LETTERS TO THE EDITOR

Impact of 2018 Changes in National Healthcare Safety Network Surveillance for *Clostridium difficile* Laboratory-Identified Event Reporting

To the Editor—Last year we reported the impact of test method (nucleic acid amplification testing [NAAT] versus toxin enzyme immunoassay [EIA]) on the *Clostridium difficile* laboratory-identified event (LabID-CDI event) standardized infection ratio (SIR) during a 13-month study period (February 2015–February 2016) at the University of Iowa Hospitals and Clinics (UIHC).[1] Our current testing algorithm involves testing all samples with combined glutamate dehydrogenase (GDH) and toxin EIA (C Diff Quik Chek Complete, Alere, Waltham, MA) followed by testing discordant samples with NAAT (GeneXpert C difficile/EpiPCR, Cepheid, Sunnyvale, CA). Using these data, we found that use of NAAT nearly doubled our hospital-onset LabID-CDI standardized incidence ratio (SIR; 0.5 for EIA versus 0.95 for NAAT). We concluded that the National Health Safety Network (NHSN) risk adjustment for test method failed to adequately account for the increased sensitivity of NAAT at our institution.[1]

Since we performed this study, the NHSN modified risk adjustment formulas for healthcare-associated infections, including LabID-CDI events, as part of their "2015 rebaseline."[2] In addition, the NHSN changed the test results that define a LabID-CDI event. Starting in 2018, "when using a multi-testing methodology . . . the final result of the last test finding which is placed into the patient medical record will determine if the CDI positive laboratory assay definition is met."[3]

We re-examined the dataset we previously used to determine whether the new risk adjustment formula more adequately accounted for test method at UIHC. As outlined in Table 1, we found that the new LabID-CDI SIR model narrowed the difference between toxin EIA and NAAT somewhat but that the SIR was still substantially higher when NAAT was the test method reported (ie, 0.89 for NAAT vs 0.61 for toxin EIA). Although the increase in the detection rate associated with NAAT use varies across centers and regions,[4] our data suggest that centers using NAAT as their only CDI detection test or that use NAAT as the last test in an algorithm are being unfairly "punished" with a higher SIR than if they used toxin EIA as the primary test or as the last test in an algorithm.

Several different approaches can be used to identify CDI, and the diagnostic tests used to identify these patients will vary substantially by healthcare facility.[5] More centers have now begun using algorithms for testing that include toxin EIA testing in combination with a more sensitive test (ie, GDH, NAAT, or both) in an effort to reduce costs, to obtain additional information about toxin production (to support clinical management), and to maintain the sensitivity of NAAT testing (to help guide infection control efforts).[6]

We are concerned that the continued inadequacy of risk adjustment by test method, combined with new guidance about the temporal sequence of test result reporting in the event definition, will have unintended adverse consequences. Choice of test approach may be driven primarily by a desire to have LabID-CDI events defined by toxin EIA results rather than NAAT rather than by a desire to choose the test approach that best balances lab resources, clinical management, and infection prevention efforts.

The 2 most common algorithms employ toxin EIA testing at different points in the algorithm. A center that starts with GDH/toxin EIA and then settles discrepant results with NAAT will report both toxin EIA- and NAAT-positive results as events, whereas a center that begins with NAAT and follows each positive NAAT with an EIA will only report toxin EIA-positive results as events. Therefore, the same result combination (NAAT-positive, toxin EIA-negative) will be counted as a LabID-CDI event at one center but not at another. If risk adjustment by test method fails to account for the difference, hospitals will be inclined to switch to an "NAAT first" algorithm so that they can report lower rates and SIRs. While an "NAAT first" algorithm is an adequate diagnostic approach, it is far more expensive than the "GDH/toxin EIA first" algorithm because it requires that laboratories test all samples with the more costly NAAT rather than testing the 10%–15% of samples that are not resolved by GDH/toxin EIA testing.

Finally, the text of the NHSN document refers to "the last test finding which is placed into the patient medical record" rather than the last test performed.[3] Thus, some healthcare providers have suggested that the laboratory enter the toxin EIA results into the medical record after the other results, regardless of when the toxin EIA test was performed in an algorithm.[7] The mere fact that some healthcare providers have suggested this interpretation indicates that facilities could "game the system" and that the definition must be more specific.

In summary, we found that changes in NHSN LabID-CDI event reporting do not adequately risk adjust for test method. Furthermore, changes in the event definition for algorithmic *C. difficile* testing approaches may further complicate the problem by driving laboratories to select testing approaches based upon the NHSN definition rather than on local laboratory and clinical factors. We propose that CDC address these problems (1) by further improving risk adjustment for hospitals using NAAT-only to detect *C. difficile* and (2) by allowing all hospitals that use toxin EIA in combination with a more sensitive test (ie, GDH EIA, NAAT, or both) for *C. difficile* detection to report only toxin EIA-positive results as

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TABLE 1. Comparison Between the Previous and the Current *Clostridium difficile* Infection (CDI) Model of Hospital-Onset (HO) LabID-CDI Event Standardized Infection Ratio (SIR) When Using Enzyme Immunoassay (EIA) Versus Nucleic Acid Amplification Test (NAAT)

Previous CDI Model			
Lab Method	HO-CDI Events Observed[a]	HO-CDI Events Expected[b]	HO LabID-CDI Event SIR[c]
EIA[d]	88	176.3	0.50
NAAT[e]	247	259.8	0.95
Current CDI Model			
Lab Method	HO-CDI Events Observed[f]	HO-CDI Events Expected[g]	HO LabID-CDI Event SIR[h]
EIA[i]	88	144.9	0.61
NAAT[j]	247	277.1	0.89

NOTE. ED, emergency department; 24 h Obs, 24-hour observation location. UIHC total facility bed size, 761.

[a]No. of predicted LabID events = exp (β0 + β1X1 + β2X2 + …) × patient days

[b]No. of predicted (expected) HO CDI LabID events = exp[− 7.8983 + 0.385 (CDI test type = NAAT*) + 0.0160 (CDI test type = EIA*) + 0.3338* (CO CDI prevalence rate) + 0.2164 (bed size >245*) + 0.0935 (bed size = 101–245 beds*) + 0.187 (medical school affiliation = major*) + 0.0918 (medical school affiliation = graduate*)] × CDI patient days

[c]The CDI LabID SIR is calculated by dividing the number of observed HO CDI LabID events by the number of expected events.

[d]No. of predicted LabID events = exp[− 7.8983 + 0.385*0 + **0.1606*1** + 0.3338*(0.43) + 0.2164*1 + 0.0935*0 + 0.187*1 + 0.0918*1]*213,404, where EIA = 1

[e]No. of predicted LabID events = exp[− 7.8983 + **0.385*1** + 0.1606*0 + 0.3338*(0.92) + 0.2164*1 + 0.0935*0 + 0.187*1 + 0.0918*1]*213,404, where NAAT = 1 and EIA = 0. Assumes that EIA positive samples are all NAAT positive.

[f]No. of predicted LabID events = exp(β0 + β1X1 + β2X2 + …)*patient days

[g]No. of predicted (expected) HO CDI LabID events = EXP[− 8.9463 + 0.7339*(CO CDI prevalence rate) −0.1579 (CDI test type = EIA*) + 0.1307 (CDI test type = NAAT*) + 0.7465 (ICU beds ≥43*) + 0.7145 (ICU beds: 20–42*) + 0.6261 (ICU beds: 10–19*) + 0.4394 (ICU beds: 5–9*) + 1.2420 (oncology hospital*) + 0.3740 (general hospital) + 0.0003 (total facility bed size*) + 0.1119 (reporting from ED or 24 h Obs) + 0.0331 (teaching hospital*)] × CDI patient days

[h]The CDI LabID SIR is calculated by dividing the number of observed HO CDI LabID events by the number of expected events.

[i]No. of predicted LabID events = exp[− 8.9463 + 0.7339*(0.43) −0.1579*1 + 0.1307*0 + 0.7465*1 + 0.7145*0 + 0.6261*0 + 0.4394*0 + 1.2420*0 + 0.3740*1 + 0.0003*761 + 0.1119*1 + 0.0331*1]*213,404, where EIA = 1

[j]No. of predicted LabID events = EXP [− 8.9463 + 0.7339*(0.92) −0.1579*0 + 0.1307*1 + 0.7465*1 + 0.7145*0 + 0.6261*0 + 0.4394*0 + 1.2420*0 + 0.3740*1 + 0.0003*761 + 0.1119*1 + 0.0331*1]*213,404, where NAAT = 1 and EIA = 0. Assumes that EIA-positive samples are all NAAT positive.

LabID-CDI events, regardless of the "direction" of the test algorithm.

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What Really Works for Scope Reprocessing?

To the Editor—Duodenoscopes used for endoscopic retrograde cholangio-pancreatography (ERCP) have complex designs that make reprocessing challenging. Infections have been linked to manual cleaning of the scope especially its forceps elevator. Other factors that contribute to infections include use of unsterile water and inappropriate storage of scopes.[1,2] Despite duodenoscope reprocessing procedures exceeding manufacturer's recommendations, high-concern organisms such as *Klebsiella* spp and *Pseudomonas* spp have been implicated in clinical infections.[3,4,5] Media reports of high-concern organisms, such as carbapenem-resistant Enterobacteriaceae (CRE) and extended-spectrum β-lactamase (ESBL) outbreaks linked to duodenoscopes, have heightened awareness regarding reprocessing procedures.[3,4] Infections from duodenoscopes have been linked to positive cultures isolated from urine, blood, abscesses, and stool.[1,2] Mortality associated with contaminated duodenoscopes is ~16% with all organisms and 56% with CRE.[4] These mortality rates emphasize the need for optimal reprocessing practices. The World Health Organization emphasizes team-based collaborations, such as multidisciplinary teams (MDTs), to improve communication among healthcare workers. [6] Many studies have shown the benefits of MDTs in reducing nosocomial infections like bloodstream infections. [7–9] Multidisciplinary teams are effective at reducing infection rates through rapid identification of breakdowns in the process.[7] We studied the impact of creating a MDT with clear roles and real-time huddles to optimize our scope-reprocessing practices.

This retrospective study was conducted at a tertiary-care academic medical center with 401 beds. We aimed to evaluate the impact of an MDT with clear roles on the reprocessing of duodenoscopes. Reprocessing Olympus TJF-Q180V duodenoscopes along with surveillance cultures of the duodenoscope tip (including forceps elevator) were evaluated during the baseline period (January 2016 through June 2016) and during our intervention period (September 2016 through July 2017). An MDT was created in July 2016 composed of representatives from the endoscopy center, the sterile processing department (SPD), the infection prevention department (IP), as well as hospital leadership. We utilized a responsibility assignment matrix (RAM) to outline responsibilities of team members (Table 1). The results of surveillance cultures were grouped based on risk to humans, as defined by Centers for

TABLE 1. Responsibility Assignment Matrix (RAM) Implemented as a Part of Our Intervention

Process Name/Description	GI Team Member	CSPD Team Member	IP Team Member	Hospital Leadership Team Member
Identify positive culture and communicate with stakeholders; blast page with culture date, scope serial number; check e-mail within 15 minutes; and meet in 3 hours in infection prevention (IP) conference room.	I	I	R	I
Gather scope reprocessing documentation and bring copies to team huddle: reprocessing log, ATP testing log, patient log sheet, HLD printout, pick up log, culture collection log, ETO record system, ETO print out.	I	R	C	I
Identify patients involved and bring intraoperative documentation to team huddle.	R	I	C	I
Determine risk to patients involved.	R	R	R	R
Determine whether patient communication is necessary.	I	I	I	R
After hours and weekends, CSPD member validates whether HLD requirements achieved and passed leak test and whether ETO cycle was completed with no errors. GI member gathers patient information. CSPD and GI members to email complete investigation to IP within 2 hours. IP member send out summary report within 1 hour.	R	R	C	I

NOTE. R, responsible; I, informed; C, consulted; GI, gastroenterology; CSPD, central sterile processing department; IP, infection prevention; ATP, adenosine triphosphate; HLD, high-level disinfection; ETO, ethylene oxide.

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