Disclosures: None

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Poster Presentation - Poster Presentation

Subject Category: C. difficile

Impact of early identification of patients meeting testing criteria for Clostridioides difficile on standard infection ratios

Brad Krier; Eric Gomez-Urena; Kristin Schultz and Ashley Brooks

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 13month 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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Effects of a hard stop for *C. difficile* testing: Provider uptake and patient outcomes

Danielle Doughman; David Weber; Nikolaos Mavrogiorgos; Shelley Summerlin-Long; Michael Swartwood; Alexander Commanday; Lisa Stancill; Nicholas Kane and Emily Sickbert-Bennett Vavalle

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 microbiome therapeutic, SER-109, in recurrent CDI $\,$

Matthew Sims; Charles Berenson; Stuart Cohen; Elaine Wang; Elizabeth Hohmann; Richard Nathan; Alberto Odio; Paul Cook; Kelly Brady; David Lombardi; Asli Memisoglu; Ananya De; Brooke Hasson; Bret Lashner; Louis Korman; Doria Grimard; Juan Carlos Moises Gutierrez; Barbara McGovern and Lisa Von Moltke

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

related TEAEs were flatulence, abdominal pain and distension, decreased appetite, constipation, nausea, fatigue, and diarrhea. No participants experienced a treatment-related TEAE leading to study withdrawal. Invasive infections were observed in 28 participants (8%); those with identified pathogens were unrelated to SER-109 species, and all were deemed unrelated to treatment by the investigators. There were 11 deaths (3.2%) and 48 participants (13.8%) with serious TEAEs, none of which were deemed treatment related. There were no clinically important differences in the safety profile across subgroups of sex, race, prior antibiotic regimen, or number of CDI recurrences. No safety signals were observed in participants with renal impairment or failure, diabetes, cardiac disease, or immunocompromised or immunosuppressed individuals. Conclusions: In this integrated analysis of phase 3 trials, SER-109, an investigational microbiome therapeutic, was well tolerated in this vulnerable patient population with prevalent comorbidities. No infections, nor those with identified pathogens, were attributed to SER-109 or product species. This safety profile might be expected because this purified product is composed of sporeforming Firmicutes normally abundant in the healthy microbiome.

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Subject Category: CLABSI

Identifying risk factors for pediatric central-line-associated blood-stream infections

Paula Conrad; Julie Murphy; Pascale Audain; Michelle Connors; Christopher Hopkinson; Jenny Chan Yuen and Jennifer Ormsby

Background: Pediatric patients often require central venous catheters (CVCs) for a variety of clinical indications, including medication administration, parenteral nutrition, and venous blood sampling. Patients with CVCs are at risk for central-line-associated bloodstream infections (CLABSI). These hospitalacquired infections are often preventable and may lead to increased morbidity and mortality. Clinicians at a 477-bed, freestanding pediatric academic hospital completed a quality improvement project to identify factors that place pediatric patients at increased risk for CLABSI and to outline strategies aimed at CLABSI reduction for our highest-risk patients. Methods: Project leaders completed a literature review to evaluate current research on the topic and then assembled a project team. The team completed a retrospective analysis and categorization of CLABSI cases and reviewed internal CLABSI root-cause analysis data. The group then completed a case-control analysis to identify risk factors in patients with CVCs who developed CLABSIs, compared to patients with CVCs who did not develop CLABSI. Following this analysis, the team created a CLABSI riskfactor tool for use by bedside nurses. This tool described patients with CLABSI risk factors and outlined best practices for CLABSI prevention. Results: Based upon literature review, root-cause analysis data, and retrospective CLABSI case review over the period from 2017 to 2021, an initial list of 9 potential CLABSI risk factors was compiled. A case-control analysis was performed comparing 97 CLABSI cases with 103 matched controls. Univariate, multivariate, and additional covariate analyses were employed to identify 3 factors placing pediatric patients at increased risk for CLABSI. These included (1) multiple enteral devices (ie, 2 or more devices, including gastrostomy tube, jejunostomy tube, gastrostomy or jejunostomy tube, ostomy, and peritoneal drain); (2) multiple CVC entries (ie, CVC used for medications and venous sampling); and (3) long-term CVC plus parenteral nutrition (CVC in place for >21 days and receiving parenteral nutrition and/or intralipids). Conclusions: Pediatric patients with central venous access are vulnerable to CLABSI, and certain patients may be at increased risk. Frontline clinicians may be able to identify these patients and adopt best practices to prevent infection. A tool for use by bedside nurses can be a useful adjunct to existing CLABSI prevention practices.

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Catheter-related bloodstream infections in patients receiving hemodialysis in a single Philippine tertiary-care center

Dan Meynard Mantaring; Rohana Elise Rollan and Cybele Abad

Background: Information regarding catheter-related bloodstream infections (CRBSIs) among patients on hemodialysis in the Philippines is lacking. Objective: In this study, we described the clinical profile, CRBSI incidence density, and outcomes of patients in a single-center hemodialysis unit. Methods: A retrospective review of patients receiving hemodialysis (HD) through a central venous catheter (CVC) from January 2016 to December 2020 in a tertiary-care, private hospital was performed. Baseline demographic data were recorded, and CRBSI incidence density rates (no. of CRBSIs per 1,000 catheter days) were calculated. Results: Of 868 hemodialysis patients (57%), 499 used a CVC and were followed for 182,135 catheter days. Half were male (248 of 499, 49.7%) with a median age of 62 years (range, 24-90). Only 48 (9.6%) of 499 developed CRBSI, with an overall CRBSI incidence of 2.63 per 1,000 catheter days. Of those with CRBSI, 31 (64.6%) of 48 were female. The median age was 74.5 years (range, 30-90). Hypertension (40 of 48, 83.3%) and diabetes mellitus (26 of 48, 54.2%) were frequent comorbidities. Fever with chills was the most common symptom, occurring in 30 (62.5%) of 48 patients. Both gram-positive (n = 24) and gram-negative (n = 25) organisms were isolated. Staphylococcus aureus was the most common gram-positive isolate (14 of 25, 56%); isolates from the order Enterobacterales (12 of 24, 50%) were the most common gram-negative organisms. More CRBSIs occurred among those with a nontunneled versus tunneled CVCs (28 vs 20). The median time to CRBSI occurrence was 7 weeks (range, 0.43-280) from CVC insertion. The most common empiric treatment was either vancomycin (n = 28) or piperacillin-tazobactam (n = 26), which were also used in combination (11 of 28, 39.3%). Treatment involved CVC removal in most patients (34 of 48, 70.8%), either alone (n = 1), or with systemic antibiotic therapy (SAT; n = 16), or SAT plus antibiotic lock therapy (ALT; n = 17). The remainder (14 of 48, 29.2%) retained their CVCs because of difficult access, and received both SAT and ALT. Attributable mortality (6 of 9, 33%) and overall mortality (9 of 48, 18.5%) were high. Mortality of those whose CVC was retained was lower compared to those whose line was removed: (3 of 9, 33%) versus (6 of 9, 66%). Conclusions: The overall CRBSI rate in our hemodialysis unit was low and occurred more commonly in the older age group with a nontunneled CVC. Both gram-positive and gram-negative pathogens were

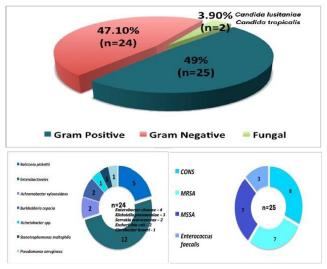


FIGURE 1. SUMMARY OF ISOLATES