

1287. Differences in Clinical Characteristics and Outcomes of Patients with Community-Onset *Clostridium difficile* Infection who Tested Positive by EIA Compared with NAAT through a Two-Step Algorithm

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Background. The low sensitivity of toxin enzyme immunoassay (EIA) for the diagnosis of *Clostridium difficile* infection (CDI) motivated many laboratories to add nucleic acid amplification tests (NAAT) to their testing protocol. However, NAAT do not distinguish between colonization and infection, and indiscriminant testing could lead to over treatment of CDI.

Methods. Active, population-based CDI surveillance has been conducted through the Emerging Infections Program in Bernalillo County, NM since 2011, with test type collected at the individual level since 2014. Community-onset (CO) CDI cases with a first positive test diagnosed by a two-step algorithm (concurrent EIA/GDH, with discordant results reflexed to NAAT) in 2014–2015 were included. We analyzed clinical characteristics and outcomes of patients EIA positive compared with NAAT positive. Demographics, risk factors, treatment, and outcomes were assessed through medical record review.

Results. Among 1,063 cases, 559 (52.6%) were EIA positive only and 504 (47.4%) were NAAT positive only. Of those with stool collected as a hospital inpatient, 57% were NAAT positive ($P < 0.001$); this increased from 43.4% if tested the day of admission to 61.4% when tested on day three. Conversely, 38.6% of patients with stool collected in an emergency department were NAAT positive ($P = 0.004$). Fewer cases with complicated outcomes were NAAT positive (40.7%, $P = 0.023$). Among those with no documentation of recent antibiotic use, 64.3% were NAAT positive ($P < 0.001$), and 67.8% of cases with no CDI treatment were NAAT positive ($P = 0.005$). Only 28.3% percent of cases with recurrent CDI were initially NAAT positive ($P < 0.001$).

Conclusion. EIA negative and NAAT positive CO-CDI cases tended to have a milder clinical presentation than those that were EIA positive. This suggests that some patients positive only by NAAT may have mild CDI or be colonized, rather than infected, with *C. difficile*. These individuals were less likely to have complicated outcomes, have recent documented antibiotic use, be treated for CDI, or have a recurrent CDI episode than those positive by EIA. Longer hospital stay correlated with increased proportion of testing NAAT positive. Providers may benefit from considering testing protocol and clinical correlation when assessing patients with positive *C. difficile* test results.

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1288. Toxin Detection by Cell Culture Neutralization Assay [CYT] and Toxin based EIA [Tox EIA] among Recurrent Episodes of CDI Diagnosed by PCR

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Background. The Ad Hoc *C. difficile* surveillance working group defines recurrent *C. difficile* infection as a second episode occurring >8 weeks after the index case. Due to its high sensitivity, diagnosis of recurrent CDI by PCR is extremely challenging in patients who may have persistent, PCR detectable shedding of toxigenic *C. difficile* (TCD) for an extended period of time after treatment of the initial CDI episode. CYT, which detects *C. difficile* toxin antigen, is a cumbersome test to perform but is considered as the current clinical diagnostic gold standard for CDI diagnosis. Aim: To determine the CYT and Toxin A/B EIA positivity among patients with recurrent CDI episodes detected by PCR. We further characterized the performance of diagnostic tests based on whether the recurrent episode was a relapse or reinfection.

Methods. During a three month study period, CYT and Tox A/B EIA was performed on consecutive stool samples submitted from PCR positive recurrent episodes of CDI. For the purpose of this study, recurrence was defined as a second episode of CDI that occurred within 120 days from the most recent episode. MLST analysis was performed as previously described to characterize relapse and reinfection among the recurrent episodes (2).

Results. Thirty-five recurrent episodes occurred over the study period. 21/35 [60%] were positive by CYT and 12/35 [34%] by Tox A/B EIA. Among the recurrent CDI episodes, 16 (46%) were genotypical confirmed as relapse with the original infecting strain. Majority of these relapses were positive by CYT (81%) when compared with Tox EIA (43%). Among patients with geno typically confirmed reinfection ($n = 8$), CYT and EIA positivity was 63 % and 50 % respectively. For the remaining 11 episodes, TCD was not retrievable in culture, CYT and EIA positivity among this group was 27 % and 9 % respectively.

Conclusion. Forty percent of recurrent CDI episodes detected by PCR could not be confirmed by CYT. EIA missed 66 % of CYT positive recurrent CDI. The performance of CYT and EIA varied among recurrences due to relapse and reinfection. These results have significant implication for reporting of CDI HAI rates.

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1289. PCR Cycle-Threshold-Derived Toxin Identifies Patients at Low-Risk for Complications of *C. difficile* Infection Who Do Not Require Treatment

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Background. Literature suggests that toxin detection differentiates those who require treatment for *C. difficile* infection (CDI) from those who do not. In-house studies have shown that free toxin can be predicted with high negative predictive value at a predefined cycle threshold (CT) using Xpert *tcdB* PCR (Cepheid, Sunnyvale, CA). In October 2016, CT-toxin was added to the PCR result and a comment recommends against CDI therapy if CT-toxin is negative (CTtox-). Here we evaluate the effect of this reporting on treatment rates and outcomes of CTtox- patients.

Methods. Patients tested from October 2016 to Apr. 2017 with a positive Xpert PCR and CTtox- result were included. Clinical data were collected by retrospective chart review and analyzed with the Chi squared and Student *t*-tests using SPSS. Due to multiple comparisons, $\alpha=0.01$.

Results. Of 1516 Xpert PCR tests, 248 (16.4%) were positive and 98 (39.5%) were CTtox-. Of these, 54 (55.7%) were treated. Patient characteristics and data at testing are shown below. There were no cases of CDI-related septic shock or toxic megacolon on review. Time to diarrhea resolution was significantly shorter in untreated patients and there was no difference in crude mortality or later onset of CTtox+ CDI.

	Treated $n = 54$ (%) [SD]	Untreated $n = 43$ (%) [SD]	p
Male	25 (46)	24 (56)	0.35
Age (Yrs)	57.9 [19.7]	52.0 [20.8]	0.15
Immunocompromised	36 (67)	21 (49)	0.08
BMT/SOT	18 (33)	5 (12)	0.02
Cancer	16 (30)	9 (21)	0.33
Other	6 (11)	10 (23)	0.11
WBC (K/ μ L)	9.9 [7.7]	7.9 [5.3]	0.20
Creatinine (mg/dL)	1.1 [0.9]	1.0 [0.7]	0.34
Initial Stools/Day	6.2 [2.8]	4.9 [2.8]	0.05
Days to <3 Stools	2.6 [1.8]	1.6 [0.8]	<0.01
Hospitalized in past mo.	31 (57)	33 (77)	0.05
Antibiotics in past mo.	35 (65)	29 (67)	0.79
CDI in past 6 mos.	7 (13)	7 (16)	0.64
In-Patient	23 (42)	30 (70)	0.02
CDI Within 90 Days	3 (6)	4 (9)	0.70
Crude Mortality (30d)	6 (11)	7 (16)	0.46

Patient data and outcomes in those with PCR+/CTtox- *C. difficile* test. Immunocompromised (Other) includes patients with cirrhosis, IBD, and rheumatological diseases on immunosuppressants.

Conclusion. This study demonstrates the impact of stand-alone PCR assay with toxin prediction on reducing CDI therapy rates and provides further evidence that PCR+/toxin- patients are at low risk for CDI-related complications and do not require treatment, though more data is needed in transplant populations.

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1290. Clinical Correlation of a *Clostridium difficile* Testing Algorithm Reflexing PCR Positive Specimens to Toxin Enzyme Immunoassay (EIA)

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Background. An algorithm promoted in the United Kingdom reflexes specimens positive for *C. difficile* by a nucleic acid amplification test (NAAT) to toxin EIA. Samples positive by NAAT and negative by toxin EIA are reported as “*C. difficile* could be present (ie, potential *C. difficile* excretor).” We explored the potential utility of this algorithm to distinguish *C. difficile* infection (CDI) from colonization compared with retrospective clinical assessment.

Methods. Liquid stool specimens ($n = 300$) from inpatients (or the Emergency Department) submitted to the Cleveland Clinic Microbiology laboratory for *C. difficile* PCR testing (Cepheid Xpert *C. difficile*/Epi) with positive results were included in the study. The CDIFF QUICK CHEK COMPLETE GDH/toxin EIA assay (Alere) was performed according to manufacturer’s instructions. The charts of all patients