NATIONAL QUALITY FORUM
Driving measurable health improvements together

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through National Quality Forum's (NQF) Consensus Development Process (CDP). The information submitted by the measure developers/stewards is included after the *Brief Measure Information* and *Preliminary Analysis* 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 #: 3688

Measure Title: Centers for Disease Control and Prevention (CDC), National Healthcare Safety Network (NHSN), Healthcare facility-onset, antibiotic-Treated Clostridioides difficile Infection (HT-CDI) Outcome Measure

Measure Steward: Centers for Disease Control and Prevention

Brief Description of Measure: Standardized infection ratio (SIR) based on fully electronic capture of healthcare facility-onset, antibiotic-Treated Clostridioides difficile Infection (HT-CDI) events among inpatients in the facility

Developer Rationale: Surveillance for HT-CDI will help hospitals monitor for *C.difficile* burden and target quality improvement initiatives that reduce HAIs and thus result in less patient harm, shorter hospitalizations, and lower healthcare costs. The HT-CDI SIR describes a healthcare facility´s performance compared to a national baseline. Facilities can see how the number of HT-CDI events they have reported compares to the number predicted, 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.

Numerator Statement: Total number of observed incident healthcare facility-onset, antibiotic-treated CDI (HT-CDI) events among all inpatients in the facility.
Denominator Statement: Total number of expected incident HT-CDI events based on predictive models using facility-level and patient-level factors.
Denominator Exclusions: Data from patients who are not assigned to an inpatient bed are excluded from the denominator counts, including outpatient clinics, 24-hour observation units, and emergency department visits. Patients who are <365 days old on the date of admission are not included in denominator counts.

Measure Type: Outcome

Data Source: Electronic Health Records

Level of Analysis: Facility

Criteria 1: Importance to Measure and Report

1a. Evidence

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 can be used, assuming the data are from a robust number of providers and the results are not subject to systematic bias. For measures derived from a patient report, the evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

The developer provides the following description for this measure:

- This is a new outcome measure at the facility level that calculates the standardized infection ratio (SIR) based on fully electronic capture of healthcare facility-onset, antibiotic-Treated Clostridioides difficile Infection (HT-CDI) events among inpatients in the facility.
- The developer provides a logic model that depicts a link between successful hospital infection prevention practices, such as hand hygiene, transmission-based isolation precautions, best practices for environmental cleaning, best practices for disinfection and sterilization, and surveillance, audit, and feedback in combination with optimal patient care to produce a reduction in the development and transmission of pathogens and subsequent infections among hospitalized patients that leads to a decrease in Healthcare facility-onset, antibiotic-Treated Clostridioides difficile Infection (HT-CDI) events.

Summary:

- The developer referenced 2017 clinical guidelines for management of CDI, and notes that an expert review panel from the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology (SHEA) of America graded existing evidence for control and prevention of CDI.
    - The guidelines note that the following actions can assist in the prevention of CDI:
        - Accommodating patients with CDI in a private room with a dedicated toilet
        - If cohorting is required, only cohorting patients infected or colonized with the same organism(s)
        - Healthcare personnel wearing gloves and gowns during entry and care of patientSuspected CDI patients should be placed on preemptive contact precautions pending the C. difficile test results
        - Continuing contact precautions for at least 48 hours after diarrhea has resolved
        - Prolonging contact precautions until discharge if CDI rates remain high despite implementation of standard infection control measures against CDI
        - Hand hygiene
        - Encouraging patients to wash hands and shower
        - Using disposable patient equipment when possible and ensuring that reusable equipment is thoroughly cleaned and disinfected
        - Cleaning patient rooms with a sporicidal agent

        - Minimize the frequency and duration of high-risk antibiotic therapy and the number of antibiotic agents prescribed
        - Implement an antibiotic stewardship program
        - Antibiotics to be targeted should be based on the local epidemiology and the C. difficile strains present
- The developer also cites the Centers for Disease Control and Prevention´s Healthcare Infection Control Practices Advisory Committee (HICPAC) graded evidence for the disinfection/sterilization, isolation precautions, and hand hygiene guidelines.
    - The developer notes that 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

Question for the Standing Committee:

- *Is there at least one thing that the provider can do to achieve a change in the measure results?*

Guidance From the Evidence Algorithm

Outcome measure (Box 1) -> Relationship between the measured health outcome and at least one health action is demonstrated by empirical data (Box 2) -> Pass.

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

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

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

- The developer notes that because this is a new measure performance gap data is not available and presents a summary of data from the literature demonstrating an opportunity for improvement:
    - In 2020, there were 40,562 Hospital-onset CDI LabID events reported to NHSN out of 28,917,177 admissions and 131,335,743 total patient days from 3,653 hospitals.
    - Additionally, the data from the annual healthcare-associated infection (HAI) progress report demonstrates there is considerable variability in SIR between states, indicating a significant variation between facilities in the prevention of CDI. In 2020, the national SIR for Hospital-onset CDI Laboratory Identified (LabID) events was 0.518, with state SIRs ranging from 0.130 to 0.824.
    - In 2018, the Emerging Infections Program found an incidence of healthcare-associated CDI of 64.18 per 100,000 persons.

Disparities

- The developer does not provide any data on disparities as this a new measure; however, the developer does provide a summary of data from the 2018 Annual CDI Report from the Emerging Infections Program which addresses current disparities in care broken down by age, sex, and ethnicity.
    - There is an increasing incidence by age (1-17 years: 9.03/100,000; 18-44 years: 17.82/100,000; 45-64 years: 72.12/100,000; >=65 years: 262.35/100,000).
    - The data shows a slight female predominance in healthcare-associated CDI incidence (66.23/100,000 persons vs. 62.04/100,000).

- The developer notes a slight predominance in white populations as compared to non-white populations (69.54/100,000 vs. 53.18/100,000).

Questions for the Standing Committee:

- *Is there a gap in care that warrants a national performance measure?*
- *If no disparities information is provided, are you aware of evidence that disparities exist in this area of healthcare?*

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

Criteria 2: Scientific Acceptability of Measure Properties

Complex measure evaluated by the Scientific Methods Panel (SMP)? ☐ **Yes** ☒ **No**

Evaluators: Staff

2a. Reliability: Specifications and Testing

2a1. Specifications require the measure, as specified, to produce consistent (i.e., reliable) and credible (i.e., valid) results about the quality of care when implemented.

2a2. Reliability testing demonstrates whether the measure data elements are repeatable and producing the same results a high proportion of the time when assessed in the same population in the same time period, and/or whether the measure score is precise enough to distinguish differences in performance across providers.

Specifications:

- Measure specifications are clear and precise.

Reliability Testing:

- Reliability testing conducted at the Patient/Encounter Level:
  - Inter-rater reliability of chart review for HT-CDI was conducted for the critical data elements of date of admission, presence of positive C.diff (CD) test, and presence of 5 or more days of Qualifying Antimicrobial Therapy (QAT).
  - A Cohen's Kappa statistic was calculated to adjust for chance agreement for categorical data assessed between electronic chart extraction and manual chart review.
    - Date of Admission - 84.3 percent of sampled encounters had an exact match between the electronic health extraction and manual chart review.
    - Positive CD test: The developer reported a Kappa of 0.9696 with a 95 percent confidence interval of 0.9567 - 0.9825.
    - 5+QAT if CD test positive: The developer reported a kappa of 0.9754 with a 95 percent confidence interval of 0.9638 – 0.987.
    - HT-CDI event determination - the developer calculated a kappa of 0.956 with a 95 percent confidence interval of 0.9511 – 0.9789.
  - The developer states that the analyses demonstrate that electronic extraction of data elements can be reliably extracted, and the HT-CDI event determination can be reliably made.

Questions for the Standing Committee regarding reliability:

- *Do you have any concerns that the measure cannot be consistently implemented (i.e., are the measure specifications adequate)?*

Guidance From the Reliability Algorithm

- Submitted specifications are precise, unambiguous, and complete (Box 1) -> Empirical reliability testing was conducted using statistical tests with the measure as specified (Box 2) -> Empirical reliability testing conducted on all critical patient/encounter data elements used to construct the performance measure (Box 8) -> Method described and appropriate for assessing the reliability of all critical patient/encounter level elements (Box 9) -> Moderate.

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

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

2b2. Validity testing should demonstrate that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality.

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

Validity Testing

- Validity testing conducted at the Patient/Encounter Level:
    - The developer tested the validity of the measure as specified using the comparison of HT-CDI events (calculated based on electronic capture of all critical patient/encounter data elements) vs Reference Standard Case Definition (explicit manual review of charts for clinical disease due to C. diff based on meeting the HT-CDI definition PLUS documentation of diarrhea within the 3 days prior to stool sample collection) to assess the electronic HT-CDI measure for sensitivity and specificity.
    - The sensitivity and specificity of the electronic HT-CDI was compared to the sensitivity and specificity of the electronically captured C.difficile LabID.
    - The developer notes that the specificities underestimate the true specificity of the measurement due to the sample being enriched for CDI cases (case rate in sample > true prevalence in the population) and as a result, positive predictive value and negative predictive value could not be calculated.
        - Sensitivity and Specificity of electronic capture of HT-CDI events as compared to Reference Standard:
            - The developer reports a sensitivity of 0.98 with a 95 percent confidence interval of 0.97 - 0.99 and a specificity of 0.96 with a 95 percent confidence interval of 0.94 - 0.97 electronic capture of HT-CDI events as compared to Reference Standard.
        - Comparison of Sensitivity and Specificity of electronic HT-CDI to electronic capture of CDI LabID (final CD test positive) as compared to Reference Standard:
            - The developer reports a sensitivity of 0.97 with a 95 percent confidence interval of 0.96 - 0.99 for Electronic LabID and a sensitivity of 0.98 with a 95 percent confidence interval of 0.97 – 0.99 for HT-CDI.

        - The developer reports a specificity of 0.93 with a 95 percent confidence interval of 0.92 – 0.95 for Electronic LabID and a specificity of 0.96 with a 95 percent confidence interval of 0.94 – 0.97 for HT-CDI.
    - The developer states that the electronic HT-CDI measure has a high likelihood of correctly including patients with HT-CDI and correctly excluding patients who do not have HT-CDI.

The developer states that the sensitivity and specificity of the electronic HT-CDI measure are higher than electronic LabID, though not statistically significant as the 95% confidence intervals overlap.

Exclusions

- The developer states the measure does not use exclusions in the threats to validity section but lists the following as exclusions in the specifications:
    - Data from patients who are not assigned to an inpatient bed are excluded from the denominator counts, including outpatient clinics, 24-hour observation units, and emergency department visits.
    - Patients who are <365 days old on the date of admission are not included in denominator counts.

Risk Adjustment

- The developer reports that the variables used for risk adjustment are obtained or directly calculated from Admission/Discharge/Transfer (ADT) systems, microbiology, and pharmacy or medication administration databases.
    - An additional multi-step process was applied to ensure that the data was clinically viable and consistent with findings of other independent peer reviewed studies or outside data sources. A statistical risk model with 9 risk factors including year, community-onset Clostridioides difficile infection (COCDI) prevalence, average length of stay (LOS), bed size, hospital-onset (HO) testing intensity, CO testing intensity, HO testing prevalence, % females, and teaching status is used in the measure.
- Rates of hospital-onset Clostridioides *difficile* infection (HOCDI) were calculated as the number of HOCDI events per 100 admissions for quarterly aggregated data. A bivariate analysis using general linear models was performed to examine the correlation between HOCDI rate and each risk factor.
    - The developer states that negative binomial regression methods were used to identify the risk factors of HOCDI and to account for the overdispersion of data. The developer conducted a modeling analysis that considered hospital-level variables easily accrued from EHRs (electronic health records) or reportable to the National Healthcare Safety Network (NHSN).
    - The developer states that the final model was selected using Akaike's Information Criteria (AIC) and Bayesian Information Criteria (BIC) based on the full data in the study cohort.
    - The developer presents a root mean squared error (RMSE) for the CDI complex model to be RMSE = 3.16, which represents the estimated standard deviation of prediction errors for the complex model.
    - The developer stated that the decile plots show that there is no pattern of systematic deviation for the model predicted HOCDI events from the line of best fit, which indicates a well specified model.
- The developer reports that the model results include finding that the following hospital level variables were significantly associated with higher HOCDI event rates: higher COCDI prevalence; the top quarter

(4th quartile) of average LOS; larger bed size; higher percent of male patients; increased HO blood culture testing intensity, increased HO blood culture prevalence, and teaching hospitals.

  - The developer states that the increased community onset period CDI testing intensity was negatively associated with HOCDI event rates.
  - The developer reports that among the identified risk factors, the most influential factors were HO period testing intensity, COCDI rate, HO period testing prevalence, and CO testing intensity.

- The developer reports that patient-level characteristics were not assessed, and risk stratification was not performed.

Meaningful Differences

- The developer states that measure performance was evaluated in a retrospective, ecological study based on electronic microbiological, medication and administrative data from adult patients 18 years or older admitted from October 1, 2015, through February 28, 2020, to one of 267 acute care hospitals within the BD (Becton, Dickinson, and Company) Insights and Research Database.
- Statistical analysis was approached in 3 steps: (1) Identify the candidate variables that influence HOCDI rates using bivariate analysis. (2) Identify the risk factors of the Complex Model and derive SIRs based on the models. (3) Compare hospital rankings using the observed (unadjusted) HOCDI rates versus using risk adjustment from the Complex Model.
- The developer reports that of the fifty hospitals with the highest observed HOCDI rate, nineteen hospitals stayed in the same ranking category of the model-based SIR, 21 hospitals improved their ranking to the third quartile, 8 hospitals improved their rank to the second quartile, and 2 hospitals moved to the first quartile.
- The developer states that a meaningful difference of in the SIR was defined as an SIR and a confidence interval that was statistically different from 1. The developer reports that of the 243 total facilities reporting in 2019, SIRs were calculated for 200 of the facilities.
  - The developer reports that 75 facilities had an SIR not significantly different from 1, 19 facilities that had an SIR significantly lower than 1, and 11 facilities that were significantly higher than 1.

Missing Data

- The developer states that at least 3 months of uninterrupted continuous data from participating hospitals is required by Becton Dickinson (BD) to meet data requirements. The developer states that this data includes ADT (admission, discharge, transfer) feeds; laboratory data including microbiology data from an uninterrupted laboratory information system data feed, and medication order/stop feeds.
- The developer conducted a data interruption analysis by extracting monthly aggregated hospital-level data from the BD database, and reports that across all 267 study hospitals, 2% of the 10,532 total data feed months were interrupted.
- The developer reports no missing data on facility characteristics such as bed size, or urban/rural status. Additionally, the developer reports no missing data for clinical factors such as community-onset bacteremia events and culture testing data.
  - Gender and Age:
    - The developer reports that 0.12% of the 9,202,650 admissions had missing values on gender status.

        - The developer states that admissions with missing gender information were excluded from the analysis.
    - Intensive Care Unit (ICU):
        - The developer reports 1.3% missing data on ICU admission status in the HOB study cohort which includes 20,310 total admissions.
        - Further, the developer states that missing data on ICU admission status would be put in its own individual category named "unknown/unreported" since ICU admission was deemed to be an influencing factor of the study outcomes (HOB rate or HOCDI rate).

Comparability

- The measure only uses one set of specifications for this measure.

Questions for the Standing Committee regarding validity:

- *Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk adjustment approach, etc.)?*
- *The developer states the measure does not use exclusions in the threats to validity section but lists exclusions in the specifications. Does the Standing Committee have any concerns about the lack of exclusion testing?*

Guidance From the Validity Algorithm

- All potential threats to validity that are relevant to the measure are empirically assessed (Box 1) -> Empirical validity testing conducted using the measure as specified (Box 2) -> Empirical validity testing conducted on all critical patient/encounter data elements used to construct the performance measure (Box 9) -> Method described was appropriate for assessing the accuracy of all patient/encounter data elements (Box 10) -> Moderate.

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

Criterion 3. Feasibility

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.

- The developer reports the data elements needed to compute the measure are generated or collected by and used by healthcare personnel during the provision of care and are all found in defined fields in a combination of electronic sources.
- The developer notes that all data elements can be found in EHR, ADT, or electronic claims.

The developer states that there are no fees or licensing requirements to use this measure.

Questions for the Standing 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**

Criterion 4: Use and Usability

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

4a. Use evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and 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 they are not in use at the time of initial endorsement, then a credible plan for implementation within the specified time frames is provided.

Current uses of the measure

Publicly reported?	☐ Yes	☒ No			
Current use in an accountability program?	☐ Yes	☒ No	☐ UNCLEAR		
Planned use in an accountability program?	☒ Yes	☐ No	☐ NA		

Accountability program details

- The developer notes that this measure is not yet in use because it is a new measure.
- Reporting into the HT-CDI NHSN module is planned to launch in 2023.
- The developer also states that CDC has a long-standing collaborative relationship with the Centers for Medicare & Medicaid (CMS), who has been kept aware of the progress of this measure and its targeted suitability for various quality programs.

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; and (3) This feedback has been considered when changes are incorporated into the measure.

Feedback on the measure provided by those being measured or others

- In terms of measure feedback, the developer notes that once a facility reports at least a month of data into the HT-CDI module, the data and initial analytics will be available for the facility within the NHSN application and provided monthly.
- The developer also notes that a national baseline will be established after the first year of data collection, which can be used by the facilities and other entities for benchmarking to drive improvement practices as well as HAI progress report that will be published on an annual basis.
    - The developer reports that there is no feedback on performance or measure implementation yet since the measure is not in use

***Questions for the Standing 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 (4b1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluates the extent to which audiences (e.g., consumers, purchasers, providers, and 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 measure has not yet been implemented in a public reporting program, so improvement cannot be evaluated. However, the developer notes that while NQF #3688 has not been in use, NQF #1717 has been used to drive improvement in *C.difficile* infection in hospitalized patients.
- The developer states that NQF #3688 represents an incremental improvement on NQF #1717 because it considers clinician decision making to improve the **clinical** validity of the measure. Additionally, the developer states that from 2015 to 2020, the national CDI LabID SIR has decreased by 48 percent, indicating a trend in performance (lower SIR = better).

4b2. Benefits versus harms. 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).

Unexpected findings (positive or negative) during implementation

- The developer did not report any unexpected findings as the measure has not been implemented yet. However, the developer states that the new measure should more accurately reflect clinical judgement and reduce the emphasis on testing stewardship while encouraging antimicrobial stewardship efforts.

Potential harms

- The developer did not report any potential harm as the measure has not been implemented yet.

Additional Feedback:

- This measure was reviewed by the Measure Applications Partnership (MAP) in 2021 for the following CMS programs: Interoperability, Hospital Inpatient Quality Reporting Program (IQR), Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (PCHQR), Long-Term Care Hospital Quality Reporting Program (LTCH QRP), Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP), and the Skilled Nursing Facility Quality Reporting Program (SNFQRP). MAP voted for the Conditional Support for Rulemaking decision category for all programs, pending NQF endorsement.

***Questions for the Standing 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**

Criterion 5: Related and Competing Measures

Competing Measures

- The developer noted one NQF endorsed competing measure.
    - NQF #1717 Centers for Disease Control and Prevention (CDC), National Healthcare Safety Network (NHSN), Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure

Harmonization

- The developer states that NQF #1717 and NQF #3688 are harmonized across the patient population included in the measures. NQF #3688 improves upon NQF #1717 in that it will be a fully electronic measure through automated transfer of data from the facility into the NHSN application and will be calculated algorithmically and objectively without the requirement for infection preventionists to directly decide each event. Therefore, it may be better suited for quality reporting programs than some related HAI measures.

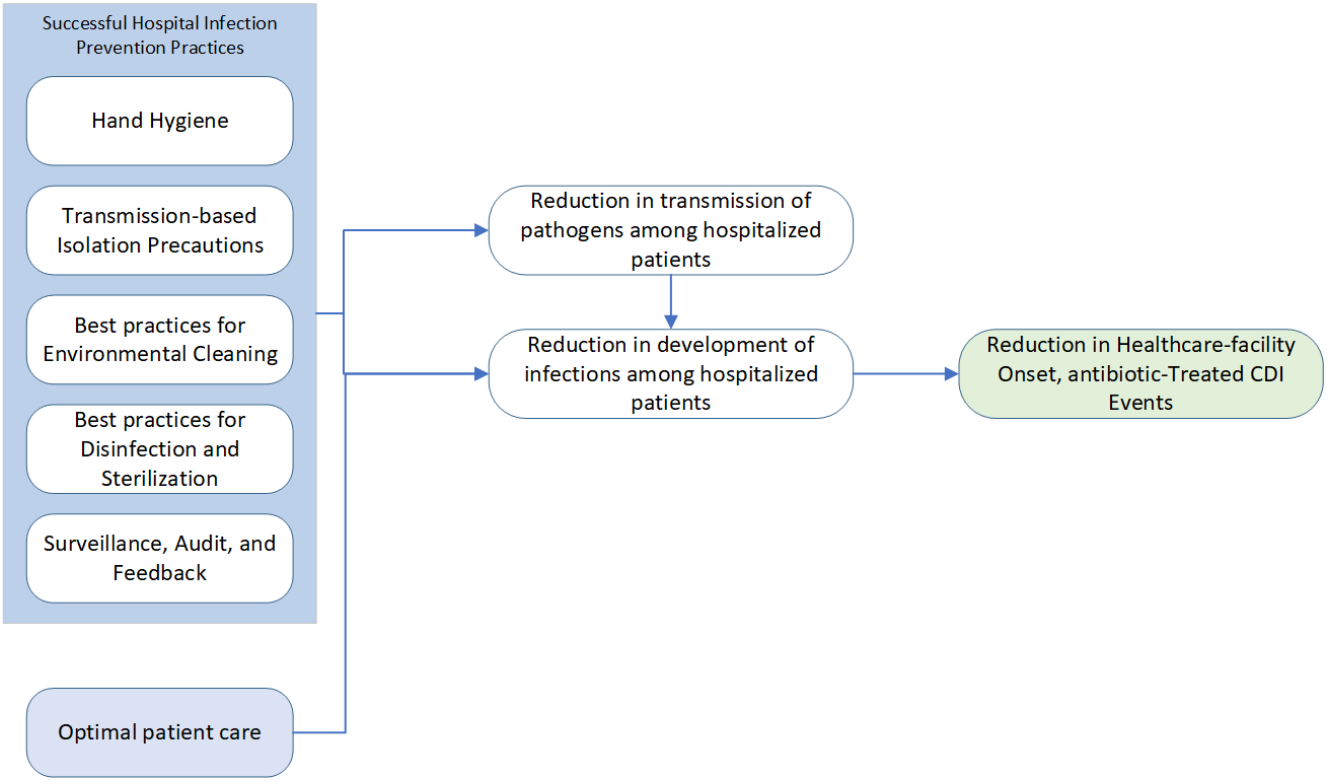
Criteria 1: Importance to Measure and Report

1a. Evidence

1a.01. Provide a logic model.

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.

[Response Begins]



The SIR describes a healthcare facility´s performance compared to a national baseline. Facilities are able to see how the number of HT-CDI events they have reported compares to the number predicted, given national data. The measure can then be used to drive prevention practices, antibiotic stewardship, proper use of isolation precautions and hand hygiene that will lead to improved outcomes, including the reduction of patient morbidity and mortality.

[Response Ends]

1a.02. Provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful.

Describe how and from whom input was obtained.

[Response Begins]

HT-CDI serves as an objective measure of Healthcare-associated infection (HAI) burden within a hospital. HAI reduction has been a national priority set by U.S. Government going back to 2008 with the U.S. Health and Human Services (HHS) National Action Plan to Prevent Health Care-associated Infections: Roadmap to Elimination.[1] The 2016 update to this national action plan has included specific HAIs as targets for benchmarking progress including "Reduce hospital-onset *Clostridioides difficile* infections (CDI)". While there has been overall progress in reducing these specific HAIs, there is room for improvement in both the surveillance and prevention of hospital-onset *Clostridioides difficile* infections.

Measuring hospital-onset *C.difficile* has also been a priority for CMS as indicated by the use of NQF#1717 (The current NHSN *C.difficile* outcome measure) in eight CMS Measure Programs, including Hospital Acquired Condition Reduction Program, Hospital Value-Based Purchasing, IRF Quality Reporting, and LTCH Quality Reporting.[2] Additionally, the HT-CDI measure (NQF#3688) was included as MUC2021-098 as part of CMS's Measures Under Consideration for inclusion into various regulatory reporting programs.[3]

1. U.S. Health and Human Services (HHS) National Action Plan to Prevent Health Care-associated Infections: Roadmap to Elimination. Accessed July 6, 2022 at https://www.hhs.gov/oidp/topics/health-care-associated-infections/hai-action-plan/index.html
2. Centers for Medicare and Medicaid Services Measures Inventory Tool at https://cmit.cms.gov/cmit/#/FamilyView?familyId=462
3. List of Measures Under Consideration for December 2021 (Pg. 17) at https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf

[Response Ends]

1a.03. Provide empirical data demonstrating the relationship between the outcome (or PRO) and at least one healthcare structure, process, intervention, or service.

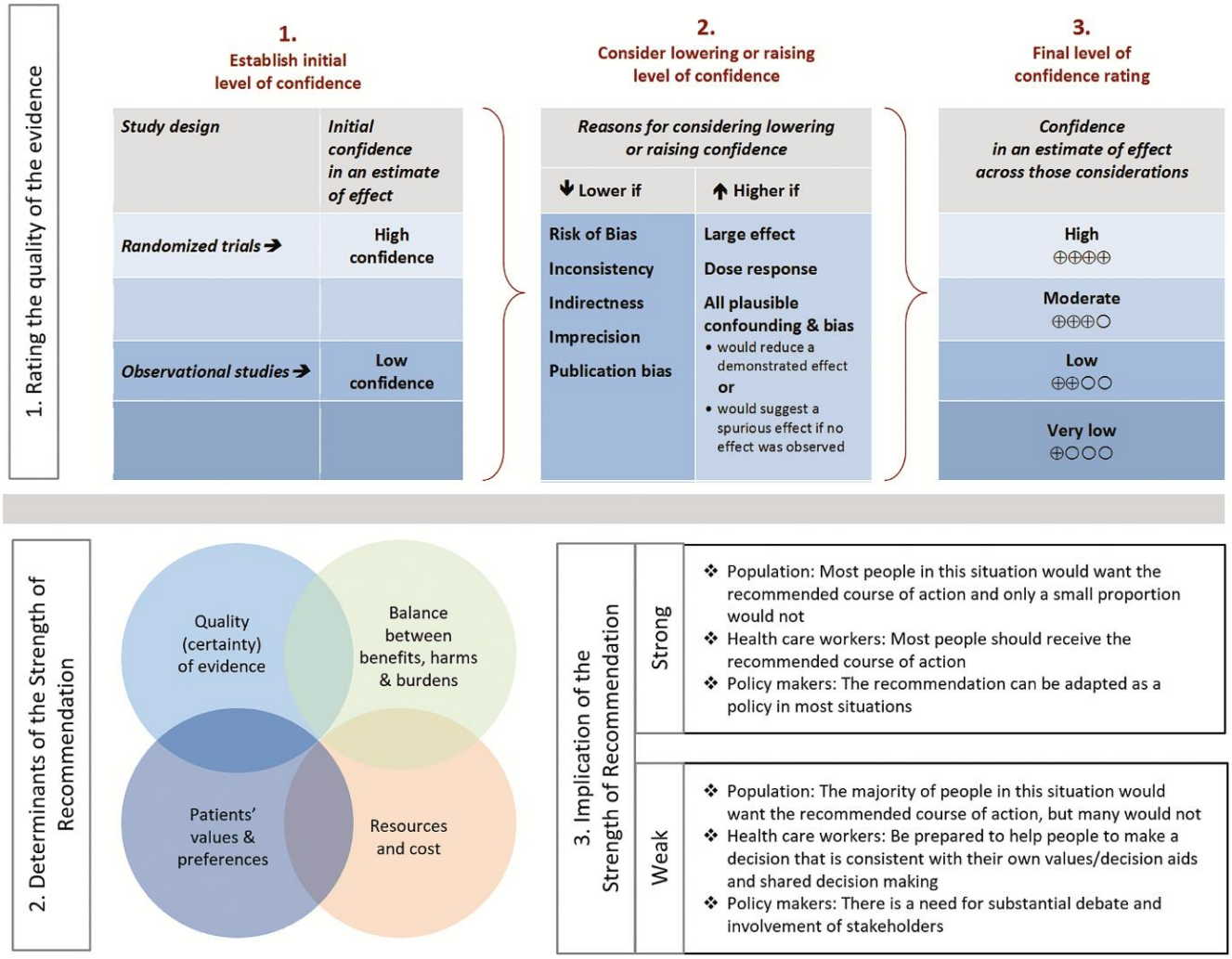
[Response Begins]

McDonald LC, Gerding DN, Johnson S, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). *Clin Infect Dis*. 2018;66(7):e1-e48. doi:10.1093/cid/cix1085

For the 2017 clinical guidelines for management of CDI, an expert review panel from the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology (SHEA) of America graded existing evidence for control and prevention of CDI. The IDSA/SHEA guidelines 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 updated guidelines have incorporated recommendations for children (following the adult recommendations for epidemiology, diagnosis, and treatment), include significant changes in the management of this infection and reflect the evolving controversy over best methods for diagnosis. *Clostridium difficile* remains the most important cause of healthcare-associated diarrhea and is one of the most commonly identified causes of healthcare-associated infection in adults in the United States. This guideline updated recommendations regarding epidemiology, diagnosis, treatment, infection prevention, and environmental management.

One specific overall guideline recommendation is not provided. Each individual recommendation in a guideline is given a grade as described below:

The panel followed a process used in the development of other Infectious Diseases Society of America (IDSA) guidelines, which included a systematic weighting of the strength of recommendation and quality of evidence using the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) system.



"A targeted systematic review of the literature was conducted in MEDLINE, EMBASE, CINAHL, and the Cochrane Library from 1998 through April 2014. A modified Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach was used to assess the quality of evidence and the strength of the resulting recommendation and to provide explicit links between them. Of 5759 titles and abstracts screened, 896 underwent full-text review by 2 independent reviewers. After exclusions, 170 studies were extracted into evidence tables, appraised, and synthesized."

http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000094

The 2018 updated IDSA/SHEA/ practice guidelines for the management of CDI included results from over 300 studies.

The following guidelines with corresponding grade are related to prevention of CDI:

XIII. Should private rooms and/or dedicated toilet facilities be used for isolated patients with CDI?

- Accommodate patients with CDI in a private room with a dedicated toilet to decrease transmission to other patients. If there is a limited number of private single rooms, prioritize patients with stool incontinence for placement in private rooms (strong recommendation, moderate quality of evidence).
- If cohorting is required, it is recommended to cohort patients infected or colonized with the same organism(s)—that is, do not cohort patients with CDI who are discordant for other multidrug-resistant organisms such as methicillin-resistant Staphylococcus aureus or vancomycin-resistant Enterococcus (strong recommendation, moderate quality of evidence).

XIV. Should gloves and gowns be worn while caring for isolated CDI patients?

- Healthcare personnel must use gloves (strong recommendation, high quality of evidence) and gowns (strong recommendation, moderate quality of evidence) on entry to a room of a patient with CDI and while caring for patients with CDI.

XV. When should isolation be implemented?

- Patients with suspected CDI should be placed on preemptive contact precautions pending the C. difficile test results if test results cannot be obtained on the same day (strong recommendation, moderate quality of evidence).

XVI. How long should isolation be continued?

- Continue contact precautions for at least 48 hours after diarrhea has resolved (weak recommendation, low quality of evidence).
- Prolong contact precautions until discharge if CDI rates remain high despite implementation of standard infection control measures against CDI (weak recommendation, low quality of evidence).

XVII. What is the recommended hand hygiene method (assuming glove use) when caring for patients in isolation for CDI?

- In routine or endemic settings, perform hand hygiene before and after contact of a patient with CDI and after removing gloves with either soap and water or an alcohol-based hand hygiene product (strong recommendation, moderate quality of evidence).
- In CDI outbreaks or hyperendemic (sustained high rates) settings, perform hand hygiene with soap and water preferentially instead of alcohol-based hand hygiene products before and after caring for a patient with CDI given the increased efficacy of spore removal with soap and water (weak recommendation, low quality of evidence).
- Handwashing with soap and water is preferred if there is direct contact with feces or an area where fecal contamination is likely (eg, the perineal region) (good practice recommendation).

XVIII. Should patient bathing interventions be implemented to prevent CDI?

- Encourage patients to wash hands and shower to reduce the burden of spores on the skin (good practice recommendation).

XIX. Should noncritical devices or equipment be dedicated to or specially cleaned after being used on the isolated patient with CDI?

- Use disposable patient equipment when possible and ensure that reusable equipment is thoroughly cleaned and disinfected, preferentially with a sporicidal disinfectant that is equipment compatible (strong recommendation, moderate quality of evidence).

XX. What is the role of manual, terminal disinfection using a C. difficile sporicidal agent for patients in isolation for CDI?

- Terminal room cleaning with a sporicidal agent should be considered in conjunction with other measures to prevent CDI during endemic high rates or outbreaks, or if there is evidence of repeated cases of CDI in the same room (weak recommendation, low quality of evidence).

XXI. Should cleaning adequacy be evaluated? Recommendation

- Incorporate measures of cleaning effectiveness to ensure quality of environmental cleaning (good practice recommendation).

XXII.What is the role of automated terminal disinfection using a method that is sporicidal against C. difficile?

- There are limited data at this time to recommend use of automated, terminal disinfection using a sporicidal method for CDI prevention (no recommendation).

XXIII. What is the role of daily sporicidal disinfection?

- Daily cleaning with a sporicidal agent should be considered in conjunction with other measures to prevent CDI during outbreaks or in hyperendemic (sustained high rates) settings, or if there is evidence of repeated cases of CDI in the same room (weak recommendation, low quality of evidence).

XXIV. Should asymptomatic carriers of C. difficile be identified and isolated if positive?

- There are insufficient data to recommend screening for asymptomatic carriage and placing asymptomatic carriers on contact precautions (no recommendation).

XXV. What is the role of antibiotic stewardship in controlling CDI rates?

- Minimize the frequency and duration of high-risk antibiotic therapy and the number of antibiotic agents prescribed, to reduce CDI risk (strong recommendation, moderate quality of evidence).
- Implement an antibiotic stewardship program (good practice recommendation).
- Antibiotics to be targeted should be based on the local epidemiology and the C. difficile strains present. Restriction of fluoroquinolones, clindamycin, and cephalosporins (except for surgical antibiotic prophylaxis) should be considered (strong recommendation, moderate quality of evidence).

Rutala WA, Weber DJ, and the Healthcare Infection Control Practice Advisory Committee. **Guideline for Disinfection and Sterilization** in Healthcare Facilities, 2008. Available at https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.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 https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines.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).

https://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

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

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.

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.

One specific overall guideline recommendation is not provided in any of the HICPAC guidelines. Each individual recommendation in a guideline is given a grade as described below:

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

Example from Siegel et al:

Monitor the incidence of epidemiologically-important organisms and targeted HAIs that have substantial impact on outcome and for which effective preventive interventions are available; use information collected through surveillance of high-risk populations, procedures, devices and highly transmissible infectious agents to detect transmission of infectious agents in the healthcare facility (Grade 1A)

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

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

The 2002 HICPAC guidelines for hand hygiene in healthcare settings include results from over 400 studies.

[Response Ends]

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

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

Surveillance for HT-CDI will help hospitals monitor for *C.difficile* burden and target quality improvement initiatives that reduce HAIs and thus result in less patient harm, shorter hospitalizations, and lower healthcare costs. The HT-CDI SIR describes a healthcare facility´s performance compared to a national baseline. Facilities are able to see how the number of HT-CDI events they have reported compares to the number predicted, 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.

[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and 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 (4b) under Usability and Use.

[Response Begins]

This is a new measure, so performance scores are not available.

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, 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. Include citations.

[Response Begins]

Although rates of hospital-associated CDI have been decreasing over recent years, in 2020 there were 40,562 Hospital-onset CDI LabID events reported to NHSN out of a total of 28,917,177 total admissions and 131,335,743 total patient days from 3,653 hospitals, indicating there continues to be room for improvement in the prevention of this HAI. Additionally, the data from the annual HAI progress report demonstrates there is considerable variability in SIR between states, indicating a significant variation between facilities in the prevention of CDI. In 2020, the national SIR for Hospital-onset CDI LabID events was 0.518, with state SIRs ranging from 0.130 to 0.824.

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

Data from the 2018 Emerging Infections Program found an incidence of Healthcare-associated CDI of 64.18 per 100,000 persons, again indicating the need for improvement in the prevention of this HAI.

https://www.cdc.gov/hai/eip/Annual-CDI-Report-2018.html

[Response Ends]

1b.04. 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.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. 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 (4b) under Usability and Use.

[Response Begins]

This is a new measure, so disparity data are not yet available.

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, 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 above.

[Response Begins]

Data available from the 2018 Annual CDI report from the Emerging Infections Program indicate a slight female predominance in Healthcare-associated CDI incidence (66.23/100,000 persons vs 62.04/100,000). There is an increasing incidence by age (1-17 years: 9.03/100,000; 18-44 years: 17.82/100,000; 45-64 years: 72.12/100,000; >=65 years: 262.35/100,000). Finally, there is a slight predominance in white populations as compared to non-white populations (69.54/100,000 vs 53.18/100,000)

https://www.cdc.gov/hai/eip/Annual-CDI-Report-2018.html

[Response Ends]

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability

sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see What Good Looks Like).

[Response Begins]

Centers for Disease Control and Prevention (CDC), National Healthcare Safety Network (NHSN), Healthcare facility-onset, antibiotic-Treated Clostridiodes difficile Infection (HT-CDI) Outcome Measure

[Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

Standardized infection ratio (SIR) based on fully electronic capture of Healthcare facility-onset, antibiotic-Treated Clostridiodes difficile Infection (HT-CDI) events among inpatients in the facility

[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Surgery: General*

[Response Begins]

Infectious Diseases (ID)

[Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins]

Safety: Healthcare Associated Infections

[Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]

Adults (Age >= 18)

Children (Age < 18)

[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

Inpatient/Hospital

[Response Ends]

sp.09. 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. If no URL is available, indicate "none available".

[Response Begins]

Will be made available on NHSN website once the new electronic module goes live

[Response Ends]

sp.12. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, contact staff. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

Available in attached Excel or csv file

[Response Ends]

Attachment: 3688_3688_3688 Data Elements_Value Sets-508.xlsx

For the question below: state the outcome being measured. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.13. State the numerator.

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.

[Response Begins]

Total number of observed incident healthcare facility-onset, antibiotic-treated CDI (HT-CDI) events among all inpatients in the facility.

[Response Ends]

For the question below: describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.14. Provide details needed to calculate the numerator.

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 sp.11.

[Response Begins]

Data elements for the calculation of incidence will be collected electronically from electronic health records.

***Healthcare facility-onset, antibiotic-Treated CDI* (HT-CDI) Event will be defined as:**

1. Any qualifying *C. difficile*-positive assay collected in an inpatient location on day 4 or later of healthcare facility admission, and
2. New qualifying antimicrobial therapy for *C. difficile* started ≤ 2 calendar days before or after the specimen collection date and continued for at least 5 calendar days or until the calendar day of or day prior to discharge.

CDI Qualifying Antimicrobial Therapy (QAT) includes administration of a **new therapeutic** agent for the indicated **treatment duration** within the appropriate **window period** for the *C. difficile* positive test according to the following criteria:

1. The therapeutic agent is considered **new** for the purposes of this definition if it was **not** given to the patient on either of the 2 calendar days preceding the current start date.
2. **Therapeutic agents** for CDI are defined as follows:
    a. Enteral* vancomycin
    b. Enteral* metronidazole
    c. Intravenous (IV) metronidazole
    d. Enteral* fidaxomicin

    *Enteral routes include any route that allows absorption via the gastrointestinal tract, and as examples include oral (PO), rectal (PR), and administration via nasogastric (NG), orogastric (OG), gastrostomy (G-tube), and gastrojejunostomy tube (G-J tube). Note: bezlotoxumab is not included as it is utilized primarily in outpatient settings.

1. **Treatment Duration**: A patient must have had at least 5 consecutive calendar days of appropriate antimicrobials to meet QAT criteria. Furthermore:

- If a patient is discharged, dies, transitions to hospice care, or is transferred to another facility before 5 QATs are met, then the QAT requirement is still met as long as the QATs are on consecutive days until the day of, or 1 calendar day prior to the discharge, death, transition to hospice care, or transfer to another facility.
- Treatment will be considered consecutive if the therapeutic agents are administered daily with a gap of up to 1 calendar day.

1. **Window Period**: The date the *C. difficile* positive stool specimen is collected is the center of a window period extending both 2 calendar days before and 2 calendar days after the stool specimen.
    - The start date of at least one therapeutic agent must fall within the window period.
        a. The therapeutic agent or route of administration of agent can be changed as long as the start date of at least one therapeutic agent falls within the window period.
    - Therapeutic agents with start dates prior to the window period will not count towards QAT.

Event Date and Location:

The date of CDI event will be based on the date of stool specimen collection. Events are determined based on the facility where the patient was located on the day of specimen collection.

Event Exclusion Criteria:

Patients will be excluded from HT-CDI event if the patient had a positive CD test ≤ 14 calendar days from the current specimen collection date, from any ED, Obs, or inpatient location from the same facility. The date of stool specimen collection is Day 1 of the 14 day timeframe for exclusion.

Each event will be further categorized with regard to incident vs. recurrent as seen in the table below.

Category	Definition
Incident CDI event	Any CDI event more than 56 days after the most recent previously reported CDI event (or with no previous CDI event documented) for that patient. Note: the date of first specimen collection is considered day 1.
Recurrent CDI event	Any CDI event less than or equal to 56 days after the most recent previously reported CDI event for that patient. Note: the date of first specimen collection is considered day 1.

[Response Ends]

For the question below: state the target population for the outcome. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.15. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

Total number of expected incident HT-CDI events based on predictive models using facility-level and patient-level factors.

[Response Ends]

For the question below: describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.16. Provide details needed to calculate the denominator.

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 sp.11.

[Response Begins]

Patient days for the time period under surveillance: The number of patient days will be calculated by summing the daily count of patients who were ≥ 365 days old on the calendar day of admission occupying beds in each inpatient location in the facility over the time period under surveillance. Data from patients who are not assigned to an inpatient bed are not included the denominator counts (examples: outpatient clinics, 24-hour observation units, and emergency department visits)

The predicted number of events will be calculated using baseline incidence data which will be reported following the first year of data collection. The variables used in the final risk model will be based on facility level statistical modeling. Variables included in previous CDI SIR included facility´s number of inpatient days, facility type, CDI event reporting from Emergency Department and 24 hour observation units, bed size, ICU bed size, affiliation with medical school, microbiological test method used to identify C. difficile, and community-onset CDI admission prevalence rate. As patient-level numerator and denominator data will be collected electronically, patient-level risk modeling will also be used in risk adjustment of the SIR.

[Response Ends]

sp.17. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

Data from patients who are not assigned to an inpatient bed are excluded from the denominator counts, including outpatient clinics, 24-hour observation units, and emergency department visits. Patients who are <365 days old on the date of admission are not included in denominator counts.

[Response Ends]

sp.18. Provide details needed to calculate the denominator exclusions.

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 sp.11.

[Response Begins]

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.

If date of inpatient admission minus patient date of birth is <365 days, patient is not included in the denominator.

[Response Ends]

sp.19. Provide all information required to stratify the measure results, if necessary.

Include 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 in the Data Dictionary field.

[Response Begins]

The measure will not be stratified, as it is an overall facility-wide summary measure. Facility and patient-level characteristics will be used for risk adjustment, described above in sp.16

[Response Ends]

sp.20. Is this measure adjusted for socioeconomic status (SES)?

[Response Begins]

No

[Response Ends]

sp.21. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins]

Statistical risk model

[Response Ends]

sp.22. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

[Response Begins]

Ratio

[Response Ends]

sp.23. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins]

Better quality = Lower score

[Response Ends]

sp.24. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]

The Standardized Infection Ratio (SIR) is calculated for each healthcare facility for a specified time period (quarterly and annually). The SIR is an indirect standardization method for summarizing healthcare-associated infection (HAI) experience, including CDI events, in a single group of data or across any number of stratified groups of data.

To produce the SIR:

1. Identify the number of observed incident HT-CDI events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of predicted incident HT-CDI events for the facility (as described in sp.16).
3. Divide the number of observed incident HT-CDI events (1 above) by the number of predicted incident HT-CDI events (2 above) to obtain the SIR.

[Response Ends]

sp.27. If measure testing is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

Examples of samples used for testing:

- *Testing may be conducted on a sample of the accountable entities (e.g., hospital, physician). The analytic unit specified for the particular measure (e.g., physician, hospital, home health agency) determines the sampling strategy for scientific acceptability testing.*
- *The sample should represent the variety of entities whose performance will be measured. The 2010 Measure Testing Task Force recognized that the samples used for reliability and validity testing often have limited generalizability because measured entities volunteer to participate. Ideally, however, all types of entities whose performance will be measured should be included in reliability and validity testing.*
- *The sample should include adequate numbers of units of measurement and adequate numbers of patients to answer the specific reliability or validity question with the chosen statistical method.*
- *When possible, units of measurement and patients within units should be randomly selected.*

[Response Begins]

No sampling methodology is used to calculate this metric.

[Response Ends]

sp.30. Select only the data sources for which the measure is specified.

[Response Begins]

Electronic Health Records

[Response Ends]

sp.31. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]

Data will be collected through the new electronic NHSN CDI module.

[Response Ends]

sp.32. Provide the data collection instrument.

[Response Begins]

Available at measure-specific web page URL identified in sp.09

[Response Ends]

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 fields in the Scientific Acceptability sections of the Measure Submission Form.

- 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.
- All required sections must be completed.
- For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.
- If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.
- An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.
- Contact NQF staff with any questions. Check for resources at the 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 the 2021 Measure Evaluation Criteria and Guidance.

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.

2a. Reliability testing 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 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;

AND

If patient preference (e.g., informed decision-making) 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).

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
- 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 non-responders) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

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).

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.

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.

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

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

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.

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous (Year) Submission:

Testing from the previous submission here.

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]

Electronic Health Records

[Response Ends]

2a.02. 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).

[Response Begins]

Not an existing dataset

[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

Validator	**Data time frame**
Emerging Infectious Program	**1-1-2018 – 12-31-2019**

[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

2a.05. List the measured entities 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.

[Response Begins]

Testing was conducted across 9 facilities representing geographic locations across the US as well as a range of hospital bed sizes.

Measured entities with descriptive characteristics

Site	Region	Number of facilities	Type	Hospital Bed Range per Facility
1	Midwest	1	Acute Care Hospital	400-500
2	West	1	Acute Care Hospital	400-500
3	Northeast	2	Acute Care Hospital	200-300 800-900
4	Northwest	1	Acute Care Hospital	100-200
5	Southeast	4	Acute Care Hospitals	100-200 300-400 500-600 600-700

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

Each site identified a retrospective cohort of patients using the approach detailed below to create a cohort that is enriched for patients with *C. difficile*. The sampling framework created a cohort that is enriched to have between 50% and 66% of patient-encounters having positive tests for *C. difficile* so that the evaluation would have adequate power.

Each site-facility sampled using the following framework for choosing the patient-encounters that were included:

1. Partition 1: Random -- 120 encounters randomly selected from the discharges in 2018 and 2019
2. Partition 2: C. dif -- All encounters (discharges for unique patients) per site where testing for *C. difficile* was positive after the first 3 days of hospitalization in 2018 and 2019 (cap at 120 randomly selected patients if more than 120; any patient is only included once)

3. Partition 3: Meds -- 120 random encounters (discharges) per site where oral and/or rectal vancomycin or fidaxomicin were administered after the first 3 days of hospitalization in 2018 and 2019

These 3 partitions were combined to create the enriched cohort for analysis. Encounters from the 3 sample partitions are expected to overlap giving a total sample size per site-facility that is between 200 and 360 for the cohort.

Table 1. Number and percentage of Unique patient encounters in each Sampling partitions.

Sampling partitions	N. Of Unique Encounters	%
1	588	42.6
2	289	20.9
3	299	21.7
Both 1&2	2	0.1
Both 1&3	2	0.1
Both 2&3	199	14.4
1,2, & 3	1	0.1
Total	1380	100.0

Note: There is overlap between sampling partitions as many patients with positive C.dif testing (partition 2) also received oral vancomycin (partition 3).

A total of 1380 unique patient encounters were sampled, distributed across partitions and sites (Tables 1&2).

Table 2. Number of unique patient encounters evaluated at each testing site

Site	Unique patient encounters evaluated
1	306
2	203
3	311
4	209
5	351

Table 3. Patient Demographics (number and percentage) of sampled encounters at each testing site.

Race, ethnicity, sex, and age varied across testing sites.

*	*	**Race/Ethnicity**	*	*	*	*	**Sex**	*	**Age**	*
Site	**N. Encounters**	**Hispanic, N(%)**	**White, Non-Hispanic, N(%)**	**Black, Non-Hispanic, N(%)**	**Other, Non-Hispanic, N(%)**	**Unknown, N(%)**	**Female, N(%)**	**Male, N(%)**	**Median (Q1 - Q3)**	**Mean (SD)**

*	*	**Race/Ethnicity**	*	*	*	*	**Sex**	*	**Age**	*
1	306	6 (2.0)	288 (94.1)	6 (2.0)	4 (1.3)	2 (0.7)	145 (47.4)	161 (52.6)	69.0 (56.0 - 79.0)	65.4 (17.5)
2	203	53 (26.1)	98 (48.3)	37 (18.2)	11 (5.4)	4 (2.0)	63 (31.0)	140 (69.0)	56.8 (42.6 - 67.5)	55.3 (17.0)
3	311	13 (4.2)	237 (76.2)	41 (13.2)	6 (1.9)	14 (4.5)	150 (48.2)	161 (51.8)	68.0 (56.9 - 75.8)	65.5 (15.9)
4	209	3 (1.4)	200 (95.7)	0 (0.0)	5 (2.4)	1 (0.5)	111 (53.1)	98 (46.9)	74.2 (63.2 - 83.2)	72.3 (14.5)
5	351	12 (3.4)	154 (43.9)	163 (46.4)	8 (2.3)	14 (4.0)	180 (51.3)	171 (48.7)	62.4 (51.0 - 71.8)	60.5 (16.4)
Total	**1380**	**87 (6.3)**	**977 (70.8)**	**247 (17.9)**	**34 (2.5)**	**35 (2.5)**	**649 (47.0)**	**731 (53.0)**	**66.0 (53.8 - 76.0)**	**63.7 (17.1)**

Cells marked with * are intentionally left blank.

Table 4. Diagnosis codes (ICD-10 codes: number and percentage) for sampled encounters at each testing site.

Diagnosis based on ICD-10 code	1	2	3	4	5	Overall
N. of Encounters	306	203	307	209	351	1376
Gastrointestinal	*	*	*	*	*	*
C. diff Diagnosis, N(%)	180 (58.8)	61 (30.1)	175 (57.0)	35 (16.8)	223 (63.5)	674 (49.0)
Peptic Ulcer Disease, N(%)	10 (3.3)	7 (3.5)	7 (2.3)	7 (3.4)	15 (4.3)	46 (3.3)
Mild Liver Disease, N(%)	49 (16.0)	43 (21.2)	29 (9.5)	27 (12.9)	71 (20.2)	219 (15.9)
Moderate-Severe Liver Disease, N(%)	25 (8.2)	25 (12.3)	19 (6.2)	16 (7.7)	37 (10.5)	122 (8.9)
Cardiovascular	*	*	*	*	*	*
Myocardial infarction, N(%)	60 (19.6)	25 (12.3)	35 (11.4)	27 (12.9)	40 (11.4)	187 (13.6)
Congestive Heart Failure, N(%)	93 (30.4)	45 (22.2)	91 (29.6)	64 (30.6)	148 (42.2)	441 (32.1)
Peripheral Vascular Disease, N(%)	41 (13.4)	17 (8.4)	42 (13.7)	31 (14.8)	69 (19.7)	200 (14.5)

Diagnosis based on ICD-10 code	1	2	3	4	5	Overall
Cerebrovascular Disease, N(%)	27 (8.8)	25 (12.3)	49 (16.0)	16 (7.7)	65 (18.5)	182 (13.2)
Pulmonary	*	*	*	*	*	*
Chronic Pulmonary Disease, N(%)	71 (23.2)	49 (24.1)	70 (22.8)	88 (42.1)	83 (23.7)	361 (26.2)
Renal	*	*	*	*	*	*
Renal Disease, N(%)	166 (54.3)	90 (44.3)	166 (54.1)	99 (47.4)	226 (64.4)	747 (54.3)
Endocrine	*	*	*	*	*	*
Diabetes without chronic complications, N(%)	63 (20.6)	43 (21.2)	84 (27.4)	55 (26.3)	137 (39.0)	382 (27.8)
Diabetes with chronic complications, N(%)	78 (25.5)	31 (15.3)	58 (18.9)	47 (22.5)	113 (32.2)	327 (23.8)
Neurologic	*	*	*	*	*	*
Dementia, N(%)	22 (7.2)	23 (11.3)	35 (11.4)	32 (15.3)	51 (14.5)	163 (11.9)
Hemiplegia/Paraplegia, N(%)	8 (2.6)	12 (5.9)	18 (5.9)	9 (4.3)	22 (6.3)	69 (5.0)
Immunologic/Rheumatologic	*	*	*	*	*	*
AIDS/HIV, N(%)	0 (0.0)	3 (1.5)	2 (0.7)	1 (0.5)	7 (2.0)	13 (0.9)
Rheumatologic Disease, N(%)	19 (6.2)	2 (1.0)	11 (3.6)	16 (7.7)	17 (4.8)	65 (4.7)
Malignancy	*	*	*	*	*	*
Metastatic Solid Tumor, N(%)	17 (5.6)	4 (2.0)	9 (2.9)	7 (3.4)	41 (11.7)	78 (5.7)
Any Malignancy, including Lymphoma and Leukemia, N(%)	73 (23.9)	18 (8.9)	76 (24.8)	29 (13.9)	135 (38.5)	331 (24.1)

Cells marked with * are intentionally left blank.

Patients included in the sampled encounters had a wide variety of diagnoses. 49% of encounters were associated with a diagnosis code for *C.difficile*.

[Response Ends]

2a.07. 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.

[Response Begins]

Not applicable

[Response Ends]

2a.08. List 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.

[Response Begins]

Social risk factors were not available for analysis

[Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.09 check patient or encounter-level data; in 2a.010 enter "see validity testing section of data elements"; and enter "N/A" for 2a.11 and 2a.12.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins]

Patient or Encounter-Level (e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements)

[Response Ends]

2a.10. For each level of reliability testing 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.

[Response Begins]

Inter-rater reliability of chart review for HT-CDI: For critical data elements--Date of admission, presence of positive C.diff (CD) test, and presence of 5 or more days of Qualifying Antimicrobial Therapy (QAT)-- we used inter-abstractor (rater) reliability to determine level of agreement between electronic chart extraction and manual chart review.

Data analysis included:

- Cohen's Kappa statistic to adjust for chance agreement for categorical data assessed between electronic chart extraction and manual chart review.

Date of admission was analyzed based on percent of encounters with the exact date matching between sources. Presence of CD test and presence of 5+QAT were analyzed with kappa statistics of agreement between sources.

The kappa statistic, which takes into account chance agreement, is defined as (observed agreement−expected agreement)/(1−expected agreement). When two measurements agree only at the chance level, the value of kappa is zero. When the two measurements agree perfectly, the value of kappa is 1.0. The kappa statistic is frequently used to test interrater reliability.

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method

yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, NQF Measure Evaluation Criteria).

[Response Begins]

Table 1. Number and percentage of sampled encounters with exact match of admission date between electronic extraction and manual chart review.

*	Exact admission date match	*
*	**No**	**Yes**
Number of encounters	217	1169
Percentage of encounters	15.7	84.3

Cells with * are intentionally left blank.

Table 2. Simple Kappa Coefficient between electronic chart extraction and manual chart review of identification of a positive CD test within the HO period.

Kappa	0.9696
ASE	0.0066
95% Lower Conf Limit	0.9567
95% Upper Conf Limit	0.9825

Table 3. Simple Kappa Coefficient between electronic chart extraction and manual chart review of presence of 5+QAT if there was a positive CD test

Kappa	0.9754
ASE	0.0059
95% Lower Conf Limit	0.9638
95% Upper Conf Limit	0.987

Table 4. Simple Kappa Coefficient between electronic chart extraction and manual chart review of identification of HT-CDI event

Kappa	0.965
ASE	0.0071
95% Lower Conf Limit	0.9511

Kappa	0.965
95% Upper Conf Limit	0.9789

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Critical data elements-

Exact Admission date (Table 1):

84.3% of encounters had an exact match of admission date as compared to manual chart abstraction. While this number is relatively high, it is likely that discrepancies occurred in the manual abstraction as "admission date" can be interpreted as the date the patient arrived at the Emergency department, date an admission order was placed, or date the patient was transferred to an inpatient ward.

Positive CD test in HO time period (Table 2):

A kappa of 0.9696 indicates a high level of agreement between electronic and manual identification of a positive CD test within the healthcare-facility onset time window. As this data element is based on abstraction of laboratory data (positive test as well as date of test collection) with comparison of test collection date to admission date to determine if it occurred in the HO time period (on or after day 4 of admission), discrepancy in admission date may account for some of the disagreement.

5+QAT if CD test positive (Table 3):

A kappa of 0.9754 indicates a high level of agreement between electronic and manual identification of a new Qualifying Antimicrobial Therapy being started within the window period of a positive CD test and continued for at least 5 days.

Event determination-

HT-CDI event (Table 4):

A kappa of 0.956 indicates a high level of agreement between the identification HT-CDI events based on electronic capture of data elements as compared to manual chart review extraction of data elements.

Overall, the analyses demonstrate that electronic extraction of all critical elements (including date of admission, date of specimen collection, CDI lab data, medication administration data) can be reliably extracted and the HT-CDI event determination can be reliably made.

[Response Ends]

2b. Validity

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

Patient or Encounter-Level (data element validity must address ALL critical data elements)

[Response Ends]

2b.02. 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.

[Response Begins]

Empirical validity testing was conducted on the measure as specified using the comparison of HT-CDI events (calculated based on electronic capture of all critical patient/encounter data elements) vs Reference Standard Case Definition (explicit manual review of charts for clinical disease due to C. diff based on meeting the HT-CDI definition PLUS documentation of diarrhea within the 3 days prior to stool sample collection) to assess the electronic HT-CDI measure for sensitivity and specificity.

Additionally, the sensitivity and specificity (as evaluated against Reference Standard Case Definition) of the electronic HT-CDI was compared to the sensitivity and specificity of the electronically captured C.diff LabID (Final positive lab test for C.diff).

Of note, the specificities underestimate the true specificity of the measurement due to the sample being enriched for CDI cases (case rate in sample >> true prevalence in the population). As the sample was enriched for CDI cases, positive predictive value and negative predictive value could not be calculated.

Risk Adjustment Data Element Validity:

For data elements used in the risk adjustment process the following validity testing was applied:

Routine Data Quality Assurance

Data used in the risk adjustment analysis was obtained from the Becton Dickinson (BD) Infection Surveillance Software platform BD HealthSight powered by Medmined, a commercial platform where robust data validity checks ensure that data collected from electronic health record systems are performed accurately. The variables used for risk adjustment are obtained or directly calculated from Admission/Discharge/Transfer (ADT) systems, microbiology, and pharmacy or medication administration databases. These are the same sources of data used for calculation of the primary measure data elements, and the processes to assure no data is missing is described in section 2b.08.

In the BD platform, ADT, Microbiology, and pharmacy data are used for near real time alerting and reporting of healthcare-associated infections. During enrollment, each hospital engages in a months long bidirectional communication between the hospital/healthcare systems' Information Technology (IT) department, Infection Prevention department, Pharmacy department, and the BD platform IT staff and clinical subject matter experts. The hospital is only able to begin use of the product and transmission of data when all data feeds have been validated as completely accurate.

The resulting validated data collected by BD has been used in multiple publications, including the more recent publications listed here:

a. Yu, K., Gupta, V., Kabler, H., Watts, J., & Amiche, A. (2022). A multicenter analysis of inpatient antibiotic use during the 2015–2019 influenza seasons in the United States: Untapped opportunities for antimicrobial stewardship. Antimicrobial Stewardship & Healthcare Epidemiology, 2(1), E140. doi:10.1017/ash.2022.265
b. Dunne, M.W., Aronin, S.I., Yu, K.C. et al. A multicenter analysis of trends in resistance in urinary Enterobacterales isolates from ambulatory patients in the United States: 2011–2020. BMC Infect Dis 22, 194 (2022). https://doi.org/10.1186/s12879-022-07167-y
c. Vikas Gupta, Kalvin C Yu, Heidi Kabler, Janet A Watts, Amine Amiche, Antibiotic Resistance Patterns and Association With the Influenza Season in the United States: A Multicenter Evaluation Reveals Surprising Associations Between Influenza Season and Resistance in Gram-Negative Pathogens, Open Forum Infectious Diseases, Volume 9, Issue 3, March 2022, ofac039, https://doi.org/10.1093/ofid/ofac039

d. Keith S Kaye, Vikas Gupta, Aruni Mulgirigama, Ashish V Joshi, Nicole E Scangarella-Oman, Kalvin Yu, Gang Ye, Fanny S Mitrani-Gold, Antimicrobial Resistance Trends in Urine Escherichia coli Isolates From Adult and Adolescent Females in the United States From 2011 to 2019: Rising ESBL Strains and Impact on Patient Management, Clinical Infectious Diseases, Volume 73, Issue 11, 1 December 2021, Pages 1992–1999, https://doi.org/10.1093/cid/ciab560
e. The impact of infections on reimbursement in 92 US hospitals, 2015-2018, AJIC, Published:April 20, 2021DOI: https://doi.org/10.1016/j.ajic.2021.04.007
f. Finelli L, Gupta V, Petigara T, Yu K, Bauer KA, Puzniak LA. Mortality Among US Patients Hospitalized With SARS-CoV-2 Infection in 2020. JAMA Netw Open. 2021;4(4):e216556. doi:10.1001/jamanetworkopen.2021.6556
g. CDC 2019 Antibiotic Threats Report **page 136**. https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf

Additional Risk Adjustment Data Element Validation

An additional multi-step process was applied to ensure that the data was clinically viable and consistent with findings of other independent peer reviewed studies or outside data sources.

As an example, hospital characteristics (teaching/non, tertiary, med school affiliation, etc) and number of hospital beds from ADT data was cross-referenced with AHD.com to ensure alignment and accuracy.

For multiple sites sharing a single CMS identifier, data was cross referenced with AHD.com or similar publicly available data sets to check and validate patient movement data: in this process 2 hospitals were excluded(a psychiatry hospital and a radiation oncology center) as they were did not meet the definition criteria of acute care or critical access sites (these were also flagged for review due to what appeared to be clinically implausible event rates for acute care or critical access hospitals).

Next, Length of Stay was evaluated in the cohort to ensure clinical plausibility: 99% of admission had LOS < 25 days; no admissions had LOS=0 and 0.002% of all admissions had a LOS>365 days.

Regarding antimicrobial use completeness, a median of 56% of the total admissions received at least one antimicrobial, which was consistent with other broad geographic sampling studies showing approximately 50% of hospitalized patients receive antimcirobials[6].

Reference

[6] Magill SS, Edwards JR, Beldavs ZG, Dumyati G, Janelle SJ, Kainer MA, Lynfield R, Nadle J, Neuhauser MM, Ray SM, Richards K, Rodriguez R, Thompson DL, Fridkin SK; Emerging Infections Program Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey Team. Prevalence of antimicrobial use in US acute care hospitals, May-September 2011. JAMA. 2014 Oct 8;312(14):1438-46. doi: 10.1001/jama.2014.12923. PMID: 25291579.

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

Table 5. Sensitivity and Specificity of electronic capture of HT-CDI events as compared to Reference Standard (manual chart review- identification of HT-CDI event plus documentation of diarrhea)

Sensitivity (95%CI)	**Specificity (95%CI)**
0.98 (0.97-0.99)	0.96 (0.94-0.97)

Table 6. Comparison of Sensitivity and Specificity of electronic HT-CDI to electronic capture of CDI LabID (final CD test positive) as compared to Reference Standard (manual chart review- identification of HT-CDI event plus documentation of diarrhea).

Sensitivity	*	*	**Specificity**	*	*
*	**Electronic LabID**	**HT-CDI**	*	**Electronic LabID**	**HT-CDI**
ALL	0.97 (0.96-0.99)	**0.98 (0.97-0.99)**	**ALL**	0.93 (0.92-0.95)	**0.96 (0.94-0.97)**

Cells marked with * are intentionally left blank.

Risk Adjustment Data Elements

The robust processes described in 2b.02 ensure that data elements used in risk adjustment were valid and without missing data.

[Response Ends]

2b.04. Provide 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?)

[Response Begins]

The sensitivity of the electronic HT-CDI measure as compared to Reference Standard Case Definition (Table 5) is 0.98 (0.97-0.99) with specificity of 0.96 (0.94-0.97). Thus, the electronic HT-CDI measure has a high likelihood of correctly including patients with HT-CDI and correctly excluding patients who do not have HT-CDI.

Additionally, the sensitivity and specificity of the electronic HT-CDI measure are higher than electronic LabID (Table 6) (though not statistically significant as the 95% confidence intervals overlap); this indicates that the electronic HT-CDI measure is likely to be as good or better at measuring true healthcare-facility onset CDI as compared to LabID.

[Response Ends]

2b.05. 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 in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

Part 1:

Measure performance was evaluated in a retrospective, ecological study based on electronic microbiological, medication and administrative data from adult patients 18 years or older admitted from October 1, 2015, through February 28, 2020 to one of 267 acute care hospitals within the BD Insights and Research Database (Becton, Dickinson and Company, Franklin Lakes, NJ).

The data, analysis, and interpretation for many of the following questions are taken directly verbatim from a manuscript in preparation- Hospital-Onset *Clostridiodes difficile*: An Evaluation of Risk Factors and Feasibility of Benchmarking Comparing Two Risk-Adjusted Models Among 265 Hospitals by Kalvin Yu et al. We will indicate this source with the following citation in each question: (Hospital-Onset *Clostridiodes difficile*, Yu et al). HOCDI is used in these questions synonymously with HT-CDI:

Statistical analysis was approached in 3 steps: (1) Identify the candidate variables that influence HOCDI rates using bivariate analysis. (2) Identify the risk factors the Complex Model and derive SIRs based on the models. (3) Compare hospital rankings using the observed (unadjusted) HOCDI rates versus using risk adjustment from the Complex Model.

Step 1. Rates of HOCDI were calculated as the number of HOCDI events per 100 admissions for quarterly aggregated data. Bivariate analysis using general linear models were performed to explore the correlation between HOCDI rate and each candidate risk factor (Table 1), which included:

Clinical measures:

Clinical variables included: COCDI prevalence (the rate of COCDI events per 100 admissions); percent of intensive care unit (ICU) admissions (per all admissions); average length of hospital stay (LOS) among hospitalized patients (days of hospitalization per admission); CD test prevalence and intensity (see definitions above).

Patient demographics:

Patient demographics included: number of female patients per 100 admissions; percent of patients in each age group (18-40, 41-64, 65-80, and > 80 years old).

Facility characteristics:

Facility characteristics: bed size; medical school/non-medical school affiliation; urban/rural status.

Step 2. To identify the risk factors of HOCDI, we used negative binomial regression methods to account for overdispersion of data. We conducted a modeling analysis: a Complex Model. Our Complex Model analysis included the following variables: hospital-level variables easily accrued from EHRs and/or already reportable to the NHSN, facility and hospital-level demographics of patients clinical practices of CD testing divided into CO or HOCDI testing intensity and prevalence.

The best (final) model was selected using model fit statistics Akaike's Information Criteria (AIC) and Bayesian Information Criteria (BIC) based on the full data in the study cohort (3,455 quarters of aggregated hospital data associated with 9,134,276 admissions). In addition, we used cross-validation methods in variable selection and confirmed that the full-data model and the validation model had the same best set of variables in the final model (Table 2 and Table 3).

Step 3. We compared hospital ranking based on the observed (unadjusted) HOCDI rate and the ranking based the SIRs from the adjusted model (Complex Model-derived SIRs). Goodman and Kruskal's gamma statistic, Spearman correlation, and confidence intervals to measure ordered association were reported. We used the calculated 1-year SIR data (2019) as an example for comparison rankings. Finally, we compared the ranking of the top 25th percentile of unadjusted HOCDI rate hospitals to their subsequent ranking using adjusted Complex Model SIR.

Part 2:

The models calculated the predicted number of HOCDI events. The Standardized Infection Ratio (SIR) and confidence interval were calculated as: reported number of HOCDI events divided by the predicted number of HOCDI events. The SIR is not calculated when the predicted value is less than 1.0. Using the mid-p exact test, the calculated SIR and its confidence interval were compared to an SIR of 1.

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include 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.

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al):

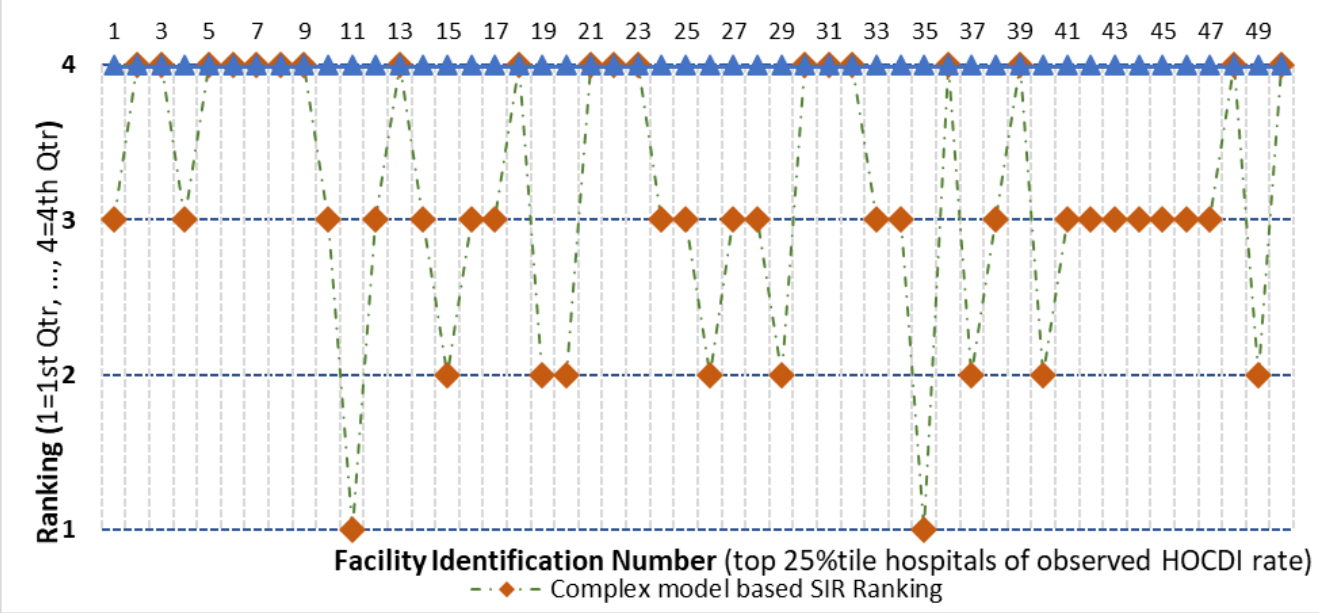
Part 1:

This study demonstrated that our risk adjustment approach results in meaningful changes in the rankings of hospitals by HOCDI performance.

This study compared rankings of the hospitals with the highest ("worst performing"/4th quartile) observed HOCDI rates (hospitals 1-50). Figure 1 demonstrates that risk adjustment after applying the final "Complex Model"-derived standardized Infection Ratio (SIR) resulted in meaningful and significant changes to the hospital rankings to unique and different degrees compared to observed HOCDI ranking.

We demonstrated a potential real-world application of risk adjustment by quantifying changes in rank of the top 25 percentile hospitals of the observed HOCDI event rates compared with the Complex Model derived SIR ranking. Of the 50 hospitals with the highest observed HOCDI rate (4th quartile), nineteen hospitals (38%) stay in the same ranking category (4th quartile) of model-based (adjusted) SIR. Twenty-one hospitals (42%) improved their ranking to the 3rd quarter; 8 hospitals (16%) improved their ranking to the 2nd quarter; 2 hospitals (4%) moved to 1st quartile (Figure 1).

Figure 1. Ranking change of hospitals for the top 25%tile (4th quarter) of unadjusted HOCDI event rates compared to the ranking based on Complex Model SIR



Interpretation of Figure 1: Among the 50 hospitals that were ranked in the 4th quarter of the unadjusted (observed) HOCDI rate, 19 hospitals (38%) remained in the same ranking category (4th quarter) of model-based (adjusted) SIR. 32 hospitals (64%) had certain degree of improved ranking when using the model-based SIR ranking. For example, 21 hospitals (42%) improved their ranking to the 3rd quarter; 8 hospitals (16%) improved their ranking to the 2nd quarter; 2 hospitals (4%) moved to 1st quarter (from bottom 25%tile moved to top 25%tile)

Part 2:

A meaningful difference in the SIR was defined as an SIR and a confidence interval that was statistically different from 1. Out of 243 total facilities reporting in 2019, SIRs were able to be calculated for 200 of them. Below is a table showing the percentage of SIRs that were significantly different from 1.

Distribution of SIRs Calculated for Hospitals Reporting in 2019.

SIR	No. of Facilities	Percent
Not Significantly different from 1	170	85.00
Significantly lower than 1	19	9.50
Significantly higher than 1	11	5.50

[Response Ends]

2b.07. Provide 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.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al):

Using a sample of hospitals, we are able to demonstrate that the incorporation of robust data in modeling expected hospital-level HOCDI events leads to meaningful and practical changes in the ranking of facilities against each other in an adjusted HOCDI Standardized Infection Ratio Measure.

The SIR enables detection of statistically significant and clinically meaningful differences in HOCDI that warrant further analysis and possible action. Although exposure volume is low, leading to few statistically significant SIRs in this population, the value of the calculated SIRs can reflect practical measures of performance.

[Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al) and communication with the study team.

Data Completeness: Becton Dickinson (BD) requires a minimum qualification of at least 3 months of uninterrupted continuous data from participating hospitals of:

1. ADT (admission , discharge, transfer) feed;
2. Laboratory data inclusive but not limited to microbiology data from an uninterrupted LIS (laboratory information system) data feed, and
3. Medication order/stop feed

These are the bare minimum data requirements; if a hospital did not meet qualifications, they were excluded from the study. Hospitals could contribute different time points to the total admissions data depending on the reason for interrupted data feeds. As an example, a hospital that initiated an electronic medical record vendor upgrade (or new vendor go live) that resulted in an interruption of any of the 3 key data feeds would be removed from the data set during the feed interruption time; however, once the data feed interruption resolved AND met our volume signal criteria, could then be included back into the aggregate admissions data. Therefore, as an example, hospital "X" could contribute data from July 2018 – July 2019, go live with a new version of their EHR August 2019, which resulted in interrupted/incomplete data feed of laboratory information system until October 2019. Once all required data feeds were back up, they could resume contribution to the aggregate admissions (i.e. August 2019 and September 2019 are NOT included in the data set, but July 2018- July 2019, and October 2019 and onward ARE included).

2 gatekeeper criteria for validating 'completeness of data feed' :

1) Historical Volume: BD has used its infection surveillance platform for more than 15 years that curates the data on the front end for infection prevention and antimicrobial stewardship efforts. As such, normal steady state volume of, as an example, the number of Staphylococcus aureus signals obtained from laboratory information system is quantified and deviations from that volume are flagged for further quality assurance checks on both BD side and hospital side.

2) Customer Initiated: Data feed interruptions are also identified by customer hospital during system upgrades or other instances. Given this is a retrospective data set, the consequences of such interruptions are flagged on the customer side ie lack of real time reporting of reportable hospital acquired infections or clinical alerts that use all 3 required data feeds. In this manner, then, there are 2 feedback loops that gives BD visibility to these data feed deficit events: 1) internal guardrails based upon historic steady state volume of microbiology, ADT and medication orders data; and 2) customer hospital initiated warning on same. Often times, BD is the one that notices the disruption first.

Data Interruption Analysis:

In the study, we extracted monthly aggregated hospital-level data from the BD database. Across all the 267 study hospitals, average of about 2% out of the total data feed months of 10,532 were interrupted. Prior to analysis, we examined the distribution of study variables pre- vs after interruption of data feed months and we found they were statistically the same for a specific hospital affected.

Among the study variables, there was no missing data on facility characteristics such as bed size, urban/rural status. There was no missing data in the study cohort for clinical factors such as community-onset bacteremia events and culture testing data.

Gender and Age-About 0.12% (out of the 9,202,650 admissions) had missing values on gender status. Admissions with missing gender information were excluded from analysis and we treated such cases as "missing at random" and didn't affect study event rates for this large sample study.

Intensive Care Unit (ICU)- There are 1.3% missing (unreported or unable to determine) data on ICU admission status in our HOB study cohort (out of 20,310 admissions); the vast majority of the cases were associated with small hospitals with

< 100 beds. Since ICU admission was deemed to be an influencing factor of the study outcomes (HOB rate or HOCDI rate), we decided to keep these cases in study cohorts and created an individual category named “unknown/unreported”. The effect of such cases was assessed in our modeling analysis in addition to evaluating the ICU effect on outcomes.

Including or excluding the ‘unreported ICU’ in analysis did not change the statistical significance (p value) of the other variables and affected the estimated effects (coefficients) of other variables very slightly.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

See above answer to 2b.08

[Response Ends]

2b.10. Provide 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 non-responders), and how the specified handling of missing data minimizes bias.

In other words, 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 was conducted, justify the selected approach for missing data.

[Response Begins]

See answer to 2b.08

Because the BD data is ingested through the core surveillance platform that is used daily/weekly, there is visibility to what data feeds may or may not be missing (because the alerts do not fire or misfire). On top of that, there are guardrails on the BD end to detect volume changes, AND on top of that when retrospective aggregate data analyses are performed, there are qualification criteria.

[Response Ends]

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 eCQMs). 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.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. 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. Indicate what statistical analysis was used.

[Response Begins]

[Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins]

[Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins]

[Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins]

N/A or no exclusions

[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

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?

[Response Begins]

N/A

[Response Ends]

2b.17. Provide 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.

[Response Begins]

N/A

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, 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.

[Response Begins]

N/A

[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins]

Statistical risk model with risk factors (specify number of risk factors)

[Statistical risk model with risk factors (specify number of risk factors) Please Explain]

9 risk factors are used in the model: Year, COCDI prevalence, Average LOS, bed size, HO testing intensity, CO testing intensity, HO testing prevalence, % females, and teaching status.

[Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al) and correspondence with study team:

The final risk model chosen was the Complex Model. The steps taken to arrive at the model were listed above in question **2b.05.**

Critical data element validity: Prior to conducting the modeling analysis, subject matter clinical experts, data query team, and statistical analysis personnel carefully examined each variable that was considered. Any implausible values of a variable were excluded from analysis. The excluded cases account for less than 0.01% of the study cohort and it was deemed not to bias the analysis.

For example- LOS admissions > 365 were removed as these tend to be in one of the following buckets: 1) “social admissions” (ie the family is suing the hospital because they do not believe the patient is ready to leave or does not have a home to go to) ; 2) “unusually protracted hospital stays” (example: a double transplant patient who is partially rejecting

one or both organs, waiting for another donor, but abdomen or chest cavity is flayed open so cannot go to home or LTAC or SNF). These events are not only unusual, but if included can severely influence the median or average LOS, for example, and are not representative of a large swath of the average patient population.

Testing intensity was defined as the number of total stool specimen episodes tested for CDI obtained in either the community-onset [CO] period (defined as the first 3 days of hospitalization) or the HO period (defined as day 4 or after of admission) divided by the number of total aggregate admissions that had any CDI test performed. Conceptually, testing intensity reflects the cumulative CDI tested stool samples collected among admissions with any CDI test performed. Testing prevalence was defined as the number of admissions with any CDI test performed in the period (CO or HO) divided by the total number of aggregate admissions and conceptually reflects the overall proportion of admissions with CDI testing. Community-onset CDI (COCDI) was defined as a first positive CDI within the first 3 days of hospital admission. Hospitals are required to submit data on bed-size and teaching status.

Table 3. HOCDI Risk Factors Identified in the Complex Model. Cells marked with * are intentionally left blank.

Parameter	Regression Coefficient (In Logarithm Scale)	Standard Error	Incidence Rate Ratio (95% CI)	P
Intercept	-3.370	0.111	*	<.0001
Year	*	*	*	*
Other years	*	*	*	reference
Year 2017 & 2018	0.078	0.020	1.08 (1.04-1.12)	0.0001
COCDI prevalence	*	*	*	*
1st quartile	*	*	*	reference
2nd quartile	0.489	0.037	1.63 (1.52-1.75)	<.0001
3rd quartile	0.847	0.037	2.33 (2.17-2.51)	<.0001
4th quartile	1.175	0.041	3.24 (2.99-3.51)	<.0001
Average LOS	*	*	*	*
≤ 3rd quartile	*	*	*	reference
4th quartile	0.106	0.026	1.11 (1.06-1.17)	<.0001
Bed size	*	*	*	*
1-50	*	*	*	reference
51-300	0.175	0.102	1.19 (0.98-1.46)	0.0865
301+	0.212	0.101	1.24 (1.01-1.51)	0.0355
HO testing intensity	*	*	*	*
1st quartile	*	*	*	reference
2nd quartile	0.371	0.043	1.45 (1.33-1.58)	<.0001
3rd quartile	0.516	0.045	1.68 (1.54-1.83)	<.0001
4th quartile	0.709	0.048	2.03 (1.85-2.23)	<.0001
CO testing intensity	*	*	*	*

Parameter	Regression Coefficient (In Logarithm Scale)	Standard Error	Incidence Rate Ratio (95% CI)	P
1st quartile	*	*	*	reference
2nd quartile	-0.136	0.028	0.87 (0.83-0.92)	<.0001
3rd quartile	-0.223	0.030	0.80 (0.75-0.85)	<.0001
4th quartile	-0.349	0.035	0.71 (0.66-0.76)	<.0001
HO testing prevalence	*	*	*	*
1st quartile	*	*	*	reference
2nd quartile	0.227	0.043	1.26 (1.15-1.36)	<.0001
3rd quartile	0.403	0.043	1.50 (1.38-1.63)	<.0001
4th quartile	0.544	0.047	1.72 (1.57-1.89)	<.0001
% Females	*	*	*	*
1st quartile	*	*	*	reference
2nd quartile	-0.088	0.027	0.92 (0.87-0.97)	0.0013
3rd quartile	-0.077	0.029	0.93 (0.87-0.98)	0.0089
4th quartile	-0.100	0.034	0.90 (0.85-0.97)	0.0032
Teaching status (medical school affiliation)	*	*	*	*
Non-teaching	*	*	*	reference
Teaching	0.083	0.024	1.09 (1.04-1.14)	0.0005

Note. CO, community-onset; COCDI, community-onset Clostridioides *difficile infection*; HO, hospital-onset; HOCDI, hospital-onset Clostridioides *difficile infection*; ICU, intensive care unit; LOS, length of stay.

[a]Goodness-of-fit statistics: Akaike's Information Criteria (AIC) = 13,106, Bayesian Information Criteria (BIC) = 13,290.

Based on the Complex Model, we found the following hospital level variables were significantly associated with higher HOCDI event rates: higher COCDI prevalence; the top quarter (4th quartile) of average LOS; larger bed size; higher percent of male patients; increased HO blood culture testing intensity, increased HO blood culture prevalence, and teaching hospitals. The increased community onset period CDI testing intensity was found negatively associated with HOCDI event rates (Table 3). Among the identified risk factors, the most influential factors were HO period testing intensity, COCDI rate, HO period testing prevalence, and CO testing intensity (negative correlation).

[Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]

[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins]

Internal data analysis

[Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins]

Patient-level risk factors were not available for analysis. However, aggregate demographic data and clinical factors were analyzed.

The broad role of social risk factors such as race, ethnicity, and social determinants of health in reporting of healthcare-associated infection metrics is not currently understood. This is currently an area of exploration for NHSN.

[Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al):

Step 1. Rates of HOCDI were calculated as the number of HOCDI events per 100 admissions for quarterly aggregated data. Bivariate analysis using general linear models were performed to explore the correlation between HOCDI rate and each candidate risk factor (Table 1), which included:

Clinical measures:

Clinical variables included: COCDI prevalence (the rate of COCDI events per 100 admissions); percent of intensive care unit (ICU) admissions (per all admissions); average length of hospital stay (LOS) among hospitalized patients (days of hospitalization per admission); CDI test prevalence and intensity.

Patient demographics:

Patient demographics included: number of female patients per 100 admissions; percent of patients in each age group (18-40, 41-64, 65-80, and > 80 years old).

Facility characteristics:

Facility characteristics: bed size; medical school/non-medical school affiliation; urban/rural status.

Summary statistics of HOCDI prevalence and bivariate analysis results

Over the study period, the median rate of HOCDI events per 100 admissions was 0.134 (Interquartile range (IQR): 0.023 - 0.243) with the mean rate 0.166 (SD = 0.18). Over time, there was a decreasing trend in HOCDI event rates based on the bivariate analysis (Table 1). Bivariate analysis also showed that all candidate risk factors considered in the analysis were correlated with HOCDI except for percent of patients aged 65-80 years and > 80 years groups (Table 1).

Table 1: Descriptive Statistics of HOCDI Rate and Bivariate Analysis Results.

Variables	**Admissions**	**HOCDI events**	**Observed HOCDI rate per 100 admissions**	*	*	*	*	*
*	*	*	**Lower Quartile**	**Median**	**Upper Quartile**	**Mean**	**SD**	**P value**
Overall	9,134,276	17,545	0.023	0.134	0.243	0.166	0.180	*
Year	*	*	*	*	*	*	*	<.0001
2015	344,056	859	0.080	0.180	0.293	0.221	0.252	*
2016	1,714,354	4,083	0.071	0.171	0.295	0.202	0.196	*
2017	2,042,560	4,445	0.063	0.167	0.286	0.206	0.208	*
2018	2,305,170	4,273	0.000	0.132	0.240	0.159	0.169	*
2019	2,226,722	3,171	0.000	0.096	0.191	0.123	0.137	*
2020	501,414	714	0.000	0.096	0.172	0.121	0.122	*
COCDI prevalence (rate per 100 admissions)	*	*	*	*	*	*	*	<.0001
1st quartile	1,686,392	1,540	0.000	0.000	0.110	0.070	0.122	*
2nd quartile	3,056,765	4,944	0.055	0.129	0.211	0.142	0.112	*
3rd quartile	2,496,840	5,342	0.089	0.171	0.268	0.188	0.149	*
4th quartile	1,894,279	5,719	0.102	0.225	0.369	0.264	0.244	*
Average LOS	*	*	*	*	*	*	*	<.0001
1st quartile	977,467	1,158	0.000	0.053	0.159	0.098	0.133	*
2nd quartile	2,206,252	3,467	0.039	0.126	0.228	0.156	0.170	*
3rd quartile	2,800,069	5,248	0.074	0.158	0.268	0.179	0.139	*
4th quartile	3,150,488	7,672	0.084	0.198	0.311	0.232	0.232	*
%ICU admissions	*	*	*	*	*	*	*	0.0493
Not reported	385,270	1,015	0.000	0.082	0.232	0.186	0.332	*
1st quartile	1,622,463	2,859	0.000	0.087	0.199	0.131	0.173	*
2nd quartile	2,611,370	4,219	0.059	0.136	0.239	0.162	0.137	*
3rd quartile	2,273,673	4,590	0.064	0.158	0.266	0.182	0.158	*
4th quartile	2,241,500	4,862	0.039	0.163	0.270	0.183	0.164	*
Testing prevalence	*	*	*	*	*	*	*	<.0001
1st quartile	1,905,258	1,988	0.000	0.028	0.123	0.076	0.110	*

Variables	Admissions	HOCDI events	Observed HOCDI rate per 100 admissions	*	*	*	*	*
2nd quartile	2,804,156	4,385	0.051	0.126	0.199	0.135	0.122	*
3rd quartile	2,473,500	4,978	0.075	0.164	0.264	0.175	0.130	*
4th quartile	1,951,362	6,194	0.114	0.245	0.389	0.278	0.252	*
CO testing prevalence	*	*	*	*	*	*	*	<.0001
1st quartile	2,257,847	2,925	0.000	0.064	0.158	0.101	0.136	*
2nd quartile	3,000,705	5,276	0.051	0.135	0.217	0.147	0.122	*
3rd quartile	2,190,180	4,396	0.068	0.162	0.263	0.178	0.140	*
4th quartile	1,685,544	4,948	0.050	0.185	0.342	0.238	0.257	*
HO testing prevalence	*	*	*	*	*	*	*	<.0001
1st quartile	1,457,185	1,184	0.000	0.000	0.082	0.052	0.086	*
2nd quartile	2,259,355	2,901	0.039	0.112	0.174	0.118	0.107	*
3rd quartile	2,680,913	5,117	0.097	0.178	0.250	0.182	0.130	*
4th quartile	2,736,823	8,343	0.171	0.279	0.399	0.312	0.237	*
Testing intensity	*	*	*	*	*	*	*	<.0001
Not calculated[a]	8,663	0	0.000	0.000	0.000	0.000	0.000	*
1st quartile	1,715,666	2,630	0.000	0.083	0.193	0.120	0.156	*
2nd quartile	2,362,434	4,778	0.061	0.157	0.249	0.172	0.141	*
3rd quartile	2,803,869	5,997	0.071	0.169	0.295	0.203	0.188	*
4th quartile	2,243,644	4,140	0.041	0.131	0.247	0.179	0.215	*
CO testing intensity	*	*	*	*	*	*	*	<.0001
Not calculated[a]	8,663	0	0.000	0.000	0.000	0.000	0.000	*
1st quartile	2,823,284	6,946	0.086	0.194	0.309	0.232	0.238	*
2nd quartile	2,479,886	4,855	0.077	0.169	0.267	0.185	0.146	*
3rd quartile	2,117,783	3,527	0.039	0.135	0.239	0.158	0.149	*
4th quartile	1,704,660	2,217	0.000	0.056	0.150	0.098	0.140	*
HO testing intensity	*	*	*	*	*	*	*	<.0001
Not calculated[a]	8,663	0	0.000	0.000	0.000	0.000	0.000	*
1st quartile	1,166,641	1,101	0.000	0.000	0.117	0.070	0.106	*
2nd quartile	2,101,608	3,320	0.055	0.132	0.222	0.155	0.135	*

Variables	Admissions	HOCDI events	Observed HOCDI rate per 100 admissions	*	*	*	*	*
3rd quartile	2,754,801	5,432	0.088	0.177	0.281	0.199	0.164	*
4th quartile	3,102,563	7,692	0.109	0.207	0.332	0.250	0.236	*
%Female	*	*	*	*	*	*	*	<.0001
1st quartile	2,553,168	5,532	0.045	0.161	0.266	0.194	0.217	*
2nd quartile	2,741,130	5,253	0.055	0.147	0.256	0.172	0.156	*
3rd quartile	2,314,064	4,320	0.038	0.137	0.250	0.173	0.184	*
4th quartile	1,525,914	2,440	0.000	0.086	0.204	0.126	0.148	*
%Patients aged 18-40 years	*	*	*	*	*	*	*	<.0001
1st quartile	1,430,875	3,056	0.000	0.093	0.243	0.162	0.243	*
2nd quartile	2,489,638	4,686	0.061	0.156	0.260	0.183	0.163	*
3rd quartile	3,024,935	5,738	0.068	0.144	0.249	0.166	0.138	*
4th quartile	2,188,828	4,065	0.000	0.128	0.228	0.154	0.156	*
%Patients aged 41-64 years	*	*	*	*	*	*	*	<.0001
1st quartile	1,478,674	2,405	0.000	0.095	0.209	0.136	0.172	*
2nd quartile	2,313,483	4,110	0.050	0.145	0.252	0.171	0.161	*
3rd quartile	2,376,773	4,592	0.042	0.138	0.249	0.166	0.152	*
4th quartile	2,965,346	6,438	0.053	0.150	0.261	0.192	0.221	*
%Patients aged 65-80 years	*	*	*	*	*	*	*	0.066
1st quartile	2,307,177	4,508	0.000	0.130	0.229	0.155	0.157	*
2nd quartile	2,589,933	5,062	0.068	0.154	0.263	0.176	0.156	*
3rd quartile	2,615,879	4,658	0.049	0.141	0.238	0.166	0.156	*
4th quartile	1,621,287	3,317	0.000	0.103	0.253	0.168	0.237	*
%Patients aged > 80 years	*	*	*	*	*	*	*	0.0647
1st quartile	3,007,521	6,362	0.058	0.146	0.244	0.184	0.212	*
2nd quartile	2,472,873	4,352	0.043	0.136	0.240	0.160	0.144	*
3rd quartile	2,213,688	3,969	0.028	0.136	0.245	0.163	0.158	*
4th quartile	1,440,194	2,862	0.000	0.120	0.243	0.158	0.195	*
Bed size	*	*	*	*	*	*	*	<.0001
< 100	587,288	763	0.000	0.000	0.154	0.101	0.189	*

Variables	Admissions	HOCDI events	Observed HOCDI rate per 100 admissions	*	*	*	*	*
100-300	3,331,644	6,002	0.060	0.147	0.255	0.182	0.186	*
> 300	5,215,344	10,780	0.113	0.183	0.279	0.208	0.136	*
Bed size (refined grouping)	*	*	*	*	*	*	*	<.0001
1-50	147,391	108	0.000	0.000	0.000	0.058	0.171	*
51-100	439,897	655	0.000	0.096	0.222	0.144	0.197	*
101-200	1,352,638	2,070	0.044	0.126	0.236	0.158	0.153	*
201-300	1,979,006	3,932	0.089	0.169	0.281	0.212	0.217	*
301-500	3,036,288	6,167	0.099	0.174	0.275	0.205	0.146	*
500+	2,179,056	4,613	0.133	0.202	0.281	0.214	0.110	*
Teaching status (medical school affiliation)	*	*	*	*	*	*	*	<.0001
Non-teaching	3,225,702	5,197	0.000	0.093	0.214	0.135	0.167	*
Teaching	5,908,574	12,348	0.095	0.173	0.283	0.209	0.187	*
Urban/rural status	*	*	*	*	*	*	*	0.013
Rural	2,391,775	4,397	0.000	0.096	0.228	0.144	0.177	*
Urban	6,742,501	13,148	0.057	0.151	0.251	0.178	0.180	*

Cells marked with * were intentionally left blank.

Note. CO, community-onset; CO CDI, community-onset Clostridioides *difficile infection*; HO, hospital-onset; HOCDI, hospital-onset Clostridioides *difficile infection*; ICU, intensive care unit; LOS, length of stay; SD, standard deviation.

[a]Due to zero denominator

Step 2. To identify the risk factors of HOCDI, we used negative binomial regression methods to account for overdispersion of data. We conducted a modeling analysis: a Complex Model. Our Complex Model considered the following variables: hospital-level variables easily accrued from EHRs and/or already reportable to the NHSN, facility and hospital-level demographics of patients, clinical practices of CDI testing divided into CO or HO CDI testing intensity and prevalence.

The best (final) model was selected using model fit statistics Akaike's Information Criteria (AIC) and Bayesian Information Criteria (BIC) based on the full data in the study cohort (3,455 quarters of aggregated hospital data associated with 9,134,276 admissions). In addition, we used cross-validation methods in variable selection and confirmed that the full-data model and the validation model had the same best set of variables in the final model (Table 3).

Risk factors of HOCDI identified using the Complex Model

Based on the Complex Model, we found the following hospital level variables were significantly associated with higher HOCDI event rates: higher COCDI prevalence; the top quarter (4th quartile) of average LOS; larger bed size; higher percent of male patients; increased HO blood culture testing intensity, increased HO blood culture prevalence, and teaching hospitals. The increased community onset period CDI testing intensity was found negatively associated with HOCDI event

rates. Among the identified risk factors, the most influential factors were HO period testing intensity, COCDI rate, HO period testing prevalence, and CO testing intensity (negative correlation).

Table 3. HOCDI Risk Factors Identified in the Complex Model. Cells marked with * are intentionally left blank.

Parameter	Estimate	Standard Error	P value
Intercept	-3.370	0.111	<.0001
Year	*	*	*
Other years	*	*	reference
Year 2017 & 2018	0.078	0.020	0.0001
COCDI prevalence	*	*	*
1st quartile	*	*	reference
2nd quartile	0.489	0.037	<.0001
3rd quartile	0.847	0.037	<.0001
4th quartile	1.175	0.041	<.0001
Average LOS	*	*	*
≤ 3rd quartile	*	*	reference
4th quartile	0.106	0.026	<.0001
Bed size	*	*	*
1-50	*	*	reference
51-300	0.175	0.102	0.0865
301+	0.212	0.101	0.0355
HO testing intensity	*	*	*
1st quartile	*	*	reference
2nd quartile	0.371	0.043	<.0001
3rd quartile	0.516	0.045	<.0001
4th quartile	0.709	0.048	<.0001
CO testing intensity	*	*	*
1st quartile	*	*	reference
2nd quartile	-0.136	0.028	<.0001
3rd quartile	-0.223	0.030	<.0001
4th quartile	-0.349	0.035	<.0001
HO testing prevalence	*	*	*
1st quartile	*	*	reference
2nd quartile	0.227	0.043	<.0001
3rd quartile	0.403	0.043	<.0001

Parameter	Estimate	Standard Error	P value
4th quartile	0.544	0.047	<.0001
% Females	*	*	*
1st quartile	*	*	reference
2nd quartile	-0.088	0.027	0.0013
3rd quartile	-0.077	0.029	0.0089
4th quartile	-0.100	0.034	0.0032
Teaching status (medical school affiliation)	*	*	*
Non-teaching	*	*	reference
Teaching	0.083	0.024	0.0005

Note. CO, community-onset; COCDI, community-onset Clostridioides *difficile infection*; HO, hospital-onset; HOCDI, hospital-onset Clostridioides *difficile infection*; ICU, intensive care unit; LOS, length of stay.

Goodness-of-fit statistics: Akaike's Information Criteria (AIC) = 13,106, Bayesian Information Criteria (BIC) = 13,290.

The Complex Model SIR -- which demonstrated best model fit— afforded robust risk-adjustment based on movement of 62% of the highest 25th percentile unadjusted HOCDI SIR ranked hospitals to lower quartiles.

Table 4. Agreement and Association Between the Model-based SIR and Unadjusted HOCDI Rate Rankings

Model comparison	Agreement test for rankings	*
*	Gamma statistic (95% CI)	Spearman correlation (95% CI)
Unadjusted HOCDI rate vs Complex Model SIR	0.63 (0.52-0.73)	0.58 (0.48-0.68)

*Cells intentionally left blank.

Note. CI, confidence interval; HOCDI, hospital-onset Clostridioides *difficile infection*; SIR, standardized infection ratio

The risk adjustment achieved with the Complex Model is distinct and uniquely distinguishes improvements in HOCDI ranking when compared to unadjusted rates. The Complex Model includes differences in CDI testing practices which in aggregate improve model fit, may achieve lower estimation error, and may more accurately reflect underlying patient risk for HOCDI than broad facility-level categories. More specifically, facility descriptors, patient characteristics, COCDI prevalence, and different aspects of CDI testing intensity and prevalence during the HO and CO period were significant factors associated with HOCDI incidence.

[Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins]

As noted above in question 2b.23, Patient-level risk factors (including social risk factors) were not available for analysis

[Response Ends]

2b.26. 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). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al) and communication with study team:

To validate the adequacy of the statistical model, we used a cross-validation method, which is one of the standard approaches for model validation, as outlined below:

- **Appropriately modeled the HOCDI events:** By plotting the histogram of number of HOCDI events per quarter per hospital, we identified skewness of HOCDI event distribution and thus we modeled the HOCDI using generalized linear models (GLMz) with log-link function.
- **Handled the overdispersion of HOCDI data:** We explored using Poisson models and finally chosen Negative Binomial model to appropriately handle the overdispersion of data.
- **Conducted a series of residual diagnosis:**
    - We plotted the residual (prediction error) and checked its normality,
    - Used decile plot, observed vs predicted plot, and standardized deviance residuals against the predicted plot to check goodness of model fit.
- **Handled possible overfit of model**: We conducted cross-validation of our model with random sampling of study data (used 30% as validation dataset). The set of predictors we identified in our model was exactly the same as the best set of variables that the cross-validation had reached and the estimated coefficients were very close between our model and the validation model.

[Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al) and communication with study team:

Root mean squared error (RMSE) for the CDI complex model, RMSE = 3.16, which represents the estimated standard deviation of prediction errors for the complex model.

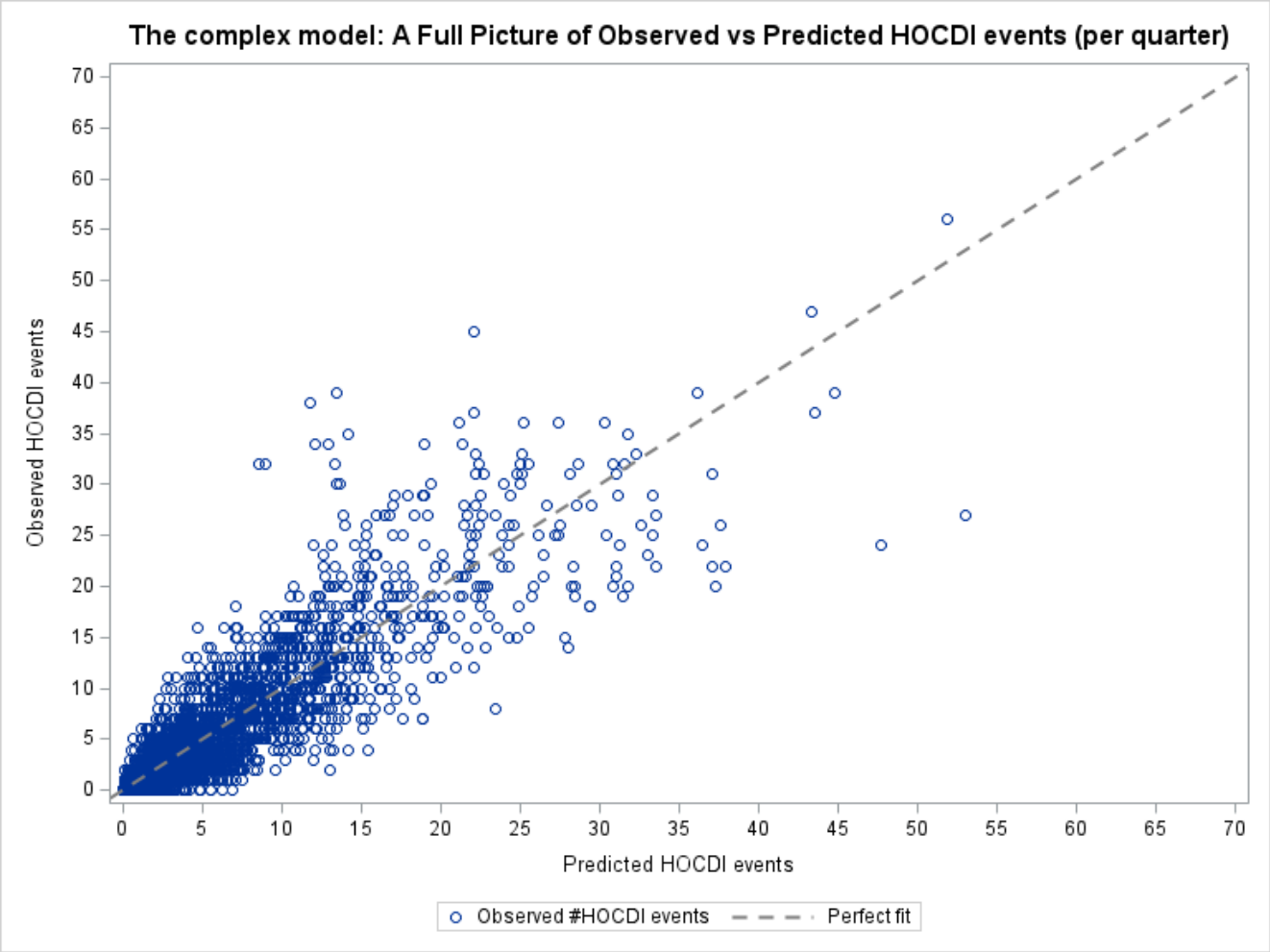
[Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al) and communication with study team:

Figure 2. Goodness-of-fit: A Full Picture of Observed vs Predicted HOCDI Events.



Interpretation: The random distribution of the scattered points of observed vs predicted events along the 'perfect fit' line indicates a well specified model.

[Response Ends]

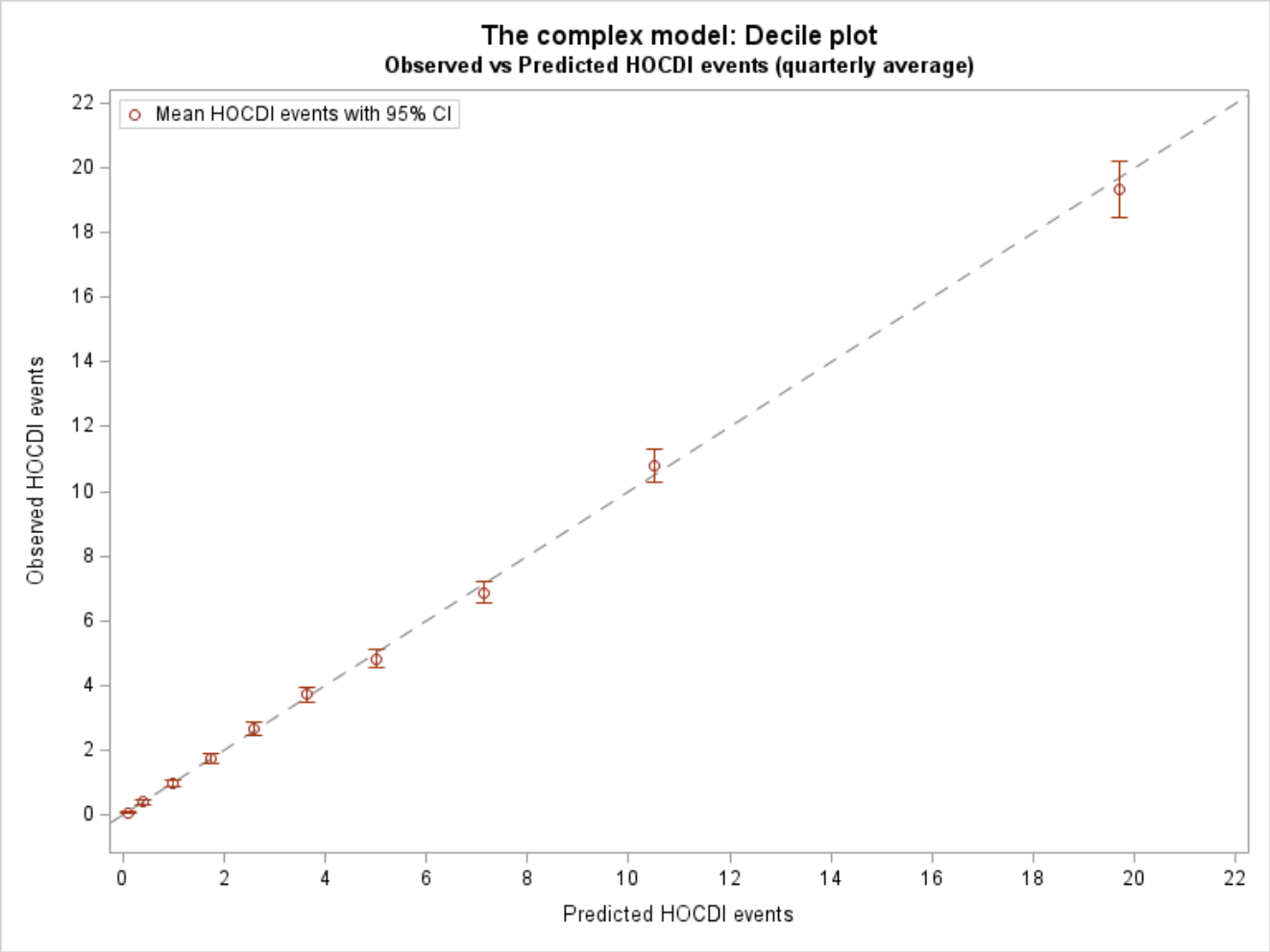
2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins]

From (Hospital-Onset *Clostridiodes difficile*, Yu et al) and communication with study team:

Figure 1. Goodness-of-fit: Decile Plot. Observed vs Predicted HOCDI events (quarterly average)



Interpretation: The decile plot shows no systematic pattern of deviation for the model predicted HOCDI events from the 'perfect fit' (gray dashline), which indicates a well specified model. The figure also indicates that the complex model might have underestimated number of events for the top 10 percentile in the predicted.

[Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins]

Risk stratification was not performed.

[Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins]

Patient-level characteristics were not assessed.

[Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins]

N/A

[Response Ends]

Criterion 3. Feasibility

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims)

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins]

ALL data elements are in defined fields in a combination of electronic sources

[Response Ends]

3.03. 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 data elements not from electronic sources.

[Response Begins]

N/A

[Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

This measure will not be an eCQM

[Response Ends]

3.06. 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.

[Response Begins]

This measure is a digital measure. From a data availability standpoint, all data elements required for the calculation of the measure are available within the EHR, ADT, or electronic claims (date of admission, laboratory results, medication administration, ICD-10 codes, etc.). As this is an electronic, digital measure, Information Technology services will need to be involved in the set-up of the data retrieval/data exchange process. However, unlike the current LabID CDI measure that is NQF endorsed (#1717), once the initial data retrieval has been set-up, the exchange can occur automatically on a monthly basis without requiring the time of an Infection Preventionist.

While PHI/PII will be collected as part of the measure to allow for patient matching across months of data, NHSN has a long history and experience with collecting and storing such data, and has extensive rules and data use agreements in place to ensure that information is only available to authorized individuals.

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail 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),

Attach the fee schedule here, if applicable.

[Response Begins]

N/A No fees or licensing requirements

[Response Ends]

Criterion 4: Use and Usability

4a. Use

4a.01. Check all current uses. For each current use checked, please provide:

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

[Response Begins]

Not in use

[Not in use Please Explain]

The measure/NHSN application for this measure has not yet been released for reporting by facilities

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Public reporting

Public Health/Disease Surveillance

Payment Program

Regulatory and Accreditation Program

Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

Quality Improvement (internal to the specific organization)

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]

This measure is not yet in use because it is a new measure and the NHSN application module to accept data from facilities has not yet been released.

[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A 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.

[Response Begins]

Reporting into the HT-CDI NHSN module is planned to launch in 2023, and the first year or so would emphasize recruitment of hospitals to begin reporting data which can be used to track internal quality improvement.

Once a full calendar year of baseline national data is collected, NHSN will begin to produce risk-adjusted Standardized Infection Ratios (SIR) which will be communicated back to the facilities to benchmark their HT-CDI performance against other facilities.

CDC has a long-standing collaborative relationship with the Centers for Medicare and Medicaid (CMS), who has been kept aware of the progress of this measure and its targeted suitability for various quality programs. This measure has received endorsement for the Hospital IQR Program in the 2021 MAP Measures Under Consideration meeting conditional upon NQF endorsement (MUC2021-098).

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail 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.

[Response Begins]

The CDC NHSN has over a decade of experience in helping hospitals and healthcare facilities collect and benchmark various healthcare quality measures for both internal quality improvement and reporting to various incentive programs.

NHSN has an existing base of >137,000 active users representing over 38,000 healthcare facilities. The enrollment process includes user education, and NHSN staff provide regular educational updates, newsletters, webinars, and online resources for users. NHSN also has an active user support desk that fielded over 90,000 tickets in 2021.

As soon as a facility reports at least a month of data into the HT-CDI module, the data and initial analytics will be available for the facility within the NHSN application. After the first year of data collection, a national baseline will be established, which can be used by the facilities and other entities for benchmarking to drive improvement practices. Much like existing NHSN measures, HT-CDI will provide monthly reports through the NHSN applications regarding HT-CDI performance. HT-CDI will be included in the HAI progress report that is published on an annual basis. Facilities will continue to receive data, analytics, and benchmarking from the current LabID CDI module during the HT-CDI development and implementation process.

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

The CDC NHSN has over a decade of experience in helping hospitals and healthcare facilities collect and benchmark various healthcare quality measures for both internal quality improvement and reporting to various incentive programs.

NHSN has an existing base of >137,000 active users representing over 38,000 healthcare facilities. The enrollment process includes user education, and NHSN staff provide regular educational updates, newsletters, webinars, and online resources for users. NHSN also has an active user support desk that fielded over 90,000 tickets in 2021.

As soon as a facility reports at least a month of data into the HT-CDI module, the data and initial analytics will be available for the facility within the NHSN application. After the first year of data collection, a national baseline will be established, which can be used by the facilities and other entities for benchmarking to drive improvement practices. Much like existing NHSN measures, HT-CDI will provide monthly reports through the NHSN applications regarding HT-CDI performance. HT-CDI will be included in the HAI progress report that is published on an annual basis. Facilities will continue to receive data, analytics, and benchmarking from the current LabID CDI module during the HT-CDI development and implementation process.

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

Facilities are not yet able to report, to no feedback is available yet from those being measured.

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

Facilities are not yet able to report, to no feedback is available yet from those being measured.

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

Facilities are not yet able to report, to no feedback is available yet from other users.

[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]

Feedback resulting from NHSN's CDI LabID (NQF#1717) directly resulted in the development of the HT-CDI measure. Feedback was provided through help desk tickets, publications, and conversations with experts in the field. The addition of the Qualifying Antimicrobial Therapy requirement is a result of concerns that *C.difficile* testing cannot distinguish between colonization and clinical infection. The change from the final *C.difficile* test to any positive *C.difficile* test was the result of feedback as well as a recent study demonstrating that while NAAT+/toxin- cases were less likely to have recurrence, they were as likely to have CDI-related complications as NAAT+/toxin+ cases. Additionally, more than twice as many potentially unreported NAAT+/toxin- cases were treated than the number of reported NAAT+/toxin+ treated cases[1]. These findings indicate that patients with NAAT+/toxin- CDI testing should be included in surveillance as they occur with relatively high frequency and are associated with clinically significant CDI-related outcomes.

[1]IDWeek 2022 Abstract. Potential underreporting of treated patients using a *Clostridioides difficile* testing algorithm that screens with a nucleic acid amplification test. Alice Guh et al.

The CDC NHSN measure development process has included collaboration with investigators from outside organizations, including EIP sites (cited earlier), Becton Dickinson (cited earlier), and the Veterans Health Administration who have provided analyses essential to developing this measure.

The measure development team has also been proactive about announcing the ongoing development of this measure to key stakeholders, including CMS, and stakeholder professional societies such as the Society for Healthcare Epidemiology of America.

Once the measure is released and available for reporting in NHSN in 2023, users will have the opportunity to provide scientific, technical, or other feedback through our NHSN Help Desk, which fields thousands of user inquiries each year.

[Response Ends]

4b. Usability

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, 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, provide an explanation. 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.

[Response Begins]

While NQF#3688 HT-CDI measure has not been in use, NQF#1717 CDI LabID has been used to drive improvement in *C.difficile* infection in hospitalized patients. NQF#3688 represents an incremental improvement on NQF#1717 as it takes into account clinician decision making to improve the clinical validity of the measure. The HT-CDI measure has additional advantages of being calculated algorithmically and objectively without the requirement for infection preventionists to directly adjudicate each event. Therefore, it may be better suited for may quality reporting programs than some related HAI measures.

From 2015 to 2020, the national CDI LabID SIR has decreased by 48 percent, indicating a trend in performance (lower SIR = better). In 2020 3,535 acute care hospitals reported 113,451 LabID CDI events. In 2020, all 50 states reported SIR < 1.

Source: C. difficile Infections | A.R. & Patient Safety Portal (cdc.gov)

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

While NQF#1717 CDI LabID has driven improvements in the national and state SIRs, the measure has led to an emphasis on CD testing stewardship and may promote changes in testing practices to decrease CDI SIRs rather than CDI prevention practices (Infection Control & Hospital Epidemiology , Volume 43 , Issue 7 , July 2022 , pp. 935 - 938). This new measure (NQF#3688 HT-CDI) should more accurately reflect clinical judgement and reduce the emphasis on testing stewardship while encouraging antimicrobial stewardship efforts as well, which is also a national priority

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

This measure has not yet been implemented.

[Response Ends]

Criterion 5: Related and Competing Measures

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

1717: Centers for Disease Control and Prevention (CDC), National Healthcare Safety Network (NHSN), Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

None

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]

Yes

[Response Ends]

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

[Response Begins]

Measure 1717 and 3688 are harmonized across the patient population included in the measures: inpatient populations.

[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]

Measure 1717 is a competing measure to 3688. Measure 3688 improves on the clinical validity of 1717 in that it captures *all (*compared to final) positive C.difficile testing while constraining to only those patients who have received anti-CD antibiotic therapy, a proxy for decision making by the clinician to treat for clinically-relevant CDI.

Additionally, 3688 improves upon 1717 in that it will be a fully electronic measure through automated transfer of data from the facility into the NHSN application, making it more efficient reporting and decreasing the burden on facility infection preventionists. Measure 3688 has additional advantages of being calculated algorithmically and objectively without the requirement for infection preventionists to directly adjudicate each event. Therefore, it may be better suited for may quality reporting programs than some related HAI measures.

[Response Ends]