### PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery

**Comment By**

Name: Ms. Roberta Aberle  
Organization: City of Hope

Date - Time: Nov 08, 2010 - 06:03 PM

**Comments**

This metric is a risk adjusted, case mix adjusted post-surgical urinary tract infection measure for select NSQIP CPT based procedures. Data collection based on CPT coding will be *problematic to compare nationwide* since different systems i.e. UHC, Premier, do not have a standardized risk-adjustment methodology.

---

### PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure

**Comment By**

Name: Ms. Roberta Aberle  
Organization: City of Hope

Date - Time: Nov 08, 2010 - 06:03 PM

**Comments**

This metric is a risk adjusted, case mix adjusted surgical site infection measure for select NSQIP CPT based procedures. Data collection based on CPT coding *will be problematic to compare nationwide* since different systems i.e. UHC, Premier, do not have a standardized risk-adjustment methodology.

---

### PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

**Comment By**

Name: Ms. Roberta Aberle  
Organization: City of Hope

Date - Time: Nov 08, 2010 - 06:02 PM

**Comments**

#### PSM-001-10: National Healthcare Safety Network Central line-associated Infections (CLABSI)

Positive: Standardized Infection Ratio derives a hospital level ICU CLABSI statistic that can be used to compare with national population data. This method produces a single CLABSI statistic for hospitals with multiple intensive care unit types with differing levels of CLABSI risk.

The base data collection utilizes the same NHSN definitions currently used for Leapfrog ICU report and the California mandated public reporting of CLABSI rates.

---

**Comments on the general draft report****Comment By**

Name: Ms. Jayne Hart Chambers  
Organization: Federation of American Hospitals

Date - Time: Nov 08, 2010 - 05:41 PM

**Comments**

Part 4 FAH

It is our understanding that the CDC and the American College of Surgeons (the developer of PSM-006-10 and PSM-007-10) are working to harmonize their measures including the data collection methodologies and data elements. We realize this will take some time, but we believe that giving endorsement to the four measures as they currently stand will be very confusing to patients, drive up hospital costs for collecting and reporting information, and not inform the processes for improving patient care. Therefore, we suggest that NQF withhold endorsement of the SSI and CAUTI measures until

such time as the CDC and ACS can develop a plan for harmonizing their measures. At that time, these measures could be taken up during the second phase of the Patient Safety Measures project.

---

**Comments on the general draft report****Comment By**

Name: Ms. Jayne Hart Chambers

Organization: Federation of American Hospitals

Date - Time: Nov 08, 2010 - 05:40 PM

**Comments**

Part 4 FAH

On the two Surgical Site Infection (SSI) outcome measures (PSM-002-10 and PSM 006-10) and the two Catheter-Associated Urinary Tract Infection (CAUTI) outcome measures (PSM-003-10 and PSM-007-10), head-to-head comparisons were conducted, but no final conclusions were reached. Instead, the report proposes to retire the current NQF-endorsed measure for SSI #0129, and the current NQF-Endorsed measure for CAUTI limited to intensive care unit patients, #0138 and replace them with four measures, which arguably are more sophisticated, but cannot be determined to be best-in-class. In our view, NQF has defaulted on its responsibility to select a best in class measure and unnecessarily complicated the collection and reporting of data on SSI and CAUTI.

---

**Comments on the general draft report****Comment By**

Name: Ms. Jayne Hart Chambers

Organization: Federation of American Hospitals

Date - Time: Nov 08, 2010 - 05:33 PM

**Comments**

Part 3 FAH To be specific, on measure PSM-001-10, National Healthcare Safety Network (NHSN) Central line-associated bloodstream infection (CLABSI) outcome measures submitted by the Centers for Disease Control and Prevention, the Steering Committee raises a series of questions. The Steering Committee also recommended that the developer define a specific reporting timeframe, particularly since this measure is being adopted by a federal regulatory agency that requires quarterly reporting. At the date the report was issued for comment, the developer had not addressed that concern, which is a key element of the measure. The Steering Committee did not express strong support for the standardized infection ratio (SIR) and asked that measure developer to clarify the "unit type classification," another basic element of the proposed measure.

---

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery****Comment By**

Name: Ms. Tracy E. Spinks

Organization: MD Anderson Cancer Center

**On Behalf Of**

Name: Ron Walters, MD

Organization: The University of Texas MD Anderson Cancer Center

Date - Time: Nov 08, 2010 - 05:32 PM

**Comments**

As written, this measure would place a large burden on Infection Preventionists. We would ask the American College of Surgeons to provide additional evidence that this measure is appropriate for the surgical cancer population.

---

**Comments on the general draft report****Comment By**

Name: Dr. Ellen Schwalenstocker, PhD, MBA

Organization: National Association of Children's Hospitals and Related Institutions

Date - Time: Nov 08, 2010 - 05:32 PM

**Comments**

On behalf of the National Association of Children's Hospitals and Related Institutions (NACHRI), thank you for the opportunity to provide comments. In general, we agree with many of the commenters. The "best in class" measure for CAUTI and SSI should be identified and endorsed, rather than having two differently specified measures.

---

**Comments on the general draft report****Comment By**

Name: Ms. Jayne Hart Chambers

Organization: Federation of American Hospitals

Date - Time: Nov 08, 2010 - 05:30 PM

**Comments**

Part 2 Federation of American Hospitals

The National Quality Forum (NQF) is in a unique position and has the responsibility to exercise its role as the premier organization evaluating national quality measures. It is assumed that a measure endorsed by the NQF is a best-in-class measure. Measures endorsed by the NQF are assumed to have been evaluated on the four NQF criteria and to meet these criteria. Part of this responsibility involves gathering the necessary information, ensuring that the science behind the measures is sound, and making difficult decisions about what is best-in-class. The report presented, while helpful, does not go far enough. It does not delineate what measures are best-in-class, rather it proposes to endorse all the measures and by doing so create confusion for patients and hospitals and also increase reporting burden for hospitals.

---

**Comments on the general draft report****Comment By**

Name: Ms. Tracy E. Spinks

Organization: MD Anderson Cancer Center

Date - Time: Nov 08, 2010 - 05:30 PM

**Comments**

We appreciate the opportunity to provide feedback on these measures. We agree with measures PSM-001-10, PSM-002-10, PSM-003-10 and PSM-006-10 as written. Moreover, we generally support the ACS NSQIP methodology of using clinical, audited, risk-adjusted data for events that occur within 30 days of the index operation (measures PSM-006-10 and PSM-007-10).

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure****Comment By**

Name: Dr. Ellen Schwalenstocker, PhD, MBA

Organization: National Association of Children's Hospitals and Related Institutions

Date - Time: Nov 08, 2010 - 05:29 PM

**Comments**

NACHRI strongly supports this measure.

**Comments on the general draft report****Comment By**

Name: Ms. Jayne Hart Chambers

Organization: Federation of American Hospitals

Date - Time: Nov 08, 2010 - 05:28 PM

**Comments**

Part I

The Federation of American Hospitals (FAH) is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay rehabilitation, and long-term care hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. The FAH is pleased to have the opportunity to comment on the very important patient safety measures evaluated in the National Voluntary Consensus Standards for Patient Safety Measures, First Report: A Consensus Report.

Healthcare Associated Infections (HAIs) are a significant public health issue, and the FAH believes it is important to develop more robust methodologies and strategies that will inform better patient care and reduce HAIs. We believe that the report addresses measures that have potential for helping hospitals in their ongoing efforts to reduce HAIs. However, we are disappointed in the final outcome of the report as it is currently written.

---

<b>PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome</b>	<b>Measure After Surgery</b>
<b>Comment By</b>	<b>On Behalf Of</b>
Name: Dr. Michael P. Phelan, MD	Name: Cleveland Clinic
Organization: Cleveland Clinic	Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:28 PM

#### Comments

part 2

We were curious if a better quality measure would be tracking the removal of Foley catheter 48hrs after surgery, one of the current NSQIP measures. What is the added value does this surveillance of UTI's have over a measure that tracks Foley removal?

---

<b>PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome</b>	<b>Measure After Surgery</b>
<b>Comment By</b>	<b>On Behalf Of</b>
Name: Dr. Michael P. Phelan, MD	Name: Cleveland Clinic
Organization: Cleveland Clinic	Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:26 PM

#### Comments

Our reviewers saw limited benefit and are concerned that this measure will lead to increased antibiotic use, increased risk of C. difficile disease, and increased antibiotic resistance. There was similar issue with the other UTI NHSN metric. The surveillance of these "UTI's" which might be confused with asymptomatic bacteruria or in order to "prevent" them result in rapidly increased use of antibiotics and the associated problems associated with their use.

In the measure evaluation ( section 4 e2) form it was estimated the data collection time to be a 0.3 FTE seems excessive for a single measure. If accurate, this would diminish feasibility of the measure. Information about costs for education, surveillance, chart abstraction, and data validity would be required to make an educated decision on whether to support such a measure nationally. Publishing the results of an actual attempt to implement this in a community hospital with all associated cost would provide useful information about the cost and other resources that may be required.

---

<b>PSM-006-10: Risk Adjusted Surgical Site Infection Outcome</b>	<b>Measure</b>
<b>Comment By</b>	<b>On Behalf Of</b>
Name: Dr. Michael P. Phelan, MD	Name: Cleveland Clinic
Organization: Cleveland Clinic	Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:23 PM

#### Comments

part 2

The existing measure #0299 has overlapping features with this proposed measure. It similarly looks at deep and organ space infection within 30 days of surgery but has cruder and less validated risk adjustment using a "risk Index", assigning points for three risk factors. Measure # 0299 also looks at infection occurring after implants occurring within one year

following surgery, requiring a different mechanism of follow-up. To avoid redundancy it may be best to use this proposed measure to follow thirty-day infection and modify or harmonize number 0299 to just follow patients having undergone implants. The validity of the measure as well as usability by the public seems better than the alternative measure submitted.

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure****Comment By**

Name: Dr. Michael P. Phelan, MD  
Organization: Cleveland Clinic

**On Behalf Of**

Name: Cleveland Clinic  
Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:22 PM

**Comments**

part 1

This is a frequent complication leading to significant patient morbidity, additional procedures, and death. This impacts hospital length of stay and cost, so it's important to measure.

The data collection, definition of SSI and risk adjustment model are the same as the current ACS NSQIP program. This has been used for greater than five years by multiple hospitals for the measurement of risk adjusted outcomes for a variety of surgical morbidities as well as mortality. Within the surgical community this is regarded as the most tested and valid outcomes reporting tool. The use of observed to expected ratio is familiar to those who use risk-adjusted reporting. Although crude infection rate is more easily understood by the lay public, lack of risk adjustment make this not useful for comparing different patient groups or institutions.

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure****Comment By**

Name: Dr. Michael P. Phelan, MD  
Organization: Cleveland Clinic

**On Behalf Of**

Name: cleveland clinic  
Organization: cleveland clinic

Date - Time: Nov 08, 2010 - 05:20 PM

**Comments**

part 2

Like other metrics commented on there were significant concerns about the CDC data validity when a rigorous process for validity is not utilized.

A harmonized measure would be much better than two competing measures.

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure****Comment By**

Name: Dr. Michael P. Phelan, MD  
Organization: Cleveland Clinic

**On Behalf Of**

Name: Cleveland Clinic  
Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:17 PM

**Comments**

part 3

Under 4e "Cost to implement" what were these estimates based on? what actual data was utilized? The actual cost seems lower than anticipated or compared to the alternative measure. Identification of patients through surveillance of charts, reviewing the charts, and uploading the data would appear to be significantly more time consuming and labor intensive besides validating the data before uploading as well as the cost of educating of personnel. Are there any published studies or better estimates of the cost?

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure**

**Comment By**

Name: Dr. Michael P. Phelan, MD  
Organization: Cleveland Clinic  
Time: Nov 08, 2010 - 05:17 PM

**Date On Behalf Of**

Name: Cleveland Clinic  
Organization: Cleveland Clinic

**Comments**

part 2

This measure appears to look for the UTI rate and encourage hospitals to achieve a lower rate on the next round of reporting. The idea appears to be looking at internal data compared to external goals or benchmarks. Data to support utilizing your metric to support this improvement model based on actual outcomes should have been clearer and easier to evaluate and look up.

The risk adjustment model appears to be based on a comparison of 15 different types of ICUs. What types of ICUs were included and were there differences based on ICU types?

Are the risk adjusted results similar based on the type of ICU? Is there a comparison for large regional referral centers or based on ICU size, not just type?

You mentioned (under 4d in the measure evaluation form) that the NHSN reporting tool tries to minimize inaccuracies and that there is some sort of business logic built into this report to minimize inaccuracies. Could you elaborate on this and explain where it might be beneficial?

---

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery****Comment By**

Name: Ms. Carmella Bocchino, MBA, RN  
Organization: America's Health Insurance Plans

Date - Time: Nov 08, 2010 - 05:16 PM

**Comments****PSM-007-10: Risk adjusted urinary tract infection outcome measure (ACS)**

In addition, this measure uses paper medical records and flow sheets, as well as administrative data to collect the measure's components. As previously stated, more information on the feasibility and burden of implementing this measure would be helpful.

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure****Comment By**

Name: Ms. Carmella Bocchino, MBA, RN  
Organization: America's Health Insurance Plans

Date - Time: Nov 08, 2010 - 05:15 PM

**Comments****PSM-006-10 Risk adjusted surgical site infection outcome measure (ACS)**

We concur with the Committee's recommendation that harmonization of #PSM-006-10 and #PSM-002-10 should be completed by the first maintenance review.

We note that this particular measure uses paper medical records and flow sheets, as well as administrative data to collect the measure's components. More information on the feasibility and burden of implementing this measure would be helpful.

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure****Comment By**

Name: Dr. Michael P. Phelan, MD  
Organization: Cleveland Clinic

**On Behalf Of**

Name: Cleveland Clinic  
Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:15 PM

**Comments**

part 1

Our main concern is that by tracking and reporting this measure there would be significant unintended consequences to our patients. In the ICU, the hallmark of CAUTI prevention is Foley removal. The ICU setting is the area where removal of Foleys is least likely. Foleys are colonized at a rate of 5% per day. The majority of CAUTIs are asymptomatic however culture of the urine is common. The NHSN definition is overly sensitive such that complex patients with indwelling Foleys who have fever and asymptomatic bacteruria at significant colony counts meet definition. Focus on this metric will have the unintended consequence of increasing antibiotic use to unnecessarily treat asymptomatic bacteruria, thereby increasing cost, increasing risk for C. difficile disease, and further driving the development of resistant pathogens. These unintended consequences have already been observed as a result of CAUTI being deemed a hospital acquired condition that will no longer be reimbursed.

There was a suggestion that perhaps the CAUTI initiative would be best applied in the non-ICU setting. Why was the ICU setting addressed rather than non-ICU inpatient setting?

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure****Comment By**

Name: Ms. Carmella Bocchino, MBA, RN

Organization: America's Health Insurance Plans

Date - Time: Nov 08, 2010 - 05:14 PM

**Comments****PSM-003-10: National Healthcare Safety Network (NHSN) catheter-associated urinary tract infection (CAUTI) Outcome Measure (CDC)**

We recognize that these measures are specifically intended for use in hospital settings and while this measure has value, limiting the measure to ICU settings can lead to under-reporting of HAIs. We therefore, encourage the NQF to broaden the measure's applicability to the entire in-patient (non-ICU) as well as out-patient populations.

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure****Comment By**

Name: Ms. Carmella Bocchino, MBA, RN

Organization: America's Health Insurance Plans

Date - Time: Nov 08, 2010 - 05:13 PM

**Comments****1. PSM-002-10: National Healthcare Safety Network (NHSN) surgical site infection (SSI) outcome measure (CDC)**

This measure could be improved by broadening the denominator to include additional surgical procedures, such as those that are high volume and for patients who are at high risk for developing an SSI (e.g., caesarean section) as well as procedures performed in the out-patient setting. We concur with the Committee's recommendation to only have one SSI measure and support the harmonization of the CDC and ACS measures.

---

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery****Comment By**

Name: Ms. Kim Lopez

Organization: Catholic Health Initiatives

Date - Time: Nov 08, 2010 - 05:13 PM

**On Behalf Of**

Name: Kim Lopez

Organization: Catholic Health Initiatives

**Comments**

Risk adjustment for any data would be most helpful for comparison data.

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure****Comment By**

Name: Ms. Carmella Bocchino, MBA, RN  
Organization: America's Health Insurance Plans

Date - Time: Nov 08, 2010 - 05:12 PM

**Comments****1. PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated bloodstream infection (CLABSI) outcome measure (CDC)**

The measure should consider exclusions of patients with compromised immune systems, such as active chemotherapy patients and patients with severe third degree burns.

Additionally limiting assessment of CLABSI to ICU settings only, misses an opportunity to track a significant volume of HAIs that may occur outside the ICU.

The CDC measures calculate a standardized infection ratio (SIR) to assess facilities observed infection rate compared to an expected rate. NQF should explore ways to ensure that these measures are understandable to consumers.

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure****Comment By**

Name: Ms. Kim Lopez  
Organization: Catholic Health Initiatives

**On Behalf Of**

Name: Kim Lopez  
Organization: Catholic Health Initiatives

Date - Time: Nov 08, 2010 - 05:12 PM

**Comments**

As with PSM-002-10, this measure is more appropriately applied across provider types. The measure provides another opportunity to close the loop on SCIP data

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure****Comment By**

Name: Dr. J. Michael Henderson, MD  
Organization: Cleveland Clinic

**On Behalf Of**

Name: Cleveland Clinic  
Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:11 PM

**Comments**

This is a frequent complication leading to significant patient morbidity, additional procedures, and death. Moreover, this impacts hospital length of stay and costs are significant. This issue was rated high for importance.

This measure targets selected high-risk procedures. There is the added practical complexity of both 30 day surgical site infections in most patients and additionally tracking patients for one year who had implants. This measure uses standard CDC criteria for the definition of deep and organ space infection. This measure uses a multi-variable procedure specific logistic regression model for risk stratification but it is not clear from the accompanying documentation the extent to which this has been validated in clinical practice for surgical site infections.

The feasibility issues may be a problematic and may need further addressing especially for smaller hospitals.

Key to the success of this measure is obtaining complete 30 day follow-up of patients as well as properly assessing whether or not the patient meets CDC criteria for surgical site infection. This may require fairly extensive clinical training to avoid over or under reporting. It would be more challenging to follow those patients with implants for one year as the likelihood of receiving care in another institution or moving to another geographic area would be increased.

---

**Comments on the general draft report****Comment By**

Name: Ms. Carmella Bocchino, MBA, RN



Organization: America's Health Insurance Plans

Date - Time: Nov 08, 2010 - 05:11 PM

## Comments

### AHIP Comments on NQF Patient Safety Measures

AHIP appreciates the opportunity to provide comments on the proposed NQF's Patient Safety Measures.

#### General Comments

We support NQF's efforts to advance the measurement of patient safety and focus specifically on patient outcomes.

We recognize that health care-associated infections (HAIs) remain a significant public health issue in the United States, and appreciate efforts to promote measures that assess the rate of HAIs. HAIs contribute to significant morbidity and mortality of patients and are a major driver of health care costs. Given, the United States Department of Health & Human Services' focus (HHS) on elimination of HAIs, we encourage NQF to expand the scope of these measures to:

- Include all surgical procedures
- Include all in-patient settings (ICU and Non-ICU), as well as out-patient settings, given the volume of outpatient surgeries routinely done.

With respect to implementation of patient safety measures, health plan experience has shown that HAIs tend to be underreported, as hospitals do not always bill for treatment arising from such complications. It would therefore be important to monitor these measures for uneven reporting across hospitals that could skew HAI rates.

---

#### PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure

##### Comment By

Name: Ms. Kim Lopez

Organization: Catholic Health Initiatives

##### On Behalf Of

Name: Kim Lopez

Organization: Catholic Health Initiatives

Date - Time: Nov 08, 2010 - 05:09 PM

## Comments

The measure is a beginning measure; however, many SSIs are undetected by hospitals because the patient develops symptoms after discharge and are not readmitted for treatment. This is one measure that needs harmonization across multiple provider types.

The measure would most likely be helpful in closing the loop on the SCIP data collected and resulting patient care outcomes

---

#### PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

##### Comment By

Name: Dr. J. Michael Henderson, MD

Organization: Cleveland Clinic

##### On Behalf Of

Name: Cleveland Clinic

Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:08 PM

## Comments

One issue surrounds NQF's own criteria for scientific acceptability of this CLABSI metric. The use of SIRS measure rated low for scientific acceptability among Cleveland Clinic colleagues who reviewed this measure. We are concerned that use of SIR as a reporting rate will be misleading, especially to the public. The proposed mechanism of risk adjustment is not sufficient and does not correct for hospitals that have a significant proportion of patients with inherent risks for bloodstream infection - i.e., immunocompromised patients. Furthermore, it does not appear to adequately adjust for centers that receive a high percentage of patient transfers. Basically it does not adequately or sufficiently risk adjust for the actual acuity of patients. The public is not aware of some of these nuances (e.g., confidence intervals and what they mean), so publishing SIRs may be misleading (ie understanding confidence intervals and what they mean). Another issue with NHSN definitions is inter-facility variability. Increasingly in the literature there are reports of significant variability in the application of NHSN definitions. This raises the issue of validity testing (which is only utilized a few states) and when performed, produces higher rates.

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI)  
Outcome Measure****Comment By**

Name: Ms. Kim Lopez

Organization: Catholic Health Initiatives

**On Behalf Of**

Name: Kim Lopez

Organization: Catholic Health Initiatives

Date - Time: Nov 08, 2010 - 05:06 PM

**Comments**

This measure covers a reporting process that is already in place in some states and will be a CMS requirement in FY12.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI)  
Outcome Measure****Comment By**

Name: Ms. Madeleine Smith

Organization: GE Healthcare

Date - Time: Nov 08, 2010 - 05:05 PM

**Comments**

(continued) In addition, this review estimated that ultrasound guidance results in decreased complications during attempted CVC placements (relative risk 0.22, 95% CI: 0.10-0.45), corresponding to a relative risk reduction of 78%. The mean number of attempted venipunctures till successful CVC insertion was significantly reduced with real-time ultrasound guidance (relative risk 0.60, 95% CI: 0.45-0.79), corresponding to a relative risk reduction of 40%.[4](#)

Clearly, use of ultrasound guidance for CVC placement to reduce complications including infections is well documented in the literature. GE Healthcare strongly recommends that ultrasound guidance be included in the guidelines for prevention of CLASBIs.

---

[4](#)Randolph AG, Cook DJ, Gonzales CA, Pribble CG. Ultrasound guidance for placement of central venous catheters: a meta-analysis of the literature. *Crit Care Med* 1996;24:2053-2058.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI)  
Outcome Measure****Comment By**

Name: Ms. Madeleine Smith

Organization: GE Healthcare

Date - Time: Nov 08, 2010 - 05:04 PM

**Comments**

**(continued) Simply put, real-time ultrasound guidance improves the success rate, reduces the number of venipuncture attempts prior to successful placement, reduces the number of complications associated with catheter insertion and decreases the complication rate associated with line placement.[\[1\]](#)**

Real-time ultrasound guidance of central line insertion improves the success rate and decreases the complication rate associated with central venous catheters (CVCs). Unsuccessful insertion of CVCs may occur in up to 20% of cases, and increased venipuncture attempts are associated with increased complication rates.[\[2\]](#) A 1996 meta-analysis estimated that real-time ultrasound guidance for CVC insertion is associated with a significant reduction in placement failures as compared with the usual landmark techniques (relative risk 0.32, 95% CI: 0.18-0.55). (to be continued)

---

[1]Ibid., p 245.

[2]Ibid., p246.

---

**Comments on the general draft report****Comment By**

Name: Dr. J. Michael Henderson, MD

Organization: Cleveland Clinic

**On Behalf Of**

Name: cleveland Clinic

Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:03 PM

**Comments**

We strongly support the recommendation of the steering committee that the ACS and CDCP work together to harmonize their respective measures. There are strengths and weakness of both UTI and both SSI measures. A single harmonized metric for each would have been ideal. One issue about the CDC measures is that only a handful of states actually require validation of the reporting. States with validation had consistently higher SIRs. The ACS is a registry that has some fixed costs to participate and is labor intensive (as are the CDC measures). The NHSN is a federal resource for hospitals to submit information to the CDC for aggregation and reporting, as already mentioned since only a handful of states require validation, more information about the cost, labor, time required for all of these of these measures should be reported or estimated for a better understanding of what would be involved in collecting this data. Any measure selceted would be assoicated with an increase cost mainly with ongoing labor-intensive data collection should be scrutinized. The ACS registry has up- front cost and back end cost estimated at 0.1-0.3 FTE(s). If this metric were selected would hospitals be mandated to participate in this registry i.e. would there be upfront cost? We recommend aligning these measures to be acquired electronically or from claims data, if at all feasible (despite the limitations.) Better data regarding feasibility and cost should be provided.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure****Comment By**

Name: Ms. Madeleine Smith

Organization: GE Healthcare

Date - Time: Nov 08, 2010 - 05:03 PM

**Comments**

(continued) The use of ultrasound guidance is one of the top 11 practices with strong evidence that supports more widespread use to reduce infections, according the Agency for Healthcare Research and Quality (AHRQ).[1] There are several advantages associated with ultrasound guidance during central line insertion. First, the healthcare provider can visualize the desired vein and surrounding anatomic structures rather than rely on the use of anatomic landmarks, such as palpable or visible structures with known relationships to the targeted vein. Second, the healthcare provider can avoid central veins with pre-existing thrombosis that may prevent successful line placement. Third, ultrasound guidance assists the healthcare provider with guidewire and catheter placement after the initial needle insertion. (to be continued)

---

[1]Shojania KG, Duncan BE, McDonald KM, et al., eds. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43 (Prepared by the University of California at San Francisco-Stanford Evidence-based Practice Center under Contract No. 290-97-1103, AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality, July 2001, p. vi.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure****Comment By**

Name: Ms. Madeleine Smith

Organization: GE Healthcare

Date - Time: Nov 08, 2010 - 05:01 PM

**Comments**

GE Healthcare supports endorsement of the PSM-001-01 National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure. We point to an important omission in guidelines for prevention of CLABSI, namely the inclusion of the use of real-time ultrasound guidance during central line insertion to prevent complications. Ultrasound guidance is not included in publication cited as the source for guidelines: O'Grady NP, Alexander M, Dellinger EP, Gerberding JL, Heard SO, Maki DG, et al. *Guidelines for the prevention of intravascular catheter-related infections*. MMWR 2002; 51 (No. RR-10: 1-26). (continued)

---

#### Comments on the general draft report

##### Comment By

Name: Ms. Jennifer Faerberg, MHSA  
Organization: Association of American Medical Colleges

Date - Time: Nov 08, 2010 - 05:01 PM

##### Comments

The measures that are collected through the CDC's NHSN still cause some concern amongst our members due to the lack of validation testing. Specifically, the new measures utilize a standardized infection ratio (SIR) that will be calculated based on data submitted to the NHSN. It is unclear how the CDC will deal with institutions underreporting infection cases. Not all institutions have the same level of resources available to report on these infections. This may lead to higher rates being assigned to those institutions with available resources for reporting and result in misleading information being publicly reported. We would like to hear more from the measure developer on how this issue is addressed.

---

#### PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

##### Comment By

Name: Dr. J. Michael Henderson, MD  
Organization: Cleveland Clinic

##### On Behalf Of

Name: Cleveland Clinic  
Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 05:01 PM

##### Comments

The measure of CLABSI rates as it exists today is useful. However some recent reports in the literature highlight the difficulty with this measure. Units with higher rates had more structured monitoring and reporting structures than some with lower rates, highlighting possible data validity issues. A perception could be created that sites could be "punished" for being scrupulous in their monitoring program. One significant issue that needs to be raised regarding the definitions is more clarity from the CDC on what actually constitutes an infection at another location. Examples include a bone marrow transplant patient who is having an episode of graft versus host disease who is sloughing his/her GI tract lining and becomes septic. This is not really a CLABSI, but it is difficult to document the infection at another site. Another example is the patient with a deep seated infection that has been incompletely treated and develops a positive blood culture or a patient with a deep seated infection that has not yet been detected. The first positive culture might be a blood culture and the infection at the deeper site may not be determined until many days later. It is likely that these scenarios would (and have in our own institution) been classified differently by different infection control practitioners.

( see part 2)

---

#### Comments on the general draft report

##### Comment By

Name: Ms. Jennifer Faerberg, MHSA  
Organization: Association of American Medical Colleges

Date - Time: Nov 08, 2010 - 04:59 PM

##### Comments

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the National Quality Forum's (NQF) National Voluntary Consensus Standards for Patient Safety Measures. The AAMC has been supportive of public reporting of infection rates as evidenced through our work in the Hospital Quality Alliance and appreciates NQF's work in moving this field forward.

While we appreciate NQF's efforts in this field, we feel further work needs to be done. We were disappointed to see that the Steering Committee failed to make a decision regarding best in class measures for SSI and CAUTI. The proliferation of measures being endorsed that measure similar patient populations but are specified slightly differently causes confusion amongst consumers and providers as well as additional burden on behalf of institutions. We believe the NQF must address this issue, albeit it difficult, to identify a singular measure for use in public reporting.

---

**Comments on the general draft report****Comment By**

Name: Dr. J. Michael Henderson, MD  
Organization: Cleveland Clinic

**On Behalf Of**

Name: Cleveland Clinic  
Organization: Cleveland Clinic

Date - Time: Nov 08, 2010 - 04:59 PM

**Comments**

We strongly support the recommendation of the steering committee that the ACS and CDCP work together to harmonize their respective measures. There are strengths and weakness of both UTI and both SSI measures. A single harmonized metric for each would have been ideal.

One issue about the CDC measures is that only a handful of states actually require validation of the reporting. States with validation had consistently higher SIRs. The ACS is a registry that has some fixed costs to participate and is labor intensive (as are the CDC measures). The NHSN is a federal resource for hospitals to submit information to the CDC for aggregation and reporting, as already mentioned since only a handful of states require validation, more information about the cost, labor, time required for all of these of these measures should be reported or estimated for a better understanding of what would be involved in collecting this data. Any measure which would increase ongoing labor-intensive data collection should be scrutinized. The ACS registry has up- front cost and back end cost estimated at 0.1-0.3 FTE(s). If this metric were selected would hospitals be mandated to participate in this registry i.e. would there be upfront cost?

We recommend aligning these measures to be acquired electronically or from claims data, if at all feasible (despite the limitations.) Better data regarding feasibility and cost should be provided.

---

**Comments on the general draft report****Comment By**

Name: Ms. Madeleine Smith  
Organization: GE Healthcare

Date - Time: Nov 08, 2010 - 04:55 PM

**Comments**

GE Healthcare (GEHC) appreciates this opportunity to comment on the draft National Quality Forum report *National Voluntary Consensus Standards for Patient Safety Measures, First Report*. GEHC applauds National Quality Forum's efforts to improve patient safety by evaluating several healthcare-associated infections (HAI) measures.

---

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery****Comment By**

Name: Ms. Melanie Young  
Organization: Society for Healthcare Epidemiology of America

Date - Time: Nov 08, 2010 - 04:32 PM

**Comments**

**SHEA does NOT support this measure.** SHEA believes there should only be one UTI measure—a catheter-associated UTI measure. We remain concerned that if this measure is NQF endorsed in addition to the current NHSN CAUTI, the result could add great confusion. SHEA has concerns as well for the added data collection and cost burden if both are adopted and possibly required in some states. The science behind the NHSN - CDC definition for CAUTI has been defined and used for decades, and used for post-surgical patients as well as in the ICU or on other units.

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure****Comment By**

Name: Ms. Melanie Young

Organization: Society for Healthcare Epidemiology of America

Date - Time: Nov 08, 2010 - 04:31 PM

**Comments**

**SHEA strongly supports this measure.** This measure permits far more accurate comparisons of CAUTI occurrences between facilities than is possible simply using CAUTI rates. Facilities continue to collect the same data using the same processes resulting in CAUTI rates consistent with the current NQF endorsed CAUTI measure. The rates are used to further develop a composite measure that is essential if one is to compare CAUTI between facilities, whether on a local, state or national level. It is critical to have a composite measure that is accurate yet retains the variability of the NHSN rates. This measure uses a standardized infection ratio (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 central line use, patient care location (*representing severity of illness*), and other factors. The ICU location type accounts for different populations and is able to capture the variability of each type of ICU into a composite in a manner rates cannot. The SIR calculation does not require additional manual work in the facilities. NHSN is currently the most universally used -and mandated by CMS--for transferring CAUTI information as rates to CDC for calculating SIRs and sending to CMS for public reporting as required.

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure****Comment By**

Name: Ms. Melanie Young

Organization: Society for Healthcare Epidemiology of America

Date - Time: Nov 08, 2010 - 04:30 PM

**Comments**

**SHEA does not support this measure.** SHEA shares the NQF committee's concern for burden of data collection and case load, which is estimated at 200-500 cases per facility annually plus the patient follow-up 30 days post-procedure. Although the NQF committee's later recommendations were to harmonize both PSM-002-10 (NHSN) and PSM-006-10, SHEA believes only one SSI measure should exist. We have major concerns with NSQIP and do NOT believe harmonization is necessary. We do not support the need for developing focus groups on NHSN versus NSQIP. NHSN is freely available and is now required in every facility eligible for CMS VBP reimbursement. NSQIP is subscription based. NHSN processes do not change because of an SIR calculation by the facility or by CDC. Rates are still developed and used internally by facilities. The data are sent to CDC where SIR is calculated and sent to CMS as appropriate. Facilities participating in CMS VBP programs are already mandated by CMS to use NHSN for reporting SSI data to CMS via CDC where the SIR measures are calculated. To even consider NSQIP as an alternative would be a major added burden. Further SHEA is concerned that NSQIP is:

- focused primarily on general and vascular surgery and does not include all SCIP procedures as NHSN does
- not transparent on risk-adjustment process
- costly - beyond participation fee, facilities need to add salary for an FTE dedicated to collect all required data.
- not universally used

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure****Comment By**

Name: Ms. Melanie Young

Organization: Society for Healthcare Epidemiology of America

Date - Time: Nov 08, 2010 - 04:23 PM

**Comments**

**SHEA strongly supports this measure.** It permits far more accurate comparisons of SSI occurrences between facilities than is possible simply using SSI rates. Facilities continue to collect the same data using the same processes resulting in SSI rates for a specific procedure. The rates are used to further develop a composite measure per procedure that is

essential to compare SSI occurrences between facilities, whether on a local, state or national level. It is critical to have a composite measure that is accurate yet retains the variability of the NHSN rates. This measure uses a SIR to compare a healthcare facility's observed procedure-specific SSI rate to that facility's expected procedure-specific SSI rate. The selected procedure categories closely correspond with CMS' SCIP quality reporting initiative and were included in the NHSN. CMS suggests using these procedures for mandated SSI reporting via NHSN starting in 2012 and endorsement of this SSI measure would greatly reduce the burden of data collection and risk of duplication. The calculation of an SIR does not add additional data collection. The use of SIR as an indirect standardization of cumulative SSI experiences across several stratified groups of data provides significant added value. NHSN is currently the most universally used—and mandated by CMS—for transferring SSI information as rates to CDC for calculating and sending specific SIRs to CMS required for public reporting.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

**Comment By**

Name: Ms. Melanie Young

Organization: Society for Healthcare Epidemiology of America

Date - Time: Nov 08, 2010 - 04:22 PM

**Comments**

**SHEA strongly supports this measure.** It permits far more accurate comparisons of CLABSI occurrences between facilities than is possible simply using CLABSI rates. Facilities continue to collect the same data using the same processes resulting in CLABSI rates consistent with current NQF endorsed CLABSI measure. The rates are used to further develop a composite measure that is essential if one is to compare CLABSI between facilities, whether on a local, state or national level. It is critical to have a composite measure that is accurate yet retains the variability of the NHSN rates. This measure uses a 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 (*representing severity of illness*), and other factors. The ICU location type accounts for different populations and is able to capture the variability of each type of ICU into a composite measure. This does not require additional manual work in the facilities. The calculation *may* be performed by the facility, since the electronic NHSN module easily enables its calculation. It is also performed by the CDC for state and national comparisons. NHSN is currently used - and is now mandated by CMS in 2011 - for transferring CLABSI information as rates to CDC for calculating the SIR used by CMS for public reporting.

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure**

**Comment By**

Name: Ms. Mary Orellana

Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:54 PM

**Comments**

PSM-003-10: (line 312) HRSA supports the concept of developing a broader application of this standard outside ICU setting at the time of measure maintenance.

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure**

**Comment By**

Name: Ms. Mary Orellana

Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:53 PM

**Comments**

PSM-002-10 & PSM-006-10: (line 286 - 288) HRSA supports the concept of conducting focus groups on the feasibility and usability of the NSQIP and NSHN surveillance systems and suggests that the Committee consider requiring this before the measures are required as a standard.

PSM-002-10: Although the surgical site infections measure (PSM-002-10) describes hospital settings, there are noted comments by the Committee (line 242) of the application of this measure to ambulatory surgical centers in the future. HRSA encourages the Committee to specifically state that the expansion of the measure to include ambulatory surgical centers should be completed at the time of measure maintenance.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

**Comment By**

Name: Ms. Mary Orellana  
Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:49 PM

**Comments**

PSM-001-10:HRSA supports the use of a risk adjustment model or specific exclusions, given the variability in clinical practice settings.

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure**

**Comment By**

Name: Ms. Mary Orellana  
Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:43 PM

**Comments**

PSM-006-10: In line 266 of the report the developer indicates that the post-follow up procedure can be completed by either a "phone call or letter." In order to promote uniform adoption and implementation of the measure, HRSA suggests that the developer provide detailed specifications around the post-follow up procedures. Identifying for example how many call attempts must be made or letters sent before a patient would no longer be considered for the measure. The lack of detailed post-follow up measure specifications will inhibit comparison amongst facilities as different facilities will implement the measure differently.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

**Comment By**

Name: Ms. Mary Orellana  
Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:41 PM

**Comments**

PSM-001-10: Line 197 specifically highlights the Committees request for the developer to provide a reporting timeframe, however, the developer has not provided NQF any clarification on a reporting timeframe at the date of this publication. HRSA requests the Committee revisit their discussion on the need for a measure reporting timeframe. If no reporting timeframe is added then a justification for the Committee's rational to not add a reporting timeframe should be included in this report.

---

**Comments on the general draft report**

**Comment By**

Name: Ms. Mary Orellana  
Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:29 PM

**Comments**



HRSA supports NQF's efforts of measure harmonization (specifically on measures PSM-002-10 & PSM-006-10), however, consideration should be given to the potential undue burden on facilities when NQF recommends two very similar measures for endorsement, but stipulates that "harmonization of both measures should be complete by the first maintenance review." The challenge is that facilities may spend significant resources and time adopting one recommended measure only to have to change their approach at a later date. Encouraging harmonization on the front end of the process (i.e., before the measure is submitted to NQF for review or before endorsement) rather than on the back end may help to reduce this potential burden.

---

**Comments on the general draft report****Comment By**

Name: Ms. Mary Orellana

Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:29 PM

**Comments**

HRSA recommends that the Committee consider the expansion of the acquired infection measures recommended for endorsement to include infections that occur as the result of surgery in ambulatory surgical centers or surgeries occurring in a clinic setting.

---

**Comments on the general draft report****Comment By**

Name: Ms. Mary Orellana

Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:27 PM

**Comments**

HRSA supports NQF's endeavors on this project and encourages the measure development community to consider the expansion of HAI measures to the ambulatory care setting. Furthermore, HRSA would suggest that ambulatory HAI measures should span the life cycles and capture granular ethnicity, race and limited English proficiency to align with IOM recommendations, section 4302 of the Affordable Care Act, and harmonize with either healthcare associated infections or infections (influenza, pneumonia) that could have been prevented if high quality ambulatory preventive care (i.e. vaccinations) had been provided. Focusing on these areas that have the highest morbidity, mortality and health disparities would provide the largest potential for improvement, a key aspect in NQF's measure evaluation criteria.

---

**Comments on the general draft report****Comment By**

Name: Ms. Mary Orellana

Organization: Health Resources and Services Administration

Date - Time: Nov 08, 2010 - 03:26 PM

**Comments**

1. The Health Resources and Service Administration (HRSA) supports the concept of healthcare-associated infection measures and the five measures recommended in this draft report, however, there is concern with the implication of these measures on small critical access hospitals or rural facilities. HRSA's primary areas of concern are in regards to the burden that these measures will place on facilities and the lack of measure specifications delineating the specific reporting time period (i.e., whether reporting is cumulative, ongoing, annual, or quarterly) and follow up specifications. While the burden of these measures may be unavoidable, HRSA suggests NQF pay particular attention to the burden on facilities reporting these measures at the time of measure maintenance. Furthermore, HRSA requests that the Steering Committee re-visit the measure reporting time periods and follow up specifications to ensure consistent public reporting across facilities.
-

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure****Comment By**

Name: Dr. Keith F. Woeltje, MD, PhD  
Organization: BJC HealthCare

Date - Time: Nov 08, 2010 - 02:44 PM

**Comments**

The definition of a true urinary tract infection (vs. simple asymptomatic bacteruria) can be difficult to distinguish. This is especially true in ICU patients who may be sedated. We are concerned that this measure will encourage unnecessary therapy for bacteruria. A less subjective measure (e.g. urinary catheter utilization) may be a more appropriate measure.

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure****Comment By**

Name: Dr. Keith F. Woeltje, MD, PhD  
Organization: BJC HealthCare

Date - Time: Nov 08, 2010 - 02:38 PM

**Comments****Strengths**

- SSI has now become a national priority which has been addressed by the Center for Medicare and Medicaid (CSM) reporting requirement.
- SSI affects a large population and has evidence based recommendations for improvement.
- Intellectual property owner American College of Surgeons, a recognized group of surgical experts
- The spotlight on deep and organ space infections allows a focus on the most devastating infections.

**Concerns**

- There is a similar proposed measure proposed, the NHSN SSI SIR. Would be confusing if both measures were approved.
  - Although it is stated that ACS NSQIP definitions are concordant with CDC, the actual measures appear to use only a 30 day time frame for implants.
  - Hospitals who are forced to use CDC definitions for CMS reporting could potentially have 2 different SSI outcome numbers
  - Could result in extensive data collection burden for hospital not already participating in NSQIP
- 

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure****Comment By**

Name: Dr. Keith F. Woeltje, MD, PhD  
Organization: BJC HealthCare

Date - Time: Nov 08, 2010 - 02:34 PM

**Comments****Strengths**

- CLABSI has now become a national priority which has been addressed by the Center for Medicare and Medicaid (CSM) reporting requirement.
- CLABSI affects a large population and has evidence based recommendations for improvement.
- The use of NHSN definitions provides a national definition that can be applied consistently across the country and will allow for comparison.
- The data that is required for the CMS reporting is the same data that is necessary to calculate the SIR so additional data collection is not necessary.
- Risk Stratification by type of ICU should be adjusted for in the calculation of the expected

**Weakness**

- This measure will be replacing a measure that has been adopted by CMS for public reporting.
- If this measure is expanded outside of the ICU without an electronic algorithm data collection could be time consuming.

**Comments on the general draft report****Comment By**

Name: Dr. Keith F. Woeltje, MD, PhD  
 Organization: BJC HealthCare

Date - Time: Nov 08, 2010 - 02:33 PM

**Comments**

We believe that the use of SIRs is easily understandable and is consistent with CDC trends. NHSN definitions and surveillance methodologies have been long recognized as a standard. We are concerned that multiple measures around SSI and UTI with different definitions will be a source of confusion, and may significantly drive up the burden of surveillance if different regulatory bodies adopt different measures.

**Comments on measures not recommended****Comment By**

Name: Dr. Rita Munley Gallagher, PhD, RN  
 Organization: American Nurses Association

Date - Time: Nov 08, 2010 - 02:28 PM

**Comments**

References relevant to comments of the American Nurses Association (ANA) include:

Kuklina, E., Meikle, S., Jamieson, D., Whiteman, M., Barfield, W., Hillis, S., Posner, S. (2009). "Severe Obstetric Morbidity in the US, 1998-2005." *Obstetrics and Gynecology* 113: 293-299.

Sakala, C. and M. P. Corry (2008). *Evidence-based maternity care: What it is and what it can achieve*. New York, Milbank Memorial Fund.

Leth, R., J. Moller, et al. (2009). "Risk of selected postpartum infections after cesarean section compared with vaginal birth: A five-year cohort study of 32,468 women." *Acta Obstetrica et Gynecologica Scandinavica* 99999 (1).

Tita, A. T. N., M. B. Landon, et al. (2009). "Timing of elective cesarean delivery at term and neonatal outcomes." *The New England Journal of Medicine* 360: 111-120.

**Comments on measures not recommended****Comment By**

Name: Dr. Rita Munley Gallagher, PhD, RN  
 Organization: American Nurses Association

Date - Time: Nov 08, 2010 - 02:27 PM

**Comments**

The American Nurses Association (ANA) recommends that measure developers add cesarean section surgeries to the list of surgical infections to be tracked. ANA also recommends the tracking of UTIs for women admitted who give birth and experience post-partum wound infections. Cesarean surgery rates are increasing and currently Cesarean surgery is the most common surgery performed in the United States overall and the most common surgery performed on women (Sakala, et al 2008). In addition, between 1998 and 2005 there has been a 27% increase in maternal morbidity that is correlated to increased rates of Cesarean sections (Kuklina, 2009). In Denmark, where they track postpartum infections rates by mode of delivery, post-partum infections affect 7.8% of women who had a Cesarean surgical birth compared to 1.6% of women who had a vaginal birth (Leth, et al). In the United States there are no data to indicate that the more than 55% increase in Cesarean surgeries has led to improvements in outcomes. However, there are data that show the increase in Cesarean surgery has had an adverse effect on infants (Tita et al) and women (Clark et al, Knight et al, and

Kuklina et al). Tracking maternity care HAIs will increase insights into important trends, help with allocation of resources, and contribute to identifying the quality of maternity care in the U.S.

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure**

**Comment By**

Name: Dr. Rita Munley Gallagher, PhD, RN  
Organization: American Nurses Association

**On Behalf Of**

Name: Rita Munley Gallagher, PhD, RN  
Organization: American Nurses Association

Date - Time: Nov 08, 2010 - 02:25 PM

**Comments**

The American Nurses Association (ANA) questions the use of the standardized infection ratio (SIR) for deep and organ space infections only. Up to this point CDC NHSN published benchmarks for SSI have included superficial incision infections also. ANA questions the wisdom of exclusion of infections that are included in the national benchmark being referenced as this would not result in a true benchmark.

---

**Comments on the general draft report**

**Comment By**

Name: Dr. Rita Munley Gallagher, PhD, RN  
Organization: American Nurses Association

**On Behalf Of**

Name: Rita Munley Gallagher, PhD, RN  
Organization: American Nurses Association

Date - Time: Nov 08, 2010 - 02:22 PM

**Comments**

The American Nurses Association (ANA) appreciates the importance to measure of healthcare-associated infections (HAI). Consideration must be given to the added burden of utilization of the standardized infection ratio (SIR) for reporting and what the demonstrated value would be to this additional measure from a patient outcomes and data collections perspective, given the availability of existing HAI rates. In addition, ANA has concerns regarding the potential for endorsement of measures which are specified based on two different definitions (NHSN and ACS). This has the potential to lead to confusion with the different reported rates.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

**Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:12 PM

**Comments**

In closing we would like express dismay that the NQF, in the managing this Patient Safety Project, has adversely affected the usability of the CDC CLABSI measure. We know this was not NQF's intent; however, we fear it is a consequence of the timing of this measure review. Prior to this project, measure #0139 was a fully-endorsed NQF measure. Subsequently, the Centers for Medicare & Medicaid Services finalized measure #0139 for national reporting, beginning January 1, 2011. As a result, it is highly likely that hospitals will be required to report a measure to CDC that is no longer endorsed. Though we recognize that NQF's intent was for PSM-001-10 to replace #0139, using a full SC to endorse PSM-001-10 communicates to the public that there is a material change to the measure and this change cannot be implemented within a federal program in sub-regulatory fashion. **To avoid such confusion in the future, we strongly recommend that NQF have detailed strategic planning discussions with all involved stakeholders regarding the timing of measure endorsement and implementation in federal programs.**

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

**Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:11 PM

**Comments**

Central line blood stream infections are very dangerous for patients, and therefore, important to measure. Many states have experience reporting the NHSN CLABSI measure, and it is through this experience that we identified areas that should be enhanced prior to readiness for public reporting. The current (#0139) endorsed and revised (PSM-001-10) CLABSI measures are limited to patients with an Intensive Care Unit (ICU) stay. Both #0139 and PSM-001-10 stratify patients by type of ICU, but they do not include a patient-level risk adjuster. Stratification by ICU poses particular problems for comparison when different types of hospitals are taken into consideration. For example, the patients in an adult medical ICU in a large academic medical center hospital may not necessarily be similar to an ICU in a Critical Access Hospital. We are also concerned about the larger operational policy context in which the CLABSI measure is currently being used. The SC report noted that “on the issue of feasibility, the SC voiced concerns about reporting a Standardized Infection Ratio (SIR) rather than a rate, since several states already mandate the reporting of CLABSI rates.” We encourage the SC to work with the measure developer to address these outstanding issues prior to their final consideration for endorsement.

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure****Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:05 PM

**Comments**

We recommend that the SC consider **choosing the NSQIP SSI measure** because it is more salient to those who care for surgical patients and can be a critically important part of the picture of overall surgical patient care.

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure****Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:04 PM

**Comments**

We suggest **choosing the NHSN measure of urinary tract infections** because many medical patients are also at risk of a UTI, particularly when they have a catheter, and we believe it would be inappropriate to simply focus attention on the surgical patients at risk.

**Comments on the general draft report****Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:03 PM

**Comments**

Reasonable individuals could differ in their perspectives about which of these measures is best and should be used as part of standardized data collection. Either choice could be made to work, but the important thing is that the SC make a choice of one SSI measure and one UTI measure.

We recommend that the SC consider **choosing the NSQIP SSI measure** because it is more salient to those who care for surgical patients and can be a critically important part of the picture of overall surgical patient care. We suggest **choosing the NHSN measure of urinary tract infections** because many medical patients are also at risk of a UTI, particularly when they have a catheter, and we believe it would be inappropriate to simply focus attention on the surgical patients at risk.

**Comments on the general draft report****Comment By****On Behalf Of**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

Name: Nancy Foster  
Date Organization: American Hospital Association

Time: Nov 08, 2010 - 02:02 PM

### Comments

#### *Best in Class*

Though we appreciate that making a best in class determination may be difficult, it is an essential building block for ensuring a well-informed public. Consumers, providers and payers rely on the NQF to set consensus standards by selecting one best in class measure among several overlapping measures for the same patient population. There are several key factors that the SC should take into consideration in determining best in class, including the following:

#### Reporting burden

The NSQIP SSI and CAUTI measures have “specifically been designed with a very parsimonious, low-burden data requirement so that NSQIP participation would not be required and the burden on hospitals for this measure would be acceptable.” The SC report does not state that the NHSN SSI and CAUTI measures are specified for reporting outside of NHSN.

The CDC estimates that yearly reporting of the NHSN SSI and CAUTI measures is approximately \$3,000, each. The ACS estimates that that yearly reporting of the NSQIP SSI and CAUTI measures is equivalent to 1/3 of a full-time employee, each. We further note that in neither case have these estimates been validated.

---

### Comments on the general draft report

#### Comment By

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

#### On Behalf Of

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:02 PM

### Comments

#### *Best in Class*

Though we appreciate that making a best in class determination may be difficult, it is an essential building block for ensuring a well-informed public. Consumers, providers and payers rely on the NQF to set consensus standards by selecting one best in class measure among several overlapping measures for the same patient population. There are several key factors that the SC should take into consideration in determining best in class, including the following:

#### Proprietary documentation

The specifications and development history for the NHSN SSI and CAUTI measures are available in the public domain. The measure submission form for the NSQIP SSI and CAUTI measures reference that some of the supporting materials are proprietary and therefore not readily available to the public.

---

### Comments on the general draft report

#### Comment By

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

#### On Behalf Of

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:01 PM

### Comments

#### *Best in Class*

Though we appreciate that making a best in class determination may be difficult, it is an essential building block for ensuring a well-informed public. Consumers, providers and payers rely on the NQF to set consensus standards by selecting one best in class measure among several overlapping measures for the same patient population. There are several key factors that the SC should take into consideration in determining best in class, including the following:

#### Specification for electronic health records

The NSQIP SSI and CAUTI measures are “specified for electronic health record collection.” The SC report does not state whether the NHSN SSI and CAUTI measures are specified for electronic health record collection.

---

**Comments on the general draft report****Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:00 PM

**Comments***Best in Class*

Though we appreciate that making a best in class determination may be difficult, it is an essential building block for ensuring a well-informed public. Consumers, providers and payers rely on the NQF to set consensus standards by selecting one best in class measure among several overlapping measures for the same patient population. There are several key factors that the SC should take into consideration in determining best in class, including the following:

Broader population coverage

The NHSN CAUTI measure includes all hospital stays. The NSQIP CAUTI measure is isolated to hospital stays including surgeries.

---

**Comments on the general draft report****Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 02:00 PM

**Comments***Best in Class*

Though we appreciate that making a best in class determination may be difficult, it is an essential building block for ensuring a well-informed public. Consumers, providers and payers rely on the NQF to set consensus standards by selecting one best in class measure among several overlapping measures for the same patient population. There are several key factors that the SC should take into consideration in determining best in class, including the following:

Exclusions of certain patient populations

The National Surgical Quality Improvement Program (NSQIP) SSI and CAUTI measures exclude “major trauma and solid organ transplant cases.” NSQIP chose to exclude these patients for relevant clinical reasons, such as the fact that major trauma patients usually have wounds that have been contaminated by the source of the trauma making them very different than patients whose wounds are made in the controlled environment of a surgical suite or procedure room. Even when everything is done exactly right, the ability of the surgical team to prevent wound infections in these two different circumstances would be different. The NHSN SSI and CAUTI measures do not exclude any patient populations.

---

**Comments on the general draft report****Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 01:58 PM

**Comments**

In this comment letter, we will recommend how one might choose “best in class” for SSI and CAUTI measures. Our intent is to suggest that the SC pick one way to measure SSI and one way to measure CAUTI. We understand that there are pros and cons of each of the candidate measures, and we hope the perspectives articulated below provide the SC with additional information for their best in class deliberations. But in the end, **the SC must select only one SSI and one CAUTI measure as “best in class.”** Our thoughts regarding the best in class determination, as well as detailed comments on the National Healthcare Safety Network (NHSN) CLABSI measure is included below.

---

**Comments on the general draft report****Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 01:57 PM

**Comments**

The National Quality Forum was conceived of as a mechanism to identify the best possible measures of important aspects of care and to drive standardization of measurement and reporting efforts to use NQF endorsed measures. Failure to choose a standard approach to measuring a particular aspect of care will have several undesirable effects. It will:

- Cause (or perpetuate) confusion in the public about which organizations actually deliver the best care because different measurement approaches produce different results;
- Inhibit efforts to improve as providers are puzzled about which measure to use and rely on in their improvement efforts;
- Drive further waste into the system as providers have to spend resources on collecting, analyzing and reporting data in two different ways;
- Inhibit hospitals' and other providers' ability to successfully embed measure collection in their electronic health records.

---

**Comments on the general draft report****Comment By**

Name: Ms. Lisa M. Grabert, MPH  
Organization: American Hospital Association

**On Behalf Of**

Name: Nancy Foster  
Organization: American Hospital Association

Date - Time: Nov 08, 2010 - 01:56 PM

**Comments**

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the National Quality Forum's (NQF) National Voluntary Consensus Standards for Patient Safety Measures. We commend the NQF for recognizing the importance of public reporting of infection rates. The work of this Steering Committee (SC) will provide the public with important information. AHA has long supported the public reporting of infection data through our work with the Hospital Quality Alliance and has been very interested in public reporting for surgical site infections (SSI) and central line blood stream infections (CLABSI). We continue to believe it is important that the public and providers receive good, reliable information on both these infections and others. However, we are deeply concerned that the SC is considering recommending endorsement of multiple infection rates that measure the same infections in the same, or virtually the same population.

---

**Comments on the general draft report****Comment By**

Name: Ms. Rabia Khan, MPH  
Organization: Centers for Medicare and Medicaid Services

**On Behalf Of**

Name: Michael Rapp  
Organization: CMS

Date - Time: Nov 08, 2010 - 10:18 AM

**Comments**

1. In regard to ACS measures PSM-006-10 and PSM-007-10, we are concerned with the use of CPT codes in a hospital setting. These measures are not physician measures, but hospital measures. Therefore, the measures should not use CPT codes, but instead should be based on ICD-10.
2. Measures PSM-002-10 and PSM-006-10 appear to be complimentary, but they may be hard to implement broadly. In possibly pairing these measures, the denominators should be harmonized. Denominator harmonization also raises concerns over the utilization of CPT codes and how they will function with the implementation of ICD-10.
3. Additional information and a clear definition of urinary tract infection are necessary to better understand the function of measure PSM-007-10.



---

**Comments on the general draft report****Comment By**

Name: Dr. Mark S. Antman, DDS, MBA  
Organization: American Medical Association-Physician Consortium for Performance Improvement

**On Behalf Of**

Name: Bernard M. Rosof, MD, MACP  
Organization: Physician Consortium for Performance Improvement

Date - Time: Nov 08, 2010 - 09:39 AM

**Comments**

The PCPI also encourages the measure developers to evaluate the applicability of the measures to other settings. For example, the Central line-associated Bloodstream Infection (CLABSI) Outcome measure targets the ICU and NICU setting. Yet, central lines that meet the measure definition are used in other settings like procedural suites and dialysis centers. Indwelling urinary catheters are used in long term care facilities and in the home. Evidence based infection prevention strategies are universal and measurement should not be limited to specific care settings.

We appreciate the opportunity to comment.

---

**Comments on the general draft report****Comment By**

Name: Dr. Mark S. Antman, DDS, MBA  
Organization: American Medical Association-Physician Consortium for Performance Improvement

**On Behalf Of**

Name: Bernard M. Rosof, MD, MACP  
Organization: Physician Consortium for Performance Improvement

Date - Time: Nov 08, 2010 - 09:38 AM

**Comments**

Improving patient safety is a high priority for physicians, other health care providers, payers and consumers alike. To achieve this goal, a single set of standardized measures must be identified to allow health care organizations to evaluate and benchmark their current infection prevention practices and focus on improvement where needed. The draft report identifies measure harmonization as a priority, with which the PCPI agrees. However, this report then includes two measures for surgical site infection evaluation (SSI) and two measures for catheter-associated urinary tract infection evaluation (CAUTI). The PCPI strongly supports the recommendation of the Steering Committee that the measure developers harmonize their measures so that there is one measure for SSI and one measure for CAUTI. Ideally, this harmonization work should occur prior to the measures being made public for comment. While we recognize that there are fundamental differences in the measure methodologies and data collection requirements, obtaining the highest level of infection control will not be achieved without harmonization. Therefore, we urge NQF to work with measure developers over the coming months to identify a strategy to facilitate measure harmonization. If measures are not harmonized, use of the data for meaningful reporting and quality improvement by health care providers, and use of the information for consumer choice will be undermined.

---

**Comments on the general draft report****Comment By**

Name: Dr. Mark S. Antman, DDS, MBA  
Organization: American Medical Association-Physician Consortium for Performance Improvement

**On Behalf Of**

Name: Bernard M. Rosof, MD, MACP  
Organization: Physician Consortium for Performance Improvement

Date - Time: Nov 08, 2010 - 09:37 AM

**Comments**

The Physician Consortium for Performance Improvement® (PCPI) is pleased to have the opportunity to comment on the National Quality Forum's (NQF) *National Voluntary Consensus Standards for Patient Safety Measures, First Report*. The PCPI believes that the identification and endorsement of patient safety performance measures is necessary, and that it helps fill an important gap in the quality enterprise. The PCPI applauds NQF for this work.

---

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery****Comment By**

Name: Ms. Christine Chen  
Organization: Pacific Business Group on Health

Date - Time: Nov 05, 2010 - 11:50 AM

**Comments**

*PSM-7: Catheter-Associated Urinary Tract Infection Outcome Measure: As with our comments on the ACS SSI measure, we support endorsement of this measure, but as for confirmation that it will meet the public reporting requirement of the consensus development process.*

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure**

**Comment By**

Name: Ms. Christine Chen

Organization: Pacific Business Group on Health

Date - Time: Nov 05, 2010 - 11:49 AM

**Comments**

*PSM-3: Catheter-Associated Urinary Tract Infection Outcome Measure: As with the CDCP SSI measure, this measure is risk-adjusted and meets the importance test, along with the other evaluation criteria. We fully support its endorsement.*

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure**

**Comment By**

Name: Ms. Christine Chen

Organization: Pacific Business Group on Health

Date - Time: Nov 05, 2010 - 11:49 AM

**Comments**

*PSM-6: Surgical Site Infection Outcome Measure: As noted above, the ACS has a similar SSI measure that is recommended for endorsement. The population it covers does not completely overlap with the patient population that would make up the denominator for the CDCP measure, thus we do think it is reasonable to potentially have both SSI measures endorsed, with a goal of harmonizing them within three years. We are concerned, however, over the potential for public reporting of SSI rates with this measure. Registry measures are typically difficult to report publicly due to the proprietary nature of the data, and we do strongly believe that HAI measures be publicly reported for both accountability and quality improvement. We understand that the NQF consensus development process requires that measures be suitable for public reporting unless the measure developers can make the case for why it is appropriate for internal quality improvement only. We would like assurance in the final report that this ACS measure, as well as the CAUTI measure, will be available for public reporting if endorsed.*

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure**

**Comment By**

Name: Ms. Christine Chen

Organization: Pacific Business Group on Health

Date - Time: Nov 05, 2010 - 11:48 AM

**Comments**

*PSM-2: Surgical Site Infection Outcome Measure: We fully support this CDCP measure, which is already being used by many states, as well as the Leapfrog Group, to determine and report the ratio of patients in a hospital experiencing an SSI to the national average.*

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

**Comment By**

Name: Ms. Christine Chen

Organization: Pacific Business Group on Health

Date - Time: Nov 05, 2010 - 11:48 AM

**Comments**

*PSM-01: Central Line-Associated Blood Stream Infection:* This CDCP measure undoubtedly meets the importance criteria of the consensus development process criteria, as well as those of feasibility, usability, and scientific acceptability. The National Healthcare Safety Network (NHSN) system for collecting and using these data is one that many states have extensive experience with, and it has been well-tested. It has a respected risk-adjustment mechanism, and we believe that this measure is critical for improving patient safety in the hospital setting.

---

#### Comments on the general draft report

##### Comment By

Name: Ms. Christine Chen

Organization: Pacific Business Group on Health

Date - Time: Nov 05, 2010 - 11:47 AM

##### Comments

Given the importance of the subject matter, and the fact that the measures do all meet the consensus development process evaluation criteria, we support all five of the measures (see our comments on specific measures below). The ACS and CDCP measures, while similar, do use different data sources and there is value to having the range of information that the various measures will provide. At the same time, however, we ask that NQF provide greater detail on the process that was used to compare the SSI and CAUTI measures in a head-to-head “best in class” evaluation. Perhaps this report is not the appropriate place for further elaboration on how this process occurred, but we would like to better understand what the process was, and how it came to be that both SSI and CAUTI measures were recommended for endorsement, so that as members of NQF we are better prepared to participate and comment when the process of comparing similar measures to determine “best-in-class” becomes a routine part of the consensus development process.

Overall, given that two CAUTI and two SSI measures were recommended, we strongly support the recommendation of the steering committee that the ACS and CDCP work together to harmonize their respective measures prior to their maintenance review

---

#### Comments on the general draft report

##### Comment By

Name: Ms. Christine Chen

Organization: Pacific Business Group on Health

Date - Time: Nov 05, 2010 - 11:47 AM

##### Comments

The Pacific Business Group on Health supports the National Quality Forum’s efforts to expand the number of endorsed patient safety measures, particularly in the area of hospital-acquired infections (HAI). The direct and indirect costs of HAIs to consumers, purchasers, and the system as a whole are enormous. Endorsing these types of measures will provide greater support to burgeoning federal efforts (e.g. including CAUTI rates, and CLABSI and SSI measures in the Medicare Inpatient Quality Reporting Program, and providing \$50 million to states to develop action plans in alignment with the DHHS Action Plan to Prevent Healthcare-Associated Infections), as well as to already-existing state efforts to report on HAIs.

.

---

#### Comments on the general draft report

##### Comment By

Name: Ms. Diana R. Jolles, CNM, MS

Organization: American College of Nurse-Midwives

Date - Time: Nov 05, 2010 - 11:44 AM

##### Comments

The project scope and accomplishment is impressive. Keep up the good work. We anxiously await the opportunity to apply your process to beginning of life issues as they influence over 8 million women and newborns annually. I understand that it was not within the scope of this project. Great work!

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure****Comment By**

Name: Dr. Sam W. Ho

Organization: UnitedHealthcare

Date - Time: Nov 04, 2010 - 06:33 PM

**Comments**

Agree w/ blending PSM-002-10 & PSM-006-10. No apparent or obvious reason(s) for having 2 separate measures for SSIs

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure****Comment By**

Name: Dr. Sam W. Ho

Organization: UnitedHealthcare

Date - Time: Nov 04, 2010 - 06:32 PM

**Comments**

Majority of HAC UTI's are CAUTI's. Should include any IP CAUTI regardless of setting of care. Should include post-operative care.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure****Comment By**

Name: Dr. Sam W. Ho

Organization: UnitedHealthcare

Date - Time: Nov 04, 2010 - 06:30 PM

**Comments**

Would consider exclusions for active chemo patients and those w/ >20% TBA 3<sup>rd</sup> degree burns.

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure****Comment By**

Name: Dr. Sam W. Ho

Organization: UnitedHealthcare

Date - Time: Nov 04, 2010 - 06:29 PM

**Comments**

- Numerator - Why limit to only 10 procedures? What % of overall surgeries do these 10 account for? What % of overall SSIs do these 10 account for?
  - Why only IP-based procedures? The majority of surgical procedures are done on an OP basis.
  - Agree w/ blending PSM-002-10 & PSM-006-10. No apparent or obvious reason(s) for having 2 separate measures for SSIs
- 

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery****Comment By**

Name: Dr. Sam W. Ho

Organization: UnitedHealthcare

Date - Time: Nov 04, 2010 - 06:26 PM

**Comments**

Majority of HAC UTI's are CAUTI's. Should include any IP CAUTI regardless of setting of care. Should include post-operative care. Unclear why there would be focus on non-CAUTI in IP setting.

---

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery****Comment By**

Name: Ms. Margaret Reagan  
Organization: Premier, Inc.

Date - Time: Nov 04, 2010 - 04:26 PM

**Comments**

**Premier does NOT support this measure.** Premier believes there should only be one UTI measure—a catheter-associated UTI measure. We remain concerned that if this measure is NQF endorsed in addition to the current NHSN CAUTI, the result could add great confusion. Premier has concerns as well for the added data collection and cost burden if both are adopted and possibly required in some states. The science behind the NHSN - CDC definition for CAUTI has been defined and used for decades, and used for post-surgical patients as well as in the ICU or on other units.

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure****Comment By**

Name: Ms. Margaret Reagan  
Organization: Premier, Inc.

Date - Time: Nov 04, 2010 - 04:25 PM

**Comments**

**Premier does not support this measure.** Premier shares the NQF committee's concern for the burden of data collection and case load, which is estimated at 200-500 cases per facility annually plus the patient follow-up 30 days post-procedure. Although the NQF committee's later recommendations were to harmonize both PSM-002-10 (NHSN) and PSM-006-10, Premier believes only one SSI measure should exist. We have major concerns with NSQIP and do NOT believe harmonization is necessary. We do not support the need for developing focus groups on NHSN versus NSQIP. NHSN is freely available and is now required in every facility eligible for CMS VBP reimbursement. NSQIP is subscription based. NHSN processes do not change because of an SIR calculation by the facility or by CDC. Rates are still developed and used internally by facilities. Data are sent to CDC where SIR is calculated and sent to CMS as appropriate. Facilities participating in CMS VBP programs are mandated by CMS to use NHSN for reporting SSI data to CMS via CDC where SIR measures are calculated. To even consider NSQIP as an alternative would be a major added burden. Further Premier is concerned that NSQIP is: focused primarily on general and vascular surgery and does not include all the SCIP procedures as NHSN does; not transparent on the risk-adjustment process; costly - beyond the participation fee, facilities need to add the salary for an FTE dedicated to collect all required data; and not universally used.

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure****Comment By**

Name: Ms. Margaret Reagan  
Organization: Premier, Inc.

Date - Time: Nov 04, 2010 - 04:20 PM

**Comments**

**Premier strongly supports this measure.** This measure permits far more accurate comparisons of SSI occurrences between facilities than is possible using SSI rates. Facilities continue to collect the same data using the same processes resulting in SSI rates for a specific procedure. The rates are used to further develop a composite measure per procedure that is essential to compare SSI occurrences between facilities, whether on a local, state or national level. It is critical to have a composite measure that is accurate yet retains the variability of the NHSN rates. This measure uses a SIR to compare a healthcare facility's observed procedure-specific SSI rate to that facility's expected procedure-specific SSI rate. The selected procedure categories closely correspond with CMS' SCIP quality reporting initiative and were included in the NHSN. CMS suggests using these procedures for mandated SSI reporting via NHSN starting in 2012 and endorsement of this SSI measure would greatly reduce the burden of data collection and risk of duplication. The calculation of a SIR does not add additional data collection. The use of SIR as an indirect standardization of cumulative SSI experiences across several stratified groups of data provides significant added value. NHSN is currently the most universally used—and mandated by CMS—for transferring SSI information as rates to CDC for calculating and sending specific SIRs to CMS required for public reporting.

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI)****Outcome Measure****Comment By**

Name: Ms. Margaret Reagan

Organization: Premier, Inc.

Date - Time: Nov 04, 2010 - 02:45 PM

**Comments**

**Premier strongly supports this measure.** This measure permits far more accurate comparisons of CAUTI occurrences between facilities than is possible simply using CAUTI rates. Facilities continue to collect the same data using the same processes resulting in CAUTI rates consistent with the current NQF endorsed CAUTI measure. The rates are used to further develop a composite measure that is essential if one is to compare CAUTI between facilities, whether on a local, state or national level. It is critical to have a composite measure that is accurate yet retains the variability of the NHSN rates. This measure uses a standardized infection ratio (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 central line use, patient care location (*representing severity of illness*), and other factors. The ICU location type accounts for different populations and is able to capture the variability of each type of ICU into a composite in a manner rates cannot. The SIR calculation does not require additional manual work in the facilities. NHSN is currently the most universally used -and mandated by CMS--for transferring CAUTI information as rates to CDC for calculating SIRs and sending to CMS for public reporting as required.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI)****Outcome Measure****Comment By**

Name: Ms. Margaret Reagan

Organization: Premier, Inc.

Date - Time: Nov 04, 2010 - 02:18 PM

**Comments**

**Premier strongly supports this measure.** This measure permits far more accurate comparisons of CLABSI occurrences between facilities than is possible simply using CLABSI rates. Facilities continue to collect the same data using the same processes resulting in CLABSI rates consistent with the current NQF endorsed CLABSI measure. The rates are used to further develop a composite measure that is essential if one is to compare CLABSI between facilities, whether on a local, state or national level. It is critical to have a composite measure that is accurate yet retains the variability of the NHSN rates. This measure uses a 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 (*representing severity of illness*), and other factors. The ICU location type accounts for different populations and is able to capture the variability of each type of ICU into a composite measure. This does not require additional manual work in the facilities. The calculation *may* be performed by the facility, since the electronic NHSN module easily enables its calculation. It is also performed by the CDC for state and national comparisons. NHSN is currently used and is now mandated by CMS in 2011 for transferring CLABSI information as rates to CDC for calculating the SIR used by CMS for public reporting.

---

**Comments on measures not recommended****Comment By**

Name: David Birnbaum, PhD, MPH

Organization: Washington State Department of Health

Date - Time: Nov 04, 2010 - 12:00 PM

**Comments**

Emphasis also should be placed on infection surveillance validation methods credible to other industries that recognize international standards for acceptance sampling (ISO & MIL). Approaches to validation that other industrial sectors would not consider credible will not serve the healthcare industry's best interests.

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI)****Outcome Measure****Comment By**

Name: David Birnbaum, PhD, MPH

Organization: Washington State Department of Health

Date - Time: Nov 04, 2010 - 11:53 AM

#### Comments

PSM-003-10 calls for use of SIR to monitor catheter-associated urinary tract infection (CAUTI). Again, evaluation of SIR and shifting base distortion should be conducted before widely promoting an indirectly standardized morbidity ratio for this type of application. Cost is mentioned in several sections of the draft report; the work of Graves should be considered in those sections and particularly in this section (INFECT CONTROL HOSP EPIDEMIOL 2007;28(3):280-92 re: regression models that demonstrate positive bias in excess cost or length of stay estimations based on smaller number of independent variables typical of the studies published to date). #PSM-003-10 and #PSM-007-10 also should consider whether only a small fraction of urinary tract infections will be captured (since NHSN eliminated the asymptomatic UTI category and now captures only septic episodes in CAUTI).

---

#### PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure

##### Comment By

Name: David Birnbaum, PhD, MPH

Organization: Washington State Department of Health

Date - Time: Nov 04, 2010 - 11:50 AM

#### Comments

PSM-002-10 calls for use of SIR to monitor surgical site infection (SSI). Our evaluation of SIR was confined to CLABSI, and we are not aware of similar evaluations to ensure SIR is reliable for inter-hospital comparison of SSI. There is no concern with SIR being used within one facility to compare itself with national rates, a long-established usage; however, once more than two groups are compared then the issue of shifting base distortion cannot be ignored. Without evaluation of the extent to which shifting base distortion may bias results, and in the logistic regression approach proposed by CDC for future use rather than the simpler formula currently used for SIR, caution is warranted.

The list of surgical procedures includes vaginal hysterectomy, which presents challenges in diagnosing SSI and classifying it as superficial, deep versus organ space. Utility of including vaginal hysterectomy might warrant reconsideration. Reliable classification of surgical site infection depth (deep vs. organ space) also might warrant additional consideration given difficulties reported in classifying sternal incision infections (Friedman et al., INFECT CONTROL HOSP EPIDEMIOL 2007;28(7):812-7).

---

#### Comments on the general draft report

##### Comment By

Name: David Birnbaum, PhD, MPH

Organization: Washington State Department of Health

Date - Time: Nov 04, 2010 - 11:47 AM

#### Comments

We appreciate the caution in lines 188-200 regarding frequency of reporting. Spiegelhalter DJ, BR MED J 2005;331:1013-5 and Walker S et al. PLoS ONE 2008;3(6):32378 raise important caveats against reporting intervals too short to estimate rates accurately, too short to have sufficient statistical power to detect trends. Their work presents a strong case for annual or longer intervals between reports of rates. Emphasis also should be placed on surveillance validation methods credible to other industries that recognize international standards for acceptance sampling.

---

#### PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

##### Comment By

Name: David Birnbaum, PhD, MPH

Organization: Washington State Department of Health

Date - Time: Nov 04, 2010 - 11:46 AM

#### Comments

PSM-001-10 calls for use of the Standardized Infection Ratio (SIR) to monitor central-line associated bloodstream infection (CLABSI) rates. Technically, SIR is an indirectly standardized morbidity ratio (SMR). It has been widely promoted without adequate evaluation. Adequate evaluation of an indirect SMR for this type of usage is important because of a long-recognized flaw inherent in the indirect (but not present in the direct) standardization calculation formula: the so-called “shifting base” distortion. Our evaluation of SIR compared it to unbiased metrics (relative risk, direct standardization and stratified rates). Results of that evaluation demonstrate that SIR’s inherent shifting base distortion is not just a theoretical concern and can lead to incorrect conclusions about hospital performance. We endorse stratified CLABSI rates, but not use of SIR for several reasons documented in Birnbaum D, Zarate R, Marfin T. SIR, you’ve led me astray! *INFECT CONTROL HOSP EPIDEMIOL in press* (also presented as Abstract #849, Fifth Decennial International Conference on Healthcare-Associated Infections, Atlanta Georgia, March 2010).

For reasons explained in our paper, we respectfully disagree with the assertion on line 206 that SIR adds significant value. In our experience, it detracts from more meaningful alternatives.

---

#### Comments on the general draft report

##### Comment By

Name: Ms. Amy Beckrich

Organization: Renal Physicians Association

Date - Time: Nov 03, 2010 - 02:12 PM

#### Comments

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease. The RPA is troubled that several important areas of hospital-associated infection were not included: ventilator-associated pneumonia; hospital-acquired *Clostridium difficile* diarrhea/colitis; and hospital-acquired antibiotic-resistant infections (Methicillin-resistant *Staphylococcus aureus*, Vancomycin-resistant enterococcus, multi-drug resistant bacteria). The RPA recommends measures for these HAIs be included in the consensus report.

---

#### Comments on measures not recommended

##### Comment By

Name: Marvin K. Acme, Jr.

Organization: Acme Corp.

Date - Time: Nov 03, 2010 - 12:54 PM

#### Comments

THIS IS A TEST. 11/3/2010. -JF

---

#### PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure

##### Comment By

Name: Ms. Gaye Fortner

Organization: HealthCare 21 Business Coalition

Date - Time: Nov 03, 2010 - 11:24 AM

#### Comments

As noted above, the ACS has a similar SSI measure that is recommended for endorsement. The population it covers does not completely overlap with the patient population that would make up the denominator for the CDCP measure, thus I



do think it is reasonable to potentially have both SSI measures endorsed, with a goal of harmonizing them within three years.

---

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery**

**Comment By**

Name: Ms. Gaye Fortner

Organization: HealthCare 21 Business Coalition

Date - Time: Nov 03, 2010 - 11:23 AM

**Comments**

As with the comments on the ACS SSI measure, I support endorsement of this measure, but as for confirmation that it will meet the public reporting requirement of the consensus development process.

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure**

**Comment By**

Name: Ms. Gaye Fortner

Organization: HealthCare 21 Business Coalition

Date - Time: Nov 03, 2010 - 11:21 AM

**Comments**

As with the CDCP SSI measure, this measure is risk-adjusted and meets the importance test, along with the other evaluation criteria. I support its endorsement.

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure**

**Comment By**

Name: Ms. Gaye Fortner

Organization: HealthCare 21 Business Coalition

Date - Time: Nov 03, 2010 - 11:21 AM

**Comments**

I fully support this CDCP measure, which is already being used by many states, as well as the Leapfrog Group, to determine and report the ratio of patients in a hospital experiencing an SSI to the national average.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

**Comment By**

Name: Ms. Gaye Fortner

Organization: HealthCare 21 Business Coalition

Date - Time: Nov 03, 2010 - 11:20 AM

**Comments**

*Central Line-Associated Blood Stream Infection:* This CDCP measure undoubtedly meets the importance criteria of the consensus development process criteria, as well as those of feasibility, usability, and scientific acceptability. The National Healthcare Safety Network (NHSN) system for collecting and using these data is one that many states have extensive experience with, and it has been well-tested. It has a respected risk-adjustment mechanism, and I believe that this measure is critical for improving patient safety in the hospital setting.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

**Comment By**

Name: Marvin K. Acme, Jr.

Organization: Acme Corp.

Date - Time: Nov 02, 2010 - 02:26 PM

#### Comments

THIS IS A TEST COMMENT (11022010) -AM

---

#### PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

##### Comment By

Name: Ms. Denise Graham

Organization: Association for Professionals in Infection Control and Epidemiology

Date - Time: Nov 02, 2010 - 02:00 PM

#### Comments

APIC supports the use of NHSN's Healthcare-associated Central line-associated Bloodstream Infection (CLABSI) Outcome Measure for ICUs displayed as a Standardized Infection Ratio as a Patient Safety Measure for NQF. Many states require reporting CLABSI rates using NHSN definition and methodology. Beginning 2011, CMS will require healthcare facilities to report CLABSI data and rates electronically through NHSN. CDC will select necessary rates to report/send on to CMS risk-stratified aggregate data in a standardized infection ratio (SIR) format. This will be timely and will allow states to compare healthcare facilities CLABSI outcome data within their states and to a national standard.

The SIR has been used for quite a while by CMS in reporting mortality rates as a Standardized Mortality Rate. Although the SIR is a relatively new CLABSI measure, CDC has made major educational efforts and needs to continue to do much as it did in May 2010 when it issued its first report of CLABSI rates as SIR composite scores. Scores were provided to all states last May particularly to states already mandated to report CLABSI infections, in order to help states make similar comparisons. APIC recommends NQF endorse the CLABSI SIR measure.

CDC's National Healthcare Safety Network (NHSN) (May, 2010). *First state specific healthcare-associated infections summary data report. January - June, 2009.*

---

#### PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery

##### Comment By

Name: Ms. Denise Graham

Organization: Association for Professionals in Infection Control and Epidemiology

##### On Behalf Of

Name: Denise Graham

Organization: APIC

Date - Time: Nov 02, 2010 - 01:50 PM

#### Comments

APIC does not support the proposed patient safety measure as suggested by the American College of Surgeons: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery.

Surveillance is performed on patients undergoing any of the listed CPT surgical procedures. The greatest risk factor for the patient acquiring a UTI is the indwelling urinary catheter. This measure does not adjust for the risk of exposure to catheters by utilizing urinary catheter days; rather the patient is risk-adjusted by virtue of having one of the listed CPT surgical procedures. The patient is observed for development of UTI for a period of 30 days. There are many medical reasons for a patient developing a UTI within 30 days of surgery that are not related to the surgical procedure. Many hospitals have no experience using this measure. To participate in the NSQIP hospitals must pay thousands as an annual participation fee. This does not include the

additional cost of an FTE to abstract information from the patient's health record and enter the data into the database. The eligible CPT codes do not include many of the proposed surgeries recommended for surveillance by CMS. This measure will add a tremendous burden to healthcare facilities that are required to report through NHSN as mandated by state law. APIC recommends that NQF not endorse this NSQIP measure.

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure****Comment By**

Name: Ms. Denise Graham

Organization: Association for Professionals in Infection Control and Epidemiology

**On Behalf Of**

Name: Denise Graham

Organization: APIC

Date - Time: Nov 02, 2010 - 01:48 PM

**Comments**

APIC does not endorse the proposed patient safety measure: American College of Surgeons Risk Adjusted Surgical Site Infection Outcome Measure for patients undergoing any of the specified list of eligible CPT surgical procedure codes. The use of this measure is not in alignment with CMS' proposed changes to the Hospital IPPS for Acute Care Hospitals. Many hospitals have no experience using this measure. To participate in the NSQIP hospitals must pay thousands for an annual participation fee. This does not include approximately the cost of a salary for one FTE to abstract information from the patient's health record and enter the data into the database. The eligible CPT codes do not include many of the proposed surgeries recommended for surveillance by CMS. This will ultimately be a tremendous burden to hospitals that receive funding from CMS.

APIC recommends that NQF not endorse the NSQIP SSI measure. Further, APIC does not support harmonization of this measure with CDC's SSI SIR measure.

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure****Comment By**

Name: Ms. Denise Graham

Organization: Association for Professionals in Infection Control and Epidemiology

**On Behalf Of**

Name: Denise Graham

Organization: APIC

Date - Time: Nov 02, 2010 - 01:46 PM

**Comments**

APIC endorses the proposed patient safety measure: NHSN's Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure using the Standardized Infection Ratio for patients in ICUs.

The greatest risk factor for a patient acquiring a UTI is an indwelling urinary catheter. CMS recognizes this in the SCIP measure, which requires the urinary catheter to be discontinued within 48 hours of surgery. Most hospitals in the United States use the NHSN definition when reporting their ICU CAUTI rates internally. Reporting rates to CDC (and/or states) electronically via NHSN with CDC reporting the risk-stratified aggregate data in a standardized infection ratio (SIR) format will be timely and will allow states to compare healthcare facilities CAUTI outcome data.

APIC recommends NQF endorse the CAUTI SIR measure.

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure****Comment By**

Name: Ms. Denise Graham

Organization: Association for Professionals in Infection Control and Epidemiology

**On Behalf Of**

Name: Denise Graham

Organization: APIC

Date - Time: Nov 02, 2010 - 01:44 PM

**Comments**

APIC supports the proposed Patient Safety measure utilizing NHSN's Surgical Site Infection (SSI) Outcome Measure utilizing the Standardized Infection Ratio of deep incision and organ/space surgical site infections among patients undergoing selected inpatient operative procedure categories. CMS has adopted the use of NHSN for surveillance of SSI for the Hospital Inpatient Prospective Payment System (IPPS) for Acute Care Hospitals for proposed fiscal year 2011 rates. The procedure categories are in alignment with CMS' SCIP procedure categories selected for its reporting initiative. This alignment supports healthcare facilities selection criteria of performing surveillance on high risk and high volume surgeries and will ultimately reduce the burden of data collection that is required. Many if not most hospitals in the United States use the NHSN definition for SSIs when reporting their rates internally. As noted, the SIR has been used for quite a while by CMS in reporting mortality rates as a Standardized Mortality Rate. However, the SSI SIR per procedure being a new SSI measure does require continued education by CDC much as it did in May 2010 when it issued its first report of CLABSI rates as SIR composite scores.<sup>1</sup> They were provided to all states last May particularly to states already mandated to report CLABSI infections, in order to help states make similar comparisons. APIC recommends NQF endorse the SSI SIR measure.

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure****Comment By**

Name: Ms. Denise Graham

Organization: Association for Professionals in Infection Control and Epidemiology

**On Behalf Of**

Name: Denise Graham

Organization: APIC

Date - Time: Nov 02, 2010 - 01:37 PM

**Comments**

APIC supports the use of NHSN's Healthcare-associated Central line-associated Bloodstream Infection (CLABSI) Outcome Measure for ICUs displayed as a Standardized Infection Ratio as a Patient Safety Measure for NQF. Many states require reporting CLABSI rates using NHSN definition and methodology. Beginning 2011, CMS will require healthcare facilities to report CLABSI data and rates electronically through NHSN. CDC will select necessary rates to report/send on to CMS risk-stratified aggregate data in a standardized infection ratio (SIR) format. This will be timely and will allow states to compare healthcare facilities CLABSI outcome data within their states and to a national standard.

The SIR has been used for quite a while by CMS in reporting mortality rates as a Standardized Mortality Rate. Although the SIR is a relatively new CLABSI measure, CDC has made major educational efforts and needs to continue to do much as it did in May 2010 when it issued its first report of CLABSI rates as SIR composite scores. Scores were provided to all states last May particularly to states already mandated to report CLABSI infections, in order to help states make similar comparisons.

APIC recommends NQF endorse the CLABSI SIR measure.

CDC's National Healthcare Safety Network (NHSN) (May, 2010). *First state specific healthcare-associated infections summary data report. January - June, 2009.*

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI)**

**Outcome Measure**

**Comment By**

Name: Ms. Denise Graham

Organization: Association for Professionals in Infection Control and Epidemiology

**On Behalf Of**

Name: Denise Graham

Organization: APIC

Date - Time: Nov 02, 2010 - 01:15 PM

**Comments**

APIC supports the use of NHSN's Healthcare-associated Central line-associated Bloodstream Infection (CLABSI) Outcome Measure for ICUs displayed as a Standardized Infection Ratio as a Patient Safety Measure for NQF. Many states require reporting CLABSI rates using NHSN definition and methodology. Beginning 2011, CMS will require healthcare facilities to report CLABSI data and rates electronically through NHSN. CDC will select necessary rates to report/send on to CMS risk-stratified aggregate data in a standardized infection ratio (SIR) format. This will be timely and will allow states to compare healthcare facilities CLABSI outcome data within their states and to a national standard.

The SIR has been used for quite a while by CMS in reporting mortality rates as a Standardized Mortality Rate. Although the SIR is a relatively new CLABSI measure, CDC has made major educational efforts and needs to continue to do much as it did in May 2010 when it issued its first report of CLABSI rates as SIR composite scores. Scores were provided to all states last May [\[1\]](#) particularly to states already mandated to report CLABSI infections, in order to help states make similar comparisons.

APIC recommends NQF endorse the CLABSI SIR measure.

---

[\[1\]](#) CDC's National Healthcare Safety Network (NHSN) (May, 2010). *First state specific healthcare-associated infections summary data report. January - June, 2009.*

---

**PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI)**

**Outcome Measure**

**Comment By**

Name: Mr. Jason A. Scull

Organization: Infectious Diseases Society of America

Date - Time: Nov 01, 2010 - 06:10 PM

**Comments**

The most controversial point about the this measure is that only a handful of states actually require validation of the reporting. As noted recently, states with validation had consistently higher standardized infection ratios (SIRS).

**Follow-Up**

Dear Dr. Pollock,

As previous mentioned, please see the following comment in order to help you prepare for the upcoming Patient Safety Measures Steering Committee call.

Thank you,

Jessica Weber  
NQF Research Analyst  
(202) 559-9533

---

**PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure**  
**Comment By**

Name: Mr. Jason A. Scull  
Organization: Infectious Diseases Society of America

Date - Time: Nov 01, 2010 - 06:09 PM

**Comments**

The most controversial point about the this measure is that only a handful of states actually require validation of the reporting. As noted recently, states with validation had consistently higher standardized infection ratios (SIRS).

**Follow-Up**

Dear Dr. Pollock,

As previous mentioned, please see the following comment in order to help you prepare for the upcoming Patient Safety Measures Steering Committee call.

Thank you,

Jessica Weber  
NQF Research Analyst  
(202) 559-9533

---

**PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**  
**Comment By**

Name: Mr. Jason A. Scull  
Organization: Infectious Diseases Society of America

Date - Time: Nov 01, 2010 - 06:08 PM

**Comments**

The most controversial point about the this measure is that only a handful of states actually require validation of the reporting. As noted recently, states with validation had consistently higher SIRs.

---

**Comments on the general draft report**

**Comment By**

Name: Mr. Jason A. Scull  
Organization: Infectious Diseases Society of America

Date - Time: Nov 01, 2010 - 06:07 PM

**Comments**

IDSA is generally supportive of the Patient Safety measures and does not think there is too much controversial here. CDC has already started using the standardized infection ratio (SIR) for reporting infection rates at the state level from NHSN and I don't think it is too controversial.

That said, the most controversial point about the CDC measures is that only a handful of states actually require validation of the reporting. As noted recently, states with validation had consistently higher SIRs.

---

**Comments on the general draft report**

**Comment By**

Name: Marion Kainer  
Organization: TDH

**On Behalf Of**

Name: Marion Kainer  
Organization: Council of State and Territorial  
Epidemiologists (CSTE)

Date - Time: Nov 01, 2010 - 05:11 PM

### Comments

The Council for State and Territorial Epidemiologists (CSTE) has read the proposed Patient Safety Measures PSM-001-10, PSM-002-10 and PSM-003-10 using the Standardized Infection Ratio (SIR).

CSTE is an organization of Member States and also a professional association with over 1,150 public health epidemiologists.

CSTE supports the use of the SIR as a summary measure. The SIR is a vast improvement over rates because it summarizes information in a manner that consumers can use much more readily than reviewing multiple rates. An example of this is difficulty in understanding and interpreting how a single neonatal intensive care unit (NICU) performs if rates were used (10 separate rates) compared to the single summary SIR that is able to risk-adjust for birth-weight and type of line.

State health departments recognize the value of the SIR as opposed to rates and believe that the SIR measure that CDC is proposing is much more easily understandable and user-friendly. The SIR is already in use, many health departments have used the SIR in their public reports of healthcare associated infections (HAI). States that have used the SIR in their reports include CO, MA, NH, NY, PA, SC and TN.

CSTE supports the use of SIR as a summary measure. Member States are already using the SIR, because it is a substantial improvement over current rates. We sincerely hope that NQF will endorse the SIR.

---

### PSM-003-10: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure

#### Comment By

Name: Dr. Barbara A. Rudolph, PhD, MSSW  
Organization: The Leapfrog Group

#### On Behalf Of

Name: Barbara Rudolph  
Organization: The Leapfrog Group

Date - Time: Nov 01, 2010 - 03:19 PM

### Comments

The Leapfrog Group is in support of endorsement of the CDC Catheter-associated urinary tract Infection outcome measure. The NHSN is a federal resource for hospitals to submit infection information to the CDC for aggregation and reporting. Over 28 states now have mandatory reporting for hospital acquired infections, which include UTI infections.

The measure is stratified by ICU location and excludes patients in NICUs. Comparisons are made within ICU types, but an overall rate is also calculated. The overall rate is a standardized infection ratio (SIR), which allows consumers, purchasers, and policy makers to see how the hospital has done overall, in terms of Catheter-associated urinary tract infections found in ICUs.

The measure is well-specified and hospitals are capable of following the specifications. The results are actionable by clinicians and ICU staff.

---

### Comments on the general draft report

#### Comment By

Name: Mr. Jim A. Schneiter, MBA  
Organization: AMS, Inc.

Date - Time: Nov 01, 2010 - 03:13 PM

### Comments

I'd like to make a recommendation to PSM 002 10, Section 1b.1 "**Benefits.**" My recommendation is to add, "*discontinued use of surgical instruments that have not been validated using AAMI Cleaning and Sterilization protocols,*" to the list of prevention activities following "*proper surgical site preparation.*"

No activity is more critical to preventing SSIs than ensuring clean, sterile, moisture-free instruments on every reprocessing cycle.

The FDA does not require surgical instrument manufacturers to submit Cleaning and Sterilization Validation Testing using protocols from the Association for the Advancement of Medical Instrumentation (AAMI) as part of their 510(k) new product

approval process. Accordingly, hospitals should request Validation test results from their instrument suppliers and stop using undocumented, non-validated instruments.

*"Healthcare facilities must start to demand from their instrument suppliers Cleaning and Sterilization documentation that has been validated by an independent testing laboratory utilizing AAMI's protocol."* (Jennifer Schraag, *Infection Control Today*, May 2006, "Designed To Kill?").

Discontinuing the use of all instruments (including 'take-aparts') that have not been Validated using AAMI protocols is the best way to reduce SSIs, patient morbidity and mortality.

Jim Schneiter

---

#### **PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure**

##### **Comment By**

Name: Dr. Barbara A. Rudolph, PhD, MSSW  
Organization: The Leapfrog Group

##### **On Behalf Of**

Name: Barbara Rudolph  
Organization: The Leapfrog Group

Date - Time: Nov 01, 2010 - 03:08 PM

##### **Comments**

The Leapfrog Group is in support of endorsement of the CDC Surgical Site Infection Outcome measure. The NHSN is a federal resource for hospitals to submit information to the CDC for aggregation and reporting. Over 28 states now have mandatory reporting for hospital acquired infections, several states mandate the reporting of the CDC standardized infection ratio (SIR).

The SIR calculation takes into account the observed number of SSI events and the expected number using national rates. The SIR allows consumers, national purchasers, and state and federal policy makers to see how the hospital has done overall, in terms of surgical site infections found in ICUs.

The measure is well-specified and hospitals are capable of following the specifications. The results are actionable by clinicians and hospital staff.

---

#### **PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure**

##### **Comment By**

Name: Dr. Barbara A. Rudolph, PhD, MSSW  
Organization: The Leapfrog Group

##### **On Behalf Of**

Name: Barbara Rudolph  
Organization: The Leapfrog Group

Date - Time: Nov 01, 2010 - 02:58 PM

##### **Comments**

The Leapfrog Group is in support of endorsement of the CDC Central-line associated Bloodstream Infection Outcome measure. The NHSN is a federal resource for hospitals to submit information to the CDC for aggregation and reporting. Over 28 states now have mandatory reporting for hospital acquired infections, many of the states utilize this measure.

In addition, the Leapfrog Group includes this measure in its Leapfrog Hospital Survey and reports the results on its free hospital comparison website, found at [www.leapfroggroup.org](http://www.leapfroggroup.org). In addition, the Consumers Union and The Commonwealth Foundation also report state and Leapfrog results for this measure.

This measure utilizes stratification by hospital ICU location and accounts for differences between teaching and non-teaching hospitals. The stratification is designed to account for differences in patient risk across types of hospitals and different ICU types. The CDC has developed a standardized infection ratio (SIR), which allows consumers, purchasers, and policy makers to see how the hospital has done overall, in terms of bloodstream infections found in ICUs.

The measure is well-specified and hospitals are capable of following the specifications. The results are actionable by clinicians and ICU staff.

---

#### **Comments on the general draft report**

##### **Comment By**

Name: Dr. Barbara A. Rudolph, PhD, MSSW  
Organization: The Leapfrog Group



Date - Time: Nov 01, 2010 - 02:58 PM

#### Comments

The Leapfrog Group is in support of endorsement of the CDC Central-line associated Bloodstream Infection Outcome measure. The NHSN is a federal resource for hospitals to submit information to the CDC for aggregation and reporting. Over 28 states now have mandatory reporting for hospital acquired infections, many of the states utilize this measure.

In addition, the Leapfrog Group includes this measure in its Leapfrog Hospital Survey and reports the results on its free hospital comparison website, found at [www.leapfroggroup.org](http://www.leapfroggroup.org). In addition, the Consumers Union and The Commonwealth Foundation also report state and Leapfrog results for this measure.

This measure utilizes stratification by hospital ICU location and accounts for differences between teaching and non-teaching hospitals. The stratification is designed to account for differences in patient risk across types of hospitals and different ICU types. The CDC has developed a standardized infection ratio (SIR), which allows consumers, purchasers, and policy makers to see how the hospital has done overall, in terms of bloodstream infections found in ICUs.

The measure is well-specified and hospitals are capable of following the specifications. The results are actionable by clinicians and ICU staff.

---

#### PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure

##### Comment By

Name: Mr. Jim A. Schneiter, MBA

Organization: AMS, Inc.

Date - Time: Nov 01, 2010 - 01:50 PM

#### Comments

I'd like to make a recommendation to Section 1b.1 "**Benefits.**" My recommendation is to add, "*discontinued use of surgical instruments that have not been validated using AAMI Cleaning and Sterilization protocols,*" to the list of prevention activities following "*proper surgical site preparation.*"

No activity is more critical to preventing SSIs than ensuring clean, sterile, moisture-free instruments on every reprocessing cycle.

The FDA does not require surgical instrument manufacturers to submit Cleaning and Sterilization Validation Testing using protocols from the Association for the Advancement of Medical Instrumentation (AAMI) as part of their 510(k) new product approval process. Accordingly, hospitals should request Validation test results from their instrument suppliers and stop using undocumented, non-validated instruments.

"Healthcare facilities must start to demand from their instrument suppliers Cleaning and Sterilization documentation that has been validated by an independent testing laboratory utilizing AAMI's protocol." (Jennifer Schraag, *Infection Control Today*, May 2006, "Designed To Kill?").

Discontinuing the use of all instruments (including 'take-aparts') that have not been Validated using AAMI protocols is the best way to reduce SSIs, patient morbidity and mortality.

Jim Schneiter

---

#### PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure

##### Comment By

Name: Mr. Jim A. Schneiter, MBA

Organization: AMS, Inc.

Date - Time: Nov 01, 2010 - 12:20 PM

#### Comments

I'd like to make a recommendation to Section 1b.1 "**Benefits.**" My recommendation is to add, "*discontinued use of surgical instruments that have not been validated using AAMI Cleaning and Sterilization protocols,*" to the list of prevention activities following "*proper surgical site preparation.*"

No activity is more critical to preventing SSIs than ensuring clean, sterile, moisture-free instruments on every reprocessing cycle.

The FDA does not require surgical instrument manufacturers to submit Cleaning and Sterilization Validation Testing using protocols from the Association for the Advancement of Medical Instrumentation (AAMI) as part of their 510(k) new product approval process. Accordingly, hospitals should request Validation test results from their instrument suppliers and stop using undocumented, non-validated instruments.

*"Healthcare facilities must start to demand from their instrument suppliers Cleaning and Sterilization documentation that has been validated by an independent testing laboratory utilizing AAMI's protocol."* (Jennifer Schraag, *Infection Control Today*, May 2006, "Designed To Kill?").

Discontinuing the use of all instruments (including 'take-aparts') that have not been Validated using AAMI protocols is the best way to reduce SSIs, patient morbidity and mortality.

Jim Schneider

---

#### Comments on the general draft report

##### Comment By

Name: Ms. Karen Reeves

Organization: South Carolina Hospital Association

Date - Time: Nov 01, 2010 - 11:52 AM

##### Comments

NQF's key role is to harmonize and align measures. We look to NQF to make a best-in-class determination and only endorse one SSI and one CAUTI measure.

---

#### PSM-002-10: National Healthcare Safety Network (NHSN) Surgical Site Infection (SSI) Outcome Measure

##### Comment By

Name: Mr. Jim A. Schneider, MBA

Organization: AMS, Inc.

Date - Time: Nov 01, 2010 - 11:49 AM

##### Comments

I'd like to make a recommendation to Section 1b.1 "**Benefits.**" My recommendation is to add, "*discontinued use of surgical instruments that have not been validated using AAMI Cleaning and Sterilization protocols,*" to the list of prevention activities following "*proper surgical site preparation.*"

No activity is more critical to preventing SSIs than ensuring clean, sterile, moisture-free instruments on every reprocessing cycle.

The FDA does not require surgical instrument manufacturers to submit Cleaning and Sterilization Validation Testing using protocols from the Association for the Advancement of Medical Instrumentation (AAMI) as part of their 510(k) new product approval process. Accordingly, hospitals should request Validation test results from their instrument suppliers and stop using undocumented, non-validated instruments.

*"Healthcare facilities must start to demand from their instrument suppliers Cleaning and Sterilization documentation that has been validated by an independent testing laboratory utilizing AAMI's protocol."* (Jennifer Schraag, *Infection Control Today*, May 2006, "Designed To Kill?").

Discontinuing the use of all instruments (including 'take-aparts') that have not been Validated using AAMI protocols is the best way to reduce SSIs, patient morbidity and mortality.

Jim Schneider

---

#### Comments on the general draft report

##### Comment By

Name: Mrs. Paula Levesque, RN

Organization: Beaumont Hospitals

Date - Time: Nov 01, 2010 - 10:02 AM

### Comments

*RE: Pursuant to section II.A of the Consensus Development Process v. 1.8, this document, is being provided to you at this time for purposes of comment on the NQF website for the NQF Hospital Acquired Infection measures: blood stream infections, surgical site infections and urinary tract infections.*

We have comments about the population base differences of the measures:

- The NHSN uses all identified cases in each strata, whereas for ACS NSQIP, hospitals have varying levels of population data.
- ACS-NSQIP has both general and vascular centers, as well as multispecialty. In our system we have both models. Additionally, our larger sites sample, while our smaller sites complete 100% of population. How will those differences be accounted for and/or accepted?
- Surgical Site Infection within NHSN also imposes a denominator challenge on institutions. In order to risk adjust, NHSN needs both ASA score and wound class of the entire surgical population. In a semi-electronic environment, this is impossible to provide electronically. This will impact both NHSN risk-adjustment and comparison.
- Lastly, we oppose any measure which would increase or retain ongoing labor intensive data collection. We recommend aligning measure to be acquired electronically or from claims data.

---

#### PSM-001-10: National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure

##### Comment By

Name: Mr. Jeff J. Maitland  
Organization: American College of Chest Physicians

##### On Behalf Of

Name: Jeffrey Maitland  
Organization: American College of Chest Physicians

Date - Time: Oct 26, 2010 - 09:11 AM

### Comments

*Approve with comments.* On behalf of the American College of Chest Physicians (ACCP) the ACCP Quality Improvement Committee (QIC) appreciates the opportunity to comment on this measure. The QIC approves this measure but would like clarification on why this particular method of outcome measurement was used, instead of tracking the total number of events/infections. The QIC would also like to see the evidentiary support for separating out neonatal intensive care unit patients from the rest of the population. The QIC also questions why this measure is restricted to the intensive care unit and not the hospital or healthcare system.

### Follow-Up

Dear Dr. Pollock,

As previously mentioned, please see the following comment in order to help you prepare for the upcoming Patient Safety Measures Steering Committee call.

Thank you,

Jessica Weber  
NQF Research Analyst  
(202) 559-9533

---

#### Comments on the general draft report

##### Comment By

Name: Dr. Michael J. Schuh, MBA, PharmD, BS  
Organization: Mayo Clinic Jacksonville

Date - Time: Oct 20, 2010 - 07:11 PM

### Comments

A simple, easily accessible system of notification should be in place for institutions to be able to retrieve frequently updated data on protocols and patterns of resistant pathogen identification to better prevent nosocomial infections at their own institution so they can be proactive about antibiotic stewardship. This system, if easy to use and accessible, would increase usage of the data and should provide better overall outcomes in all the stated areas targeted for improvement.

**Michael J. Schuh, BS, PharmD, MBA**

**Ambulatory Pharmacist**

**Assistant Professor of Pharmacy**

**School of Health Sciences**

**College of Medicine**

**Mayo Clinic Florida**

---

**PSM-007-10: Risk Adjusted Urinary Tract Infection Outcome Measure After Surgery**

**Comment By**

Name: Ms. Teresa Fulton, RN, MSN CIC

Organization: Whidbey General Hospital

Date - Time: Oct 13, 2010 - 05:34 PM

**Comments**

Most surgical procedures require a foley cath during the procedure so this measure encompasses a great many patients who are discharged from the hospital and capture of this data would be very difficult. NQF states this measure is best collected with an EMR- perhaps we need to wait on this measure until more hospitals have an EMR. Additionally NQF estimated the data collection time to be a .3FTE. This is 30% of my infection preventionist's time for 1 measure when we have state mandated surveillance and public reporting on top of running a sound infection prevention program in a critical access hospital. I do not feel this would be good use of the IP's time or resources. I applaud NQF's desire to reduce HAIs and feel these measures need to be balanced with state mandated measures as well as internally selected measures for improvement based on historical data.

---

**PSM-006-10: Risk Adjusted Surgical Site Infection Outcome Measure**

**Comment By**

Name: Ms. Teresa Fulton, RN, MSN CIC

Organization: Whidbey General Hospital

Date - Time: Oct 13, 2010 - 05:27 PM

**Comments**

For a small rural critical access hospital this measure is not feasible. There are 26 variables to collect on all surg patients that need to be included in the denominator- a daunting task with 1 FTE in infection prevention and a paper chart. NQF's time estimate is almost a .1 FTE which results in a huge bite from the IP's time. It does not harmonize with the SSI public reporting for the state of Washington.