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Presentation Type:

Poster Presentation - Poster Presentation

Subject Category: *C. difficile***Impact of early identification of patients meeting testing criteria for *Clostridioides difficile* on standard infection ratios**

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Background: *Clostridioides difficile* infection (CDI) poses a health burden to patients and a financial burden to hospital systems. Timely identification of CDI patients can reduce the impacts by allowing for prompt treatment and ensuring that proper isolation precautions are in place to prevent spread. It also ensures correct CDI event categorization according to the NHSN. Community-onset (CO) CDI cases are tested on or prior to hospital day 3, and hospital-onset (HO) CDI are tested on or after hospital day 4. The objective of this study was to determine the effectiveness of utilizing an electronic health record (EHR) report to reduce CDI standard infection ratios (SIRs) by identifying potential CDI cases prior to hospital day 4. **Methods:** From August of 2021 to September 2022, an EHR report was implemented in a 5-hospital healthcare system in the Midwest to identify patients with 3 or more type 6 or 7 stools in a 24-hour period based on Bristol stool chart classification. All inpatients with 3 or more type 6 or 7 stools in 24 hours without an active order for a *Clostridioides difficile* test were listed. Patients with a laxative in the previous 48 hours, tube feedings without fever or leukocytosis, or a known cause of diarrhea were excluded. The attending provider of the patients meeting criteria were notified with a recommendation to test for *C. difficile* or provide alternative reason for symptoms. **Results:** In total, 26 patients were tested for *C. difficile* using polymerase chain reaction testing. Of those tested, 5 (19.2%) tested positive for *C. difficile*. There were 13 HO-CDI cases for the healthcare system during this period, for an SIR of 0.351. If the early identified cases were not identified until after hospital day 3, the SIR had the potential to have been 35.6% greater at 0.476. **Conclusions:** We were able to identify 5 CDI cases prior to hospital day 4 using an early identification report during this 13-month period. Although these cases may have been identified without the use of the EHR report, we were able to obtain a timely CDI diagnosis, potentially limiting the spread of *C. difficile* and preventing an increase in the CDI SIR by 35.6%. An EHR report to identify patients meeting *C. difficile* testing criteria may be an effective way to identify CO-CDI prior to HD 4 and thus reduce CDI SIR

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Subject Category: *C. difficile***Effects of a hard stop for *C. difficile* testing: Provider uptake and patient outcomes**

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Background: *Clostridioides difficile* infection (CDI) is a serious healthcare-associated infection responsible for >12,000 US deaths annually. Overtesting can lead to antibiotic overuse and potential patient harm when patients are colonized with *C. difficile*, but not infected, yet treated. National guidelines recommend when testing is appropriate; occasionally, guideline-noncompliant testing (GNCT) may be warranted. A multidisciplinary group at UNC Medical Center (UNCMC) including the antimicrobial stewardship program (ASP) used a best-practice alert in 2020 to improve diagnostic stewardship, to no effect. Evidence supports use of hard stops for this purpose, though less is known about provider acceptance. **Methods:** Beginning in May 2022, UNCMC implemented a hard stop

in its electronic medical record system (EMR) for *C. difficile* GNCT orders, with exceptions to be approved by an ASP attending physician. Requests were retrospectively reviewed May–November 2022 to monitor for adverse patient outcomes and provider hard-stop compliance. The team exported data from the EMR (Epic Systems) and generated descriptive statistics in Microsoft Excel. **Results:** There were 85 GNCT orders during the study period. Most tests (62%) were reviewed by the ASP, and 38% sought non-ASP or no approval. Of the tests reviewed by the ASP, 33 (62%) were approved and 20 (38%) were not. Among tests not approved by the ASP, no patients subsequently received CDI-directed antibiotics, and 1 patient (5%) warranted same-admission CDI testing (negative). Of tests that circumvented ASP review, 18 (56%) ordering providers received a follow-up email from an associate chief medical officer to determine the rationale. No single response type dominated: 3 (17%) were unaware of the ASP review requirement, 2 (11%) indicated their patient's uncharted refusal of laxatives, 2 (11%) indicated another patient-specific reason. Provider avoidance of the ASP approval mechanism decreased 38%, from 53% of noncompliant tests in month 1 to 33% of tests in month 6. Total tests orders dropped 15.5% from 1,129 during the same period in 2021 to 954 during the study period (95% CI, 13.4%–17.7%). Compliance with the guideline component requiring at least a 48-hour laxative-free interval prior to CDI testing increased from 85% (95% CI, 83%–87%) to 95% (95% CI, 93%–96%). CDI incidence rates decreased from 0.52 per 1,000 patient days (95% CI, 0.41–0.65) to 0.41 (95% CI, 0.32–0.53), though the change was neither significant at $P = .05$ nor attributable to any 1 intervention. **Conclusions:** Over time and with feedback to providers circumventing the exception process, providers accepted and used the hard stop, improving diagnostic stewardship and avoiding unneeded treatment.

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Subject Category: *C. difficile***Integrated safety analysis of phase 3 studies for investigational micro-biome therapeutic, SER-109, in recurrent CDI**

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Background: *Clostridioides difficile* infection (CDI) often recurs in patients aged ≥ 65 years and those with comorbidities. Clinical trials often exclude patients with history of immunosuppression, malignancy, renal insufficiency, or other comorbidities. In a phase 3 trial (ECOSPOR III), SER-109 was superior to placebo in reducing recurrent CDI (rCDI) risk at week 8 and was well tolerated. We report integrated safety data for SER-109 in a broad patient population through week 24 from phase 3 studies: ECOSPOR III and ECOSPOR IV. **Methods:** ECOSPOR III was a double-blind, placebo-controlled trial conducted in participants with ≥ 2 CDI recurrences randomized 1:1 to placebo or SER-109. ECOSPOR IV was an open-label, single-arm study conducted in 263 patients with rCDI enrolled in 2 cohorts: (1) rollover participants from ECOSPOR III with on-study recurrence and (2) participants with ≥ 1 CDI recurrence, inclusive of the current episode. In both studies, the investigational product was administered as 4 oral capsules over 3 days. Treatment-emergent adverse events (TEAEs) were collected through week 8; serious TEAEs and TEAEs of special interest (ie, bacteremia, abscess, meningitis) were collected through week 24. **Results:** In total, 349 participants received SER-109 in ECOSPOR III and/or ECOSPOR IV (mean age 64.2; 68.8% female). Chronic diseases included cardiac disease (31.2%), immunocompromised or immunosuppressed (21.2%), diabetes (18.9%), and renal impairment or failure (13.2%). Overall, 221 (63.3%) of 349 participants who received SER-109 experienced TEAEs through week 24. Most were mild to moderate and gastrointestinal. The most common (>5% of participants) treatment