

# Reporting for *Clostridium difficile*: LabID events

Michele Schoonmaker, Ph.D.  
Government Affairs, Cepheid

## ▼ CDC, NHSN, and Reporting Data for the *C. difficile* LabID Metric<sup>1</sup>

The *C. difficile* CDI LabID module first became available as part of the National Healthcare Safety Network (NHSN) MultiDrug-Resistant Organism (MDRO) reporting system in 2009. The CDI LabID measure is the Standardized Infection Ratio (SIR), which is calculated as:

$$\text{SIR} = \frac{\text{observed hospital-onset (HO) CDI LabID Events}}{\text{predicted HO CDI LabID events}}$$

Since its inception, the predicted number of events calculated by CDC (the denominator) has been statistically adjusted to control for factors that are out of a facility's control, i.e., to normalize the SIR among different facilities having different characteristics that are known to be associated with *C. difficile* infection rates. The measure has evolved over time, with the most recent re-baseline established in December 2016. Re-baselining ensures that adjustment factors continue to be relevant and sufficient to the calculation of accurate SIRs.

Given earlier concerns of providers that the adjustment factors were not sufficient, particularly with regard to test method, NHSN presented the updated calculation of the SIR via various training programs with particular attention to how the predicted number of CDI LabID events is calculated. With regard to test method, the metric was re-defined such that antibody-based methods (e.g. EIA toxin) receive a negative adjustment, while testing strategies that include nucleic acid amplification test (NAAT) methods (e.g., PCR) receive a positive adjustment. Anything else ("other") receives no adjustment. In acute care hospitals, CDI test type is only one of seven variables that are used to standardize predicted infection rates among hospitals. Others are: inpatient community-onset (CO) prevalence rate (which is defined as CDI LabID events on days 1-3 of admission divided by total admissions X 100), medical school affiliation, number of ICU beds, total number of inpatient beds, facility type, and reporting from an Emergency Department (ED) or 24-hr observation unit. Of note, NHSN stressed the following:

- When reporting test method, **PCR should be entered as NAAT** (not "other") to ensure the appropriate positive adjustment factor is applied, otherwise the SIR will be too high.

- Only unformed stool specimens collected on day 4 or later after admission are scored as HO and counted as observed events in the numerator of the SIR.
- If the number of observed events (numerator of SIR) decreases with use of a less sensitive test method (e.g., EIA), if all other variables are equal, the denominator also decreases proportionately. This is because the **less sensitive test method would result in a lower CO-prevalence rate and a negative adjustment factor for test method** – both of which reduce the number of predicted HO cases (the denominator of SIR). **Because test method is reflected in both the numerator and denominator of the SIR, there is no significant net impact on SIR.**
- A facility should indicate when reporting from an ED or 24-hour observation unit because:
  - Positive *C. difficile* tests in this location do not count toward the SIR
  - Additional positive tests from the same patient within 56 days do not count toward the SIR (even for patients who are subsequently admitted)
  - A positive adjustment factor for these units is applied to the denominator of the SIR

## ▼ CMS' Role in Incorporating the CDI LabID Metric in Payment Incentive Programs<sup>2</sup>

Once the hospital data are collected, validated, and calculated, CDC provides observed, predicted, and total SIR data to CMS for each hospital. In 2011, CMS published a notice in the Federal Register that reporting of CDI LabID events through CDC's NHSN system would be required beginning January 2013. However, the rates were not included in payment adjustments for the value-based purchasing (VBP) and hospital-acquired conditions reduction programs (HACRP) until 2017.

Under VBP, CDI LabID is one of six possible measures that make up the Safety Domain, which accounts for 20% of the total VBP score. Under HACRP, CDI LabID is only one of five possible measures that comprises 85% of the total score used to determine the facilities performing in the bottom 25th percentile, which will face a 1% penalty.

- Because there are so many other measures in each calculation, **a high CDI LabID rate alone will not likely result in a score that would trigger a penalty.**

## ▼ Office of Inspector General (OIG) Report on Hospital Reporting of HAIs<sup>3</sup>

In 2017, the OIG released an evaluation that focused on “CMS’ efforts to ensure the integrity of hospital-submitted data regarding healthcare-associated infections (HAIs) and clinical process of care.” CMS validates data by looking at sample medical records from a random sample of hospitals each year. Validation typically lags two years behind the payment adjustment (i.e., payment adjustments for 2017 were based on data from 2015). CMS can also select specific hospitals that represent outliers that have abnormal or conflicting data patterns, or that have rapidly changing data patterns, among other factors for further scrutiny. “Gaming,” where hospitals manipulate their data to show better performance with respect to HAI reporting, was identified as:

- Over-culturing: ordering too many diagnostic tests to determine that a condition was “present on admission”
- Adjudication: clinicians over-ruling hospital personnel responsible for reporting
- Under-culturing: not ordering diagnostic tests to avoid having to report, and empirically treating symptomatic patients, promoting poor antibiotic stewardship.

OIG found that CMS followed its own process to validate hospital data. Nearly all hospitals passed the validation, leading to speculation that the process was not rigorous enough. OIG recommended that CMS make better use of analytics that can help identify gaming. For CDI, CMS uses a contractor to analyze infection rates, while CDC looks for outliers or changes in data reported to NHSN as quality indicators. CMS and CDC are working together to provide CMS with patient-level HAI data that may improve the accuracy with which CMS can identify hospitals that provide better care, and differentiate those hospitals from poor performers.

## ▼ Summary

It is clear from NHSN data that facilities will not be able to reduce their SIR simply by changing test methods for detecting *C. difficile*. From CMS, facilities will not get penalized for their CDI LabID rates alone and, in fact, may potentially expose themselves to the risk of “under-diagnosing” in order to avoid reporting. Not detecting CDI will not solve the problem. Testing by PCR on the **appropriate specimen** – unformed stool – is the best way to positively impact the SIR by:

- Minimizing the likelihood that labs will over-report CDI LabID events (i.e., report colonization as infection)
- Minimizing the number of cases that are missed using a less sensitive test method
- Maximizing the likelihood that the appropriate patients are identified, isolated, and treated (if required) to avoid transmission in the facility.

## ▼ Agency for Healthcare Research and Quality (AHRQ) Report on *C. difficile* Prevention, Diagnosis, and Treatment<sup>4</sup>

The 2016 report from AHRQ stressed that “effective containment and treatment of CDI depends on accurate and swift diagnosis.” The report found a high strength of evidence showing that NAATs are highly sensitive and specific for *C. difficile*. In summary:

- A negative PCR test is as effective at decreasing the probability that a patient has CDI as are loop-mediated isothermal amplification (LAMP) and glutamate dehydrogenase (GDH), and more effective than multi-step algorithms, while a positive PCR test is more effective at increasing the post-test probability that a patient has CDI than is a positive GDH test, but less effective than algorithms.
- A negative algorithmic test is one of the least effective strategies at decreasing the probability that a patient has CDI, but is the most effective approach to increase the post-test probability that a patient has CDI (i.e., is insensitive – will miss cases, but is specific).

Literature on test algorithms was rated as “low” for strength of evidence. **The report also noted that test algorithms did not perform “as a class as well as NAAT tests.”** Further, to reduce the likelihood that false positive results are received, laboratories should ensure **only unformed specimens from patients at risk for CDI are tested.**

The review did not examine identification of asymptomatic carriers as a possible prevention strategy, although recent studies show that this may be a feasible strategy if using PCR followed by aggressive infection control to prevent transmission.

## REFERENCES

1. Weiner L. Analyzing *C. difficile* & MRSA Bacteremia LabID Event Data, NHSN Training, March 2017. Accessed 7/6/2017. [https://www.cdc.gov/nhsn/pdfs/training/2017/Weiner\\_March23.pdf](https://www.cdc.gov/nhsn/pdfs/training/2017/Weiner_March23.pdf) See also: McDonald LC. NHSN Intersection with CDI Laboratory Testing, July 2016. Accessed 7/6/2016. [http://c.ymcdn.com/sites/www.cste.org/resource/dynamic/forums/20160719\\_084244\\_30213.pdf](http://c.ymcdn.com/sites/www.cste.org/resource/dynamic/forums/20160719_084244_30213.pdf)
2. CMS Document, Hospital value based purchasing, hospital acquired conditions reduction program, readmission reductions program. Accessed 7/6/2017. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html>
3. DHHS, OIG Report. CMS Validated Hospital Inpatient Quality Reporting Program Data, But Should Use Additional Tools To Identify Gaming. April 2017. Accessed 7/6/2017. <https://oig.hhs.gov/oei/reports/oei-01-15-00320.pdf>
4. AHRQ Comparative Effectiveness Review, No 172: Early Diagnosis, Prevention and Treatment of *Clostridium difficile*: Update. March 2016. Accessed 7/6/2017. <https://effectivehealthcare.ahrq.gov/ehc/products/604/2208/c-difficile-update-report-160502.pdf>

### CORPORATE HEADQUARTERS

904 Caribbean Drive  
Sunnyvale, CA 94089 USA

TOLL FREE 1.888.336.2743  
PHONE 1.408.541.4191  
FAX 1.408.541.4192

### EUROPEAN HEADQUARTERS

Vira Soleih  
81470 Maurens-Scopont France

PHONE 33.563.82.53.00  
FAX 33.563.82.53.01

[www.Cepheid.com](http://www.Cepheid.com)