NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Brief Measure Information

NQF #: 0138

Corresponding Measures:

De.2. Measure Title: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure

Co.1.1. Measure Steward: Centers for Disease Control and Prevention

De.3. Brief Description of Measure: Standardized Infection Ratio (SIR) of healthcare-associated, catheter-associated urinary tract infections (UTI) will be calculated among patients in bedded inpatient care locations, except level II or level III neonatal intensive care units (NICU).

This includes acute care general hospitals, long-term acute care hospitals, rehabilitation hospitals, oncology hospitals, and behavior health hospitals.

1b.1. Developer Rationale: The use of this measure will promote CAUTI prevention activities that will lead to improved patient outcomes including reduction of avoidable medical costs, and patient morbidity and mortality through reduced need for antimicrobials and reduced length of stay.

S.4. Numerator Statement: Total number of observed healthcare-associated CAUTI among patients in bedded inpatient care locations (excluding patients in Level II or III neonatal ICUs).

S.6. Denominator Statement: Total number of predicted healthcare-associated CAUTI among inpatient care locations under surveillance for CAUTI during the data period, based on the national CAUTI baseline Data is calculated using the facility's number of catheter days and the following significant risk factors:

- Acute Care Hospitals: CDC Location, Facility bed size, Medical school affiliation, and Facility type
- Critical Access Hospitals: Medical school affiliation
- Long-Term Acute Hospitals: Average length of stay, Setting type, and Location type
- Inpatient Rehabilitation Facilities: Setting type, Proportion of admissions with traumatic and non-traumatic spinal cord dysfunction, Proportion of admissions with stroke

S.8. Denominator Exclusions: The following are not considered indwelling catheters by NHSN definitions:

1.Suprapubic catheters

2.Condom catheters

3."In and out" catheterizations

4. Nephrostomy tubes

Note, that if a patient has either a nephrostomy tube or a suprapubic catheter and also has an indwelling urinary catheter, the indwelling urinary catheter will be included in the CAUTI surveillance.

De.1. Measure Type: Outcome

S.17. Data Source: Electronic Health Data, Electronic Health Records, Other, Paper Medical Records

S.20. Level of Analysis: Facility, Other, Population : Regional and State

IF Endorsement Maintenance – Original Endorsement Date: Aug 10, 2009 **Most Recent Endorsement Date:** Dec 10, 2015

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a health outcome measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data not available, data demonstrating wide variation in performance, assuming the data are from a robust number of providers and results are not subject to systematic bias. For measures derived from patient report, evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

Changes to evidence from last review

☐ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

☒ **The developer provided updated evidence for this measure:**

Updates:

- The developer identifies a number of prevention activities that can reduce the incidence of CAUTI. These include:
  - Appropriate catheter use
  - Proper techniques for urinary catheter insertion
  - Proper techniques for urinary catheter maintenance
- To support these practices, the developer cites a guideline from the Healthcare Infection Control Practices Advisory Committee (HICPAC): Guideline for Prevention of Catheter-Associated Urinary Tract Infections (2009) revised February 15, 2017.

Question for the Committee:

- *The evidence provided by the developer is updated, directionally the same, and stronger compared to that for the previous NQF review. Does the Committee agree there is no need for repeat discussion and vote on Evidence?*

Guidance from the Evidence Algorithm

Health outcome [Box 1] → Relationship between the measured health outcome and at least one healthcare action is demonstrated by empirical data [Box 2] → Pass

Preliminary rating for evidence: ☒ **Pass** ☐ **No Pass**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer provides national Standardized Infection Ratios (SIRs) for CAUTI in 2015, 2016, and 2017:
  - National Catheter-associated UTI SIR in 2015 is 0.993 = 28,712 observed / 28,910.634 predicted
  - National Catheter-associated UTI SIR in 2016 is 0.930 = 26,983 observed / 29,002.430 predicted
  - National catheter-associated UTI SIR in 2017 is 0.880 = 24,865 observed / 28,241.960 predicted
- The developer also reports that there was a 6% decrease in CAUTI between 2015 and 2016, and a 5% decrease between 2016 and 2017.

Disparities

- The developer reports that, among patients hospitalized with acute cardiovascular disease, pneumonia, and major surgery, Asian and Hispanic patients had significantly higher rates of HAIs than white, non-Hispanic patients.

Questions for the Committee:

- Is there a gap in care that warrants a national performance measure?

Preliminary rating for opportunity for improvement: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence

Comments:

**Updated information supplied. Link between measure intent and outcome is clear.

**no need for repeat discussion

**Agree there is no need for repeat discussion on evidence.

**Not aware of any new studies that changes the evidence base. Would like to see evidence on the rationale for excluding NICUs. There is not any mention in the measure application.

**updated evidence provided

**The developer provided some updated evidence

1b. Performance Gap

Comments:

**Disparity was demonstrated by population subgroups without any explanation of the cause.

**Gap remains

**Yes it demonstrates a gap in care. For Disparities, there is scant evidence provided and that evidence is meaningful but rather old. It would be ideal for the field to explore this further as recently there is evidence to suggest that a bias in voluntary reporting exists. Would the same types of bias apply to management of a urinary catheter?

**yes demonstrated gap

**There still appears to be some room for improvement,though at least one reviewer noted that it is not clear whether the remaining gap is "meaningful"

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Complex measure evaluated by Scientific Methods Panel? ☒ **Yes** ☐ **No**

Evaluators: NQF Scientific Methods Panel Subgroup

Methods Panel Review (Combined)

Evaluation of Reliability and Validity:

Scientific Methods Panel Votes: Measure passes

- Reliability: H-0, M-4, L-0, I-0
- Validity: H-0, M-3, L-1, I-0

This measure was reviewed by the Scientific Methods Panel and discussed on their call. A summary of the measure is provided below:

Reliability

- Reliability testing was performed at the data element level.
- Data Element
  - Data element validity testing was conducted, which NQF allows to serve as a demonstration of data element reliability.
  - The methods and results of data element validity testing are described in the validity section below.
  - There was some question from reviewers about the appropriateness of using data element validity testing to stand in for reliability testing. NQF reminded the subgroup that NQF allows this substitution.

Validity

- Validity testing was performed at the data element level.
- Data Element
  - The developer notes that the critical data elements of this measure have been validated by a number of state health departments that require mandatory reporting of CAUTI through the NHSN.
  - Data validation is conducted by trained auditors, who review medical records and determine whether facilities' identification of patients meeting CAUTI criteria were accurate.
  - Sensitivity, specificity, positive predicted value, and negative predicted value are calculated.
  - Validation results from 10 states are provided—the developers report that these validations indicated a pooled mean sensitivity of 88.1% (range: 50%-95.6%), specificity of 99.1% (range: 91.4% - 100%), positive predictive value of 94.4% (range: 84.6% - 100%) and negative predictive value of 97.9% (range: 91.4% - 99.8%).
  - Some reviewers expressed concern about the lack of measure score testing, given that this is a maintenance measure. NQF clarified that either empirical data element or score-level testing are acceptable validity testing methods for maintenance measures.
- The measure uses a statistical risk model with risk factors relevant to the facility type. No social risk factors applied in the modeling.
  - There was some concern that no statistical results (e.g., c-statistic) of model power were reported.

Standing Committee Action Item(s): The Standing Committee can discuss reliability and/or validity or accept the Scientific Methods Panel ratings.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

Preliminary rating for validity: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Methods Panel Evaluation (Combined): Scientific Acceptability

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 0138

Measure Title: NSHN National Healthcare Safety Network Catheter-associate Urinary Tract Infection (CAUTI)

Type of measure:

☐ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**
☒ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☐ **Composite**

Data Source:

☐ **Claims** ☒ **Electronic Health Data** ☒ **Electronic Health Records** ☐ **Management Data**
☐ **Assessment Data** ☒ **Paper Medical Records** ☐ **Instrument-Based Data** ☐ **Registry Data**
☐ **Enrollment Data** ☒ **Other**

Level of Analysis:

☐ **Clinician: Group/Practice** ☐ **Clinician: Individual** ☒ **Facility** ☐ **Health Plan**
☐ **Population: Community, County or City** ☐ **Population: Regional and State**
☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☐ **New** ☒ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☐ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

   ***NOTE**: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**

   Methods Panel member 1:None.

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☐ **Measure score** ☐ **Data element** ☒ **Neither**

   Methods Panel member 2:Data are drawn from NHSN database, which (apparently) is a nationally recognized source for these types of data (section 1.2).

4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure** ☐ **Yes** ☒ **No**

Methods Panel member 1: The measure is specified for Population (regional and state) and "Other," but only tested at the "hospital/facility/agency" level, specifically hospitals, long term acute care hospitals (LTACH), and inpatient rehabilitation facilities (IRF).

Methods Panel member 2:States that reliability testing was conducted (2.1), but I could not find any results of this testing. Section 2a2.2 states to look at section 2b1 for validity testing; 2a2.3 references 2b1.3 for reliability testing; 2a2.4 references 2b1.4 for reliability testing at either the score or date element levels. These referenced sections do provide reliability testing results.

5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

☒ Yes ☐ No

Methods Panel member 2: Systematic assessment of face validity (2b1); NOTE—as this is not the initial measure submission, face validity alone is not sufficient. Later section (2b1.3 does provide some level of validity with positive and negative predictive percentages (although the results for the latter are disturbing).

6. **Assess the method(s) used for reliability testing**

Submission document: Testing attachment, section 2a2.2

NQF Staff: Data element validity testing was conducted, which NQF allows to serve as a demonstration of data element reliability. The methods and results of data element validity testing are described in the validity section below.

Methods Panel member 2: Disorganization of how reliability information was presented could suggest a misunderstanding of the difference between reliability and validity as assessed at date element and performance score level

Methods Panel member 1:Data element reliability testing is described under validity (sections 2b1.2-4). Basically, state state health departments review medical records and look at the concordance with CAUTI infections documented in the statistics used in the measure. External validation across the 10 states consisted of 4,970 chart reviews

Methods Panel member 3:Note that MD sates in section sa2.2 that "As per NQF email "…data element validity testing may serve as a demonstration of data element reliability." Please see section 2b1.2 for demonstration of data element reliability.

Methods Panel member 4:Used data collected externally by 10 states to assess the reliability of the data elements.

7. **Assess the results of reliability testing**

Submission document: Testing attachment, section 2a2.3

Methods Panel member 1:These validations indicated a pooled mean sensitivity of 88.1% (range: 50%-95.6%), specificity of 99.1% (range: 91.4% - 100%), positive predictive value of 94.4% (range: 84.6% - 100%) and negative predictive value of 97.9% (range: 91.4% - 99.8%).

Methods Panel member 2:Source data are for all 50 states. However, only data from 10 states and "Overall" (aggregated across these 10 states) were presented. Why? Results presented in section 2b1.2 appear to be only at the Data Element and not the Performance Measure level for state health departments. The measure level specification (section 1.4) states "hospital/facility/agency" level. Additionally, Positive and Negative Predicitve Value operational definitions should be specified.

Methods Panel member 4:The sensitivity, specificity, PPV, and NPV were all high for the data collected in the 10 states.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

Submission document: Testing attachment, section 2a2.2

☐ **Yes**

☐ **No**

☒ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

Submission document: Testing attachment, section 2a2.2

☐ **Yes**

☐ **No**

☒ **Not applicable** (data element testing was not performed)

Methods Panel member 3:Data element validity testing was only performed for the outcome variable. However, the factors used in the risk adjustment model are all facility-level variables. Hence, it is reasonable to assume that these variables are valid.

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)

☒ **Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

☒ **Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

Methods Panel member 1:The application refers to an NQF email stating "…data element validity testing may serve as a demonstration of data element reliability." The methods described were appropriate and the results good, but since score-level testing was not conducted, Moderate is the highest eligible rating.

Methods Panel member 2:See previous comments regarding omissions, restriction of data analyzed, and/or possible confusion between reliability and validity.

Methods Panel member 3:Note that MD sates in sa2.2 that "As per NQF email "…data element validity testing may serve as a demonstration of reliability." Please see section 2b1.2 for demonstration of data element reliability

Methods Panel member 5:Outcome measure up for maintenance; note reliability testing for elements conducted and to see validity section; however, element validity testing and score face validity (not empirical validity) purportedly conducted.

Methods Panel member 4:Did not conduct score-level testing; data element testing in 10 states was robust and produced good results.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

Submission document: Testing attachment, section 2b2.

Methods Panel member 1:None.

Methods Panel member 3:There are no exclusions.

Methods Panel member 5:N/A

Methods Panel member 4:Not applicable.

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

Submission document: Testing attachment, section 2b4.

NQF Staff: The number of facilities that have SIRs that are either lower (~13.66%) or higher (~8.68%) than expected/predicted could be seen as relatively low.

Methods Panel member 2:There were no results presented for the "CAUTI SIR" performance measure. There are statements such as "**In some places where large scale CAUTI prevention programs have been implemented over the past several years, significant reductions in the CAUTI SIR have been seen, reflecting better quality. However, there are still facilities with significantly high CAUTI SIRs, indicating that they have not made progress in reducing CAUTI (high SIRs indicate poor quality)." (section 2b1.4)** with no numerical results presented to support this claim.

Methods Panel member 1:None.

Methods Panel member 3:I have no concerns. 14% of facilities were high-performing and 9% were low-performing, as defined by the SIR (analogous to OE ratio)

Methods Panel member 5:Note that "~8.68%" of faciltities may have an opportunity for improvement, which means ~91% don't; while CAUTI should never happen, there is not provided rationale of how meaningful this remaining difference is to performance. What impact is this gap having? How does it relate to the effort of this measure? Is this measure valuable enough to close this remaining gap?

Methods Panel member 4:No concerns. See variation in performance across facilities (13.66% were stat sig less than 1.0; 8.68% were stat sig bettern than 1.0)

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**

Submission document: Testing attachment, section 2b5.
Methods Panel member 1:None.
Methods Panel member 2:No empirical results submitted.
Methods Panel member 5:N/A
Methods Panel member 4:Not applicable.

15. **Please describe any concerns you have regarding missing data.**

Submission document: Testing attachment, section 2b6.

Methods Panel member 1:None.

Methods Panel member 2:Per information in this section--all data elements must be submitted.

Methods Panel member 3:No missing data, as per MD.

Methods Panel member 5:None

Methods Panel member 4:There are no mssing data, as facilities have to submit full numerators and denominators.

16. **Risk Adjustment**

16a. **Risk-adjustment method** ☐ **None** ☒ **Statistical model** ☐ **Stratification**

16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes ☐ No ☒ Not applicable

16c. **Social risk adjustment:**

16c.1 Are social risk factors included in risk model? ☐ Yes ☒ No ☐ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☒ Yes ☐ No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☒ No

Methods Panel member 3:MD states, without justification, that there is a "paucity" of evidence to support social risk factors inclusion. Since patient-level data is not collected (other than the outcome), it would be difficult for MD to test whether inclusion of social risk factors has an impact.

16d.**Risk adjustment summary:**

16d.1 All of the risk-adjustment variables present at the start of care? ☒ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☒ Yes ☐ No

Methods Panel member 2:The value to enter model (p=0.25) seems a bit high given the 27,251,517 urinary catherer days reported.

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☒ Yes ☐ No

Methods Panel member 2:No statistical results (e.g., c-statistic) of model power were reported

16d.5.Appropriate risk-adjustment strategy included in the measure? ☒ Yes ☐ No

Methods Panel member 2:Cannot determine without model results statistics.

16e**. Assess the risk-adjustment approach**

Methods Panel member 1:The SIR approach is well described and tested in the CDC document referenced.

Methods Panel member 2:Model development process is probably sound. Quality of model to predict results is not possible to evaluate given no empirical information on this question.

Methods Panel member 3:The risk modeling was conducted using negative binomial regression, in which risk factors were evaluated using univariate and multivariate modeling. The risk adj model only adjusts for ward versus ICU location (and type of ICU), teaching status, bed size, and facility type. It does not adjust for patient factors. The MD states that patient-level data is not collected in order to minimize data collection burden.
Facility performance is evaluated using Standardized Infection Ratio (SIR) – which is identical to OE ratio.
The MD also estimates the same model using a hierarchical framework in which facilities are specified as a random effect. Facility performance is then evaluated using the PE ratio (which they designate as an Adjusted Ranking Metric [ARM].
The MD state that model discrimination and calibration were performed using a combination of deviance, log likelihood and Akaike information criterion statistics. These statistics are useful for comparing nested models during model building, and for comparing alternative models. They are not very useful for assessing the performance of the final model. For example, in the case of logistic regression, there are generally well understood thresholds for what constitutes adequate values of the C statistic. This is not the case for the Akaike information criteria statistic. It would have been useful for the measure developer to provide calibration curves

Methods Panel member 5:Provided an empirical approach; however, would have liked to also have seen the rationale for theoretically adding the variables to be tested in the first place.

Methods Panel member 4:I could not find any informaiton on the discrimination and calibration

of the risk models.

VALIDITY: TESTING

17. **Validity testing level: ☐ Measure score ☒ Data element ☐ Both**

18. **Method of establishing validity of the measure score:**

☐ Face validity

☒ Empirical validity testing of the measure score

☒ **N/A (score-level testing not conducted)**

19. **Assess the method(s) for establishing validity**

Submission document: Testing attachment, section 2b2.2

Methods Panel member 1:The face validity of the CAUTI definition and criteria were assessed by the Healthcare Infection Control Practices Advisory Committee (HICPAC) Subject Matter Expert (SME) panel using Delphi process in a previous endorsement.

Methods Panel member 2:Data element level is probably sufficient; there were no empirical results provided for performance measure validity.

Methods Panel member 3:MD assessed the predictive validity of the risk adjustment model in development data using deviance, log likelihood and Akaike information criterion statistics. No calibration curves presented.

Methods Panel member 4:10 states validated the data elements used for the CAUTI measure. It appears as if they used a TEP for face validity of the measure scor, but this was poorly described.

20. **Assess the results(s) for establishing validity**

Submission document: Testing attachment, section 2b2.3

NQF Staff:

- Testing was conducted at the data element level.
- The developer notes that the critical data elements of this measure have been validated by a number of state health departments that require mandatory reporting of CAUTI through the NHSN.
- Data validation is conducted by trained auditors, who review medical records and determine whether facilities' identification of patients meeting CAUTI criteria were accurate.
- Sensitivity, specificity, positive predicted value, and negative predicted value are calculated.
- Validation results from 10 states are provided—the developers report that these validations indicated a pooled mean sensitivity of 88.1% (range: 50%-95.6%), specificity of 99.1% (range: 91.4% - 100%), positive predictive value of 94.4% (range: 84.6% - 100%) and negative predictive value of 97.9% (range: 91.4% - 99.8%).

Methods Panel member 1:Data element validation tests described above under reliability indicated a pooled mean sensitivity of 88.1% (range: 50%-95.6%), specificity of 99.1% (range: 91.4% - 100%), positive predictive value of 94.4% (range: 84.6% - 100%) and negative predictive value of 97.9% (range: 91.4% - 99.8%).

Methods Panel member 2:Data element level validity is probably sufficient; there were no empirical provided for performance measure validity

Methods Panel member 3:The model deviance, log likelihood and Akaike information criterion statistics are not adequate to assess validity of risk adjustment model. No testing was performed in a validation data set.

Methods Panel member 4:The results for the data element validity testing were very good (sensitivity, specificity, NPV, and PPV). It was unclear what the results were for the face validity.

21. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

Submission document: Testing attachment, section 2b1.

☐ **Yes** Methods Panel member 2: (for data elements)

☐ **No**

☒ **Not applicable** (score-level testing was not performed)

22. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?**

NOTE that data element validation from the literature is acceptable.

Submission document: *Testing attachment, section 2b1.*

☒ **Yes**

☐ **No**

☐ **Not applicable** (data element testing was not performed)

23. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

☒ **Low** (NOTE: Should rate LOW if you believe that there are threats to validity and/or relevant threats to validity were not assessed OR if testing methods/results are not adequate)

☒ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

24. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

Methods Panel member 1:The methods described were appropriate and the results good, but since score-level was not conducted, Moderate is the highest eligible rating.

Methods Panel member 2:Given that this is a resubmission for a performance measure, the rating probably should be either Low or Insufficient given that no performance measure results (neither general descriptive nor meaningful differences at the proposed measurement level—hospital/facility) were provided.

Methods Panel member 3:MD tested sensitivity, specificity, PPV and NPF of outcome variable (CAUTI) by re-abstracting data using trained auditors. Pooled mean sensitivity was 88%, specificity 99%, PPV 94.4%, and NPV of 98%. NQF does not have thresholds for acceptable levels for sensitivity, specificity, PPV, and NPV. These values are, in my opinion, acceptable levels.

As per NQF criteria, a measure can be deemed scientifically valid if data reliability and data validity testing is provided. NQF provided guidance to MD that data validity testing incorporates data reliability testing. This guidance is reasonable. However, this is a risk-adjusted measure, and the risk-adjustment model was not adequately tested. In particular, no testing was performed in a validation data set. This is an important threat to validity. Hence, I assigned "low" to overall measure of validity. In addition, there was no attempt to support the decision to not include any measure of social risk in the risk adjustment model – other than to state that there is a "paucity of evidence." At a minimum, the MD needs to describe the evidence and make an argument as to why there is a "paucity of evidence."

Methods Panel member 5:Outcome measure up for maintenance; note reliability testing for elements conducted and to see validity section; however, element validity testing and score face validity only, no empirical validity conducted. Additionally, no maintenance analyses reported, simply noted that the panel didn't make any changes to the definitions, so they are therefore valid. Some 2015 data from last submission are still included.

Methods Panel member 4:Given the lack of information on discriminaton and calibration, it is not clear about the appropriateness of the risk adjustment models.

ADDITIONAL RECOMMENDATIONS

25. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

Methods Panel member 2:Perhaps the measure developer has the missing information (e.g., performance measure and risk adjustment model performance) and was—for some reason—unaware that s/he was supposed to provide this in the form.

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability – Specifications

Comments:

** Reliability data are moderate, with suppled testing assessments at the element level.

** How are yeast infections handled?

** Moderate reliability

**No concerns

**None

**No concerns

2a2. Reliability – Testing

Comments:

**No concerns

**Reliability seems OK, but are paper records still reliable?

**No concerns

**Appreciate the data on independent verification of application of the definitions of the measure.

**seems as though the methods panel could not agree - but i dont have any concerns with reliability

**No

2b1. Validity –Testing

Comments:

** No. Others had analytic questions, but I do not have any concerns.

**No concerns

**No

**No

** methods panel again did not agree but validity testing seems appropriate

**No

2b4-7. Threats to Validity
2b4. Meaningful Differences

Comments:

** This maintanence mesaure meets moderate and above thresholds for all of these features, and the measure appears to have impact on care and outcomes. I see no other pervasive threats.

** Social risk adjustment was indicated 'none' but there was a model suggested for this.

**no

**no concerns

**none

** There does not appear to be any problem with these areas

2b2-3. Other Threats to Validity
2b2. Exclusions
2b3. Risk Adjustment

Comments:

** Social adjustment not used; other adjustments have basis and appear reasonable. No concerns.

**No comment

**Appropriate

**No concerns

** agree with scientific panel that risk adjusted model is not fully tested

**No concerns

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- Data for the measure are collected through the National Healthcare Safety Network (NHSN) using a set of standardized forms.
- The developer reports that CAUTI and catheter days (the numerator and denominator) must be collected by trained hospital staff from information available in clinical data sources.
- The developer notes that some of the data used in the measure can be mined from electronic sources, adding that NHSN is moving towards an electronically captured CAUTI measure for future use. However, development and testing is not complete at this time.

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?
- Is the data collection strategy ready to be put into operational use?

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility

Comments:

**No concerns

** Use of paper records seems unnecessary. How have paper-based results compared with electronic sources in the past.

** In use

** In use today, no issues

**No concerns

**No concerns

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☐ **Yes** ☐ **No**

Accountability program details

- The measure is used in several accountability programs, including:
  - Hospital Inpatient Quality Reporting Program (HIQR)
  - Hospital Value-Based Purchasing
  - Hospital-Acquired Condition Reduction Program (HACRP)

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- The developer notes that SIR results are available to NHSN users at any time, based on their current data entry. Data provided within the analysis report includes numerator, denominator, SIR, p-value, and 95% confidence interval. Educational materials are available on the NHSN website that explain each data element.
- Based on results from a polling survey, hospitals have indicated that they are running SIR analysis reports within NHSN on a monthly basis, and that they use SIRs for prevention activities in their hospital. State health departments are using the SIR for public reporting purposes and to help target facilities for additional prevention. Feedback was received via email regarding the extent of risk adjustment and the limitations.

***Questions for the Committee**:*

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The developer refers to trend data provided in section 1b
- The developer states that, combined with declining non-yeast CAUTI SIRs, which change in relation to the number of CAUTIs per urinary catheter days, declines in the device (i.e. urinary catheter) use highlight the net benefit to patients afforded by both safer and reduced urinary catheter use. Reducing unnecessary urinary catheter use is a key prevention strategy for CAUTI.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency

Comments:

** Widely reported and used in multiple qulaity assessment activities; change in outcomes that are piositive speak to impact and knowledge of measure/activity to respond.

**Pass

**Yes

** Well implemented measure that has led to meaningful improvement. Please strongly consider inclusion of Neonatal ICUs in the next cycle.

**No concerns

** Currently used in accountability programs across a few different provider types

4b1. Usability – Improvement

Comments:

** Limited harm information supplied, but benefits discussed and link to measure.

** What organisms are associated with infections in facilities that have too many CAUTIs?

** In use and reported.

** Well established and meaningful measure.

**No concerns

** I believe this measure is still usable to improve quality

Criterion 5: Related and Competing Measures

Related or competing measures
N/A
Harmonization
N/A

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing

Comments:

**None

**None

**No

**None

**No concerns at this time

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 6/5/2019

- **Of the 2 NQF members who have submitted a support/non-support choice:**
  - 1 support the measure
  - 1 do not support the measure

Public Comments (31 comments)

**The NQF is to be commended for this medication to Quality Improvement in health care, as well as a strong commitment to patient–centereness, consensus–building, and protection of vulnerable populations. Foley catheter removal in patients with neurogenic bladder due to Spinal Cord Injury (SCI) can have extremely negative consequences on genitourinary system health and function, and places patient's an undue risk of life–threatening outcomes such as renal failure and autonomic dysreflexia. Additionally, Foley removal carries important implications regarding independence, quality of life, and transition from hospital to home. Furthermore, the benefit of reducing Foley–related UTIs is tempered by increased risk of UTIs due to intermittent catheterization, which go unmeasured.

These complexities are acknowledged in clinical practice guidelines from the Consortium for Spinal Cord Medicine, the American Urological Association, and the CDC. Given these guidelines–driven principles, it is unreasonable to require the healthcare providers for this small patient population produce definitive proof of harm from a quality measure for a careful analysis of risk and benefits is done.

As a healthcare professional who cares for patients with SCI, I'm requesting that the NQF work to create better alignment between the financial incentives and SCI–specific recommendations in evidence–based clinical practice guidelines.

**ARN has previously commented the CAUTI Outcome Measure, joining with the American Spinal Injury Association, United Spinal Association, and Academy of Spinal Cord Injury Professionals, in a December 11, 2017 letter requesting additional studies from acute care hospials in bladder management in SCI. ARN expressed concern that non-specialty hospitals would not have the requisite competency in dealing with conditions like neurogenic bladder.

ARN is still in agreement with the December 11, 2017 letter we submitted. We respectfully request additional data collection from SCI centers with direct oversight from the NQF in order to continue to study the CAUTI Outcome Measure.

**I am both supportive and applaud Matt Davis for his efforts and advocacy to exclude the diagnosis of spinal cord injury/Neurogenic bladder from Quality Measure 0138 to allow for the proper care of spinal cord injured patients. I have been involved in the care of patients with spinal cord injury both in the ICU and acute rehabilitation settings for over a decade, and after the “pay for performance” model arrived I have noticed an increase in the inappropriate care of the bladder of persons with spinal cord injury in efforts to comply with guidelines. I believe that this is diametrically opposite to best practices and best patient care as outlined below in SCI guidelines. I have witnessed the deleterious results and damage to the urological system when physicians directly try to keep to this guideline without understanding the ramifications on the patient and patient population.The benefit of earlier catheter withdrawal has merits in many patient populations but I am hopeful that the NQF will see that a one size fits all policy may not only be ineffective for the neurogenic bladder but does cause harm for this specific patient population.

**I am submitting this letter electronically in order to remind the Committee of the letter we sent last year. This letter was signed by representatives from professional societies of virtually every healthcare discipline that works with SCI, and we have asked for a thorough, transparent review of the risks and benefits of including them in this current form of surveillance. You will see that 7 of the 10 organizations represented here are also institutional members of the NQF.

RE: NQF Measure 0138 and patients with Spinal Cord Injury

Dear Dr. Agrawal and Ms. Munthali:

On behalf of the undersigned interdisciplinary organizations representing individuals with spinal cord injuries (SCI) and the professionals (physicians, researchers, nurses, therapists and mental health professionals) who care for them, we are requesting that the NQF conduct a review of the risks and benefits of Quality Measure 0138 for SCI patients and consider downgrading it to conditional endorsement status.

In the spring of 2014, care providers of patients with SCI reported a surge in unsafe bladder management practices soon after the transition toward “Pay for Performance” status of the National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure. These practices include indiscriminate removal of Foley catheters in non-specialty hospitals, with little understanding of the importance of intermittent catheterization volumes, patient independence, bladder compliance, and overflow incontinence in SCI patients. This incomplete understanding has led to undiagnosed Autonomic Dysreflexia (AD) and UTIs related to bladder overdistension and retained urine. Bladder overdistension is

the leading cause of AD,[1] which leads to hypertensive emergency and potentially life-threatening consequences. Understanding of the recognition and treatment of AD has been shown to be quite limited among non-specialty healthcare providers,[2,3,4] and we have data from a Level I trauma center demonstrating 57% of intermittent catheterization volumes exceeding the maximum recommended by published guidelines. These patients demonstrated blood pressures consistent with AD.

SCI providers also raised concerns about the validity of this measure's definition of UTI for these patients. The NHSN definition of UTI includes symptoms of suprapubic tenderness, flank pain, and fever. SCI patients typically have impaired sensation in the suprapubic and flank areas, and thermoregulation is altered in this patient group.[5] Hence, we have reason to believe that the benefits of this particular type of surveillance have been overestimated for SCI, as demonstrated by a poor sensitivity (42%) and a high false-positive rate (58%) for the NHSN definition of UTI in SCI patients seen in data from an SCI center. This unpublished data corroborates the findings of previous published work.[6,7]

It is well established that the duration of indwelling catheterization is directly related to risk for developing UTI. Therefore, expeditious Foley removal is a mainstay of CAUTI prevention,[8,9] and is one of the most evidence-based strategies hospitals can use to reduce their CAUTI Standardized Infection Ratio. Since Quality Measure 0138 is included in Medicare's Quality Reporting and Value-Based Purchasing programs, and is subject to public reporting through Medicare's Hospital Compare website, non-specialty hospitals now have financial and public reporting incentives to remove Foleys and assume care over neurogenic bladder in SCI – a competency which is not widely taught outside of SCI centers.

Soon after we raised our concerns in 2014, the NQF connected us with the measure developers, for which we are grateful. We arranged for two separate informal phone conferences between the measure developers and some highly-respected members of the SCI academic community. These discussions did not occur with NQF oversight, and we did not reach any mutually satisfactory conclusions. To our knowledge, no minutes were taken at these meetings. Furthermore, subsequent Measure Summaries submitted to the NQF by the measure developers contained no mention of our concerns in section 4c – the section concerning "unintended consequences to individuals or populations." This informal process lacked the organized structure, transparency, and accountability that is characteristic of the NQF.

When SCI providers approached the Joint Commission with similar concerns regarding their CAUTI National Patient Safety Goal (NPSG), the Joint Commission assigned two people to conduct an investigation, meet with SCI experts, and produce a written report. The findings of this investigation culminated in changes to the CAUTI NPSG that acknowledge these safety concerns and recognize the important role that indwelling catheters play in safely managing SCI neurogenic bladder.

Despite the changes to the CAUTI NPSG that took effect last January, the problems our members are seeing in acute care hospitals continue unabated, and financial incentives remain unchanged. We believe this issue is worth revisiting – this time with data that has been collected from SCI centers. This time, however, we are requesting the direct oversight and wisdom of the NQF, along with its characteristic organization, transparency, and accountability.

We hope that you agree that this situation merits a more structured approach. We are open to any intervention that

addresses our concerns about patient safety, that conforms with Clinical Practice Guidelines regarding selection of

bladder management method,[10] and that has a reasonable chance of success. This could include the development of an alternative quality measure that more specifically addresses quality of care in bladder management in SCI. If you have further questions or wish to reply to this letter, please feel free to reach out to Dr. Matthew Davis, who serves as the chair of the advocacy committees of ASIA and ASCIP and who has been involved in this issue from the beginning.

Sincerely, [co-signers listed below]

Keith Tansey, MD, PhD
President

American Spinal Injury Association
Jeffrey Johns, MD
President

Academy of Spinal Cord Injury Professionals
Matthew Davis, MD
Chair, ASIA HPAC Vice President, Government Relations
Chair, ASCIP Advocacy Committee United Spinal Association

Alexandra Bennewith, MPA
Vice President, Government Relations

Supporting Organizations:
William J. Maloney, MD
President
American Academy of Orthopaedic Surgeons

Scott Laker, MD
Chair, Quality, Practice, Policy and Research Committee
American Academy of Physical Medicine & Rehabilitation

Neil Harvison, PhD, OTR/L, FAOTA
Chief Professional Affairs Officer
American Occupational Therapy Association

Katy Neas, APTA
Executive Vice President of Public Affairs
American Physical Therapy Association

J. Stuart Wolf, MD
Chair, Science & Quality Council

American Urological Association

John Chae, MD

President

Association of Academic Physiatrists

Karion Gray Waites, DNP FNP-BC MSN RN CRRN

President

Association of Rehabilitation Nurses

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1) The Consortium for Spinal Cord Medicine Clinical Practice Guideline. Acute management of autonomic dysreflexia: individuals with spinal cord injury presenting to health-care facilities. J. of Spinal Cord Medicine, 2002, volume 25, supplement 1, pages S68-S88.

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4) Krassioukov A, Tomasone J, Pak M, Craven C, Ghoti M, Ethans K, Ginis K, Ford M, Krassioukov-Enns D. "The ABCs of AD": A prospective evaluation of the efficacy of an educational intervention to increase knowledge of autonomic dysreflexia management among emergency health care professionals. J Spinal Cord Med 2016;39(2):190-196.

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Implementation Guide: Links to Example Resources. (2017, December 1). Retrieved from

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10) Consortium for Spinal Cord Medicine. Bladder management for adults with spinal cord injury: a clinical practice guideline for health care providers. J Spinal Cord Med. 2006; 29(5): 537-73.

**Based on my experience practicing as an SCI Medicine physician for 23 years, providing care to patients with acute and chronic SCI, I have concerns about inappropriate discontinuation of indwelling urinary catheters. An indwelling catheter is sometimes the most appropriate option for long-term management of neurogenic bladder. This is particularly true when a patient with tetraplegia and limited hand function would be dependent on others to perform intermittent catheterization. This adds an extra burden of caregiver assistance that must be available at various times throughout the day and night. This need for care is a potential barrier to employment or school, whereas most patients with indwelling catheters can be

independent for 8 or more hours before needing to empty a urinary collection bag. In the SCI population with neurogenic bladder dysfunction, the benefits of intermittent catheterization over indwelling catheters are minimal at best (urethral complications), and intermittent catheterization introduces other risks and greatly increases the chances of urinary incontinence which negatively affects quality of life. Research performed by myself and colleagues at the University of Washington demonstrates that 20% of individuals with SCI who use intermittent cathterization experience urinary incontinence weekly or more frequently (Stillman M, Hoffman J, Barber J, Williams S, Burns SP. Bladder management and related complications after spinal cord injury over the first year after discharge from inpatient rehabilitation. Spinal Cord Case Series 2019 [in press; accepted 28 sept 2019]). Incontinence is frequently a barrier to participation in community activities. Intermittent catheterization in this population has not been demonstrated to have a lower risk of urinary tract infections, and a large percentage of people with SCI who perform intermittent catherization have chronic colonization of the bladder with bacteria. Risks of renal stones and bladder cancer are also not significantly different between patients with SCI using indwelling vs. intermittent catheterization. The big push to discontinue indwelling catheters, leaving patients with inadequate bladder drainage, has negatively affected patients with acute and chronic SCI who I have treated. There is potential to cause renal failure when catheters are inappropriately removed. Due to the high prevalence of asymptomatic bacteriuria in this population, plus the potential for negative consequences on health and quality of life if a catheter is inappropriately removed, it would be most appropriate for patients with SCI and neurogenic bladder dysfunction to be excluded from any quality measure involving indwelling catheters. These statements are in alignment with clinical practice guidelines from the Consortium for Spinal Cord Medicine, the American Urological Association, and the CDC. As a healthcare professional who treats patients with acute and chronic SCI, I am requesting that NQF work to create better alignment between the financial incentives and SCI-specific recommendations in evidence-based clinical practice guidelines.

**as an SCI physicain in a freestanding rehab facility affiliated with a level 1 trauma center we see a number of acute SCI injuries admitted to our facility - unfortunately the ones with acute renal failure as an additional diagnosis - due to the foley being removed in the acute hospital are upsetting to all of us that parctice SCI medicine - as I type this we have one such example currently in our hospial now - and this is not uncommon to this population with the CAUTI measures as they are written currently - while I agree with removing indwelling catherters to prevent infections etc- I would strongly urge you to reconsider the Spinal Cord Injury population - - the neurogenic bladder is a special diagnosis - and should be treated as such - I applaud Dr. Matt Davis and his efforts addressing this issue.

**Our hospital is very adament about removing indwelling catheters early in patient care and do not want to have them if possible due to the risk of having a CAUTI and a documented CAUTI at that. As a nurse that works primarily with patient's with a spinal cord injury, I witness many issues in the acute phase of care with the catheter being removed. Patient's with neurogenic bladder should not be under the same umbrella of care as those with temporary retention issues or non-neurogenic needs.

The current issue that I run into is that the catheters are removed very early in care due to the CAUTI outcome measure tracking but most of our services are not familiar enough with neurogenic bladder in order to have a proper management plan in place to follow the removal. We have a new urinary catheter removal protocol and algorithm but it is still new and requires that a "plan" be made at the 24 hr mark post removal. Most times an adequate bladder management plan is not made or cathters are being replaced and then removed again, or an intermittent straight catheter schedule may be started but not written appropriately.

I try to advocate for these patients to keep their catheters in place if they are not going to be able to be independent in their own bladder management plan, if they are still in the acute phase of recovery (on the vent, in ICU with fluids being given, etc) and if they are just not mentally ready to tackle this new life change so early in a traumatic injury. Patients with higher levels of injury are also at risk for Autonomic Dysreflexia and by removing these catheters in patient's who cannot manage their own bladders, we are putting them at significant risk for harm. The biggest argument I recieve for removing catheters is the risk of CAUTI's. This patient population should not be in the same outcome measure bundle as the rest of the population. I believe we do these patient's more harm than good by having them in this bundle.

**APTA does support this measure, however, we believe that NQF and the CDC should modify this measure to exclude patients with spinal cord injury. Foley catheter removal in patients with neurogenic bladder due to Spinal Cord Injury (SCI) can have extremely negative consequences on genitourinary system health and function, and place patients at undue risk of life-threatening outcomes such as renal failure and autonomic dysreflexia. Additionally, Foley removal carries important implications regarding independence, quality of life, and transition from hospital to home. Furthermore, the benefit of reducing Foley-related UTIs is tempered by increased risk of UTIs due to intermittent catheterization, which go unmeasured.

These complexities are acknowledged in clinical practice guidelines from the Consortium for Spinal Cord Medicine, the American Urological Association, and the CDC. Given these guideline-driven principles, it is unreasonable to require that healthcare providers for small patient populations produce definitive proof of harm from a quality measure before a careful analysis of risks and benefits is done.

As a healthcare profession who cares for patients with SCI, we are requesting that the NQF work to create better alignment between the financial incentives and SCI-specific recommendations in evidence-based clinical practice guidelines.

**The American Association on Health and Disability and the Lakeshore Foundation encourage the NQF to review the risks and benefits of existing and proposed modifications to the CAUTI measure #0138. There appears to be consensus among the three national associations focused on persons with spinal cord injury regarding the approach to CAUTI. Matt Davis, M.D., University of Texas Health Science Center at Houston works closely with these 3 national associations as well as numerous rehabilitation professionals, and has previously submiited comments. Thank you for your consideration. Clarke Ross for both AAHD & Lakeshore Foundation

**The CDC has a straight forward mechanism to improve the CAUTI standard by removing Spinal Cord Injury (SCI) from aggregated data. There is precedent for this improvement in that the CAUTI accreditation standards for the Joint Commission have removed SCI from aggregate reporting. I would encourage the CDC to be open to input from that community of clinicians who have witnessed specific harm arising from the CAUTI standard in the subset of patients with SCI.

The failure of the CDC is to recognize that CAUTI data does not quantify the danger of urinary catheters equally across all populations. This is particularly concerning for rare diseases with different pathophysiology such as Spinal Cord Injury. The CDC has created an unfunded mandate to adopt an objectively dangerous standard for patients with rare neuromuscular diseases. Hospitals are forced to disclose aggregated CAUTI cases for disease conditions such as SCI which they may encounter less than once per year in a specific acute trauma unit. For the individual hospital, the resources required to appropriately manage patients with SCI related neurogenic bladder do not rise to the level of significance necessary to

drive universal competency. However, for the individual with SCI removal of the catheter often spells acute renal insufficiency and occasionally death. The CDC should acknowledge that aggregated reporting of CAUDI is causing harm to patients with SCI and remove this condition from the current CAUTI reporting requirements.

**As a social worker in the outpatient setting, I focus on helping patients adapt to life outside of the hospital. Before they can return to work or school, they need to be able to independently manage their bladder. Intermittent catheterization is not practical in some circumstances due to clothing management, hand function, availability of attendant care or financial resources. Removal of the Foley can force dependence on patients when we are trying to teach them independence in the community.

I have several co-workers and patients working in the community that would be unable to maintain their current jobs without the use of an indwelling catheter in the workplace setting. They are tax-paying members of society, rather than being reliant on Social Security.

Our goal in rehabilitation is to support the transition to the next phase of their "new normal". Quality of life includes being able to independently manage your bladder as much as possible.

**Thank you Dr. Davis for your efforts in this area, and for your commitment to advocating for those with Spinal Cord Injury (SCI). As someone who practices at a tertiary care center, I routinely consult on acute SCI patients in the ICU and admit patients with SCI to our inpatient rehabilitation facility. I am quite sympathetic to this issue. Since CAUTIs have become a quality metric for inpatient care, I have noticed a trend toward the use of condom catheters for patients with SCI and neurogenic bladder who are transferred to our hospital. We have seen cases of autonomic dysreflexia and renal insufficiency from this practice. While it is important to minimize UTI risk, I would advocate for a more sophisticated approach in the care of SCI patients without volitional bladder control who are subsequently at high risk for bladder spasticity, autonomic dysreflexia, and renal deterioration if Foleys are removed without an appropriate bladder management strategy such as intermittent bladder catheterization (which is often not practical given high urine output volumes acutely after SCI, as well as a lack of feasibility for RN staff at most hospitals to perform intermittent caths every 4 hours). Hopefully, the CAUTI dilemma in SCI can be seen as an opportunity for policy-makers to guide appropriate clinical practice.

**Based on my 23 years as a spinal cord injury (SCI) medicine physician and my 35 years as a person with SCI, I concur with the comments from other SCI professionals. Indwelling catheters, while not our first choice, are sometimes the only viable option for certain subgroups of persons with SCI and some other causes of neurogenic bladder dysfunction. Removal of an indwelling catheter and placement of an external or "condom" catheter can put such persons at risk for a number of serious complications, including vesicoureteral reflux due to bladder outlet obstruction, leading to renal stone disease and/or kidney and upper urinary tract structural damage.

The SCI literature does not demonstrate evidence of superiority of intermittent catheterization in persons who require a caregiver to perform the technique. In fact, outcomes may be worse in this scenario, and quality of life, freedom and mobility can be hampered.

Further, insistence on intermittent catheterization could cause persons with SCI to be denied admission to health care facilities.

I recommend allowing justification of indwelling catheter use or making other accommodations for these persons.

**I have been fortunate enough to be recruited and serve in a facility that provides the only acute inpatient rehab for catastrophic diagnoses as SCI in the state of MS. It has not been uncommon to receive referrals and admissions for SCI patients who have been told and felt that they have been voiding on their own since their indwelling had been removed in acute care, only to realize that their 'spontaneous void' is the the result of overflow -- retaining a significant amount of urien that may eventually transform into frequent infections, pain (with bladder distention), and as stated in our advocacy statement, RENAL FAILURE. It is certainly scary to realize that many more patient have probably been sent home with the same perception and come back rehospitalized as a result of inadequate screening (bladder scan or at least a referral to urology) prior to discharge clearance.

I full heartedly support this advocacy program for more education and re-considerations for practices of a more inclusive bladder management practice for our spinal cord population patients.

**The NQF is to be commended for its dedication to Quality Improvement in healthcare, as well as its strong commitment to patient-centeredness, consensus-building, and protection of vulnerable populations. Foley catheter removal in patients with neurogenic bladder due to Spinal Cord Injury (SCI) can have extremely negative consequences on genitourinary system health and function, and place patients at undue risk of life-threatening outcomes such as renal failure and autonomic dysreflexia. Additionally, Foley removal carries important implications regarding independence, quality of life, and transition from hospital to home. Furthermore, the benefit of reducing Foley-related UTIs is tempered by increased risk of UTIs due to intermittent catheterization, which go unmeasured.

These complexities are acknowledged in clinical practice guidelines from the Consortium for Spinal Cord Medicine, the American Urological Association, and the CDC. Given these guideline-driven principles, it is unreasonable to require that healthcare providers for small patient populations produce definitive proof of harm from a quality measure before a careful analysis of risks and benefits is done.

**Our hospital is very adament about removing indwelling catheters early in patient care and do not want to have them if possible due to the risk of having a CAUTI and a documented CAUTI at that. As a nurse that works primarily with patient's with a spinal cord injury, I witness many issues in the acute phase of care with the catheter being removed. Patient's with neurogenic bladder should not be under the same umbrella of care as those with temporary retention issues or non-neurogenic needs.

The current issue that I run into is that the catheters are removed very early in care due to the CAUTI outcome measure tracking but most of our services are not familiar enough with neurogenic bladder in order to have a proper management plan in place to follow the removal. We have a new urinary catheter removal protocol and algorithm but it is still new and requires that a "plan" be made at the 24 hr mark post removal. Most times an adequate bladder management plan is not made or cathters are being replaced and then removed again, or an intermittent straight catheter schedule may be started but not written appropriately.

I try to advocate for these patients to keep their catheters in place if they are not going to be able to be independent in their own bladder management plan, if they are still in the acute phase of recovery (on the vent, in ICU with fluids being given, etc) and if they are just not mentally ready to tackle this new life change

so early in a traumatic injury. Patients with higher levels of injury are also at risk for Autonomic Dysreflexia and by removing these catheters in patient's who cannot manage their own bladders, we are putting them at significant risk for harm. The biggest argument I recieve for removing catheters is the risk of CAUTI's. This patient population should not be in the same outcome measure bundle as the rest of the population. I believe we do these patient's more harm than good by having them in this bundle.

**I support NQF's efforts to hold health care providers and health systems accountable for patient outcomes, but respectfully recommend the NQF include spinal cord injury consumers, providers, and professional organizations in the guideline development and revision process to identify whether this population may contain legitimate sub-groups that would qualify for an exception based upon best practice guidelines used in the field currently that are based upon the best possible medical knowledge of this unique population. For instance, some individuals who have selected a suprapubic catheter for bladder management may have to wait as an inpatient until this procedure is performed due to issues of access, scheduling, or medical stability (e.g. anticoagulation adjustment). An indwelling urethral catheter would be clinically appropriate until a suprapubic catheter could be placed for an individual who has had impaired kidney function and/or refractory autonomic dysreflexia caused by bladder distension in order to avoid elevated hydrostatic pressures in the bladder that may trigger autonomic dysreflexia or kidney injury. Yet, such a clear algorithmic approach based on an individual's clinical needs may be abrogated by the incentives created with broad application of the NQF measure across clinically diverse populations that currently include people with spinal cord injury. Thank you for the opportunity to comment and contribute to the NQF Outcome Measure process.

**The management of the neurogenic bladder following spinal cord injury has significant impact to the overal patient's health, quality of life, and funcitonal independence. Achieving the best clinical and functional outcome should be paramount when clinical decision making in this area occurs. Patient outcomes should be the primary considerantion for medical management of the neurogenic bladder - not generalized rules that do not focus on the unique clinical needs of patients with neurogenic bladder following spinal cord injury. Spinal Cord Injured patients must have their bladders managed with a holistic approach. Often, the foley is removed without consideration related to caregiver availability, funcitonal independence, and risk of secondary complications including autonomic dysreflexia. I like to say that spinal cord injuries are like snow flakes - no 2 are alike. In the same way - no two neurogenic bladders are alike. Please allow medical professionals to utilize their specialized training to ensure appropriate medical management of the neurogenic bladder. Please do not encourage facilities to discontinue the use of a foley catheter when they do not have a plan to manage the neurogenic bladder effectively. Patient's deserve the opportunity to make informed decisions after consulting with their primary medical team. Often times, a foley catheter provides increased independence, ability to be away from the home for >4 hours, allows return to work or school.

**Foley catheter removal in patients with neurogenic bladder due to spinal cord injury can have extrememly negative consequences on genitourinary system health and function and place individuals at undue risk of life threathening outcomes such as renal failure and autonomic dysreflexia. Additionally, Foley removal carries important implications regarding independence, quality of life and transition from hospital to home. Furthermore, the benefit of reducing Foley-related UTIs is tempered by increased risk of UTIs due to intermittent catheterization, which go unmeasured.

These complexities are acknowledged in clinical practice guidelines from the Consortium for Spinal Cord Medicin, the American Urological Association, and the CDC. Given these guideline driven principles, it is

unreasonable to require healthcare providers for small patient populations to produce definitive proof of harm from a quality measure before a careful analysis of risks and benefits is done.

As a healthcare professional who works daily with individuals with spinal cord injury I have seen the impact on quality of life when we allow for bladder management solutions that work for the individual. For example, the teenager who doesn't have the hand function and trunk control to perform clothing management and self intermittent catheterization who has a Foley and is now able to independently go off to college because they do not need mom or caregiver to assist them to the bathroom and perform intermittent catheterization throughout the day. Or the mom or whose pair shape and short weak arms limits her independence with transfers and clothing management to be able to perform self catheterization who, wiht a Foley, is able to independently stay at home and care for her toddler since she doesn't need a caregiver to assist her with toileting every 4 hours. Or the individual who did not have resources to hire a caregiver who was able to stay home safely and independently during the day while their spouse went to work to support the family because they had a Foley to manage their bladder. Or the patient with a high level spinal cord injury who had no hand function or ability to manage their bladder and who relied on a caregiver (their spouse) to perform 100% of their self care needs. Having a Foley reduced the burden on the caregiver to allow for more time to perform other daily care needs and allowed them the freedom to more easily leave their home and not be tied to a 4 hour catheterization schedule. And the list goes on. Every person with a spinal cord injury has a unique situation. And removal of a Foley is not always the best bladder management method. For some, removal of the Foley increases the burden of care, cost of care, risk of autonomic dysreflexia and even death.

I and my colleagues and our patients are requesting the NQF work to create better alignment between the financial incentives and spinal cord injujry specific recommendations in evidence based clinical practice guidelines.

**Monitoring of CAUTI outcomes is vital to the overall health and well-being of all patients currently served by our medical system, and the NQF is a leader in developing patient-centered practices. While developing these patient-centered practices, it is imperative to consider multiple populations, while maintaining awareness that some populations have more at stake than others. As an occupational therapist I work daily with patients on skills to increase their independence and quailty of life, as well asways they can maintain good health practices. For individuals with hand dexterity impairments, foley catheter removal in patients with neurogenic bladder due to Spinal Cord Injury (SCI) can have extremely negative consequences on genitourinary system health and function, and place patients at undue risk of life-threatening outcomes such as renal failure and autonomic dysreflexia. Additionally, Foley removal carries important implications regarding independence, quality of life, and transition from hospital to home. For individuals who are learning to complete "in and out" catheterization, there is increased difficulty maintaining a sterile environement, and therefore increasing risk of CAUTI which could be reduced by continuation of use of a foley. One patient in particular has been injured for 3 years, learned to complete intermittent catherization, and whose health care needs have been managed through outpatient appointments. This gentleman has limited use of his hands, and while he completes intermittent catheterization, he has experienced a period longer than 6 weeks without UTI. During times where he has had a foley catheter temporarily placed, his incidence of CAUTI was significantly reduced. This man's experience is an example of how the benefit of reducing Foley-related UTIs is tempered by increased risk of UTIs due to intermittent catheterization, which go unmeasured.

These complexities are acknowledged in clinical practice guidelines from the Consortium for Spinal Cord Medicine, the American Urological Association, and the CDC. Given these guideline-driven principles, it is

unreasonable to require that healthcare providers for small patient populations produce definitive proof of harm from a quality measure before a careful analysis of risks and benefits is done.

As a healthcare professional who cares for patients with SCI, I am requesting that the NQF work to create better alignment between the financial incentives and SCI-specific recommendations in evidence-based clinical practice guidelines.

**I applaud the NQF's desire to encourage accountability and incentivize internal quality improvement efforts to reduce the number of hospital-acquired UTIs. This is done by applying measures through federal programs that affect funding and ultimately incentivize facilities to optimize their "bladder bundles."

Since measure #0138 is a voluntary consensus standard that is implemented into federal programs, the National Technology Transfer and Advancement Act of 1995 (NTTAA), Executive Orders 13563 and 12866, and the OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, revised 2016, apply. These documents outline: (1) the process of review and (2) the criteria of a voluntary consensus standards that are incorporated into federal programs (i.e. measure #0138).

In terms of the process of review:

1. Procedures should provide meaningful opportunity and involvement of stakeholders, including "experts in relevant disciplines," to participate in standards development; and
2. The decision-making process should be transparent, including disclosures of the "agency's interactions with technical committees and/or technical advisory groups involved."

In terms of criteria, measure developers must consider:

1. "Best available science" and reasonably obtainable information;
2. Maximizing benefits and minimizing risks (both quantitative and qualitative); and
3. Logical reasoning with quantitative and qualitative information, recognizing that some benefits and risks are difficult to quantify.

Unfortunately, the processes and criteria listed above may have fallen short for the spinal cord injury population. People with spinal cord injury (SCI) are a unique and small proportion of our population that suffer from neurogenic bladder, resulting in unique needs for chronic alternative bladder management strategies. The National Spinal Cord Injury Statistical Center recognizes the annual incidence of SCI as approximately 54 cases per million population in the U.S. with approximately 282,000 persons alive in 2016 who have SCI. (National Spinal Cord Injury Statistical Center, Facts and Figures at a Glance. Birmingham, AL: University of Alabama at Birmingham, 2016.) Thus, although a small proportion, the SCI population is particularly affected by the incorporation of measure #0138 into federal programs, buttheir needs have not been adequately considered in the measure development process.

First, the SCI community is not meaningfully represented in the process of review of measure #0138. I did not see any physiatrist, spinal cord injury specialist, or neuro-urologist included in Healthcare Infection Control Practices Advisory Committee (HICPAC), the Ex-officio Members, Liaisons, or expert reviewers.

However, this could be rectified by including specialists of neurogenic bladder as expert reviewers such as physiatrists, spinal cord injury (SCI) specialists, and/or neuro-urologists. These specialists are intimately familiar with the nuances of neurogenic bladder and bladder of people with disabilities as they manage this on a regular basis. Moreover, the spinal cord injury specialty has long been studying the management of neurogenic bladder with eight English language clinical practical guidelines throughout the world that are "robust in stating their scope and clearly presenting recommendations," with three scoring over 70% in methodological rigor. (Bragge P, Guy S, Boulet M, et. al. A systematic review of the content and quality of clinical practice guidelines for management of the neurogenic bladder following spinal cord injury. Spinal Cord. April 10, 2019. https://doi.org/10.1038/s41393-019-0278-0). Physiatrists, SCI specialists, and neuro-urologists have the expertise to provide information on best available science as well as quantitative and qualitative information on the benefits and risks of measure #0138 as it applies neurogenic bladder management in SCI. Incorporating these specialists as expert reviewers is in line with both federal rules and NQF policy to gatherall stakeholder groups.

Second, disclosure as it relates to how measure #0138 affects the SCI community has been limited. The American Spinal Injury Association, Academy of Spinal Cord Injury Professional, and the United Spinal Association submitted a joint letter on December 11, 2017, but there is no mention of the agency's interaction with these associations. Furthermore, in the most recent iteration of measure #0138,there is no explanation as to how considering the "proportion of admissions with traumatic and non-traumatic spinal cord dysfunction" in the denominator will minimize any unintended consequences. Therefore, I recommendincluding disclosures of the agency's interactions with the above associations and clearly explaining how these changes in the denominator statement will limit unintended consequences.

Third, I am unsure that this measure maximizes net benefits and minimizes risks (both quantitative and qualitative.) Executive Order 13563 and 12866 both require quantitative and qualitative review of the costs and benefits of the measure. This includes both inclusions and exclusions to the measure. The CDC acknowledged that, "for patients with spinal cord injury, very low-quality evidence suggested a benefit of avoiding indwelling urinary catheters." (2009 Guideline for Prevention of Catheter-Associated Urinary Tract Infections, p. 34). Had they been confident that the benefits of avoiding indwelling catheters in SCI outweighed the risks, a "Category IB" recommendation would be appropriate. (p10) Instead, this was assigned "Category II" recommendation, acknowledging the "tradeoff between clinical benefits and harms," and indicating a lack of certainty of net benefit. Category II recommendations are "not intended to be enforced." (p32). Thus, in using the Category II designation, it seems clear that in 2009 the CDC lacked confidence of a favorable risk/benefit ratio in avoiding indwelling catheters in the SCI population. Therefore, it seems it violates federal law and rules to implement measure #0138 into federal programs in its current form.

Furthermore, to minimize risks and to understand the qualitative costs, the unintended consequences must be tracked. This is a significant concern especially in SCI as urinary stasis and overdistended bladders have significant and sometimes irreparable damage to our patient population. Because of the uniqueness of the SCI population, I emphasize the need to include specialists in physiatry, SCI, and/or neuro-urology to participate as expert reviewers to provide further information about any possible unintended consequences that should be tracked. These side effects are the qualitative costs of implementing measure #0138 and should be measured.

Finally, in considering the potential risks posed to SCI patients, Executive Orders 13563 and 12866 require consideration of qualitative input. This recognizes that some costs are difficult to quantify or not reasonably obtainable. Many unsafe conditions because of early removal of indwelling catheters are not expected to

manifest as adverse events until after hospital discharge, so it is unreasonable to limit measures of unintended consequences to only harm manifested during hospitalization. On the other hand, it may be costly for long range data collection on unintended consequences and thus, excluding SCI patients from measure #0138 may be practical. Likewise, patient-centered considerations about quality of life should be included in qualitative analysis. Furthermore, anecdotal reports of harm, near-misses, and strong potential for harm should carry weight in the decision-making process.

In conclusion, measure #0138 does not meet the required processes of review and criteria of NTTAA, Executive Orders 13563 and 12866, and the OMB Circular A-119. This would eliminate measure #0138 from incorporation into federal programs. This is unfortunate, as the goal to reduce the number of hospital acquired UTI is important. To ensure that federal laws and rules are followed such that measure #0138 can be incorporated into federal programs and to improve our joint effort to maximize our patients' health, I recommend the following:

1. Include physiatrists, spinal cord injury (SCI) specialists, and/or neuro-urologists as expert reviewers;
2. Thoroughly and transparently review both the costs and benefits of excluding SCI patients from measure #0138 as has been done for pediatric cases and provide this information to the public so that stakeholders have an opportunity to meaningfully participate in the voluntary standard development process;
3. Thoroughly and transparently evaluate the costs and benefits of incentivizing the reduction of hospital-acquired symptomatic UTIs for all alternative bladder management strategies, including indwelling catheters, suprapubic catheters, condom catheters, and "in and out" catheterizations, with input from stakeholders and experts in the field so that stakeholders have an opportunity to meaningfully participate in the standard development process;
4. Include spinal cord injury as an example of an appropriate indication for indwelling urethral catheter; and
5. Monitor and study qualitative costs of any unintended consequences of measure #0138.

**The NQF is to be commended for its dedication to Quality Improvement in healthcare, as well as its strong commitment to patient-centeredness, consensus-building, and protection of vulnerable populations. Foley catheter removal in patients with neurogenic bladder due to Spinal Cord Injury (SCI) can have extremely negative consequences on genitourinary system health and function, and place patients at undue risk of life-threatening outcomes such as renal failure and autonomic dysreflexia. Additionally, Foley removal carries important implications regarding independence, quality of life, and transition from hospital to home. Furthermore, the benefit of reducing Foley-related UTIs is tempered by increased risk of UTIs due to intermittent catheterization, which go unmeasured.

These complexities are acknowledged in clinical practice guidelines from the Consortium for Spinal Cord Medicine, the American Urological Association, and the CDC. Given these guideline-driven principles, it is unreasonable to require that healthcare providers for small patient populations produce definitive proof of harm from a quality measure before a careful analysis of risks and benefits is done.

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removal carries important implications regarding independence, quality of life, and transition from hospital to home. Furthermore, the benefit of reducing Foley-related UTIs is tempered by increased risk of UTIs due to intermittent catheterization, which go unmeasured.

These complexities are acknowledged in clinical practice guidelines from the Consortium for Spinal Cord Medicine, the American Urological Association, and the CDC. Given these guideline-driven principles, it is unreasonable to require that healthcare providers for small patient populations produce definitive proof of harm from a quality measure before a careful analysis of risks and benefits is done.

As a healthcare professional who cares for patients with SCI, I am requesting that the NQF work to create better alignment between the financial incentives and SCI-specific recommendations in evidence-based clinical practice guidelines.

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As a healthcare professional who cares for patients with SCI, I am requesting that the NQF work to create better alignment between the financial incentives and SCI-specific recommendations in evidence-based clinical practice guidelines.

**The American Urological Association (AUA) is a globally-engaged organization with more than 22,000 members practicing in the United States and worldwide. AUA members represent the world's largest collection of expertise and insight into the treatment of urologic disease and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy.

The AUA writes to express concern with the CAUTI outcome measure which encourages the removal of Foley catheters in patients with neurogenic bladder due to Spinal Cord Injury (SCI). SCI patients represent a unique population that should be excluded from the measure, due to the potential negative outcomes of catheter removal for these particular patients. The AUA's white paper on Catheter-Associated Urinary Tract Infections: Definitions and Significance in the Urologic Patient specifically addresses the complexities associated with care for SCI patients and the risks regarding intermittent catheterization.

We are concerned about the quality of care for these vulnerable patients and recommend exclusion of these patients from the measure.

Thank you for the opportunity to provide feedback.

**The dedication of NQF's to quality healthcare is commended, especially during this interesting politicial times.

I am an advance practice registered nurse in the field of spinal cord injury. Indwelling catheterization is an important option for the management of the neurogenic bladder, especially if the individual has limited hand function or ability to perform self intermittent catheterization from the wheelchair. In addition approximately to 40 to 60 % a persons with traumatic spinal cord injury, have a concurrent brain injury which can also make self intermittent catheterization a difficult task to do efficiently to avoid complications such as missed catheterization resulting in urinary incontinence, skin integrity issues, and autonomic dysreflexia.

The CAUTI prevention initiative, including early removal of indwelling catheters, can cause detrimental healthcare issues for persons with spinal cord injury, especially those with levels T6 and above secondary to autonomic dysreflexia. If catheters are removed in settings where healthcare providers have minimal or no education regarding neurogenic bladder and spinal cord injury, person with spinal cord injury may experience bladder over distension if not placed on a timely intermittent catheterization regimen and fluid schedule. This requires consultation of spinal cord injury providers to assist in the management of the persons with spinal cord injury and neurogenic bladder to avoid long term complications such as renal failure, autonomic dysreflexia that can cause stroke or death.

Systematic guidelines have been produced by the Paralyzed Veteran's Association, written by specialists in the field of spinal cord injury and urology. I, as a healthcare worker in the field of spinal cord injury, recommend that NQF work to create better alignment between the financial incentives and SCI-specific recommendations available in the evidence-based clinical practice guidelines.

**First, let me commend NQF's dedication to quality improvement in healthcare.

The purpose of this comment is to support changes suggested by Dr Matthew Davis (with support from the American Spinal Injury Association, Advocacy Committee). As a clinician caring for people with spinal cord injury and a researcher studying urinary tract infection among people with spinal cord injury, it is important to consider the very different needs of this unique population. Because people with spinal cord injury largely have some degree of neurogenic bladder that requires some form of catheterization, indwelling urethral or suprapubic catheterization have a very important role. This is especially important for those with limited hand function and/or caregiver support, which may limit or preclude the use of intermittent catheterization, those with body habitus or other injuries that makes intermittent catheterization difficult or impossible, skin breakdown such that maintenance of dry/incontinence-free skin is of utmost importance for healing, and other factors. In these (and other) situations, indwelling catheterization has an important role for these patients.

Moreover, a systematic review (with expert consensus), of which I was a lead author (Paralyzed Veteran's of America Consortium Guideline) did NOT confirm that the risk of UTI is necessarily higher for a particular type of bladder management of neurogenic bladder (indwelling urethral versus intermittent urethral catheterization). Rather, our clinical experience supports this finding that innate factors and catheterization technique and care are important contributors to UTI risk.

In the past few years, with the CAUTI prevention initiatives leading to early removal of indwelling catheters, we (myself and colleagues) have seen detrimental effects in the SCI population. Very early urethral catheter removal in a patient with new neurogenic bladder requires significant time and attention to balance fluid intake with output, while avoiding incontinence (putting a patient at risk for skin breakdown), excessive urinary retention, and low pressures. I and others have seen first hand the results of an inability to attend to ALL of the individual's genitourinary needs in this tenuous period, with resulting more frequent UTIs, kidney infections, renal failure and (potentially deadly) autonomic dysreflexia.

Due to the very unique and complex needs of patients with SCI (of whom the vast majority have neurogenic bladder), I recommend that NQF work to create better alignment between the financial incentives and SCI-specific recommendations available in the evidence-based clinical practice guidelines.

**The NQF is to be commended for its dedication to Quality Improvement in healthcare, as well as its strong commitment to patient-centeredness, consensus-building, and protection of vulnerable populations. Foley catheter removal in patients with neurogenic bladder due to Spinal Cord Injury (SCI) can have extremely negative consequences on genitourinary system health and function, and place patients at undue risk of life-threatening outcomes such as renal failure and autonomic dysreflexia. Additionally, Foley removal carries important implications regarding independence, quality of life, and transition from hospital to home. Furthermore, the benefit of reducing Foley-related UTIs is tempered by increased risk of UTIs due to intermittent catheterization, which go unmeasured. These complexities are acknowledged in clinical practice guidelines from the Consortium for Spinal Cord Medicine, the American Urological Association, and the CDC. Given these guideline-driven principles, it is unreasonable to require that healthcare providers for small patient populations produce definitive proof of harm from a quality measure before a careful analysis of risks and benefits is done. As a healthcare professional who cares for patients with SCI, I am requesting that the NQF work to create better alignment between the financial incentives and SCI-specific recommendations in evidence-based clinical practice guidelines.

**As our healthcare system transitions toward value-based care, the NQF has been charged with maintaining a difficult balance between patient safety, patient-centered care, consensus-building, and protecting vulnerable populations. This is a prodigious undertaking, and the NQF has shown a strong commitment. Any worthwhile change will meet resistance, and this transition is no exception.

Among the various groups clamoring for special consideration, how do we differentiate between those who are merely resistant to change and those who truly merit unique consideration? If we open the door to special treatment for one group, how do we close that door to other, less-deserving groups? These are important concerns that should not be taken lightly.

Following the CAUTI measure's transition to "pay for performance" status, healthcare providers for patients with Spinal Cord Injury (SCI) began reporting Patient Safety Events related to aberrant bladder management practices in facilities that lack expertise in SCI – where most of these patients begin their medical journey. We have also raised concerns about patient-centered care, quality of life, and measure validity for this population.

As the Patient Safety Standing Committee reviews this measure for re-endorsement, I am requesting that you consider this specific population in discussing each of the 5 Measure Evaluation Criteria:

1) Importance: Is there a reliable way to reduce CAUTIs in SCI patients without also adding risk? Given that we are not tracking UTIs related to intermittent catheterization, how confident are we that we're reducing overall UTI rates at all? How much room for improvement is really available for this population? Is that improvement worth the risk?

2) Reliability/Validity: How accurate is this definition of "UTI" for a population of chronically-catheterized patients who have altered temperature regulation, lack sensation, and are susceptible to a variety of other infections? Would this definition of UTI be considered acceptable if we were considering using it in a study in to be published in an SCI journal?

3) Use: If SCI specialty-centers that exercise judicious, patient-centered catheter use are more likely to be penalized than hospitals that indiscriminately remove catheters, how accurately does this measure reflect Quality of Care and Accountability?

4) Usability: How do we track the effects of unintended consequences, the most serious of which would be expected to fully manifest after discharge? How confident are we that the benefits for this population outweigh the risks?

5) Comparison to Related Measures: The developers of NQF measure #686 excluded SCI patients due to concerns about patient safety and Autonomic Dysreflexia. Similarly, the CDC CAUTI guidelines contain special mention of SCI, acknowledge a trade-off between benefits and harms, and recommend non-enforcement in this population. How do we reconcile these differences with the incentives associated with the CAUTI measure in its current form?

There is no shortage of relevant, SCI-specific literature covering each of the above topics. We are eager to delve into this body of literature with you.

About Consensus: Last year, we submitted a letter requesting a review of Risks and Benefits of this current form of CAUTI surveillance for patients with SCI. This letter was cosigned by national organizations representing SCI patients and virtually every specialty healthcare discipline that cares for these patients clinically – including several organizational members of the NQF.

SCI presents unique challenges with bladder management, and the stakes are high if the bladder is not handled in a safe manner after the Foley is removed. Unfortunately, the non-specialty hospitals in which SCI patients begin their care are untrained in detecting, preventing, and treating these adverse events (no, a bladder scanner is not sufficient …). These hospitals now have an incentive to take ownership over a complex process but lack an appreciation of its complexity, patient safety hazards, or implications on independence and quality of life.

Imagine, for a moment, that you visited a family member in the hospital and discovered that a surgery resident had performed an aneurism repair without an attending Cardiovascular Surgeon present. Imagine that this occurred in an operating room that lacked appropriate equipment and specialty surgical staff experienced in monitoring and managing the complications unique to that surgery. You have no way of knowing if the surgery was done well, whether any sequelae that occur after discharge might have been related to inadequate training, whether the Informed Consent form provided an accurate description of risks, benefits, and alternatives to surgery.

- We see an analogous process occurring for SCI patients in many settings today.

- We have a quality measure that gives high scores to hospitals that indiscriminately remove catheters and penalizes the hospitals that have sufficient expertise to understand independence and quality of life for SCI patients.

Change is hard.

Review of the literature is time-consuming and often confusing.

It's intimidating to consider opening the door to the uncertainty that accompanies the type of policy change we are requesting.

If we choose not to delve deeply into these uncomfortable issues, how can we be confident that small, under-represented patient populations with complex needs won't see more harm than good from this system of Quality Measures?

**The American Occupational Therapy Association appreciates the opportunity to comment on Measure 0138. This measure has fueled improvement in care quality and processes achieving a rate of just 0.88 in 2017. The measure has seemingly prevented unneeded care and improved outcomes for many people who receive care.

As the incidence of CAUTIs get smaller, the potential for unintended consequences for small populations increases because facilities and organizations work to decrease already small numbers to achieve pay for performance targets. Therefore, AOTA encourages the committee to undertake a comprehensive discussion on potential unintended consequences of the measure as specified.

Maintaining an indwelling catheter can mean maintaining functional independence and control of one's life for some with a spinal cord injury. Being able to independently transfer in any given public restroom, complete toileting and hygiene, and manage clothing is out of reach for some. However, with the right adaptations, someone who is unable to independently toilet is often still able to engage in community mobility (drive or public transit), participate in work, and socialize. With an indwelling catheter, this person is able to participate in life. However, without an indwelling catheter, this person is dependent on a personal care aide, a friend, or even a colleague to participate in these daily activities. This reliance on others for such a personal task can mean the difference between full engagement and avoiding any extended time outside of their home at all costs.

In an effort to provide the best care possible, organizations without specialty spinal cord experience, may remove indwelling catheters to prevent potential CAUTIs. This well-meaning action may mean that after completing a hospital stay and recovering from the acute condition, this person is again home bound until they are able to get back to a specialist. In the worst cases, complications related to neuronegenic bladder may arise. AOTA believes that it is important to understand and have a meaningful discussion around the potential for unintended consequences. We appreciate the meaningful gains and improved quality of care that have resulted from Measure 0138. But as the measure performance approaches a rate of 0, the potential for unintended consequences in small populations should be considered thoroughly.

**CAUTI issues in spinal cord injury (SCI) patients

SCI may result in severe impairment of motor, sensory, and autonomous functions. SCI does not affect only the bladder but also limits activities due to immobility and difficulty in self-care. Appropriate treatment for neurogenic bladder helps to protect the integrity of the upper urinary tract and the renal function. However, and due to participation restrictions influenced by environmental factors, e.g. accessibility and availability of adaptive equipment and support, bladder management for an individual with SCI must not be chosen based on one data alone without considering biopsychosocial factors that need be considered in every decision. Because dedicated SCI care achieves better outcomes than general, nonspecialized care, before removing a Foley catheter in a patient with SCI an integrative and comprehensive care involving multidisciplinary teams under the supervision of a physiatrist should be established. To illustrate this better, a patient with high cervical level of injury may need assistant with internment catheterization and they may not be suitable for returning to work, thus another type of bladder management may be selected. In conclusion, bladder management in SCI should be tailored to the patient's level of function and severity and not only based on generalizations and guidelines that may not be applicable to this population. thank you!

Brief Measure Information

NQF #: 0138

Corresponding Measures:

De.2. Measure Title: National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure

Co.1.1. Measure Steward: Centers for Disease Control and Prevention

De.3. Brief Description of Measure: Standardized Infection Ratio (SIR) of healthcare-associated, catheter-associated urinary tract infections (UTI) will be calculated among patients in bedded inpatient care locations, except level II or level III neonatal intensive care units (NICU).

This includes acute care general hospitals, long-term acute care hospitals, rehabilitation hospitals, oncology hospitals, and behavior health hospitals.

1b.1. Developer Rationale: The use of this measure will promote CAUTI prevention activities that will lead to improved patient outcomes including reduction of avoidable medical costs, and patient morbidity and mortality through reduced need for antimicrobials and reduced length of stay.

S.4. Numerator Statement: Total number of observed healthcare-associated CAUTI among patients in bedded inpatient care locations (excluding patients in Level II or III neonatal ICUs).

S.6. Denominator Statement: Total number of predicted healthcare-associated CAUTI among inpatient care locations under surveillance for CAUTI during the data period, based on the national CAUTI baseline Data is calculated using the facility's number of catheter days and the following significant risk factors:

- Acute Care Hospitals: CDC Location, Facility bed size, Medical school affiliation, and Facility type
- Critical Access Hospitals: Medical school affiliation
- Long-Term Acute Hospitals: Average length of stay, Setting type, and Location type
- Inpatient Rehabilitation Facilities: Setting type, Proportion of admissions with traumatic and non-traumatic spinal cord dysfunction, Proportion of admissions with stroke

S.8. Denominator Exclusions: The following are not considered indwelling catheters by NHSN definitions:

1.Suprapubic catheters

2.Condom catheters

3."In and out" catheterizations

4. Nephrostomy tubes

Note, that if a patient has either a nephrostomy tube or a suprapubic catheter and also has an indwelling urinary catheter, the indwelling urinary catheter will be included in the CAUTI surveillance.

De.1. Measure Type: Outcome

S.17. Data Source: Electronic Health Data, Electronic Health Records, Other, Paper Medical Records

S.20. Level of Analysis: Facility, Other, Population : Regional and State

IF Endorsement Maintenance – Original Endorsement Date: Aug 10, 2009 **Most Recent Endorsement Date:** Dec 10, 2015

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

NQF_CAUTI_evidence_final_review.docx

1a.1 <u>For Maintenance of Endorsement:</u> Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

Yes

1a. Evidence (subcriterion 1a)

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** NQF 0138

Measure Title: National Healthcare Safety Network Catheter-associated Urinary Tract Infection (CAUTI)

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Click here to enter composite measure #/ title

Date of Submission: Click here to enter a date

Instructions

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

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

1a. Evidence to Support the Measure Focus

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

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

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

4. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines and/or modified GRADE.

5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

6. Measures of efficiency combine the concepts of resource use and quality (see NQF's Measurement Framework: Evaluating Efficiency Across Episodes of Care; AQA Principles of Efficiency Measures).

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

Outcome

☒ Outcome: National Healthcare Safety Network Catheter-associated Urinary Tract Infection (CAUTI)

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

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

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

☐ Process: Click here to name what is being measured

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

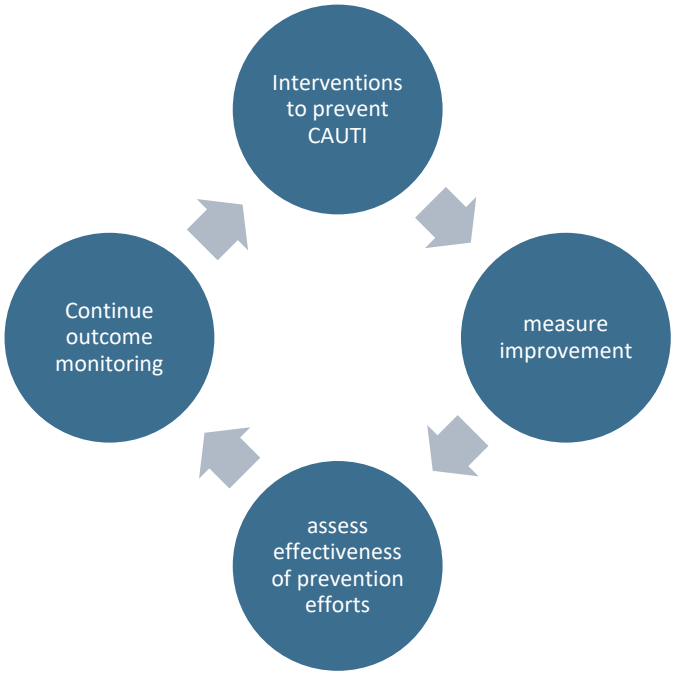
☐ Structure: Click here to name the structure

☐ Composite: Click here to name what is being measured

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram

should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

A collection of prevention efforts have been identified to reduce the incidence of CAUTI. These interventions include (i) Appropriate catheter use: reducing the number of unnecessary indwelling catheters inserted, removing indwelling catheters at their earliest, clinically-appropriate time; (ii) Implementing catheter insertion using best practice using aseptic insertion techniques;(iii) Implementing best catheter maintenance practice : keeping urinary collection bags below the level of the bladder, and securing the catheter to the leg to avoid bladder or urethral trauma (iv) Establishing quality improvement programs to achieve appropriate placement, care, and removal of catheters (v) Providing required administrative infrastructure (vi) Implementing surveillance strategies



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

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

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

Source: Carolyn V. Gould, MD, MSCR, Craig A. Umscheid, MD, MSCE, Rajender K. Agarwal, MD, MPH, Gretchen Kuntz, MSW, MSLIS, David A. Pegues, MD, and the Healthcare Infection Control Practices Advisory Committee (HICPAC). **Guideline for Prevention of Catheter-Associated Urinary Tract Infections (2009) revised February 15, 2017**

Table 1. Modified HICPAC Categorization Scheme* for Recommendations	
Category IA	A strong recommendation supported by high to moderate quality evidence suggesting net clinical benefits or harms
Category IB	A strong recommendation supported by low quality evidence suggesting net clinical benefits or harms or an accepted practice (e.g., aseptic technique) supported by low to very low quality evidence
Category IC	A strong recommendation required by state or federal regulation.
Category II	A weak recommendation supported by any quality evidence suggesting a tradeoff between clinical benefits and harms
No recommendation/ unresolved issue	Unresolved issue for which there is low to very low quality evidence with uncertain tradeoffs between benefits and harms

These specific interventions include practices to reduce catheter related infections:

Healthcare intervention #1
Ensuring **appropriate catheter use** includes inserting catheters only for appropriate indications and leaving in place as long as needed.

The recommendation was based on a targeted systematic review of the best available evidence, with explicit links between the evidence and recommendations. The literature review include 1 systematic review study, 9 randomized controlled trials and 12 observational studies.

1. Minimize urinary catheter use and duration of use in all patients, particularly those at higher risk for CAUTI or mortality from catheterization such as women, the elderly, and patients with impaired immunity (Category IB)

2. Avoid use of urinary catheters in patients and nursing home residents for management of incontinence (Category IB).

3. Use urinary catheters in operative patients only as necessary, rather than routinely (Category IB).

4. For operative patients who have an indication for an indwelling catheter, remove the catheter as soon as possible postoperatively, preferably within 24 hours, unless there are appropriate indications for continued use (Category IB).

Healthcare intervention #2

Implement **proper techniques for urinary catheter insertion**

The recommendation was based on a targeted systematic review of the best available evidence, with explicit links between the evidence and recommendations. The literature review include 6 systematic review study, 16 randomized controlled trials and 18 observational studies.

1. Perform hand hygiene immediately before and after insertion or any manipulation of the catheter device or site. (Category IB)

2. Ensure that only properly trained persons (e.g., hospital personnel, family members, or patients themselves) who know the correct technique of aseptic catheter insertion and maintenance are given this responsibility. (Category IB)

3. In the acute care hospital setting, insert urinary catheters using aseptic technique and sterile equipment. (Category IB)

4. In the non-acute care setting, clean (i.e., non-sterile) technique for intermittent catheterization is an acceptable and more practical alternative to sterile technique for patients requiring chronic intermittent catheterization. (Category IA)

5**.** Properly secure indwelling catheters after insertion to prevent movement and urethral traction. (Category IB)

6. Unless otherwise clinically indicated, consider using the smallest bore catheter possible, consistent with good drainage, to minimize bladder neck and urethral trauma. (Category II)

7. If intermittent catheterization is used, perform it at regular intervals to prevent bladder over distension. (Category IB)

8. Consider using a portable ultrasound device to assess urine volume in patients undergoing intermittent catheterization to assess urine volume and reduce unnecessary catheter insertions. (Category II)

Healthcare intervention #3

Implement **proper techniques for urinary catheter maintenance.**

The recommendation was based on a targeted systematic review of the best available evidence, with explicit links between the evidence and recommendations. The literature review include 6 systematic review study, 56 randomized controlled trials, 34 observational studies and 1 economic analysis.

1. Following aseptic insertion of the urinary catheter, maintain a closed drainage system (Category IB)

2. Maintain unobstructed urine flow. (Category IB)

3. Use Standard Precautions, including the use of gloves and gown as appropriate, during any manipulation of the catheter or collecting system. (Category IB)

4. Complex urinary drainage systems (utilizing mechanisms for reducing bacterial entry such as antiseptic-release cartridges in the drain port) are not necessary for routine use. (Category II)

5. Changing indwelling catheters or drainage bags at routine, fixed intervals is not recommended. Rather, it is suggested to change catheters and drainage bags based on clinical indications such as infection, obstruction, or when the closed system is compromised. (Category II)

6. Unless clinical indications exist (e.g., in patients with bacteriuria upon catheter removal post urologic surgery), do not use systemic antimicrobials routinely to prevent CAUTI in patients requiring either short or long-term catheterization. (Category IB)

7. Do not clean the periurethral area with antiseptics to prevent CAUTI while the catheter is in place. Routine hygiene (e.g., cleansing of the meatal surface during daily bathing or showering) is appropriate. (Category IB)

8. Unless obstruction is anticipated (e.g., as might occur with bleeding after prostatic or bladder surgery) bladder irrigation is not recommended. (Category II)

9. Routine irrigation of the bladder with antimicrobials is not recommended. (Category II)

10. Routine instillation of antiseptic or antimicrobial solutions into urinary drainage bags is not recommended. (Category II)

11. Clamping indwelling catheters prior to removal is not necessary. (Category II)

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

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

Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

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

☐ Other

Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If	

not a guideline, summarize the conclusions from the SR.	
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	
Provide all other grades and definitions from the evidence grading system	
Grade assigned to the **recommendation** with definition of the grade	
Provide all other grades and definitions from the recommendation grading system	
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	
Estimates of benefit and consistency across studies	
What harms were identified?	
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	

1a.4 OTHER SOURCE OF EVIDENCE

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

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

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

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

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

The use of this measure will promote CAUTI prevention activities that will lead to improved patient outcomes including reduction of avoidable medical costs, and patient morbidity and mortality through reduced need for antimicrobials and reduced length of stay.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis*. (This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

When SIRs are compared over time, assessment of performance can be made. Although CAUTIs that include those caused by yeast declined on wards from 2012 through 2014, they failed to decline in ICUs, where they increased and then remained elevated from 2012 through 2014 (Figure 5). However, using the more clinically-relevant CAUTI definition that no longer includes yeast, and applying this retrospectively as well as in the new baseline, there have been consistent year-to-year declines in CAUTIs in both ICUs and wards from 2012 through 2016.For figures related to performance data please see
https://www.cdc.gov/hai/data/portal/progress-report.html

CAUTI using 2015 baseline:

National Catheter-associated UTI SIR in 2015 is 0.993 = 28,712 observed / 28,910.634 predicted

National Catheter-associated UTI SIR in 2016 is 0.930 = 26,983 observed / 29,002.430 predicted

National catheter-associated UTI SIR in 2017 is 0.880 = 24,865 observed / 28,241.960 predicted

Percent Change 2016 v. 2015 6% decrease

There was about a 5% statistically significant decrease in CAUTI between 2016 and 2017

2015-

facilities: 3,658

Median: 0.872

Range, at 5% and 95%: (0.000 – 2.369)

2016-

facilities: 3,644

Median: 0.819

Range, at 5% and 95%: (0.000 – 2.184)

The 2017 National and State Healthcare-associated infections progress report:

https://www.cdc.gov/hai/data/portal/progress-report.html

The Healthcare-associated Infections in the United States, 2006-2016: A Story of Progress located here:
https://www.cdc.gov/hai/surveillance/data-reports/data-summary-assessing-progress.html

The 2016 National and State Healthcare-associated Infection Data Report:

https://www.cdc.gov/hai/data/portal/progress-report.html

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of*

patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

No studies provide evidence of a direct relationship between social risk and HAIs. Instead, they provide evidence that social risk factors are associated with an increased risk of chronic disease conditions, suboptimal care for those conditions, compromised functional status, exposure to nursing homes, and colonization with bacterial pathogens. While these associations may be meaningful, they do not establish a direct relationship between social risk factors and HAIs.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

Among patients hospitalized with acute cardiovascular disease, pneumonia, and major surgery, Asian and Hispanic patients had significantly higher rates of HAIs than white, non-Hispanic patients.

Bakullari, Anila, Mark L. Metersky, Yun Wang, Noel Eldridge, Sheila Eckenrode, Michelle M. Pandolfi, Lisa Jaser, Deron Galusha, and Ernest Moy. "Racial and Ethnic Disparities in Healthcare-Associated Infections in the United States, 2009–2011." Infection Control and Hospital Epidemiology 35, no. S3 (2014): S10-16. doi:10.1086/677827

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Infectious Diseases (ID)

De.6. Non-Condition Specific*(check all the areas that apply):*

Primary Prevention, Safety, Safety : Complications, Safety : Healthcare Associated Infections

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Children, Elderly, Populations at Risk, Populations at Risk : Dual eligible beneficiaries, Populations at Risk : Individuals with multiple chronic conditions, Populations at Risk : Veterans, Women

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

https://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf, https://www.cdc.gov/nhsn/acute-care-hospital/cauti/index.html;

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** Copy_of_nhsn-data-dictionary.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

Scope of measurement has been broadened to include some patient care areas outside of intensive care units (ICUs) and to also include oncology hospitals as urinary catheters are utilized broadly in these locations. The standardized infection ratio is a summary metric suitable for quarterly and annual reporting of CAUTI data. The SIR can be used to describe performance in a particular calendar quarter or annually and can be used to measure change in performance over those time periods. The adjusted ranking metric (ARM) has been added and is a suitable summary measure to rank facilities and is preferred to the SIR for that purpose. The ARM also can be used to measure performance of facilities over time. Risk models were updated using the 2015 incidence and risk factor data.

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Total number of observed healthcare-associated CAUTI among patients in bedded inpatient care locations (excluding patients in Level II or III neonatal ICUs).

S.5. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

1. Definition of Infection that is Present on Admission (POA): An infection where all of the elements of an infection definition are present during the two calendar days before the day of admission, the first day of admission (day 1) and/or the day after admission (day 2) and are documented in the medical chart. Infections that are POA should not be reported as healthcare-associated infections (HAI) and are not reported as CAUTI. Symptoms must be documented in the chart by a healthcare professional during the POA time frame (e.g., nursing home documents fever prior to arrival to the hospital, patient reports fever >38.0°C). Physician diagnosis alone cannot be accepted as evidence of a urinary tract infection that is POA.

2. Definition of Healthcare-associated Infection (HAI): Any infection reported to NHSN must meet the definition of an NHSN HAI, that is, a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that was not present on admission to the acute care facility. An infection is considered an HAI if the date of event of the NHSN site-specific infection criterion occurs on or

after the 3rd calendar day of admission to an inpatient location where day of admission is calendar day 1. All elements of the site-specific infection criterion must occur during the infection window period.

3. Definition of Infection Window Period: The NHSN Infection Window Period is defined as the 7-days during which all site-specific infection criteria must be met. It includes the day the first positive diagnostic test that is an element of the site-specific infection criterion, was obtained, the 3 calendar days before and the 3 calendar days after.

4. Definition of CAUTI: A UTI (either a Symptomatic Urinary Tract Infection [SUTI], or an asymptomatic bacteremic urinary tract infection [ABUTI]) where an indwelling urinary catheter was in place for more than 2 consecutive days in an inpatient location on the date of event, with day of device placement being Day 1, AND an indwelling urinary catheter was in place on the date of event or the day before. If an indwelling urinary catheter was in place for more than 2 consecutive days in an inpatient location and then removed, the UTI date of event must be the day of discontinuation or the next calendar day to be catheter-associated.

5. Definition of indwelling catheter: A drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a drainage bag (including leg bags). These devices are also called Foley catheters. Condom or straight in-and-out catheters are not included nor are nephrostomy tubes or suprapubic catheters unless a indwelling urinary catheter is also present. Indwelling urethral catheters that are used for intermittent or continuous irrigation are included in CAUTI surveillance.

6. NHSN UTI criteria: Symptomatic Urinary Tract Infection criteria or Asymptomatic Bacteremic Urinary Tract Infection criteria. See below:

A Symptomatic Urinary Tract Infection (SUTI) that is catheter associated must meet A) or B) below:

A) Patient must meet 1, 2, and 3 below:

1. Patient had an indwelling urinary catheter that had been in place for more than 2 consecutive days as an inpatient on the date of event (day of device placement = Day 1) AND was either:

- Present for any portion of the calendar day on the date of event†,

OR

- Removed the day before the date of event‡

2. Patient has at least one of the following signs or symptoms:

• fever (>38.0°C) (To use fever in a patient > 65 years of age, the IUC needs to be in place for more than 2 consecutive days in an inpatient location on date of event and is either still in place OR was removed the day before the DOE.)

• suprapubic tenderness*

• costovertebral angle pain or tenderness*

• urinary urgency ^

• urinary frequency ^

• dysuria ^

3. Patient has a urine culture with no more than two species of organisms identified, at least one of which is a bacterium of =105 CFU/ml (See Comments). All elements of the UTI criterion must occur during the Infection Window Period (See Definition Chapter 2 Identifying HAIs in NHSN).

† When entering event into NHSN choose “INPLACE” for Risk Factor for Urinary Catheter

‡ When entering event into NHSN choose “REMOVE” for Risk Factor for Urinary Catheter

*With no other recognized cause (see Comments)

^ These symptoms cannot be used when catheter is in place. An indwelling urinary catheter in place could cause patient complaints of “frequency” “urgency” or “dysuria”.

B) Patient must meet 1, 2, and 3 below:

1. Patient is =1 year of age

2. Patient has at least one of the following signs or symptoms:

- fever (>38.0°C)
- hypothermia (<36.0°C)
- apnea*
- bradycardia*
- lethargy*
- vomiting*
- suprapubic tenderness*

3. Patient has a urine culture with no more than two species of organisms, at least one of which is a bacterium of =105 CFU/ml. All elements of the SUTI criterion must occur during the Infection Window Period

*With no other recognized cause

‡ If patient had an indwelling urinary catheter in place for more than 2 consecutive days in an inpatient location, and catheter was in place on the date of event or the previous day the CAUTI criterion is met. If no such indwelling urinary catheter was in place, UTI (non-catheter associated) criterion is met.

Note: Fever and hypothermia are non-specific symptoms of infection and cannot be excluded from UTI determination because they are clinically deemed due to another recognized cause.

An Asymptomatic Bacteremic Urinary Tract Infection (ABUTI) that is catheter associated must meet the following:

Patient must meet 1, 2, and 3 below:

1.Patient has no signs or symptoms of SUTI 1 or 2 according to age

2.Patient has a urine culture with no more than two species of organisms, at least one of which is a bacterium of =105 CFU/ml

3.Patient has organism identified** from blood specimen with at least one matching bacterium to the bacterium identified in the urine specimen, or meets LCBI criterion 2 (without fever) and matching common commensal(s) in the urine. All elements of the ABUTI criterion must occur during the Infection Window Period

(See Definition Chapter 2 Identifying HAIs in NHSN).

** Organisms identified by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (e.g., not Active Surveillance Culture/Testing (ASC/AST).

7. Definition of Location of Attribution: The inpatient location where the patient was assigned on the date of the UTI event.

8. Definition of Date of Event: The date when the first element used to meet the UTI criterion occurred during the infection window period.

9. Definition of Repeat Infection Timeframe (RIT): The RIT is a 14-day timeframe during which no new infections of the same type are reported. The date of event is Day 1 of the 14-day RIT. Additional pathogens recovered during the RIT from the same type of infection are added to the event. The RIT will apply at the level of specific type of infection with the exception of BSI, UTI, and PNEU where the RIT will apply at the major type of infection.

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

Total number of predicted healthcare-associated CAUTI among inpatient care locations under surveillance for CAUTI during the data period, based on the national CAUTI baseline Data is calculated using the facility's number of catheter days and the following significant risk factors:

- Acute Care Hospitals: CDC Location, Facility bed size, Medical school affiliation, and Facility type
- Critical Access Hospitals: Medical school affiliation
- Long-Term Acute Hospitals: Average length of stay, Setting type, and Location type
- Inpatient Rehabilitation Facilities: Setting type, Proportion of admissions with traumatic and non-traumatic spinal cord dysfunction, Proportion of admissions with stroke

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Numbers of indwelling urinary catheter days attributed to each location are counted for each data period using the following definitions and guidelines. All indwelling urinary catheter days for each location and data period are summed.

1. Definition of indwelling catheter day: For each patient, a day that an indwelling urinary catheter was present at the time of the indwelling urinary catheter day count.

2. CDC Location (acute care hospitals, long term acute care hospitals): Each patient care area in a facility that is monitored in NHSN is "mapped" to one or more CDC Locations. The specific CDC Location code is determined by the type of patients cared for in that area according to the 80% Rule. That is, if 80% of patients are of a certain type (e.g., pediatric patients with orthopedic problems) then that area is designated as that type of location (in this case, an Inpatient Pediatric Orthopedic Ward). https://www.cdc.gov/nhsn/pdfs/pscmanual/15locationsdescriptions_current.pdf

3. Medical school affiliation categories:

a. Major – facility has a program for medical students and post-graduate medical training

b. Graduate – facility has a program for post-graduate medical training (i.e., residency and/or fellowships)

c. Undergraduate: facility has a program for medical students only

4. Facility bedsize: Number of beds set up and staffed in the healthcare facility

5. Setting (Freestanding or Within a Hospital): Describes physical placement of LTACH or IRF and does not define financial or administrative relationship with other healthcare facility types.

6. Definition for Facility Physician Education Status: Teaching statuses: major, graduate, undergraduate - Major: Facility has a program for medical students and post-graduate medical training; Graduate: Facility has a program for post-graduate medical training (i.e., residency and/or fellowships); Undergraduate: Facility has a program for medical students only.

7. Proportion of admissions within a diagnostic category: number of admissions during the calendar year where the primary diagnosis of that type (e.g. traumatic spinal cord dysfunction) divided by the total number of admissions during the calendar year

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

The following are not considered indwelling catheters by NHSN definitions:

1.Suprapubic catheters

2.Condom catheters

3."In and out" catheterizations

4. Nephrostomy tubes

Note, that if a patient has either a nephrostomy tube or a suprapubic catheter and also has an indwelling urinary catheter, the indwelling urinary catheter will be included in the CAUTI surveillance.

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

See S. 10

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

CAUTI data is stratified by facility-specific and individual patient location data (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, undergraduate, not affiliated - See definitions S.7. above.

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

Statistical risk model

If other:

S.12. Type of score:

Ratio

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Lower score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

The Standardized Infection Ratio (SIR) for annual and quarterly data aggregation and analysis of CAUTI events is calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, including CAUTI events, in a single group of data or across any number of stratified groups of data. To produce the SIR:

1. Identify number of observed healthcare-associated CAUTIs for a given time period by adding the total number of observed CAUTIs across the facility.

2. Calculate the number of predicted healthcare-associated CAUTIs for each CDC location using a negative binomial regression model and the risk factors described above.

3. Calculate the number of predicted healthcare-associated CAUTIs for the facility and time period by adding the predicted number of CAUTIs for each location across the facility.

4. Divide the number of observed healthcare-associated CAUTIs (1 above) by the number of predicted healthcare-associated CAUTIs (3 above) to obtain the SIR.

5. Perform a Poisson test to compare the SIR obtained in 4 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

(The NHSN analysis tool will perform the calculations once the patient infection data, denominator information, and related facility-level information are entered into the system.)

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including CAUTI events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient case-mix, exposure volume (e.g. patient days, indwelling urinary catheter days, central line-days, surgical procedure volume), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of CAUTI in each location

2. Obtain the adjusted number of observed CAUTIs by using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.

3. Total these numbers for an observed number of CAUTIs

4. Obtain the predicted number of CAUTIs in the same locations by multiplying the observed indwelling urinary catheter days according to the factors significantly associated with predicting CAUTI incidence as identified through a Log-linear Negative Binomial Regression Model.

5. Divide the total number of adjusted CAUTI events ("3" above) by the predicted number of CAUTIs ("4" above).

6. Result = ARM

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

Not based on sample or survey

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

Not PRO-PM

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Electronic Health Data, Electronic Health Records, Other, Paper Medical Records

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

NHSN Urinary Tract Infection form; NHSN Denominators for Intensive Care Unit (ICU)/Other Locations (not NICU or SCA) form; NHSN Denominators for Specialty Care Areas/Oncology form.

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

Available at measure-specific web page URL identified in S.1

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Facility, Other, Population : Regional and State

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Inpatient/Hospital, Other, Post-Acute Care

If other: Oncology hospital

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

2. Validity – See attached Measure Testing Submission Form

CAUTI_NQF_testing_Final_revision2.26.19_-003-.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Yes - Updated information is included

Measure Testing (subcriteria 2a2, 2b1-2b6)

NATIONAL QUALITY FORUM—Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** NQF 0138
Measure Title: National Healthcare Safety Network Catheter-associate Urinary Tract Infection (CAUTI)
Date of Submission: 1/23/2019

Type of Measure:

☒ **Outcome (*including PRO-PM*)**	☐ **Composite – *STOP – use composite testing form***
☐ Intermediate Clinical Outcome	☐ Cost/resource
☐ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	

Instructions

- **Measures must be tested for all the data sources and levels of analyses that are specified. *If there is more than one set of data specifications or more than one level of analysis, contact NQF staff* about how to present all the testing information in one form.**
- **For all measures, sections 1, 2a2, 2b1, 2b2, and 2b4 must be completed.**
- **For outcome and resource use measures, section 2b3 also must be completed.**
- **If specified for multiple data sources/sets of specificaitons (e.g., claims and EHRs), section 2b5 also must be completed.**
- **Respond to all questions as instructed with answers immediately following the question. All information on testing to demonstrate meeting the subcriteria for reliability (2a2) and validity (2b1-2b6) must be in this form. An appendix for *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.**
- **If you are unable to check a box, please highlight or shade the box for your response.**
- **Maximum of 25 pages (*incuding questions/instructions;* minimum font size 11 pt; do not change margins). *Contact NQF staff if more pages are needed.***
- **Contact NQF staff regarding questions. Check for resources at Submitting Standards webpage.**
- **For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for version 7.1 of the Measure Testing Attachment.**

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a2. Reliability testing [10] demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing [11] demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument-based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure; [12]

AND

If patient preference (e.g., informed decisionmaking) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately). [13]

2b3. For outcome measures and other measures when indicated (e.g., resource use):

- **an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; [14,15] and has demonstrated adequate discrimination and calibration**

OR

- **rationale/data support no risk adjustment/ stratification.**

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful [16] differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias.

Notes

10. Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

11. Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

12. Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

13. Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

14. Risk factors that influence outcomes should not be specified as exclusions.

15. With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From:	Measure Tested with Data From:

(*must be consistent with data sources entered in S.17*)	
☒ abstracted from paper record	☒ abstracted from paper record
☐ claims	☐ claims
☐ registry	☐ registry
☒ abstracted from electronic health record	☒ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☒ other: NHSN Urinary Tract Infection form; NHSN Denominators for Intensive Care Unit (ICU)/Other Locations (not NICU or SCA) form; NHSN Denominators for Specialty Care Areas/Oncology form.	☐ other:

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

The NHSN data set that was used was drawn from the NHSN database, which is an aggregation of data that healthcare facilities throughout the US submit, much of which is data required for submission to NHSN by state and federal mandates or both.

CDC NHSN used 2015 **healthcare-associated infection (**HAI) incidence and risk factor data to develop new predictive models for CAUTI and other HAI's. The number of facilities in 2015 reporting CAUTI data includes: 3,664 acute care hospitals (ACH), 486 long term acute care hospitals (LTACH), 1,168 inpatient rehabilitation facilities (IRF) throughout the US national database.

Please refer to (p. 4) the SIR Guide at:

https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf

1.3. What are the dates of the data used in testing? January 1, 2015- December 31, 2015

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (***must be consistent with levels entered in item S.20***)	**Measure Tested at Level of:**
☐ individual clinician	☐ individual clinician
☐ group/practice	☐ group/practice
☒ hospital/facility/agency	☒ hospital/facility/agency
☐ health plan	☐ health plan
☐ other:	☐ other:

1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the*

analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample)

CAUTI data is reported to NHSN from over 3,664 acute care hospitals, 486 LTACHs, 1,168 IRF in all 50 states, the District of Columbia, and several US territories. In 2015 for CAUTI: 31% of hospitals reporting CAUTI data have fewer than 50 beds, 37% have between 51 and 200 beds, and 32% have more 200 beds.

1.6. How many and which <u>patients</u> were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

Facilities reporting CAUTI data to NHSN do not report a count of patients under surveillance. The number of urinary catheter days is reported, as described in the measure submission. In 2015, 27,251,517 urinary catheter days were reported by participating facilities. Urinary catheter counts are reported by patient care location in the hospital and are not stratified by patient level factors such as age, race, and sex.

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

Reliability testing from state studies conducted 2015 forward; validity testing- no further testing after the **Healthcare Infection Control Practices Advisory Committee** (HICPAC) reviewed and recommended use of the criteria; sample used to test CAUTI risk models consists of 5318 number of facilities reporting CAUTIs in 2015.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

No patient-level sociodemographic variables are used in the measure and none were available for analysis. No compelling evidence is available that supports an association between social risk factors and CAUTIs. Instead, they provide evidence that social risk factors are associated with an increased risk of chronic disease conditions, suboptimal care for those conditions, compromised functional status, exposure to nursing homes, and colonization with bacterial pathogens. While these associations may be meaningful, they do not establish a direct relationship between social risk factors and HAI

s.2a2. RELIABILITY TESTING

***<u>Note</u>**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)
☒ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)
☐ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

See section 2b1 for validity testing of data elements.

As per NQF email "…data element validity testing may serve as a demonstration of data element reliability." Please see section 2b1.2 for demonstration of data element reliability

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

As per NQF email "…data element validity testing may serve as a demonstration of data element reliability." Please see section 2b1.3 for statistical results from reliability testing.

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

As per NQF email "…data element validity testing may serve as a demonstration of data element reliability." Please see section 2b1.4 for interpretation of data element reliability.

2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☒ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Performance measure score**

☐ **Empirical validity testing**

☒ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

CAUTI definition and criteria are unchanged from prior submission and definition and criteria which were reviewed by the Healthcare Infection Control Practices Advisory Committee (HICPAC) Subject Matter Expert (SME) panel using Delphi process, which culminated with definition and criteria.

The HICPAC is a federal advisory committee chartered to provide advice and guidance to the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance and related events in United States healthcare settings.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

CAUTI definition and criteria are unchanged from prior submission and definition and criteria which were reviewed by HICPAC Subject Matter Expert panel using Delphi process which culminated with definition and criteria.

Reliability testing of critical data elements is performed by many of the state health departments that have implemented mandatory reporting of CAUTI data to the state using NHSN as the data entry system and the source of case definitions and surveillance methodology. Trained state health department validators apply NHSN CAUTI definition criteria in medical record reviews of records that were compiled during the stay in which patients reportedly met criteria of the CAUTI definition. The validator's determination of whether or not the patient in question had a CAUTI is compared to the facility's determination. Sensitivity, specificity, positive predictive value, and negative predictive value are then calculated. As part of the validation process, some state health departments validate counts of urinary catheter days through structured interviews with personnel who collect and report these data to NHSN to ensure that correct data collection methodology is used.

	Year of data validated	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
New Hampshire	2014-2015	87.2	100	100	94.7
Kansas	2015	50	100	100	98.2
Maryland	2015	86.7	91.4	86.7	91.4
New Mexico	2016	85.0	100	100	98.9
Massachusetts	2016	83.9	98.1	93.3	95.1
Utah	2016	93.2	99.5	97.1	98.8
North Carolina	2016	91.7	97.6	84.6	98.8
Alabama	2016	87.5	99.7	87.5	99.8
Texas	2016	95.6	99.4	96.8	99.2
Tennessee	2016	88.8	99.1	94.9	99.4
Overall		88.1	99.1	94.4	97.9

External validation of NHSN CAUTI data has been conducted by at least 10 states since 2015 (NH, KS, MD, NM, MA, UT, NC, AL, TN and TX), using different sampling methods. These validations indicated a pooled mean sensitivity of 88.1% (range: 50%-95.6%), specificity of 99.1% (range: 91.4% - 100%), positive predictive value of 94.4% (range: 84.6% - 100%) and negative predictive value of 97.9% (range: 91.4% - 99.8%). External validation across the 10 states consisted of 4,970 chart reviews and of these 127 charts were incorrectly classified, yielding an overall classification error rate of 2.6%.

In 2015, overall HAI definitions and CAUTI definition underwent modifications which were aimed to streamline and simplify the definition without sacrificing usefulness.

Chart reviews were conducted by trained auditors across the 10 state health departments. These audits identified 741 CAUTI events that should have been reported and among those 653 events were correctly reported by healthcare facilities (88 missed events). Major reasons for missed CAUTI events identified during these audits included failure in identifying symptoms, misapplication of general surveillance definitions, missed case finding, and clinical documentation issues. Three states (KS, NH, and MA) noted a failure to identify symptoms that occurred during the infection window period resulting in at least 36 missed CAUTIs. Two states (KS, TN) noted misapplication of general surveillance definitions (date of event, infection window period, repeat infection timeframe) leading to at least 8 missed CAUTIs. One state (NM) cited a lack of case finding that resulted in 3 missed CAUTIs. Three states (KS, NC, and TX) noted that inconsistency in clinical documentation of symptoms and catheter presence contributed to underreporting of CAUTI events.

Among the 4,229 charts that were identified as not meeting the NHSN CAUTI definition, 4,190 charts were correctly called as "CAUTI negative" by the healthcare facilities, thereby leading to 39 over reported CAUTIs. Major reasons for overcalling CAUTI events identified during these audits included misunderstanding of present on admission (POA) vs. healthcare-associated infection (HAI), misapplication of CAUTI criteria, and clinical documentation issues. Four states (MA, MD, NC, and TX) found POA CAUTI events that were incorrectly reported as HAI CAUTI events, resulting in at least 6 over reported CAUTIs. Two states (MA, MD) noted reporting of CAUTI events that did not meet the CAUTI definition (no symptoms, no catheter), resulting in at least 8 over reported CAUTIs. Two states (NC, TX) noted that inconsistency in clinical documentation of symptoms and catheter presence contributed to over reporting of CAUTI events.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

Expert review of current CAUTI definition was completed in 2013 using HICPAC SME and Delphi process. The definition and criteria reflect those changes and were incorporated in 2015 and are unchanged since that time.

These validations indicated a pooled mean sensitivity of 88.1% (range: 50%-95.6%), specificity of 99.1% (range: 91.4% - 100%), positive predictive value of 94.4% (range: 84.6% - 100%) and negative predictive value of 97.9% (range: 91.4% - 99.8%).

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i*.e., what do the results mean and what are the norms for the test conducted?*)

The results of the expert review substantiate that the CAUTI measure is valid for use as a quality measurement. The SIR is based on the standardized mortality ratio, an observed to predicted ratio which is a widely accepted method for summarizing mortality experience. The CAUTI SIR can distinguish good from poor quality. In some places where large scale CAUTI prevention programs have been implemented over the past several years, significant reductions in the CAUTI SIR have been seen, reflecting better quality. However, there are still facilities with significantly high CAUTI SIRs, indicating that they have not made progress in reducing CAUTI (high SIRs indicate poor quality). The CAUTI SIR is used by many state health departments in public reporting of HAI data, and the Centers for Medicare and Medicaid Services (CMS) has included the CAUTI SIR in its Hospital Inpatient Quality Reporting Program and Hospital Value Based Purchasing Program, indicating its acceptance as a measure.

The CAUTI SIR is only calculated when sufficient denominator data has been reported, i.e. when the number of predicted CAUTIs is greater than 1. In order to allow for an assessment of CAUTI experience in facilities with lower exposure to urinary catheters, the ARM is used. The ARM uses statistical techniques to adjust for lower exposure to urinary catheters, in addition to other risk factors, and produces a measure that is interpreted similarly to the SIR.

Norms have not been established however we have a series of studies that show agreement.
Very high specificity, PPV and NPV and high sensitivity.

2b2. EXCLUSIONS ANALYSIS

☒ **no exclusions — *skip to section 2b4***

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

Not applicable.

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)
Not applicable.

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: **If patient preference is an exclusion**, the measure must be specified so that the*

effect on the performance score is transparent, e.g., scores with and without exclusion)
Not applicable.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES
If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b5.

2b3.1. What method of controlling for differences in case mix is used?

☐ **No risk adjustment or stratification**

☒ **Statistical risk model with ___risk factors relevant to the facility type**

☐ **Stratification by ___risk categories**

☐ **Other,**

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

The risk modeling was conducted using negative binomial regression, in which risk factors were evaluated by both univariate and multivariate modeling steps. Univariate models were fist constructed to evaluate the relationship between each risk factor and the CAUTI incidence rate.

For detailed specifications of the risk model please refer to (p. 5) the SIR Guide at:

https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

Not Applicable

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*)

Also discuss any "ordering" of risk factor inclusion; for example, are social risk factors added after all clinical factors?

In the interest of minimizing reporting burden, denominator data are aggregate data at the patient care level. As a result, the candidate risk factor data available are descriptive characteristics for patient care locations and healthcare facility. To risk adjust the CAUTI SIR, national NHSN data is analyzed to assess for differences in rates between different patient care locations (ICU, ward, different specialty types, etc.) within the data. Additional facility level characteristics (bed size, affiliation with a medical school, etc.) are included in the analysis.

In the risk adjustment for the CAUTI ARM, national NHSN data is used to produce a negative binomial risk model that includes patient care location type, medical school affiliation, facility bed size, and central line device utilization.

Model selection was used with variables added if significance level for staying in the model was less than 0.05. Order of variables included in the model was based on a combination of deviance, log likelihood and Akaike information criterion statistics.

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☒ **Other (please describe)**

No social risk factors applied in the modeling.

Due to the paucity of evidence to support social risk factors and data burden data collection for risk adjustment purposes, social risk factors are not collected in NHSN for any patients in the patient population; therefore, these variables are not available in NHSN to be used for risk adjustment modeling.

2b3.4a. What were the statistical results of the analyses used to select risk factors?

Variables were eligible for entering the model at p-value=0.25 and retaining in the model at p-value=0.05 significance level. Factors were entered into a multivariate model using forward selection, based on the lowest Wald Chi-square value. Goodness of fit was assessed at each modeling step using the Akaike Information Criterion (AIC) statistics. The final model resulting from forward selection was confirmed via backwards elimination, in which each variable was sequentially removed based on the highest p-value.

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

Did not include social risk factors.

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Model validation steps:

1. **For each negative binomial regression model to be validated, produce a table of the regression parameters from the final model**
2. **Generate at least 100 new replicate samples using "sampling with replacement" from the original dataset so that each replicate sample contains the same number of observations as the original dataset**
3. **Fit the final model to each of those new replicate samples and store the regression parameters**
4. **This will produce a set of regression parameters as defined in the original final model for each model fit to each new replicate sample**
5. **Produce a distribution of each regression parameter across all the results from the at least 100 new replicate samples**
6. **Construct an empirical "percentile-based" confidence range using the 2.5 and 97.5 percentile for each parameter**
7. **Consider the model validated among all parameters if the respective confidence range does not include null value**

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to 2b3.9

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**
See 2b3.7

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):
Negative binomial model discrimination and calibration were performed using a combination of deviance, log likelihood and Akaike information criterion statistics. Markov chain Monte Carlo sampling methods inherently rely on large scale simulation to produce posterior parameter estimates evaluated using trace plots and highest probability density intervals. In addition, Markov chain convergence, sampling, and stationarity were assessed using Geweke, Raferty-Lewis and Heidelberger-Welch diagnostics, respectively.

Negative Binomial model calibration was further assessed by calculating the root mean squared error (RMSE) between the observed and model predicted values for the final versus null model across 1000 bootstrap samples. The average RMSE for the final model was 1.602 compared to 1.828 for the null model and demonstrates a 12% significant improvement.

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:
See 2b3.7

2b3.9. Results of Risk Stratification Analysis:

See 2b3.4a

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

Both risk adjustment methodologies (stratification based on patient care location type and facility-level factors for the CAUTI SIR and risk modeling using similar factors for the ARM) allow for adequate controlling of factors that can lead to differences in CAUTI risk for patients in acute care hospitals.

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

Not Applicable

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

NHSN uses the mid p exact test for determining statistically significant differences in performance measurement. This test is applied to facility-specific performance summary statistics. CDC calculates these summary statistics i.e. the CAUTI SIR and ARM, to identify variation from a predicted occurrence of CAUTI based on the experience of a standard population, as well as an assessment of the magnitude of that variation (for example, an SIR of 2.0 indicates a level of occurrence two times higher than what would be predicted). The measures are produced with a confidence interval that can be used to assess the likelihood that the SIR or ARM occurs within a specified range. The confidence interval can be used to assess the SIR or ARM compared to its nominal value of 1.0 (where the number of observed equals the number of predicted CAUTIs).

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

Published data from the CDC national and state 2016 HAI progress report shows that nearly 2,600 ACH reported sufficient data to generate a CAUTI SIR in 2016. Approximately 354 healthcare facilities (~13.66%) had SIRs that were statistically significantly less than 1.0, indicating that the facility reported fewer CAUTIs than predicted. Approximately 225 healthcare facilities (~8.68%) had SIRs that were statistically significantly greater than 1.0, indicating that the facility reported more CAUTIs than predicted.

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean in terms of statistical and meaningful differences?*)

The SIR and the ARM have been demonstrated to produce results showing statistically significant differences in CAUTI performance across healthcare facilities. Facilities that have SIRs or ARMs significantly lower than 1 are possibly succeeding in preventing CAUTI. Facilities with SIRs or ARMs that are significantly higher than 1 may not have implemented CAUTI prevention efforts and are potential targets for interventions to improve prevention practices.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

Note: *This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

Not Applicable

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

Not Applicable

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)

Not Applicable

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

Healthcare facilities that submit quality measure data to NHSN for CAUTI and other HAIs must submit all data required for measure calculation; otherwise their data cannot be successfully submitted to NHSN.
Within the NHSN reporting system, facilities are prompted each month that they have entered infection (numerator) data but no urinary catheter days (denominator) data and vice versa to ensure that monthly data submission is complete for each location that is reported. Facilities are required to verify if no CAUTI events occurred for an inpatient care unit and month.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)
All CAUTI numerator and denominator data submitted to NHSN must be complete or the data submission is not accepted by NHSN. As a result there is no missing data for which distributions or other characteristics can be tested.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

NHSN does not produce results pertaining to systematic missing data because the system requires that all data submissions include data used to calculate measure results.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry), Other

If other: CAUTI and catheter days must be collected by trained hospital staff from information available in clinical data sources. The standard population's CAUTI rates are available from the NHSN Report. The NHSN analysis tool will automatically calculate SIRs. Some of the data used in the measure can be mined from electronic data sources.

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

Some data elements are in defined fields in electronic sources

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

NHSN is moving towards an electronically captured CAUTI measure for future use. However, development and testing is not complete at this time.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

CAUTI surveillance in hospitals participating in CDC surveillance systems since the 1990s, and the CAUTI measure has been endorsed by NQF in 2 measure sets since 2004. The criteria for UTI were streamlined in 2009 and the asymptomatic bacteriuria specific site of UTI dropped as it was felt to represent colonization rather than infection.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

There are no fees to utilize NQF measure 0138. Participants must sign a Rules of Behavior document which states that they will follow the CAUTI surveillance protocol in its entirety and report data that is in accordance with this manual.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	**Current Use (for current use provide URL)**

	Public Reporting Hospital Inpatient Quality Reporting Program (HIQR) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772356060 IRF Quality Reporting Program http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html LTCH Quality Reporting Program https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html Hospital-Acquired Condition Reduction Program (HACRP) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HAC/Hospital-Acquired-Conditions.html Hospital Inpatient Quality Reporting Program (HIQR) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772356060 IRF Quality Reporting Program http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html LTCH Quality Reporting Program https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html Hospital-Acquired Condition Reduction Program (HACRP) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HAC/Hospital-Acquired-Conditions.html Public Health/Disease Surveillance National Healthcare Safety Network http://www.cdc.gov/nhsn/ Payment Program Hospital Inpatient Quality Reporting Program (HIQR) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772356060 IRF Quality Reporting Program

	http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html LTCH Quality Reporting Program http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html Hospital Value-Based Purchasing https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Hospital-Value-Based-Purchasing-.html Hospital Inpatient Quality Reporting Program (HIQR) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772356060 IRF Quality Reporting Program http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html LTCH Quality Reporting Program http://cms.hhs.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html Hospital Value-Based Purchasing https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Hospital-Value-Based-Purchasing-.html Quality Improvement (Internal to the specific organization) Hospital Inpatient Quality Reporting Program (HIQR) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772356060 IRF Quality Reporting Program http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Details.html Hospital-Acquired Condition Reduction Program (HACRP) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html

4a1.1 For each CURRENT use, checked above (update for <u>maintenance of endorsement</u>), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

1) Name: Hospital Inpatient Quality Reporting Program (HIQR)
Sponsor: Centers for Medicare and Medicaid Services

Purpose: To improve health, improve care and lower cost (triple aims) of Medicare beneficiaries.
Geographic area and number and percentage of accountable entities and patients included: Nationwide, currently covers all acute care hospitals with ICUs (approximately 3300).*
Level of measurement and setting: Facility-Level, acute inpatient hospital
2) Name: Prospective Payment System Exempt Cancer Hospital Quality Reporting Program
Sponsor: Centers for Medicare and Medicaid Services
Purpose: To establish a quality reporting program for PPS-Exempt Cancer Hospital to improve health, improve care and lower cost (triple aims)of Medicare beneficiaries.
Geographic area and number and percentage of accountable entities and patients: 11 Patient Prospective Payment Exempt Cancer Hospitals in 7 U.S. states with 19,203 average discharges each in FY 2012*.
Level of measurement and setting: Facility-Level, PPS-Exempt cancer hospital
3) Name: Inpatient Rehabilitation Facility (IRF) Quality Reporting Program
Sponsor: Centers for Medicare and Medicaid Services
Purpose: To establish a quality reporting program for IRFs to improve health, improve care and lower cost (triple aims) of Medicare beneficiaries.
Geographic area and number and percentage of accountable entities and patients: All 50 U.S. States are included, 371,288 IRF discharges in 2011*.
Level of measurement and setting: Facility-Level, acute inpatient hospital
4) Name: Long Term Care Hospital (LTCH) Quality Reporting Program
Sponsor: Centers for Medicare and Medicaid Services
Purpose: To establish a quality reporting program for LTCHs to improve health, improve care and lower cost (triple aims) of Medicare beneficiaries.
Geographic area and number and percentage of accountable entities and patients included: All 442 Medicare certified long-term care hospitals are required to participate to receive 100% of reimbursement money due. In 2012, this included 202,050 patient discharges*.
Level of measurement and setting: Facility-Level, LTAC inpatient
5) Name: Hospital Value-Based Purchasing
Sponsor: Centers for Medicare and Medicaid Services
Purpose: To establish a quality reporting program to improve health, improve care and lower cost (triple aims) of Medicare beneficiaries.
Geographic area and number and percentage of accountable entities and patients included: 2808 entities*
Level of measurement and setting: Facility-Level, acute inpatient hospital
6) Name: Hospital-Acquired Condition Reduction Program (HACRP)
Sponsor: Centers for Medicare and Medicaid Services
Purpose: To establish a quality reporting program to improve health, improve care and lower cost (triple aims) of Medicare beneficiaries.
Geographic area and number and percentage of accountable entities and patients included: 3,216 entities*
Level of measurement and setting: Facility-Level, acute inpatient hospital
*provided by Centers for Medicare and Medicaid Services

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)
N/A

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

N/A

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

NHSN has developed numerous training resources to assist users with the proper understanding and interpretation of this measure. Several webinars and written training materials have been provided. Annual in-person trainings are held to discuss the SIR calculations, risk adjustment, and proper interpretation. Training materials are available online to all hospitals enrolled in NHSN, as well as external partners such as state health departments, quality improvement organizations, and healthcare corporations. NHSN users can run monthly analysis reports within NHSN to view their SIR data. On an annual basis, NHSN publishes national and state-level SIRs in the National and State HAI Progress Report.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

SIR results are available to NHSN users at any time, based on their current data entry. Data provided within the analysis report includes numerator, denominator, SIR, p-value, and 95% confidence interval. Educational materials are available on the NHSN website that explain each data element

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

Feedback on measure performance and implementation is obtained via email to the NHSN helpdesk email system. Feedback is provided to us by hospital staff, physicians, epidemiologists, statisticians, state and local health department staff, quality improvement staff, and other personnel. An online survey is provided to all live-training attendees who provide feedback on whether objectives were met, usefulness of the training, and whether additional training is needed.

4a2.2.2. Summarize the feedback obtained from those being measured.

Feedback from Hospitals and states: Based on results from a polling survey, hospitals have indicated that they are running SIR analysis reports within NHSN on a monthly basis, and that they use SIRs for prevention activities in their hospital. State health departments are using the SIR for public reporting purposes and to help target facilities for additional prevention. Feedback was received via email regarding the extent of risk adjustment and the limitations

4a2.2.3. Summarize the feedback obtained from other users

Feedback from consumers, media, policy, etc. on measure performance and implementation is obtained via email to the NHSN helpdesk email system. Feedback is provided to us by hospital staff, physicians, epidemiologists, statisticians, state and local health department staff, quality improvement staff, infection prevention and other personnel. See 4.a2.2.1.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

Feedback from all stakeholders is considered when developing and implementing the SIR. Different risk factor variables were analyzed for potential inclusion in the statistical model due to input from users. Additional training formats, such as live chats and “quick learn” videos, were created in order to address different training environment that best meet the needs of our audience. We have also provided live demonstrations to users showing how to generate their SIRs in NHSN based on earlier feedback received.

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the

same target population), the measures are compared to address harmonization and/or selection of the best measure.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

To a substantial extent the quality measure is a driver of patient care practices and particularly decisions on catheter insertion and removal. The trend data in section 1b. display the reductions in catheter utilization over time and the reduction in the SIR for this measure before and after the 2015 rebaseline. Combined with declining non-yeast CAUTI SIRs, which change in relation to the number of CAUTIs per urinary catheter days, declines in the device (i.e. urinary catheter) use highlight the net benefit to patients afforded by both safer and reduced urinary catheter use. Reducing unnecessary urinary catheter use is a key prevention strategy for CAUTI.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

Patient medical records and other sources of patient data must be reviewed to determine if the patient meets the necessary criteria for a healthcare-associated CAUTI. It is possible that reviewers may miss symptoms or fail to identify that patients meet criteria thereby under-reporting CAUTI events. Data collectors might also intentionally under-report CAUTIs. Both of these actions would result in an SIR that is calculated to be lower than actual. Alternatively, patients may be identified as having a CAUTI when in fact they do not meet CAUTI criteria and thereby calculate an SIR that is higher than actual. In addition, it is possible SIRs may be miscalculated. The NHSN reporting tool includes business logic to minimize misclassification of CAUTI and inaccurate reporting of catheter days and the NHSN system generates SIR rates automatically, reducing the possibility of manual error in SIR calculation. In addition, site visits can be conducted to audit data validity and this has been done for other infection types by some of the states using NHSN as their mandatory reporting tool (for example, see New York's audit process summary: http://www.health.state.ny.us/statistics/facilities/hospital/hospital_acquired_infections/2008/docs/hospital-acquired_infection.pdf, p20).

NHSN has developed a validation toolkit which includes an audit tool for U.S. state health departments to analyze a facility´s CAUTI data for over and under-reporting to NHSN.

Concerns have been expressed about unintended consequences of the CAUTI measure on catheter use in spinal cord injury patients. More specifically, concerns have focused on the premature removal of indwelling urinary catheters without institution of proper bladder management and with unintended adverse consequences on renal function. However, only anecdotal data have been cited to substantiate these concerns, without compelling evidence of a connection to the measure itself. Safe bladder management in spinal cord injury patients is a priority, and if management is unsafe then interventions should target improvements in

clinical practices where they are needed. CAUTI is also a prevention priority in spinal cord injury patients, and efforts to prevent these infections should be driven by quality measure data.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

No

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):
Are the measure specifications harmonized to the extent possible?

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):
Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment **Attachment:** NHSN_Data_Dictionary_7.2-635231324141894764.xlsx

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Centers for Disease Control and Prevention

Co.2 Point of Contact: Daniel, Pollock, dap1@cdc.gov, 404-639-4237-

Co.3 Measure Developer if different from Measure Steward: Centers for Disease Control and Prevention

Co.4 Point of Contact: Daniel, Pollock, dap1@cdc.gov, 404-639-4237-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

The Healthcare Infection Control Practices Advisory Committee (HICPAC) consists of experts in the field of HAI surveillance, prevention, and control to provide advice and guidance to CDC. The measure was vetted through the technical panel of HICPAC that informed subsequent changes to measure development.

https://www.cdc.gov/hicpac/about.html

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2004

Ad.3 Month and Year of most recent revision: 01, 2014

Ad.4 What is your frequency for review/update of this measure? when needed as NHSN definitions/protocols are updated

Ad.5 When is the next scheduled review/update for this measure? 04, 2019

Ad.6 Copyright statement:

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: