Conclusion. The Cdiff32 allowed to estimate the important impact on quality of life of CDI especially on the physical domain.

Disclosures. **All authors:** No reported disclosures.

1284. The *Clostridium difficile* Infection – Daily Symptoms (CDI-DaySyms™) Patient-Reported Outcome (PRO) Questionnaire: Final Validation and Responder Thresholds

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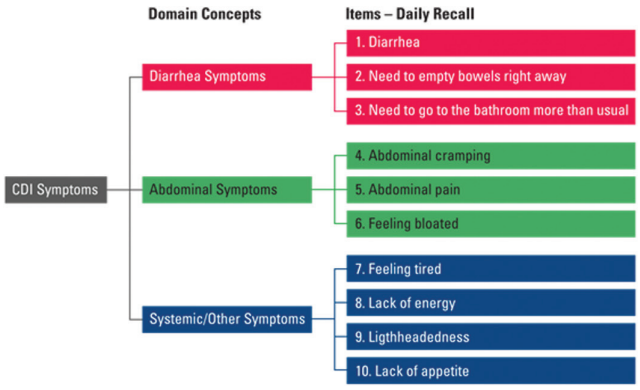
Background. Patient perspectives on their disease are undoubtedly important in clinical trials and in practice. To date, no patient-reported outcome (PRO) questionnaire assessing symptoms of *Clostridium difficile* infection (CDI) has been developed following FDA guidance. The CDI-DaySyms™ is a new comprehensive measure of a broad range of local and systemic CDI symptoms (not only diarrhea) that patients report as meaningful. Objectives were to: finalize the CDI-DaySyms™ items (questions); assign them to domains (concepts); evaluate the questionnaire's measurement properties; and define responder thresholds.

Methods. Blinded data from a sub-study of two Phase III trials (NCT01987895 and NCT01983683) in CDI patients were analyzed following FDA guidance for validating PRO questionnaires. Patients completed the CDI-DaySyms™ daily from Day 1 until end of treatment. Items were selected for inclusion in the final questionnaire based on a range of validation analyses, input from expert clinicians, and findings from prior qualitative patient research. Responder-threshold analyses used Day-3 data to align with the rapid symptom improvement generally seen in response to CDI therapy.

Results. Data were analyzed for 168 CDI patients (median age 60 years; 67.9% female; 81.5% mild/moderate, 11.3% severe, 7.1% unknown disease severity; 80.4% first CDI occurrence, 19.6% first recurrence). Three of the 13 items in the draft CDI-DaySyms™ were deleted; the remaining 10 were statistically assigned to three domains measuring different symptom concepts (Figure). Individual items in each domain correlated strongly with one another and their domain. Domain scores demonstrated acceptable consistency over time in stable patients, were sensitive to change, and correlated in expected directions with scores of other relevant symptom and disease-severity measures. Responder thresholds were defined as score changes of -1.00, -0.80, and -0.70 for Diarrhea, Abdominal, and Systemic/Other Symptoms domain scores, respectively.

Conclusion. The CDI-DaySyms™ is a valid measure of diarrhea and other CDI symptoms useful in assessing response to therapy. It has good measurement properties, and with only 10 items can be easily administered in clinical trials and in practice.



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1285. *Clostridium difficile* Testing Algorithm: Is There a Difference in Patients Who Test Positive by Enzyme Immunoassay vs. Those Who Only Test Positive by Nucleic Acid Amplification Methodology?

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Background. Testing for *Clostridium difficile* infection (CDI) commonly involves checking for the presence of toxins A and B by enzyme immunoassay (EIA) or nucleic acid amplification (NAA). The former is very specific, but not very sensitive. The latter is very sensitive. Beginning in 2011, our hospital incorporated an algorithm that involved testing liquid stool specimens for glutamate dehydrogenase (GDH) and toxin by EIA. For discrepant results, the stool specimen was tested for the presence of toxin by NAA. We sought to determine whether there was a difference in the baseline characteristics or outcomes between the two groups.

Methods. We performed a chart review of all subjects who tested positive for CDI by either method between 2011 and 2016 at Vidant Medical Center, a 909 bed, tertiary care teaching hospital. Testing was only performed on liquid stool specimens. Subjects less than 18 years of age were excluded. Repeat positive specimens were excluded. We collected demographic data including age, gender, baseline temperature, white blood cell count, and serum lactate and albumin. Length of stay and in-hospital mortality were also determined for both groups. Comparison of the two groups was done using t-test for continuous and chi-square analysis for categorical variables.

Results. Over the 6 year period, there were 535 positive test results. 243 specimens tested positive by EIA/GDH (EIA +); 292 specimens tested positive by GDH/NAA (NAA +). Compared with the EIA + group, the NAA + group was younger (61.8 years vs. 65.1 years, $P = 0.01$). There were no statistical differences in the presence of abdominal tenderness, temperature >38°C, serum albumin, serum lactate, length of stay, or mortality between the two groups. The EIA + group was statistically more likely to have leukocytosis (WBC >20,000 cells/mm^3) at the time of the CDI testing compared with the NAA + group ($P = 0.0002$).

Conclusion. There do appear to be some clinical differences in the presentation of subjects who test positive for CDI by EIA/GDH compared with those who test positive only by GDH/NAA. These differences do not appear to affect length of stay or mortality.

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1286. Line of Service-Specific Performance and Antibiotic Prescribing Habits Following Introduction of a Two-Step Diagnostic Approach Using NAAT Followed by Enzyme Immunoassay in Cancer Patients with Suspected *Clostridium difficile* Infection

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Background. Patients with cancer are at an increased risk for *C. difficile* infection (CDI). A two-step approach with a Nucleic Acid Amplification Test (NAAT) followed by enzyme immunoassay (EIA) increases diagnostic sensitivity and specificity and can be used to guide antibiotic therapy. We retrospectively investigated the relative performance of the two-step approach in cancer patients with solid tumors (ST), hematologic malignancies (HS), and hematopoietic stem cell transplant recipients (HSCT).

Methods. We identified 204 patients with a positive NAAT test for CDI as determined by GI multiplex (Biofire) or by Illumigene (Meridian, Bioscience) in whom a reflex EIA was performed for *C. difficile* A/B toxins between November 2015 and February 2017. Patients were stratified into ST, HM, HSCT groups. We compared the proportion of discordant NAAT+, EIA- results among the three groups. We then compared the clinical presentation and antibiotic use for patients in the NAAT+/EIA- to those with NAAT+/EIA+ results.

Results. Overall an EIA+ result was found in 53 (26%) patients. The proportion of patients with NAAT+/EIA+ results was significantly different between the three lines of service; ST 31/86 (36%), HM 16/62 (26%), and HSCT 6/56 (11%) $P < 0.01$. A trend towards a higher proportion of positive results was observed for ST compared with the HM group ($P = 0.06$). Results were similar between the HM and HSCT group. However, patients in the ST were more likely to have a positive EIA when compared with HSCT patients (36% vs. 11% $P < 0.01$). Clinical presentation and healthcare-association were similar in all three groups regardless of the EIA result. Despite the low proportion of EIA+ confirmatory results, the majority of patients (196/204 96%) received antibiotic therapy targeting CDI. Discontinuation of CDI antibiotics prior to 10 days of therapy was similar in the EIA+ (12%) vs. EIA- (10%).

Conclusion. The relevance of discordant results needs to be interpreted in the context of the line of service/patient care unit. The presence of CDI as determined by NAAT/EIA is low in patients with other potential causes of diarrhea such as in HSCT recipients. A substantial proportion of cancer patients are treated unnecessarily for CDI.

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