CBE ID

1717

Title

Clostridioides difficile (CDI) LabID Event Standardized Infection Ratio

Project

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

Endorsement Status

Endorsed with Conditions

E&M Committee Rationale/Justification

When the measure comes back for maintenance in 3 years, the developer will have: Explored the possibility of using other all-payer data sources to expand the use of patient-level factors in the risk adjustment model and reduce reliance on facility-level factors.

Is Under Review

No

Next Maintenance Cycle

Spring 2029

Previous Endorsement Cycle

Fall 2025

Initial Endorsement

Fri, 12/14/2012 - 21:32

Steward

Centers for Disease Control and Prevention, National Healthcare Safety Network

1.0 New or Maintenance

Maintenance

1.1 Measure Structure

Single Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

Annual risk-adjusted standardized infection ratio (SIR) of *Clostridioides difficile* (CDI) LabID events among adults and pediatrics hospitalized as inpatients at acute care hospitals, critical

access hospitals, oncology hospitals, long-term acute care hospitals, and acute care rehabilitation hospitals. SIR is reported annually and is calculated by dividing the number of observed CDIs into the number of predicted CDIs.

1.6a Material Specification Change(s)

No

1.7 Measure Type

Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Hospital: Acute Care Facility, Hospital: Critical Access, Inpatient Rehabilitation Facility, Long-Term Acute Care Facility, Other

1.9b Other Care Setting

Oncology hospitals

1.10 Measure Rationale

The use of this measure will promote Clostridioides difficile (CDI) prevention activities that will lead to improved patient outcomes, including reductions of CDI infections, avoidable medical costs, and patient morbidity and mortality, through reduced need for antimicrobials and reduced length of stay.

1.11 Measure Webpage

https://www.cdc.gov/nhsn/psc/cdiff/index.html

1.13 Data Dictionary

Not attached. I attest that all information will be provided where codes and/or value sets are needed (1.14a - 1.15c).

1.14 Numerator

Number of annually observed Clostridioides difficile (CDI) LabID events in hospital inpatients.

1.14a Numerator Details

1. Determine the patients who developed a *Clostridioides difficile* LabID event
    1. *C. difficile*-positive laboratory assay: A positive laboratory test result for *C. difficile* toxin A and/or B, (includes molecular assays [PCR] and/or toxin assays) tested on an unformed stool specimen (must conform to the container). OR
    2. A toxin-producing *C. difficile* organism detected by culture or other laboratory means performed on an unformed stool sample (must conform to the container).
2. Determine if the patient is in an inpatient location.
3. Determine if a healthcare facility-onset event, defined as an event occurring on or after the

4th day of admission.

1. There should be 14 days with no *C. difficile* toxin-positive laboratory result for the patient and specific location before another *C. difficile* LabID event is entered into NHSN for the patient and location.

1.15 Denominator

Number of annually predicted Clostridioides difficile (CDI) LabID events in hospital inpatients.

1.15a Denominator Details

Determine the total number of patient days for all inpatient locations.

Determine the total number of patient admissions for all inpatient locations.

The number of predicted infections in NHSN is calculated based on the 2022 national hospital acquired infection (HAI) aggregate data and is adjusted for each facility using variables found to be significant predictors of HAI incidence. The number of predicted CDI LabID events is calculated using a negative binomial regression model.

The general formula for the negative binomial regression model is

log (λ) = α + □1□1 + □2□2 + ⋯ + □i□i, where:

α = Intercept

βi = Parameter estimate

Xi = Value of risk factor (categorical variables: 1 if present, 0 if not present)

i = Number of predictors

The tables below represent the variables found to be statistically significant predictors of C*lostridioides difficile* (CDI) LabID events and used in the negative binomial regression model to calculate the number of predicted healthcare facility-onset CDI LabID events in hospital inpatients under the 2022 baseline data.

See 7.1 Supplemental Information Attachment Pages 1-4 for risk models.

1.15b Denominator Exclusions

Baby based locations such as, neonatal ICU, special care nursery and well-baby nurseries, are excluded from the denominator count. In LDRP locations, moms and babies must each be counted separately (as two patients). Any locations that predominantly house infants, including NICU, SCN, or well-baby locations (for example, nurseries, babies in LDRP) are excluded.

1.15c Denominator Exclusions Details

Baby based locations are removed from the total facility denominator.

1.15d Age Group

Children (0-17 years), Adults (18-64 years), Older Adults (65 years and older)

1.16 Type of Score

Ratio

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

See attachment under 1.18a for details.

1.18a Attach measure score calculation diagram

1.18-Calculation-of-Measure-Score.pdf

1.19 Measure Stratification Details

The measure is not stratified.

1.20 Types of Data Sources

Electronic Health Records, Paper Patient Medical Records

1.21a Data Collection Tool URL(s)

http://example.com

1.25 Data Source Details

https://www.cdc.gov/nhsn/psc/cdiff/index.html
http://www.cdc.gov/nhsn/pdfs/pscmanual/12pscmdro_cdadcurrent.pdf
https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/VarLabelXref-PS_cur...
http://www.cdc.gov/nhsn/PDFs/pscManual/14_Tables_of_Instructions.pdf
https://www.cdc.gov/nhsn/PDFs/pscManual/16pscKeyTerms_current.pdf
https://www.cdc.gov/nhsn/forms/57.128_LabIDEvent_BLANK.pdf
https://www.cdc.gov/nhsn/forms/57.127_MDROMonthlyReporting_BLANK.pdf

https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/mrsacdi_tips.pdf
NHSN Standard Infection Ratio (SIR) Guide NHSN SIR Guide
https://wwwdev.cdc.gov/nhsn/2022rebaseline/index.html

1.26 Minimum Sample Size

N/A

2.1 Attach Logic Model

2.1-Logic-Model.pdf

2.2 Evidence of Measure Importance

Clostridioides difficile infection (CDI) is the leading cause of antibiotic-associated diarrhea and one of the most common healthcare-associated infections in the United States (CDC, 2024). In 2017, an estimated 223,900 cases of CDI occurred in hospitalized patients, resulting in an estimated 12,800 deaths, and an estimated $1 billion in healthcare costs were attributed to CDI (CDC, 2025). Multiple studies provide strong empirical support for the association between CDI infection prevention practices, such as environmental disinfection, antimicrobial stewardship, hand hygiene, chlorhexidine bathing, bundled approaches, and other interventions, and the reduction of CDI. Also in 2017, the state of Maryland implemented the Statewide Prevention and Reduction of *C. difficile* collaborative to reduce hospital-wide *C. difficile*. The state recruited 12 Maryland acute care hospitals that participated in the collaborative and 36 hospitals that participated as control hospitals. The collaborative team created assessment tools and resources to support quality improvement efforts in four domains: infection prevention, environmental cleaning, antimicrobial stewardship, and diagnostic stewardship (Rock, et. al, 2022). The collaborative team assessed the hospitals' hand hygiene, use of personal protective equipment (PPE), and environmental cleaning and then provided feedback to the participating hospitals (Rock, et. al, 2022). In addition, the collaborative provided webinars and training on antimicrobial stewardship, funding to train pharmacists through the Society of Infectious Diseases Pharmacists' antimicrobial stewardship certification program, and a peer-to-peer workshop on environmental cleaning and infection prevention (Rock, et. al, 2022). Within the first two quarters of involvement with the collaborative and implementation of the bundle interventions, the 12 intervention hospitals had a greater SIR reduction compared to control hospitals (Rock, et. al, 2022). The Maryland state-wide SIR for hospital-onset *C. difficile* decreased from 0.92 in 2017 to 0.8 in 2018 during initiation of the collaborative, and then to 0.61 in 2019 while the collaborative was ongoing (Rock, et. al, 2022). A three-hospital system in Florida also implemented a bundle approach to improve their C. difficile SIRs. Specific interventions included providing education to healthcare personnel regarding early detection and isolation of CDI patients, updating the electronic medical record to include a criteria-for-use *C. difficile* order form, which required providers to confirm appropriate criteria were met prior to testing for (White, et. al, 2020). Antibiotic stewardship interventions included physician education and EHR updates that required prescribers to select an appropriate indication upon order of fluoroquinolones (White, et. al, 2020). The hospital system level SIR decreased from 1.0 to 0.87, while the largest hospital in the system, hospital A, decreased its SIR from 1.03 to 0.84 by implementing this bundle of

interventions (White, et.al, 2020). Another study found that implementing a multifaceted approach, including a new laboratory testing policy, enhanced cleaning and disinfection of patient rooms, antibiotic stewardship, use of PPE and proper isolation precautions, reduced CDI rates. Implementing these multiple interventions allowed the facility to reduce their CDI SIR from 1.10 in 2017 to 0.65 in 2018 (Read, et.al, 2020).

- Centers of Disease Control and Prevention. *C. diff: Facts for Clinicians, March 2024* https://www.cdc.gov/c-diff/hcp/clinical-overview/index.html. Accessed May 27, 2025.
- Centers of Disease Control and Prevention. *2019 Antibiotic Resistance Threats Report* https://www.cdc.gov/antimicrobial-resistance/data-research/threats/inde…. Accessed May 27, 2025.
- Read ME, Olson AJ, Calderwood MS. Front-line education by infection preventionists helps reduce Clostridioides difficile infections. Am J Infect Control. 2020 Feb;48(2):227-229.
- Rock C, Perlmutter R, Blythe D, et al. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. BMJ Quality & Safety. 2022 Feb;31(2):153-162.
- White KA, Soe MM, Osborn A, Walling C, Fike LV, Gould CV, Kuhar DT, Edwards JR, Cochran RL. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce *Clostridioides difficile* infection rates. Infect Control Hosp Epidemiol. 2020 Mar;41(3):295-301.

Adherence to recommendations in the clinical guidelines published for the management of *C. difficile* can result in decreased rates of *C. difficile* transmission and infection. Decreased rates of infection translate to a lower standardized infection ratio (SIR), which indicates improved performance.

The Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America's (SHEA) Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children assesses the body of evidence existing in the literature. The two societies convened an expert panel to review and grade existing evidence for control and prevention of CDI. The panel used a standard process that included weighing the quality of evidence for practices that lead to successful diagnosis, treatment, infection prevention and environmental management of CDI in the inpatient setting. A single overall guideline recommendation was not provided. Each recommendation in the guidelines was given a grade.

Grading Scale: The panel followed a process used in the development of other IDSA guidelines, which included a systematic weighting of the strength of recommendation and quality of evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system. http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1…. The 2018

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

- McDonald LC, Gerding DN, Johnson S, Bakken JS, Carroll KC, Coffin SE, Dubberke ER, Garey KW, Gould CV, Kelly C, Loo V, Shaklee Sammons J, Sandora TJ, Wilcox MH. 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 Mar 19;66(7):e1-e48. doi: 10.1093/cid/cix1085. https://pubmed.ncbi.nlm.nih.gov/29462280/

The following guidelines with corresponding grade are related to the surveillance, testing, and prevention of CDI.

EPIDEMIOLOGY

I. How are CDI cases best defined?

Recommendation

1. To increase comparability between clinical settings, use available standardized case definitions for surveillance of (1) healthcare facility-onset (HO) CDI; (2) community-onset, healthcare facility-associated (CO-HCFA) CDI; and (3) community-associated (CA) CDI (good practice recommendation).

II. What is the minimal surveillance recommendation for institutions with limited resources?

Recommendation

1. At a minimum, conduct surveillance for HO-CDI in all inpatient healthcare facilities to detect elevated rates or outbreaks of CDI within the facility (weak recommendation, low quality of evidence)

IV. How should CDI surveillance be approached in settings of high endemic rates or outbreaks?
Recommendation

1. Stratify data by patient location to target control measures when CDI incidence is above national and/or facility reduction goals or if an outbreak is noted (weak recommendation, low quality of evidence)

DIAGNOSIS

VI. What is the preferred population for C. difficile testing, and should efforts be made to achieve this target?

Recommendation

1. Patients with unexplained and new-onset ≥3 unformed stools in 24 hours are the preferred

target population for testing for CDI (weak recommendation, very low quality of evidence).

IX. What is the role of repeat testing, if any? Are there asymptomatic patients in whom repeat testing should be allowed, including test of cure?

Recommendation

1. Do not perform repeat testing (within 7 days) during the same episode of diarrhea and do not test stool from asymptomatic patients, except for epidemiological studies (strong recommendation, moderate quality of evidence).

INFECTION PREVENTION AND CONTROL

Isolation Measures for Patients With CDI

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

Recommendations

1. 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).

2. 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?

Recommendation

1. 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?

Recommendation

1. 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?

Recommendations

1. Continue contact precautions for at least 48 hours after diarrhea has resolved (weak recommendation, low quality of evidence). 2. 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?

Recommendations

1. 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).

2. 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).

3. 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?

Recommendation

1. 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?

Recommendation

1. 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?

Recommendation

1. 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).

XX. What is the role of manual, terminal disinfection using a C. difficile sporicidal agent for

patients in isolation for CDI?

1. 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?

1. 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?

1. 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?

1. 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).

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

Recommendations

1. 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).

2. Implement an antibiotic stewardship program (good practice recommendation).

3. 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)

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2.4 Performance Gap

In data submitted to NHSN for 1/1/2024 – 12/31/2024, a total of 2,875 acute care hospitals had at least one predicted event and qualified for the measure. The mean CDI SIR across all hospitals was 0.781 with a range of 0-8.73. A total of 334 hospitals had an SIR=0, meaning they had zero*C. difficile* events. The decile groups represent 287 or 288 hospitals.. The range of mean

performance across the 10 groups ranged from 0 to 2.08, indicating a wide range of performance across hospitals.

A total of 224 critical access hospitals had at least one predicted event and qualified for the measure. The mean CDI SIR across all hospitals was 0.822 with a range of 0-6.32. A total of 81 hospitals had an SIR=0 meaning they had zero *C. difficile* events. The decile groups represent 22 or 23 hospitals. The range of mean performance across the 10 groups ranged from 0 to 2.73, indicating a wide range of performance across hospitals.

A total of 345 long-term care hospitals had at least one predicted event and qualified for the measure. The mean CDI SIR across all hospitals was 0.779 with a range of 0-5.43. A total of 77 hospitals had an SIR=0, meaning they had zero *C. difficile* events. The decile groups represent 34 or 35 hospitals. The range of mean performance across the 10 groups ranged from 0 to 2.62, indicating a wide range of performance across hospitals.

A total of 633 inpatient rehabilitation hospitals had at least one predicted event and qualified for the measure . The mean CDI SIR across all hospitals was 0.658 with a range of 0-4.69. A total of 217 hospitals had an SIR=0 meaning they had zero *C. difficile* events. The decile groups represent 63 or 64 hospitals. The range of mean performance across the 10 groups ranged from 0 to 2.40, indicating a wide range of performance across hospitals.

Table 1. Performance Scores by Decile

Performance Gap

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	0.781	0	0.00	0.156	0.351	0.493	0.628	0.767	0.910	1.079	1.342	2.081	8.733
N of Entities	2875		287	288	287	288	287	288	287	288	287	288	
N of Persons / Encounters / Episodes	151749866		5186641	14001734	13947429	16974075	17712744	18422534	18761071	19291832	17935621	9516185	

2.4a Attach Performance Gap Results

2.4a-Performance-Gap-Results-CDI.pdf

2.6 Meaningfulness to Target Population

The Patient Safety Action Network is a coalition of individuals and organizations consisting of patients who have been medically harmed, their loved ones, and concerned patient safety advocates.

“Please accept these comments from the Patient Safety Action Network regarding the following HAI measures; we are commenting on all of them together:

- Catheter-Associated Urinary Tract Infections (CAUTI)
- Central Line Associated Blood Stream Infections (CLABSI)
- 30-Day Post-Operative Colon Surgery (COLO) and Abdominal Hysterectomy (HYST) Surgical Site Infection (SSI)
- Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia LabID Event
- *Clostridioides difficile* (CDI) LabID Event
- Antimicrobial Use Measure

"Fundamentally, each of these measures is important and essential to preventing infections. If we do not measure and publicly report these events in a continuous, standardized way, we cannot truly know or understand when actual progress is made.

There are several target populations for these measures. First, members of the public who may need to use the services of a local hospital at any given point without warning or who have an interest in seeing how their hospital compares to others on hospital acquired infections. The published HAI measures provide that public service. Second, patients being treated at a hospital who are infected might not benefit from the past published HAI measures, but they probably are interested in accountability. One of the first questions many ask is "will my infection be counted?" The next question typically is, "how can we prevent it from happening again to someone else?" To them, these measurements are very important.

The value and meaningfulness of these outcome measures lie in tracking reduction of patient harm over time using individual hospitals' HAI measures. Progress means fewer infections at each point of measurement with a goal toward no infections. Unfortunately, these measures are rarely presented on a continuum demonstrating whether each hospital has reduced this harm over the years. And they are no longer presented with the actual numbers of infections, which reflect actual infections reported and not an estimate.

We also believe the value of these measures is lowered because of the way they are reported to the public. It appears that the standardization using an SIR of 1.0 as the baseline has established that as the status quo, even though the baseline has been adjusted over time. We wonder how often hospitals accept SIRs of around 1.0 as acceptable. Further, the use of risk adjustment skews the real results in each of these measures, i.e., the patients who got infected. We would rather see a stratified presentation that compares similar hospitals together – without risk adjustments. We believe that would be more meaningful to the public.

Also, the terms used to present the data lead to confusion, such as predicted number of infections and better than/no different/worse than the national benchmark. Many hospitals' data is "not available," without context (the hospital failed to report, the hospital does not have enough cases to rate, etc).

Even with these limitations, the measures are important to retain because of their value to patients who expect to be free from preventable harm when hospitalized. You ask about the full meaning of these measures to patients, but that requires some understanding of what happens to them following a hospital acquired infection. These events affect each person in a different way. It can mean a round of antibiotics; a longer stay in the hospital or the need to seek further treatment; continued chronic conditions, including recurrences of the infection; significant medical debt; losing a job due to missing work as a consequence of an infection; losing one's home due to mounting medical bills and other debts; permanent disability; sepsis that is only survived after intense medical care; and death. This should clearly explain why all these measures are meaningful to patients.

Frankly, we need more infection measures so that all hospital acquired infections are accounted for, like what is done in California. It seems to us that every time federal agencies ask for feedback about these measures, the result is less information to the public."

The Clostridium difficile (CDI) LabID Event Standardized Infection Ratio 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 the measure in six CMS Measure Programs, including Hospital Acquired Condition Reduction Program, Hospital Value-Based Purchasing, Hospital Inpatient Quality Reporting, Inpatient Rehabilitation Facility Quality Reporting, Long-Term Care Hospital Quality Reporting and Prospective Payment System-Exempt Cancer Hospital Quality Reporting.[2]

[1]U.S. Health and Human Services (HHS) National Action Plan to Prevent Health Care-associated Infections: Roadmap to Elimination. Accessed May 5, 2025 at https://www.hhs.gov/oidp/topics/health-care-associated-infections/hai-a...;

[2]Centers for Medicare and Medicaid Services Measures Inventory Tool at

https://cmit.cms.gov/cmit/#/FamilyView?familyId=462

3.1 Contributions Towards Closing Care Gaps

This criteria is optional for the Fall 2025 cycle.

4.1a Data Structure and Availability

This is a maintenance measure, and the measure specifications have not changed. Facilities have not notified NHSN of any feasibility issues within the last year.

All required data elements are routinely generated, in structured fields, and used during care delivery. Facilities can choose to submit this data manually via a web form or via submission of CDA electronic files. NHSN has built-in business rules for mandatory data elements and does not allow for the submission of incomplete records.

Addressing NHSN data quality issues is integral to NHSN's ability to help facilities collect the data necessary to identify areas needing prevention efforts, measure progress of prevention efforts, and push toward C. difficile elimination. The NHSN Team routinely reviews the data reported to NHSN and will contact facilities to resolve confirmed and suspected data quality flags. Multiple data quality checks are conducted to help confirm the accuracy of the data being reported. These data quality checks include confirming numerator and denominator data, verifying business rules within the application, verifying alerts, and confirming the flags triggered by incomplete data.

NHSN provides facilities with internal validation toolkits, which facilities can choose to use to audit their internal data to identify any potential inaccuracies or problems. The internal validation toolkit also provides recommendations to facilities for implementing quality control processes to ensure data is accurate and complete.

Additionally, NHSN offers external validation toolkits, which can be used by state or local health departments, or other auditors, to perform checks on the data that facilities submit to NHSN. External validation allows for the auditors to identify gaps in understanding of surveillance definitions or other errors and provide education to ensure data reported to NHSN follows the standardized specifications.

4.1b Implementation Costs and Burden

Per the Paperwork Reduction Act (PRA) of 1995, federal agencies cannot conduct or sponsor the collection of information unless the Office of Management and Budget (OMB) has reviewed and approved the proposed data collection. Federal agencies must submit a set of documents known

as an Information Collection Request (ICR) to request OMB approval of an information collection. The ICR documents describe what information is needed, why it is needed, how it will be collected, and how much time, money, and effort it will cost the respondents to collect the information.

Multiple data collection forms are used to provide surveillance data on CDI LabID events. Below are the OMB-approved estimated total annual burden hours and annual cost for all facilities that complete this data collection.

See 7.1 Supplemental Information Attachment Page 5 for cost and burden details.

4.1c Confidentiality

While CDC can retrieve data by personal identifier, CDC does not, as a matter of practice or policy, retrieve data in this way. Specifically, the primary practice and policy of CDC regarding NHSN data are to retrieve data by the name of the hospital or another non-personal identifier, not an individual patient, for surveillance and public health purposes. Furthermore, patient identifiers are not necessary for NHSN to operate.

An Assurance of Confidentiality is granted for all data collected under NHSN. NHSN's Assurance of Confidentiality states the following:

"the voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d))."

4.3 Feasibility Informed Final Measure

This is a maintenance measure, and the measure specifications have not changed.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

Reliability Testing:

The dataset used for testing came from CDC NHSN, which collects data about healthcare-associated infections (HAI) from healthcare facilities throughout the United States. Data reported for the period from 1/1/2024 to 12/31/2024 were used for reliability testing.

Validity Testing:

The dataset used for testing came from CDC's NHSN, which collects HAI data from facilities throughout the United States. Data reported for the period from 1/1/2024 to 12/31/2024 were used for validity testing.

Validation Studies:

1. Rock C, Perlmutter R, Blythe D, et al. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. BMJ Quality & Safety. 2022 Feb;31(2):153-162.

   Dates of data used in testing: April 2017 to March 2020

2. White KA, Soe MM, Osborn A, Walling C, Fike LV, Gould CV, Kuhar DT, Edwards JR, Cochran RL. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce Clostridioides difficile infection rates. Infect Control Hosp Epidemiol. 2020 Mar;41(3):295-301.

   Dates of data used in testing: January 2015- December 2016

3. Garcia Reeves AB, Lewis JW, Trogdon JG, Stearns SC, Weber DJ, Weinberger M. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant Staphylococcus aureus bacteremia and Clostridioides difficile infection in the United States. Infect Control Hosp Epidemiol. 2020 Apr;41(4):430-437.

   Dates of data used in testing: January 2014-December 2016.

4. Bartles R, Reese S, Gumbar A. Closing the gap on infection prevention staffing recommendations: Results from the beta version of the APIC staffing calculator. Am J of Infect Control. 2024; 52(12): 1345-1350.

Date of data used in testing: December 2023 to June 2024.

Risk Adjustment: The dataset used for the risk adjustment model was derived from CDC's NHSN, which collects data about HAIs from healthcare facilities throughout the United States. Data reported from 1/1/2022 to 12/31/2022 was used in the risk adjustment analysis. In-plan CDI LabID data and risk factors were derived from facility enrollment information and the annual facility survey.

5.1.1a Dates of Testing Data

Reliability Testing:

The dataset used for testing came from CDC NHSN, which collects data about healthcare-associated infections (HAI) from healthcare facilities throughout the United States. Data reported for the period from 1/1/2024 to 12/31/2024 were used for reliability testing.

Validity Testing:

The dataset used for testing came from CDC's NHSN, which collects HAI data from facilities throughout the United States. Data reported for the period from 1/1/2024 to 12/31/2024 were used for validity testing.

Validation Studies:

1. Rock C, Perlmutter R, Blythe D, et al. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. BMJ Quality & Safety. 2022 Feb;31(2):153-162.

Dates of data used in testing: April 2017 to March 2020

2. White KA, Soe MM, Osborn A, Walling C, Fike LV, Gould CV, Kuhar DT, Edwards JR, Cochran RL. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce Clostridioides difficile infection rates. Infect Control Hosp Epidemiol. 2020 Mar;41(3):295-301.

   Dates of data used in testing: January 2015- December 2016

3. Garcia Reeves AB, Lewis JW, Trogdon JG, Stearns SC, Weber DJ, Weinberger M. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant Staphylococcus aureus bacteremia and Clostridioides difficile infection in the United States. Infect Control Hosp Epidemiol. 2020 Apr;41(4):430-437.

   Dates of data used in testing: January 2014-December 2016.

4. Bartles R, Reese S, Gumbar A. Closing the gap on infection prevention staffing recommendations: Results from the beta version of the APIC staffing calculator. Am J of Infect Control. 2024; 52(12): 1345-1350.

   Date of data used in testing: December 2023 to June 2024.

Risk Adjustment: The dataset used for the risk adjustment model was derived from CDC's NHSN, which collects data about HAIs from healthcare facilities throughout the United States. Data reported from 1/1/2022 to 12/31/2022 was used in the risk adjustment analysis. In-plan CDI LabID data and risk factors were derived from facility enrollment information and the annual facility survey.

5.1.2 Differences in Data

Reliability Testing:

The dataset used for testing came from CDC's NHSN, which collects data about HAIs from

healthcare facilities throughout the United States. Data reported for the period from 1/1/2024 to 12/31/2024 were used for reliability testing.

Validity Testing:

The dataset used for testing came from CDC's NHSN, which collects data about HAIs from healthcare facilities throughout the United States. Data reported for the year 2024 were used for validity testing. Facilities with both C. difficile (CDI) and methicillin-resistant Staphylococcus aureus (MRSA) SIRs were included in the analysis (facilities with ≥1 predicted event for both event types were included).

Validation Studies:

1. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. Facilities participating in the intervention reported CDI SIR data to NHSN from April 2017 to March 2020 and control hospitals reported CDI SIR data from October 2017 to March 2020.

Rock C, Perlmutter R, Blythe D, et al. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. BMJ Quality & Safety. 2022 Feb;31(2):153-162.

2.Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce *Clostridioides difficile* infection rates. Facilities reported CDI SIR data to NHSN from January 2015 to December 2016.

White KA, Soe MM, Osborn A, Walling C, Fike LV, Gould CV, Kuhar DT, Edwards JR, Cochran RL. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce *Clostridioides difficile* infection rates. Infect Control Hosp Epidemiol. 2020 Mar;41(3):295-301.

3. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant *Staphylococcus aureus* bacteremia and *Clostridioides difficile* infection in the United States. This study merged 2014–2017 hospital-level data from the Centers for Medicare & Medicaid Services' (CMS) Hospital Compare data, Provider of Service files, Medicare cost reports, and 2014–2016 state-level data from the

CDC’s Patient Safety Atlas website.

Garcia Reeves AB, Lewis JW, Trogdon JG, Stearns SC, Weber DJ, Weinberger M. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant *Staphylococcus aureus* bacteremia and *Clostridioides difficile* infection in the United States. Infect Control Hosp Epidemiol. 2020 Apr;41(4):430-437.

4. Closing the gap on infection prevention staffing recommendations: Results from the beta version of the APIC staffing calculator. For each facility, SIRs were entered from CMS’s Hospital Compare website for central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), CDI and colon surgical site infection (SSI).

Bartles R, Reese S, Gumbar A. Closing the gap on infection prevention staffing recommendations: Results from the beta version of the APIC staffing calculator. Am J of Infect Control. 2024; 52(12): 1345-1350.

Risk Adjustment:

The 2022 national aggregate data were reviewed for all potential data quality issues, including outlier values, prior to performing the risk adjustment modeling of the SIR denominator for the CDI LabID model. Based on the surveillance protocol for CDI, data submitted from inpatient rehabilitation locations and inpatient psychiatric locations that have their CMS Certification Number (CCN) were excluded from modeling consideration. NICUs and well-baby units, such as newborn nurseries, are excluded.

5.1.3 Characteristics of Measured Entities

See 7.1 Supplemental Information Attachment Pages 6-8 for details.

5.1.4 Characteristics of Units of the Eligible Population

Reliability Testing:
The C. difficile risk models used to calculate the predicted number of events were developed using facility-level factors and testing practices.

Validity Testing:
The C. difficile risk models used to calculate the predicted number of events were developed using facility-level factors and testing practices.

Validation Studies:
I. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. Descriptive characteristics of patients were not available because demographic data on patients is not collected in NHSN.

Rock C, Perlmutter R, Blythe D, et al. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. BMJ Quality & Safety. 2022 Feb;31(2):153-162.

II. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce Clostridioides difficile infection rates. Descriptive characteristics of patients were not available because demographic data on patients is not collected in the NHSN module.

White KA, Soe MM, Osborn A, Walling C, Fike LV, Gould CV, Kuhar DT, Edwards JR, Cochran RL. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce Clostridioides difficile infection rates. Infect Control Hosp Epidemiol. 2020 Mar;41(3):295-301.

III. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant Staphylococcus aureus bacteremia and Clostridioides difficile infection in the United States. Descriptive characteristics of patients were not available because demographic data on patients is not collected in the NHSN Module.

Garcia Reeves AB, Lewis JW, Trogdon JG, Stearns SC, Weber DJ, Weinberger M. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant Staphylococcus aureus bacteremia and Clostridioides difficile infection in the United States. Infect Control Hosp Epidemiol. 2020 Apr;41(4):430-437.

IV. Results from the beta version of the APIC staffing calculator: Most of the hospitals had an intensive care unit (ICU) (n = 355, 91.0%) and an emergency department (ED) (n = 386, 99.0%), performed surgery (n = 385, 98.7%), and were a part of a system (n = 329, 84.4%) (Table 1). Almost 90% of hospitals with > 500 beds had a burn unit, stem cell transplant unit (SCTU) or an inpatient rehabilitation unit (IRF) (n = 64, 87.7%), compared to about 50% of hospitals with < 200 beds. The case mix index (CMI) increased by hospital size; hospitals with 101 to 200 beds had a

lower CMI (median: 1.54, IQR: 0.25) compared to hospitals with > 750 beds (2.27, 0.39).

Bartles R, Reese S, Gumbar A. Closing the gap on infection prevention staffing recommendations: Results from the beta version of the APIC staffing calculator. Am J of Infect Control. 2024; 52(12): 1345-1350.

Risk Adjustment: The risk models used to calculate the predicted number of CDI events were developed using facility-level factors and testing practices.

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

To measure facility-level reliability, we computed the signal-to-noise ratio (SNR).

SNR reliability testing was performed to distinguish measure scores between facilities (Adams J.L. 2009). SNR reliability scores can range from 0 to 1. A reliability of zero implies that all the variability in a measure is attributable to measurement error. Reliability of one implies that all variability is attributable to real difference in performance. The annual standardized infection ratio (SIR) was defined as the sum of observed (O) events at the facility divided by the sum of predicted (P) events calculated from the risk-adjustment model. SNR reliability testing denotes between-facility variance and within-facility variance (Adams J.L. 2009). The SNR for each facility SIR was calculated using both the between- facility and within-facility variance across eligible facilities with a predicted number of CDI events ≥1. The between-facility variance was the total variance of the SIR facility distribution. The within-facility variance of the SIR for each facility was then calculated as Var(O/P) where P is a constant, a nuisance factor with no random variation. The observed (O) was assumed to follow a Poisson distribution with a mean parameter lambda approximated by P. The result was Var(O/P) = Var(O)/P2 = P/P2 = 1/P.

References:

- Adams, J. L. (2009). *The reliability of provider profiling: a tutorial*. RAND.

5.2.3 Reliability Testing Results

See attachment under 5.2.3a for reliability testing results for each care setting.

The estimated SNR reliability score was ≥0.6 in 72% of acute care hospitals (ACH), 21% of critical access hospitals (CAH), 84% of long-term acute care facilities (LTACF), and 39% of inpatient rehabilitation facilities (IRF).

The median SNR reliability score was 0.712 among ACH, 0.546 among CAH, 0.73 among LTACF, and 0.571 among IRF.

5.2.3a Attach Additional Reliability Testing Results

5.2.3-Reliability-Testing-Results.pdf

5.2.4 Interpretation of Reliability Results

We calculated the signal-to-noise ratio (SNR) reliability score for each facility that had at least one predicted CDI event. SNR reliability scores vary across facilities from zero to one, with a score of zero indicating that all variation is attributable to noise (variation across patients within facilities) and a score of one indicating that all variation is caused by real differences in performance across facilities. Reliability testing was performed on data reported for the year 2024 from all care settings that report the measure.

The estimated SNR reliability score was ≥0.6 in 72% of acute care hospitals (ACH), 21% of critical access hospitals (CAH), 84% of long-term acute care facilities (LTACF), and 39% of inpatient rehabilitation facilities (IRF). The decile distribution of reliability measurements is presented above in section 5.2.3a.

The median SNR reliability score was 0.712 among ACH, 0.546 among CAH, 0.73 among LTACF, and 0.571 among IRF. The median SNR reliability scores for ACH and LTACH demonstrate substantial reliability, and the scores for CAH and IRF demonstrate moderate reliability. Our interpretation of the results is based on the standards established by Landis and Koch (1977):

< 0 – Less than chance agreement

0 – 0.2 Slight agreement

0.21 – 0.39 Fair agreement

0.4 – 0.59 Moderate agreement

0.6 – 0.79 Substantial agreement

0.8 – 0.99 Almost perfect agreement

1 Perfect agreement

Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *biometrics*, 159-174.

5.3.1 Level(s) of Validity Testing Conducted

Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.2 Type of Accountable Entity Level Validity Testing Conducted

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.3.3 Method(s) of Validity Testing

Validity Testing:

A Spearman correlation coefficient was calculated to assess a hypothesized monotonic relationship in the positive direction between annual CDI and MRSA standardized infection ratios (SIR). The annual SIR was defined as the sum of observed (O) events at the facility divided by the sum of predicted (P) events calculated from the risk-adjustment model. Facility that reported both CDI and MRSA data for 2024 with at least 1 predicted event for each were included. Facility that reported only CDI, reported only MRSA, or did not have at least 1 predicted event for both HAIs were excluded from the analysis. Correlation coefficients range from -1 to +1, where a coefficient of -1 implies a perfect negative correlation, 0 implies no correlation, and +1 implies a perfect positive correlation. A significance threshold of 0.05 was used.

We hypothesized that there would be a positive correlation between CDI and MRSA SIRs because there is some overlap in the infection prevention practices that protect against both types of infections (for example, implementing hand hygiene, standard precautions, contact isolation, environmental cleaning, and antimicrobial stewardship). However, there are also differences in prevention practices as well, such as insertion and maintenance practices for vascular access devices for the prevention of MRSA bloodstream infections. Thus, we predicted that while the correlation would be positive, it would be a weak correlation.

Validation Studies:
These studies assess a hypothesized relationship between a reduction in the CDI SIR and implementation of CDI prevention techniques. An SIR > 1.0 represents that more CDIs were observed than predicted, an SIR <1.0 represents that fewer CDIs were observed than predicted, and an SIR =1.0 represents the same number of CDIs were observed as predicted. No published literature that examined prevention activities and reported the results of the NHSN C. difficile (CDI) LabID Event SIR in long-term acute care hospitals or inpatient acute rehabilitation hospitals was identified during a literature review. After consultations with experts in the field, it was determined that healthcare facilities utilize the same strategies to prevent C. diff. regardless of facility type. Therefore, we selected the following articles that address C. diff prevention in acute care hospitals. The studies support the hypothesis that the measure score (CDI SIR) correctly

reflects the quality of care provided and adequately identifies differences in quality.

I. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention.

The Maryland Statewide Prevention and Reduction of C. difficile (SPARC) collaborative was created to decrease rates of C. diff. across the state. Twelve Maryland acute care hospitals participated in the collaborative and 36 hospitals served as controls. The collaborative created assessment tools and resources to support quality improvement efforts across the hospitals in four domains: infection prevention, environmental cleaning, antimicrobial stewardship, and diagnostic stewardship. The SPARC team conducted site visits to observe hand hygiene, use of personal protective equipment (PPE), and environmental cleaning and provided feedback reports to the participating hospitals. Feedback from the site visits was also discussed with hospital leadership. SPARC also provided webinars and training on antimicrobial stewardship, funding to train pharmacists through the Society of Infectious Diseases Pharmacists antimicrobial stewardship certification program and a peer-to-peer workshop on environmental cleaning and infection prevention. The unit of analysis was hospital-quarter. Data used from intervention hospitals included four quarters of pre-intervention and six quarters of post-intervention data from NHSN. For control hospitals, 10 quarters of data from October 2017 to March 2020 were used.

Rock C, Perlmutter R, Blythe D, et al. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. BMJ Quality & Safety. 2022 Feb;31(2):153-162.

II. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce Clostridioides difficile infection rates.

The Targeted Assessment for Prevention (TAP) strategy was initiated within a three-hospital system in Florida. TAP assessments were administered to staff at each hospital to identify infection control gaps and inform CDI prevention interventions. Based on priority areas identified by the assessments, the healthcare organization worked with their QIO to prioritize opportunities for improvement and CDI prevention interventions. These interventions included providing education to healthcare personnel regarding early detection and isolation of CDI patients, updating the electronic medical record to include a criteria-for-use C. difficile order form requiring providers to confirm that appropriate criteria were met prior to testing for C. difficile, executing antibiotic stewardship interventions including physician education, and implementing an update to the electronic health record that required prescribers to select an appropriate indication upon order of fluoroquinolones. The study hypothesized that identifying opportunities for improvement and implementing CDI prevention interventions in these areas would decrease

the hospitals' CDI SIR. Reductions in CDI events were determined by assessing the system level CDI event SIR and each individual hospital CDI SIR provided by NHSN.

White KA, Soe MM, Osborn A, Walling C, Fike LV, Gould CV, Kuhar DT, Edwards JR, Cochran RL. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce Clostridioides difficile infection rates. Infect Control Hosp Epidemiol. 2020 Mar;41(3):295-301.

III. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant Staphylococcus aureus bacteremia and Clostridioides difficile infection in the United States.

In 2014, the CDC launched seven core elements for antimicrobial stewardship programs: leadership commitment, accountability, drug expertise, action, tracking, reporting, and education. A study was conducted to examine compliance with the core elements from 2014 - 2016 and the association between statewide adoption of the core elements and hospital MRSA and CDI rates in all US states. The study hypothesized that states with higher percentages of reported compliance with the core elements would have significantly lower MRSA and CDI rates. The study used the CDC's Patient Safety Atlas website, which provides access to state-level data on hospital-acquired infections, antimicrobial resistance, and antibiotic stewardship programs from acute-care hospitals nationwide. The data presented on the website were collected through the CDC National Healthcare Safety Network (NHSN) Patient Safety Component Annual Hospital Survey. Antibiotic stewardship program data, also collected through NHSN, was used to assess whether facilities met the criteria for each of the 7 recommended core elements. For each year from 2014-2016, between 4,173 and 4,764 acute-care facilities completed the NHSN survey. The study used descriptive statistics to measure state-level variation in the percentage of hospitals meeting the core elements during the study period.

Garcia Reeves AB, Lewis JW, Trogdon JG, Stearns SC, Weber DJ, Weinberger M. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant Staphylococcus aureus bacteremia and Clostridioides difficile infection in the United States. Infect Control Hosp Epidemiol. 2020 Apr;41(4):430-437.

IV. Closing the Gap on Infection Prevention Staffing Recommendations: Results from the beta version of the APIC staffing calculator: In this study, a staffing calculator was developed and piloted to provide facilities with customized infection prevention staffing recommendations. The study hypothesized that facilities with lower staffing levels would have higher SIRs for central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), CDI, and colon surgical site infection (SSI).

Bartles R, Reese S, Gumbar A. Closing the gap on infection prevention staffing recommendations: Results from the beta version of the APIC staffing calculator. Am J of Infect Control. 2024; 52(12): 1345-1350.

5.3.4 Validity Testing Results

Validity Testing:

Among 1,906 acute care hospitals, we identified a weak but significant positive correlation between CDI SIR and MRSA SIR (rho= 0.06775, p= 0.0031).

Validation Studies:

1. Impact of Statewide Prevention and Reduction of *Clostridioides difficile* (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention.

Within the first two quarters of involvement with the collaborative, 12 intervention hospitals had a greater standardized infection ratio (SIR) reduction compared to control hospitals. A SIR > 1.0 represents that more CDI events were observed than predicted, a SIR < 1.0 represents that fewer CDI events were observed than predicted, and a SIR= 1.0 represents the same number of CDI events were observed as predicted. The Maryland state-wide SIR for hospital-onset *C. difficile* decreased from 0.92 in 2017 to 0.8 in 2018 during initiation of the collaborative, and then to 0.61 in 2019 while the collaborative was ongoing.

This study demonstrated that implementation of a state-wide collaborative that focused on prevention activities for *C. diff.* along with ongoing collaborative support led to a significant reduction in the reported NHSN CDI SIRs. These data support the hypothesis that the measure score correctly reflects the quality of care provided and adequately identifies differences in quality.

Rock C, Perlmutter R, Blythe D, et al. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. BMJ Quality & Safety. 2022 Feb;31(2):153-162.

2. Implementation of the Targeted Assessment for Prevention strategy in a healthcare system to reduce *Clostridioides difficile* infection rates.

The hospital system level SIR decreased from 1.0 to 0.87, while the largest hospital in the system, hospital A, decreased its SIR from 1.03 to 0.84. A SIR > 1.0 represents that more CDI events were observed than predicted, a SIR < 1.0 represents that fewer CDI events were observed than predicted, and a SIR= 1.0 represents the same number of CDI events were observed as predicted. This study demonstrated that the implementation of a targeted assessment and infection control practices that focused on *C. diff.* prevention led to a reduction in the reported NHSN CDI SIRs. The study and data support the hypothesis that the measure score correctly reflects the quality of care provided and adequately identifies differences in quality.

White KA, Soe MM, Osborn A, Walling C, Fike LV, Gould CV, Kuhar DT, Edwards JR, Cochran RL. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce *Clostridioides difficile* infection rates. Infect Control Hosp Epidemiol. 2020 Mar;41(3):295-301.

3. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant *Staphylococcus aureus* bacteremia and *Clostridioides difficile* infection in the United States.

The study’s results supported its hypothesis that compliance with the antibiotic stewardship program core elements was associated with a significant 0.3% decrease (P < .01) in CDI SIR in 2016 relative to 2014. A SIR > 1.0 represents that more CDI events were observed than predicted, a SIR < 1.0 represents that fewer CDI events were observed than predicted, and a SIR= 1.0 represents the same number of CDI events were observed as predicted. This study demonstrates that compliance with the CDC’s Antimicrobial Stewardship Programs Core Elements led to a significant reduction in CDI LabID event SIRs. Thus, this data supports the hypothesis that the measure score correctly reflects the quality of care provided and adequately identifies differences in quality.

Garcia Reeves AB, Lewis JW, Trogdon JG, Stearns SC, Weber DJ, Weinberger M. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant *Staphylococcus aureus* bacteremia and *Clostridioides difficile* infection in the United States. Infect Control Hosp Epidemiol. 2020 Apr;41(4):430-437.

4. Closing the Gap on Infection Prevention Staffing Recommendations: Results from the beta version of the APIC Staffing Calculator

This study showed a significant association between staffing status and higher SIRs for central line-associated bloodstream infections (p=0.02), catheter-associated urinary tract infections (p=0.001), *Clostridioides difficile* infections (p=0.003), and colon surgical site infections (p=0.0001).

Bartles R, Reese S, Gumbar A. Closing the gap on infection prevention staffing recommendations: Results from the beta version of the APIC staffing calculator. Am J of Infect Control. 2024; 52(12): 1345-1350.

See attachment under 5.3.4a for additional details.

5.3.4a Attach Additional Validity Testing Results

5.3.4--Validity-Testing-Results.pdf

5.3.5 Interpretation of Validity Results

Validity Testing:
The CDI SIR and MRSA SIR are both laboratory-identified healthcare associated infection outcome measures. Implementation of infection prevention strategies, such as hand hygiene, have been shown to decrease the spread of C.difficile and MRSA. Environmental cleaning and disinfection, and appropriate use of contact/isolation precautions are also important prevention practices that can decrease the transmission of both pathogens.

However, other factors or prevention strategies may differ between the two pathogens. For example, facilities may focus antimicrobial stewardship resources to avoiding or limiting antibiotics associated with high CDI risk (such as fluoroqinolones). Alternatively, some facilities may choose to implement decolonization strategies aimed to reduce MRSA bloodstream infections. We hypothesized that there would be a weak positive correlation between the CDI SIR and MRSA SIR. We predicted only a weak correlation between the two measures because some facilities may choose to focus quality improvement on the prevention of a single HAI (CDI or MRSA) due to resource limitations or other factors.

The significant positive correlation between CDI and MRSA SIRs (rho= 0.06775, p= 0.0031) in acute care hospitals demonstrate that the SIRs are valid measures of healthcare quality, as SIRs for both infections are both driven by clinically relevant patient care practices and evidence-based infection prevention strategies implemented by the healthcare facilities.

Validation Studies:
I-III. These studies support the hypothesis that the measure score correctly reflects the quality of care provided and adequately identifies differences in quality.

Rock C, Perlmutter R, Blythe D, et al. Impact of Statewide Prevention and Reduction of Clostridioides difficile (SPARC), a Maryland public health-academic collaborative: an evaluation of a quality improvement intervention. BMJ Quality & Safety. 2022 Feb;31(2):153-162.

White KA, Soe MM, Osborn A, Walling C, Fike LV, Gould CV, Kuhar DT, Edwards JR, Cochran RL. Implementation of the Targeted Assessment for Prevention Strategy in a healthcare system to reduce *Clostridioides difficile* infection rates. Infect Control Hosp Epidemiol. 2020 Mar;41(3):295-301.

Garcia Reeves AB, Lewis JW, Trogdon JG, Stearns SC, Weber DJ, Weinberger M. Association between statewide adoption of the CDC's Core Elements of Hospital Antimicrobial Stewardship Programs and rates of methicillin-resistant *Staphylococcus aureus* bacteremia and *Clostridioides difficile* infection in the United States. Infect Control Hosp Epidemiol. 2020 Apr;41(4):430-437.

IV. This study showed a correlation between staffing levels and infection outcomes (CAUTI, CLABSI, CDI, and colon SSI). Programs with below-expected staffing levels according to the calculator were more likely to have higher SIRs. This finding reinforces the value of well-staffed infection prevention programs in maintaining lower SIRs.

Bartles R, Reese S, Gumbar A. Closing the gap on infection prevention staffing recommendations: Results from the beta version of the APIC staffing calculator. Am J of Infect Control. 2024; 52(12): 1345-1350.

5.4.1 Methods Used to Address Risk Factors

Statistical risk adjustment model with risk factors

5.4.2 Conceptual Model Rationale

NHSN follows a highly rigorous process while developing risk adjustment models for its measures. The process begins with a thorough clinical and epidemiological review of all eligible potential risk factors that are currently collected in NHSN. The data available in NHSN are a combination facility-level and testing practice risk factors. Experts then recommend risk factors to be evaluated statistically. CDC obtains the risk factors considered for inclusion in the model for

predicted events (i.e., denominator) by estimating the parameters, or probability of risk occurrence. The final model is chosen by identifying the optimal parameterizations of all covariates (i.e., risk factors) in linear regression procedures. In other words, risk factors are included in a model if they are determined to significantly impact *C. difficile* incidence. The model is then double-tested by a reverse process that removes non-significant factors. Each best model is fit-tested, calibrated, and validated using industry standard techniques.

References:

- NHSN's Guide to the 2022 Baseline Standardized Infection Ratios. Centers for Disease Control and Prevention website. https://www.cdc.gov/nhsn/2022rebaseline/sir-guide.pdf.
- Obtaining the Number of Predicted Events for the Standardized Infection Ratio (SIR)
- https://wwwdev.cdc.gov/nhsn/2022rebaseline/index.html

5.4.2a Attach Conceptual Model

5.4.2a-Conceptual-Models.pdf

5.4.3 Variable Distribution Across Measured Entities

See attachment under 5.4.3a for details.

5.4.3a Attach Descriptive Statistics for Risk/Case-mix Variables

5.4.3-Variable-Distribution-Across-Measured-Entities.pdf

5.4.4 Risk/Case-Mix Adjustment Modeling and/or Stratification Results

First, a multidisciplinary team of subject matter experts, database experts, statisticians, and internal leadership specified the variables to move forward for testing as potential risk factors. Each potential risk factor was tested for association with the outcome using Wald, likelihood ratio and type III Chi-square tests at significance level for entry ≤ 0.25. This initial analysis was repeated by adding successive model parameters guided by a statistician that assessed model fit using AIC, BIC, and Deviance and, where possible, evaluated model prediction using the pseudo-adjusted R-squared. Model diagnostics were used to assess potential multicollinearity by variance decomposition and the conditional index. Data points were assessed for high influence and leverage. Linearization and monotonicity were assessed using splines or other regularization methods. Each resulting model from this process was fit using backward elimination (or selection) to detect any possible associations not identified in the former forward stagewise selection process and to obtain additional confirmation of associations. Variables were retained in the final model if $p<0.05$ in both the forward stagewise and the backward selection approaches. Next, the best model was validated via bootstrap sampling that relied on 1000 replications selected randomly with replacement. Variables for which the confidence interval of the beta estimate for a contained 0 using the 2.5 and 97.5 percentiles were removed from the final model. Finally, the model discrimination was computed with the pseudo-adjusted R-squared.

Below is a list of variables that were initially sent forward for testing by the multidisciplinary group but not included in the final models. Briefly, for the acute care hospital model, two variables were not included in the final model due to collinearity with other variables in the model. For the critical access hospital model, three variables that were not significant on the univariate associations were not included in the final model. For the long-term acute care model, a total of 16 variables were not included in the final model. Of these, seven were non-significant on univariate associations, seven were significant in univariate analysis but not in the multivariable model, and two were collinear with other variables in the final model. For the inpatient rehabilitation facility model, eight variables were not included in the final model. Four of these were non-significant in univariate analysis and four were significant in univariate analysis but not in the multivariable model.

See attachment under 5.4.4a for further details.

5.4.4a Attach Risk/Case-mix Adjustment Modeling and/or Stratification Specifications

5.4.4-Risk-Case-Mix-Adjustment-Modeling-and-or-Stratification-Results.pdf

5.4.5 Calibration and Discrimination

Discrimination was assessed for each risk model using the dispersion-based pseudo-R-square, and calibration was visually investigated by dividing the predicted number of events into deciles and plotting the observed number of events. Additionally, the root mean square error (RMSE) was calculated between observed and predicted events.

For the acute care hospital model, the dispersion-based pseudo r-square was 44.0% for acute care hospitals, 37.9% for critical access hospitals, 17.5% for long-term acute care facilities, and 15.1% for inpatient rehabilitation facilities. The RSME for each model was 2.9 for acute care hospitals, 0.45 for critical access hospitals, 1.56 for long-term acute care facilities, and 0.79 for inpatient rehabilitation facilities.

See attachment under 5.4.5a for calibration plots

5.4.5a Attach Calibration and Discrimination Testing Results

5.4.5a-Calibration-and-Discrimination-Testing-Results.pdf

5.4.6 Interpretation of Risk/Case-mix Factor Findings

The final risk adjustment models demonstrated that differences in facility-level factors were adequately accounted for. Variables were retained based on both statistical significance ($p < 0.05$) and validation through forward stagewise and backward elimination techniques. For the acute

care hospital model, all but two variables that were sent forward for testing was retained in the final model. These two variables were removed because of collinearity with other variables. This indicates that every variable tested was independently associated with CDI events and the number of events we had to model. The other 3 models (critical access hospital/long-term acute care hospital/inpatient rehabilitation facilities) were created using fewer hospitals and fewer CDI events so those models are not as robust. A full listing of variables not included in the models are given in section 5.4.4, but briefly three variables were not retained in the critical access hospital model, 16 in long-term acute care facilities model, and eight in the inpatient rehabilitation facility model. The reasons for not being retained included non-significance in univariate analysis, non-significance in the multivariable model, and collinearity. The models were validated using bootstrap sampling, which helped identify and remove any variables with unstable beta estimates, ensuring that the model maintained generalizability. Overall, the modeling approach demonstrated that the retained risk factors sufficiently captured variation in patient case-mix across facility types. The use of model diagnostics such pseudo-R-squared confirmed good model fit and predictive utility. This indicates that outcome comparisons using the risk-adjusted results are fair and not confounded by underlying differences in population or facility. The retained variables meaningfully explain differences in outcome risk, and the exclusion of non-significant variables and variables that were limited in the model helps to avoid unnecessary model complexity.

See 7.1 Supplemental Information Attachment Pages 9-12 for risk models

5.4.7 Final Approach to Address Risk Factors

Statistical risk adjustment model with risk factors

6.1.1 Current Status

In use

6.1.2 Current or Planned Use(s)

Public Reporting, Public Health/Disease Surveillance, Payment Program, Regulatory and Accreditation Programs, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

6.1.3 Program Details

Name of the program and sponsor
Center for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN)
URL of the program
http://www.cdc.gov/nhsn
Purpose of the program

NHSN HAI tracking system provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate HAIs.

Geographic area and percentage of accountable entities and patients included

Healthcare facilities across the US

Applicable level of analysis and care setting

Facility, Acute, IRF, LTACF

,
Name of the program and sponsor
CMS Care Compare
URL of the program
https://www.medicare.gov/care-compare
Purpose of the program

The tool can be used to find and compare different types of Medicare providers.

Geographic area and percentage of accountable entities and patients included

Over 4,000 Medicare-certified acute-care hospitals, LTAC hospitals and over 1,100 acute IRF in the nation.

Applicable level of analysis and care setting

Facility, Inpatient/Hospital

,
Name of the program and sponsor
CMS Hospital-Acquired Condition (HAC) Reduction Program
URL of the program
https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatien...
Purpose of the program

Encourages hospitals to improve patient safety and reduce the number of conditions people experience from their time in a hospital.

Geographic area and percentage of accountable entities and patients included

General acute-care hospitals across the nation.

Applicable level of analysis and care setting

Facility, Inpatient/Hospital

,
Name of the program and sponsor
CMS Hospital Inpatient Quality Reporting Program (HIQR)
URL of the program
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments...

Purpose of the program

The program collects quality data from hospitals paid under the Inpatient Prospective Payment System, with the goal of driving quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care. It is also intended to encourage hospitals and clinicians to improve the quality and cost of inpatient care provided to all patients.

Geographic area and percentage of accountable entities and patients included

Over 4,000 Medicare-certified acute-care hospitals across the nation.

Applicable level of analysis and care setting

Facility, Inpatient/Hospital

,
Name of the program and sponsor
CMS Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) Program
URL of the program
https://qualitynet.cms.gov/pch/pchqr
Purpose of the program

The program is intended to equip consumers with quality-of-care information to make more informed decisions about healthcare options.

Geographic area and percentage of accountable entities and patients included

Eleven cancer hospitals across the nation.

Applicable level of analysis and care setting

Facility, Inpatient/Hospital

,
Name of the program and sponsor
CMS Inpatient Rehabilitation Facility (IRF) Quality Reporting Program
URL of the program
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments...
Purpose of the program

The program collects data from IRFs with the goal of driving quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care.

Geographic area and percentage of accountable entities and patients included

Over 1,100 acute rehabilitation hospitals across the nation.

Applicable level of analysis and care setting

Facility, Inpatient/Hospital

,
Name of the program and sponsor
CMS Long-Term Care Hospital (LTCH) Quality Reporting Program
URL of the program
https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments...
Purpose of the program

The program collects data from LTCHs with the goal of driving quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care.

Geographic area and percentage of accountable entities and patients included

Over 350 LTCHs across the nation.

Applicable level of analysis and care setting

Facility, Inpatient/Hospital

,
Name of the program and sponsor
CMS Hospital Value-Based Purchasing Program
URL of the program
https://www.cms.gov/medicare/quality/value-based-programs/hospital-purchasing
Purpose of the program

This program adjusts payments to hospitals under the Inpatient Prospective Payment System (IPPS), based on the quality of care they deliver.

Geographic area and percentage of accountable entities and patients included

Over 3,000 hospitals across the country.

Applicable level of analysis and care setting

Facility, Inpatient/Hospital

6.2.1 Actions of Measured Entities to Improve Performance

To improve performance on this measure, facilities should review best practices and available guidelines and recommendations to determine which prevention strategies they can implement. The capability of a facility to implement CDI LabID Event prevention strategies can vary. Success in reducing rates depends on factors such as available resources, leadership support, and staff engagement.

Prevention strategies can include hand washing, performing routine surveillance, implementing enhanced environmental cleaning and patient and healthcare personnel education, assessing for signs or symptoms of infection, and adhering to clinical guidelines. Conducting root cause analysis of increased prevalence or outbreaks of *C. difficile* can help identify weak points in infection control and guide targeted interventions. Additionally, antimicrobial stewardship programs play a crucial role in preventing CDI LabID Events by promoting the appropriate use of antibiotics. These programs aim to reduce unnecessary antibiotic prescriptions, which are a major risk factor for CDI LabID Events, and to ensure that patients who need antibiotics receive the right drug, dose, and duration.

CDC's Targeted Assessment for Prevention (TAP) strategy provides a structured framework to minimize *C. difficile* events. This strategy involves assessing infection prevention policies and practices through TAP Facility Assessments and implementing tailored interventions to address gaps and reduce HAIs. It is primarily focused on CAUTIs, CLABSIs, and *C. difficile* infections.

The CDI LabID event standardized infection ratio (SIR) is an important indicator of *C. difficile* LabID event prevention efforts.

6.2.2 Feedback on Measure Performance

Facilities provide feedback by generating monthly standardized infection ratio (SIR) analysis reports within CDC NHSN and by using their SIR to determine if process improvement initiatives should be implemented to reduce *C. difficile* events.

State health departments publicly report facility-level SIRs, which allows patients and families within the state to select high-quality facilities. State health departments also utilize the CDI LabID event SIRs to target specific facilities with higher SIRs for additional support in initiating prevention activities.

Reporting facilities and state health departments send feedback on measure performance and implementation to the CDC NHSN Helpdesk. Additionally, during live training such as ‘Ask the Experts’ webinars and educational sessions, an online survey is provided to attendees to share feedback on the measure.

There was no feedback given by users and there was no change to the measure or implementations strategy.

6.2.3 Consideration of Measure Feedback

CDC NHSN teams conduct an annual review of every measure protocol. For any measure revision recommendation received, CDC NHSN follows a standard operational procedure designed to ensure thorough evaluation and implementation if appropriate. The process begins with a preliminary discussion and decision making by the NHSN subject matter expert (SME) team. User inquiries are then assessed to understand the extent of the concern or improvement. A literature review is conducted to determine whether the recommendations align with current guidelines. If supporting evidence is identified, the findings are reviewed collaboratively by the NHSN team and then receive input from branch leadership and clinicians. External experts are consulted on an ad hoc basis.

Since 2015, NHSN has released an annual 'Summary of Updates' that outlines changes to the Patient Safety Component protocol based on the review process. These modifications aim to enhance clarity and address feedback received from measured entities. It is important to note that the measures are not changed every year.

There was no feedback given by users and there was no change to the measure or implementations strategy.

6.2.4 Progress on Improvement

See 7.1 Supplemental Information Attachment Pages 13-15 for details.

6.2.5 Unexpected Findings

Patient medical records and other sources of patient data must be reviewed to determine if the patient meets the necessary criteria for a CDI LabID event. It is possible that reviewers may miss symptoms or fail to identify that a patient meets the criteria. This might result in under-reporting of CDI LabID Events. Data collectors might also intentionally under-report CDI LabID Events. Both of these circumstances would result in an SIR that is calculated to be lower than the actual SIR. Alternatively, patients may be identified as having a CDI LabID Event, when in fact they do not meet CDI LabID Event criteria. This may result in a calculated SIR that is higher than the actual SIR. CDC NHSN reporting tool includes business logic to minimize misclassification of CDI LabID Events and the CDC NHSN system generates SIRs automatically, reducing the possibility of manual error in SIR calculation.

7.1 Supplemental Attachment

7.1-Supplemental-Information-Attachment--CDI.pdf

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Measure Developer POC

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The measure developer is different from the measure steward

No

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Steward Organization

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