NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 1717   **NQF Project:** Patient Safety Measures-Complications Project
(for Endorsement Maintenance Review) **Original Endorsement Date:**   **Most Recent Endorsement Date:**   **Last Updated Date:** Sep 14, 2011

BRIEF MEASURE INFORMATION
De.1 Measure Title: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure
Co.1.1 Measure Steward: Centers for Disease Control and Prevention
De.2 Brief Description of Measure: Standardized infection ratio (SIR) of hospital-onset CDI Laboratory-identified events (LabID events) among all inpatients in the facility, excluding well-baby nurseries and neonatal intensive care units (NICUs)
2a1.1 Numerator Statement: Total number of observed hospital-onset CDI LabID events among all inpatients in the facility, excluding well baby-nurseries and NICUs
2a1.4 Denominator Statement: Total number of expected hospital-onset CDI LabID events, calculated by multiplying the number of inpatient days for the facility by the hospital-onset CDI LabID event rate for the same types of facilities (obtained from the standard population).
2a1.8 Denominator Exclusions: Data from patients who are not assigned to an inpatient bed are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count.
1.1 Measure Type: Outcome **2a1. 25-26 Data Source:** Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Paper Records **2a1.33 Level of Analysis:** Facility, Population : National, Population : State **1.2-1.4 Is this measure paired with another measure?** No **De.3 If included in a composite, please identify the composite measure** (*title and NQF number if endorsed*):

STAFF NOTES (*issues or questions regarding any criteria*)
Comments on Conditions for Consideration:
Is the measure untested?   Yes☐   No☐   If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*): 5. Similar/related endorsed or submitted measures (*check 5.1*): Other Criteria:
Staff Reviewer Name(s):

1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas (*Check all the areas that apply*):   Infectious Diseases
De.5 Cross Cutting Areas (*Check all the areas that apply*):   Safety : Healthcare Associated Infections

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Patient/societal consequences of poor quality, Severity of illness

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (*Provide epidemiologic or resource use data*):
Clostridium difficile is responsible for a spectrum of C. difficile infections (CDI), including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon which can, in some instances, lead to sepsis and even death.

In recent years, a previously unrecognized strain of C. difficile with increased virulence and high levels of antimicrobial resistance has resulted in outbreaks in healthcare facilities in the United States (1). Additionally, CDI has become more common in the community setting, with increased risk in those with a recent inpatient stay in a healthcare facility (2).

Significant increases in cost of inpatient care and post-hospitalization care have been seen in cases of CDI (3).

1a.4 Citations for Evidence of High Impact cited in 1a.3: (1) An Epidemic, Toxin Gene-Variant Strain of Clostridium difficile. N Engl J Med, 2005. 353(23):2433-2441.

(2) Recommendations for Surveillance of Clostridium difficile-associated Disease. Infect Control Hosp Epidemiol, 2007. 28(2):140-145.

(3) Short and Long-Term Attributable Costs of Clostridium difficile-associated Disease in Nonsurgical Inpatients. Clin Infect Dis, 2008. 46(4):497-504.

1b. Opportunity for Improvement: H☐ M☐ L☐ I☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
The SIR compares a healthcare facility´s performance compared to a national baseline. Facilities are able to see whether the number of hospital-onset C. difficile LabID events that they have reported compares to the number that would be expected, given national data. The measure can then be used to drive prevention practices that will lead to improved outcomes, including the reduction of patient morbidity and mortality.

1b.2 Summary of Data Demonstrating Performance Gap (*Variation or overall less than optimal performance across providers*):
[*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
Hospital-onset CDI LabID event rates vary when examining various facility characteristics.

1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
Zilberberg MD, Tabak YP, Sievert DM, et al. Using Electronic Health Information to Risk-Stratify Rates of Clostridium difficile Infection in US Hospitals. Inf Control Hosp Epidemiol, 2011. 32(7):649-655.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results*

for this measure by population group]
Rates of CDI are highest for patients in healthcare facilities. Rates also increase with patient age.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
QuickStats: Rates of Clostridium difficile Infection Among Hospitalized Patients Aged =65 Years, by Age Group - National Hospital Discharge Survey, United States, 1996-2009. MMWR, 2011. 60(34):1171.

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome?   Yes☐ No☐   **If not a health outcome**, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐   Quality: H☐ M☐ L☐ I☐   Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No**☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise **No**☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship *(Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome)*:
Clinical guidelines for the management of C. difficile have been published. Adherence to the recommendations in the guidelines can result in decreased rates of C. difficile transmission and infection. Decreasing rates of infection
will result in a lower SIR, which indicates improving performance.

1c.2-3 Type of Evidence *(Check all that apply)*:
Clinical Practice Guideline, Systematic review of body of evidence (other than within guideline development)

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
A wide ranging variety of studies examining hospital-onset CDI rates and prevention practices exist. The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) have recently updated their clinical practice guideline for the management and prevention of CDI, which assesses the body of evidence existing in the literature.

Additionally, the Centers for Disease Control and Prevention´s Healthcare Infection Control Practices Advisory Committee (HICPAC) has issued at least three clinical guidelines that assess evidence for prevention practices that can limit transmission and increase prevention of CDI - hand hygiene, isolation, and disinfection.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: The 2010 updated SHEA/IDSA practice guideline for the management of CDI included results from over 230 studies.

The 2008 HICPAC guideline for sterilization and disinfection in healthcare facilities included results from over 1,000 studies.

The 2007 HICPAC guideline for isolation precautions in healthcare facilities included results from over 1,100 studies.

The 2002 HICPAC guideline for hand hygiene in healthcare settings included results from over 400 studies.

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): The SHEA/IDSA guideline for management of CDI uses a standard process that includes a weighing of quality of evidence for practices that lead to successful management of CDI in the inpatient setting.

The HICPAC guidelines for sterilization and disinfection, isolation precautions, and hand hygiene provide recommendations for practices that result in the reduction of transmission of infections within healthcare facilities, including CDI. As is standard with all HICPAC guidelines, recommendations were categorized
on the basis of existing scientific data, theoretical rationale, applicability, and economic impact.

1c.7 Consistency of Results across Studies (*Summarize the consistency of the magnitude and direction of the effect):* The recommendations in these guidelines can consistently be used to reduce the incidence and transmission of CDI in healthcare facilities.

1c.8 Net Benefit (*Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
The bodies of evidence reviewed in the preparation of the guidelines referenced in 1c.4 and 1c.5 indicates that following recommended prevention practices can reduce incidence and transmission of CDI in healthcare settings.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: For the 2010 clinical guideline for management of CDI, an expert review panel from the Society for Healthcare Epidemiology of America and the Infectious Diseases Society of America graded existing evidence.

The Centers for Disease Control and Prevention´s Healthcare Infection Control Practices Advisory Committee graded evidence for the disinfection/sterilization, isolation precautions, and hand hygiene guidelines.

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: The IDSA/SHEA grading scale for the 2010 guideline for management of CDI is as follows:

Strength of recommendation:
A - Good evidence to support a recommendation for or against use
B - Moderate evidence to support a recommendation for or against use
C - Poor evidence to support a recommendation

Quality of evidence:
I - Evidence from at least 1 properly randomized, controlled trial
II - Evidence from at least 1 well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than 1 center), from multiple time-series, or from dramatic results from uncontrolled experiments
III - Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

The CDC/HICPAC grading system used in the creation of the sterilization/disinfection, isolation precautions, and hand hygiene guidelines is as follows:

Category IA - strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.

Category IB - strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.

Category IC - required for implementation, as mandated by federal and/or state regulation or standard.

Category II - suggested for implementation and supported by suggestive clinical or epidemiologic studies for a theoretical rationale.

No recommendation - unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.

1c.13 Grade Assigned to the Body of Evidence: The body of evidence is not assigned a grade as a whole. Individual recommendations are graded as shown in 1c.12.

1c.14 Summary of Controversy/Contradictory Evidence: None

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:
Citations for evidence are cited individually at the end of each relevant clinical guideline cited in 1c.17.

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
One specific overall guideline recommendation is not provided in any of the guidelines cited in 1c.17. Each individual recommendation in a guideline is given a grade as described in 1c.12.

1c.17 Clinical Practice Guideline Citation: Cohen SH, Gerding DN, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Infect Control Hosp Epidemiol, 2010. 31(5):431-455.

Rutala WA, Weber DJ, and the Healthcare Infection Control Practices Advisory Committee. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Available at http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf.

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. Available at http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.

Boyce JM, Pittet D, et al. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory
Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR, 2002. 51(RR-16).

1c.18 National Guideline Clearinghouse or other URL: HICPAC guidelines are located at http://www.cdc.gov/hicpac. SHEA/IDSA guidelines are located at http://www.idsociety.org/content.aspx?id=4430.

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: CDC´s Healthcare Infection Control Practices Advisory Committee or the SHEA/IDSA expert review panel reviewed each of the guidelines.

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: Grading scales for each group are described in 1c.12.

1c.23 Grade Assigned to the Recommendation: There is no overall grade assigned to the guideline, which contains many recommendations. Individual recommendations are graded as shown in 1c.12.

1c.24 Rationale for Using this Guideline Over Others: SHEA and IDSA are the leading professional societies for practitioners

interested in prevention, treatment, and control of infections that can be transmitted in the healthcare setting.

HICPAC is a federal advisory committee made up of 14 external infection control experts who 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 health care infection control, strategies for surveillance and prevention and control of health care associated infections in United States health care facilities.

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High   1c.26 Quality: High 1c.27 Consistency: High
1c.28 Attach evidence submission form:
1c.29 Attach appendix for supplemental materials:

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*)   Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

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2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (<u>evaluation criteria</u>)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See <u>guidance on measure testing</u>.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained)*. Do you have a web page where current detailed specifications for <u>this</u> measure can be obtained? Yes

S.2 If yes, provide web page URL: http://www.cdc.gov/nhsn

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Total number of observed hospital-onset CDI LabID events among all inpatients in the facility, excluding well baby-nurseries and NICUs

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
Cases are included if toxin-producing C. difficile is identified from a specimen that is classified as hospital-onset LabID event and is collected from an inpatient in the facility during a month in which the facility chose to perform surveillance. It is necessary to have sufficient sample size to generate an SIR - given low numbers of expected infections, the time window will be longer than monthly.

2a1.3 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, codes with descriptors, and/or specific data collection items/responses*:
1. Definition of CDI-positive laboratory assay - A positive laboratory test result for C. difficile toxin A and/or B or a toxin-producing C. difficile organism detected by culture or other laboratory means performed on a stool sample.

2. Definition of duplicate CDI-positive test - Any C. difficile toxin-positive laboratory result from the same patient and location, following a previous C. difficile toxin-positive laboratory result within the past two weeks (14 days).

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3. Definition of CDI LabID event - All non-duplicate C. difficile toxin-positive laboratory results, including specimens collected during an emergency department or other outpatient clinic visit, if collected the same day as patient admission to the facility.

4. Definition of hospital-onset LabID event – LabID event with specimen collected >3 days after admission to the hospital (i.e. on or after calendar day 4 of admission, where date of admission = day 1)

5. Definition of inpatient - A patient who is located in an inpatient location for care and treatment at the time of specimen collection.

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
Total number of expected hospital-onset CDI LabID events, calculated by multiplying the number of inpatient days for the facility by the hospital-onset CDI LabID event rate for the same types of facilities (obtained from the standard population).

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care, Children's Health

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
A facility-wide number of inpatient days is collected for the surveillance period minus inpatient days from neonatal intensive care units and well baby nurseries. An expected number of hospital-onset LabID events for the facility is calculated using the standard population's baseline data from 2009-2010. It is necessary to have sufficient sample size to generate an SIR – given low numbers of expected infections, the time window will be longer than monthly.

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
1. Number of inpatient days for the facility for the time period under surveillance. The number of inpatient days is obtained by summing the daily count of patients occupying beds in each inpatient location in the facility over the time period under surveillance. The count of patients occupying inpatient beds is collected at the same time each day.

2. Hospital-onset CDI LabID event rate per 1,000 patient days for similar facility types, obtained from the standard population from 2009-2010.

3. Facility–specific information, including facility type, bedsize, and affiliation with a medical school (see 4 below).

4. Medical school affiliation categories:
a. Major – a hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services
b. Graduate – a hospital used by the medical school for graduate trainings only (residency and/or fellowships)
c. Limited – a hospital that is used in the medical school's teaching program to a limited extent

5. The CMS case mix index is also being investigated as a potential factor in determining expected number of LabID events.

5. Number of admission-prevalent CDI LabID events (identified within the first 3days after admission to the facility, where date of admission = day 1).

6. Microbiological test method used to identify C. difficile (PCR for toxin, EIA assay for toxin, stool antigen, culture, other).

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Data from patients who are not assigned to an inpatient bed are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count.

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:

Definition of inpatient - A patient who is located in an inpatient location for care and treatment at the time of the daily inpatient census count.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
The measure will not be stratified, as it is an overall facility-wide summary measure. Facility characteristics will be used for risk adjustment, described in 2a1.13.

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: Other **2a1.12 If "Other," please describe:** Standardized Infection Ratio (SIR)

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
The SIR is a method of indirect standardization that summarizes HAI experience across a series of groups of data. The SIR compares a facility's observed number of hospital-onset CDI LabID events for a given time period to the 2009-2010 standard population's experience, which can be used to calculate an expected number of LabID events. Dividing observed by expected numbers of LabID events produces the SIR.

The rate of hospital-onset CDI LabID events identified per 1,000 patient days from the standard population is used to calculate the number of expected hospital-onset CDI LabID events for a given facility. These rates are stratified by facility-specific factors, including facility type, facility bedsize, and medical school affiliation (major, graduate, or limited, see 2a1.7), the number of admission prevalent CDI LabID events, the type of microbiological test the facility uses to identify C. difficile, and possibly CMS case mix index.

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:
URL
No such URL. Please refer to 2a1.20

2a1.17-18. Type of Score: Ratio

2a1.19 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

2a1.20 Calculation Algorithm/Measure Logic *(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; aggregating data; risk adjustment; etc.)*:
1. Identify number of observed hospital-onset CDI LabID events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of expected hospital-onset CDI LabID events for the facility by multiplying the number of inpatient days observed by the hospital-onset CDI LabID event rate for similar facilities (using data from the 2009-2010 standard population) and dividing by 1,000.
3. Divide the number of observed hospital-onset CDI LabID events (1 above) by the number of expected hospital-onset CDI LabID events (2 above) to obtain the SIR.
4. Perform a Poisson test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
URL
No such URL exists. Refer to 2a1.20

N/A

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
No sampling methodology is used in calculating the metric.

2a1.25 Data Source (*Check all the sources for which the measure is specified and tested*). If other, please describe:
 Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Paper Records

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): NHSN Laboratory-identified MDRO or CDI Event Form and NHSN MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring Form

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
http://www.cdc.gov/nhsn/forms/57.128_LabIDEvent_BLANK.pdf,
http://www.cdc.gov/nhsn/forms/57.127_MDROMonthlyReporting_BLANK.pdf

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
http://www.cdc.gov/nhsn/forms/instr/57_128_Instructions.pdf, http://www.cdc.gov/nhsn/forms/instr/57_127_Instructions.pdf

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested*): Facility, Population : National, Population : State

2a1.34-35 Care Setting (*Check all the settings for which the measure is specified and tested*): Behavioral Health/Psychiatric : Inpatient, Dialysis Facility, Hospital/Acute Care Facility, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Post Acute/Long Term Care Facility : Rehabilitation

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

2a2.1 Data/Sample (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):
The standard populations´s hospital-onset CDI rates that were used in the SIR calculation came from all inpatient locations reporting CDI LabID events to NHSN from 2009-2010. 723 facilities reported CDI LabID events during that time period. A total of 66 different inpatient location types reported CDI LabID events during that time period.

The numerators for each of the locations range from 0 to 560 CDI LabID events, and the denominators range from 2 to 431,146 patient days.

For 535 of the 723 location types, at least 10,000 patient days were reported (internal, unpublished NHSN analysis). Therefore, we conclude that the standard population´s rates are robust enough to use for determining the expected number of CDI LabID events in the SIR calculation.

2a2.2 Analytic Method (*Describe method of reliability testing & rationale*):
The SIR is the ratio of the number of observed CDI LabID events to the number of expected CDI LabID events, given the experience of the standard population described in 2a2.1. The SIR is very similar in concept to the standardized mortality ratio (SMR), which is a commonly used and accepted metric in public health.

If the number of observed events is equal to the number of expected events based on the standard population, then the SIR will equal 1.0. If more events are observed than what would be expected, the SIR will be greater than 1 (i.e, an SIR of 2.0 indicates that twice as many events are observed than what would be expected given the standard population). If fewer events are observed than what would be expected, the SIR will be less than 1 (i.e, an SIR of 0.5 indicates that half as many events are observed than what

would be expected).

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
The baseline rates of the standard population will remain the same for the purposes of calculating the number of expected events in the denominator of the SIR calculation. The number of inpatient days reported by the facility is multiplied by the standard population´s rate of CDI LabID events to obtain an expected number of events. Because the standard population´s rates will remain constant, reliable and reproducible SIRs will be produced into the future, allowing comparison the the baseline period to assess progress in reducing incidence.

2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>:   H☐ M☐ L☐ I☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* are consistent with the evidence cited in support of the measure focus (*criterion 1c*) and identify any differences from the evidence:
Clinical guidelines for practices that can reduce transmission of C. difficile in the inpatient setting have been published. Adherence to recommendations in the guidelines can result in decreased rates of C. diffile transmission and infection.

The numerator of the SIR measure is the observed number of CDI LabID events for a given time period, which serves as a proxy for an infection event. Improving prevention practices as prescribed in existing clincical guidelines should result in a decrease in the number of observed CDI LabID events. This will result in a lower SIR, which indicates improving performance.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.*)

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Data used to construct the standard population are described in 2a2.1.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
The SMR, upon which the SIR is based, is a widely accepted method for summarizing mortality experience. Therefore, we conclude that the SIR has inherent face validity. However, validity studies of the SIR are ongoing. The American Recovery and Reinvestment Act of 2009 provided funding to CDC which was used to support validity studies at the state health department level, among other tasks. Validation methods have been descibed in annual public reports of healthcare-associated infection data in at least three states - New York (http://www.health.state.ny.us/statistics/facilities/hospital/hospital_acquired_infections/), South Carolina (http://www.scdhec.gov/health/disease/hai/), and Pennsylvania (http://www.portal.state.pa.us/portal/server.pt/community/healthcare_associated_infections/14234). Other states continue to work on validation of healthcare associated infection surveillance data and metrics.

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
The SMR, upon which the SIR is based, is a widely accepted method for summarizing mortality experience. Therefore, we conclude that the SIR has inherent face validity.

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results*.)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Neonatal intensive care units and well-baby nurseries are excluded from NHSN LabID event surveillance for CDI. Event numerators and patient day denominator counts for the measure do not include data from these locations.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):
CDI is not accurately identifed in neonates less than 1 year of age due to colonization of the gut. Therefore, this age group is excluded from NHSN LabID Event surveillance for CDI.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
N/A

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Data used to construct the standard population are described in 2a2.1.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
The SIR is an internally risk-adjusted measure that can be used to produce a risk-adjusted summary statistic for a facility. Expected numbers of events are calculated based on factors that lead to different levels of risk. Risk adjustment methods and stratification variables used in the creation of this measure can be found in 2a1.13 and 2a2.1.

2b4.3 Testing Results *(Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata)*:
722 of the 723 facilities that were used to construct the standard population reported their facility type. 658 facilities (91%) were general acute care facilities. 30 facilities (4%) were long term acute care facilities. The remaining 5% of facilities were one of the other NHSN-defined facility types.

722 of the facilities that were used to construct the standard population reported their facility´s bedsize. 443 facilities (61%) had less than or equal to 200 beds, 230 facilities (32%) had between 201 and 500 beds, and 49 facilities (7%) had more than 500 beds.

495 facilities (68%) used to construct the standard population reported that they were non-teaching facilities. The remaining 228 facilities (32%) indiciated that they were affiliated with a medical school to some extent. Of these 228 facilities, 89 (39%) identified themselves as being a major teaching facility, 75 (33%) identified themselves as having a graduate teaching affiliation with a medical school, and 64 (28%) identified themselves as having a limited affiliation with a medical school (see definitions in 2a1.7).

682 (94%) of the 723 facilities that were used to construct the standard population reported the microbiological test used to identify C. difficile on specimens collected at the facility. Of these 682 facilities, 360 (53%) reported that an enzyme immunoassay (EIA) for C. difficile-produced toxin was used. 236 facilities (35%) reported the use of a nucleic acid test, such as PCR, to identify C. difficile toxin. The remaining 12% of facilities reported using other tests, including stool culture and stool antigen testing.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: N/A

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
CDC has used the SIR as a metric to identify differences in performance and potential improvement over time. State-specific SIRs for central line-associated bloodstream infection data reported to NHSN from 2006-2009 has been reported at http://www.cdc.gov/HAI/surveillance/statesummary.html.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
The SIR identifies variation from an expected rate of occurence of an infection or event based on the experience of a standard population, as well as a sense of the magnitude of that variation (i.e. an SIR of 4 indicates a level of occurence four times higher than what would be expected). The SIR is presented with a confidence interval that can be used to assess the likelihood that the SIR

occurs within a specified range.

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
The SIR is calculated and presented with its 95% confidence interval. This can be plotted graphically to assess its relationship with the nominal value of 1, where observed=expected. The SIR and confidence interval can also be plotted over time to compare SIR values for the same facility over a series of time periods.

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
All facilities participating in NHSN and reporting LabID events to the MDRO module follow the same protocol for reporting events using similar laboratory and admission/discharge/transfer data sources.

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
N/A

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
N/A

2c. Disparities in Care: H☐ M☐ L☐ I☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: N/A

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
N/A

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (**evaluation criteria**)

C.1 Intended Actual/Planned Use *(Check all the planned uses for which the measure is intended)*:   Payment Program, Public Health/Disease Surveillance, Public Reporting, Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Reporting, Public Health/ Disease Surveillance, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I☐

(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. **Use in Public Reporting - disclosure of performance results to the public at large** *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s))*. If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]

The standardized infection ratio for healthcare-associated infections is identical in concept to the standardized mortality ratio, which is a widely accepted measurement tool in public health. In 2005, NHSN introduced an SIR measure for surgical site infections (SSI), and in 2009, an SIR measure for central line associated bloodstream infections (CLABSI) was implemented in NHSN as well.

Facilities have been able to use the SIR for internal performance tracking for many years. In recent years, laws that require facilities to report healthcare-associated infections to state health departments using NHSN for public reporting have led to increased use of the SIR at the state level. Several states have produced public reports of healthcare-associated infection data using the SIR for both CLABSI and SSI. Examples include:

-Pennsylvania (http://www.portal.state.pa.us/portal/server.pt?open=18&objID=848541&mode=2)

-Tennessee (http://health.state.tn.us/Downloads/TROHAI2011.pdf)

-South Carolina (http://www.scdhec.gov/health/disease/hai/reports.htm)

3a.2. **Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting**. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The SIR provides a single summary statistic that can be used to represent the HAI experience for a given facility. This differs from rate data produced by NHSN. For example, CLABSI rates are only reported out by location in NHSN to maximize risk adjustment. It is not possible to provide a risk-adjusted overall CLABSI rate for a facility. The SIR is internally risk-adjusted to allow for presentation as a single summary statistic for public consumption.

The structure of the SIR as the number of observed events divided by the number of expected events given a national baseline allows for simple interpretation of the metric. If the value is greater than 1, a facility identified more infections than what would be expected. If the value is less than 1, a facility identified fewer infections than what would be expected.

3.2 **Use for other Accountability Functions (payment, certification, accreditation).** If used in a public accountability program, provide name of program(s), locations, Web page URL(s): Hospital-onset C. difficile infection has been added to the Center for Medicare and Medicaid Services´ Hospital Inpatient Quality Reporting (IQR) Program for events identified starting in January 2013. Facilities that are eligible for the IQR program that do not participate and report required data have their Medicare annual payment update reduced. The SIR will be the outcome measure used for the hospital-onset C. difficile reporting requirement in the IQR program.

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. **Use in QI.** If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
Several state-based prevention collaboratives are using the standardized infection ratio as a metric to track progress towards reducing healthcare-associated infections. States that have implemented prevention collaboratives using funds allocated by CDC can be found at http://www.cdc.gov/HAI/stateplans/HAIstatePlans-map.html.

3b.2. **Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement**. If usefulness was demonstrated *(e.g., QI initiative)*, describe the data, method and results:
Facilities can track monthly, quarterly, or yearly SIRs to examine if the prevention practices implemented by the collaborative have resulted in reduced numbers of infections (indicated by a decreasing SIR).

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry), Other
LabID events and denominator data can be collected manually by trained hospital staff or via electronic data capture from hospital laboratory and ADT systems. The SIR is automatically calculated by the NHSN web application.

4b. Electronic Sources: H☐ M☐ L☐ I☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements are in a combination of electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
Laboratory and other clinical data must be reviewed to determine if the patient meets the criteria for a LabID event. It is possible that medical record reviewers will miss positive cultures or important dates that would indicate that a LabID event should be recorded. Similarly, reviewers might miss data in the medical record that would indicate a positive culture should not result in a LabID event. It is also possible that data abstractors could intentionally underreport LabID events.

Business logic is built into the NHSN application to minimize incorrect entry of LabID events. Additionally, agencies including state health departments and others have indicated interest in performing validation of LabID event surveillance as they have for other healthcare-associated infections, such as central line-associated bloodstream infections.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I☐

A.2 Please check if either of the following apply (*regarding proprietary measures*):
4d.1 Describe what you have learned/modified 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 *(e.g., fees for use of proprietary measures)*:
The NHSN Multidrug Resistant Organism and C. difficile Infection (MDRO/CDI) module has been available for facilities to use since 2009. The ability to perform facility-wide surveillance with a single denominator was introduced in 2010, reducing data collection burden on participating facilities. To further reduce case finding and data entry burden on facilities, LabID event reporting for C. difficile is now able to be performed electronically via NHSN's Clinical Document Architecture import function.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND 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 before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population)*, list the NQF # and title of all related and/or competing measures:

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?

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

5b. Competing Measure(s)

5b.1 If this measure has 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)*:
N/A

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Centers for Disease Control and Prevention, 1600 Clifton Rd NE, MS A24, Atlanta, Georgia, 30333

Co.2 Point of Contact: Daniel, Pollock, MD, Surveillance Branch Chief, Division of Healthcare Quality Promotion, CDC, dpollock@cdc.gov, 404-639-4237-

Co.3 Measure Developer if different from Measure Steward: Centers for Disease Control and Prevention, 1600 Clifton Rd NE, MS A24, Atlanta, Georgia, 30333

Co.4 Point of Contact: Daniel, Pollock, MD, Surveillance Branch Chief, Division of Healthcare Quality Promotion, CDC, dpollock@cdc.gov, 404-639-4237-

Co.5 Submitter: Daniel, Pollock, MD, Surveillance Branch Chief, Division of Healthcare Quality Promotion, CDC, dpollock@cdc.gov, 404-639-4237-, Centers for Disease Control and Prevention

Co.6 Additional organizations that sponsored/participated in measure development:

Co.7 Public Contact: Daniel, Pollock, MD, Surveillance Branch Chief, Division of Healthcare Quality Promotion, CDC, dpollock@cdc.gov, 404-639-4237-, Centers for Disease Control and Prevention

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:
Measure Developer/Steward Updates and Ongoing Maintenance **Ad.3 Year the measure was first released:** 2009 **Ad.4 Month and Year of most recent revision:** 05, 2010 **Ad.5 What is your frequency for review/update of this measure?** Annually and as needed **Ad.6 When is the next scheduled review/update for this measure?** 01, 2012
Ad.7 Copyright statement:
Ad.8 Disclaimers:
Ad.9 Additional Information/Comments:
Date of Submission (*MM/DD/YY*): 09/14/2011