Reporting for *Clostridium difficile*: LabID events

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Executive Summary

Data from the Center of Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN) demonstrates that facilities will not be able to decrease their standardized infection rate (SIR) simply by changing test methods for detecting *C. difficile*. CMS reimbursement incentive/penalty programs do not penalize facilities for their *C. difficile* infection (CDI) LabID rates alone and, in trying to adjust their SIR, facilities may potentially expose themselves to the risk of "under-diagnosing" in order to avoid reporting rates as discussed in a report by the Office of Inspector General (OIG). Not detecting *C. difficile* will not solve the problem of CDI in a facility. Testing by polymerase chain reaction (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.

CDC, NHSN, and Reporting Data for the *C. difficile* LabID Metric[1]

The CDI LabID module first became available as part of the NHSN MultiDrug-Resistant Organism (MDRO) reporting system in 2009. The CDI LabID measure is a 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 (the denominator) calculated by NHSN has been statistically adjusted to control for factors that are largely out of a facility's control. The factors 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. Periodic re-baselining ensures that adjustment factors continued to be relevant and sufficient for the calculation of accurate SIRs.

Given the 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 as a result of the re-baseline via various training programs at the end of 2016 and beginning of 2017. These presentations emphasized that the test method adjustment factor does account for the difference in sensitivity between test methods and demonstrated that the SIR is not impacted by the test method utilized. **Stated differently, test method is accounted for in both the numerator and denominator, and thus any changes cancel out.**

As a result of the re-baseline, to accurately account for test method sensitivity, enzyme immunoassay (EIA) test methods began receiving a negative adjustment factor and nucleic acid amplification tests (NAAT) not only maintained a positive adjustment factor but increased when compared to the prior adjustment factor. In 2018, NHSN implemented a policy that focused on the test method that was used for patient management to determine the test adjustment factor that the facility should receive. Prior to this, any test algorithm that incorporated NAAT received the NAAT adjustment factor. With the implementation of the new policy the test method, PCR followed by EIA, would now receive the EIA test adjustment factor understanding that it is the EIA test result that would influence the patient management.

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, the following are important considerations:

- In 2018, the CO definition was adjusted to ensure that NHSN is truly capturing the prevalence rate in the community. Now prior admission to the facility is part of the criteria when determining whether the specimen is CO.
  - The addition to the definition to qualify for CO is whether the "specimen is collected in an outpatient location in which the patient was not previously discharged from an inpatient location within the same facility ≤28 days prior".
- HO events are test results from specimens that are collected on day 4 or later of admission and performed on unformed stool samples.
- 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.
- 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). **In summary, since the test method is reflected in both the numerator and denominator of the SIR, there is no significant net impact on SIR by changing test types.**

- 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.
- Asymptomatic screening testing (AST) to detect carriers of *C. difficile* is different than reporting symptomatic cases (i.e., tests on unformed stool specimens). Facilities that are conducting AST should ensure they are properly following policies to ensure that they are not incorrectly reporting.

CMS' Role in Incorporating the CDI LabID Metric in Payment Incentive Programs[2]

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. Because there are other measures in each calculation, ***a high CDI LabID rate alone will not likely result in a score*** that would trigger a penalty. In 2018:

- In VBP, CDI LabID is one of six possible measures that make up the Safety Domain, which accounts for 25% of the total VBP score.
- In 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.

Office of Inspector General (OIG) Report on Hospital Reporting of HAIs[3]

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.

Agency for Healthcare Research and Quality (AHRQ) Report on *C. difficile* Prevention, Diagnosis, and Treatment[4]

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.

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