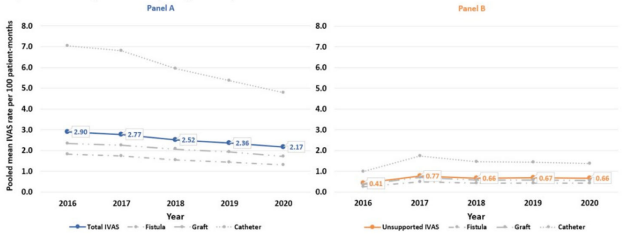
Table 1. IV antibiotic start (IVAS) rates per 100 patient-months among outpatient hemodialysis facilities reporting to NHSN, 2016-2020.

	Total	2016		2017		2018		2019		2020	
	n or rate	n or rate	%	n or rate	%	n or rate	%	n or rate	%	n or rate	%
Total IVAS											
Unique facilities	7,429	6,370	86%	6,551	88%	6,852	92%	7,035	95%	7,129	96%
IVAS	648,410	139,656	22%	136,872	21%	133,252	21%	125,480	19%	113,150	17%
Patient-Months	25,578,128	4,812,170	19%	4,932,849	19%	5,296,099	21%	5,320,438	21%	5,216,572	20%
Overall Rate	2.54	2.90		2.77		2.52		2.36		2.17	
By Access IVAS Patient-Months											
Fistula 246,892 15,801,408	1.56	1.81		1.74		1.53		1.44		1.30	
Graft 92,308 4,487,104	2.06	2.34		2.26		2.07		1.94		1.71	
Catheter 307,576 5,214,145	5.90	7.04		6.80		5.94		5.37		4.79	
Unsupported IVAS											
Unique facilities with >=1 IVAS	7,278	6167	84.7%	6370	87.5%	6642	91.3%	6821	93.7%	6885	94.6%
Unique facilities with >=1 unsupported IVAS	5,948	3340	54.2%	3584	56.3%	4591	69.1%	4856	71.2%	4994	72.5%
IVAS	161,317	19,708	12.2%	37,500	23.2%	34,680	21.5%	35,419	22.0%	34,010	21.1%
Patient-Months	25,386,892	4,788,598	18.9%	4,899,472	19.3%	5,262,560	20.7%	5,280,546	20.8%	5,155,716	20.3%
Overall Rate	0.64	0.41		0.77		0.66		0.67		0.66	
By Access IVAS Patient-Months											
Fistula 63,605 15,682,448	0.41	0.26		0.49		0.42		0.43		0.42	
Graft 24,776 4,459,172	0.56	0.36		0.69		0.58		0.58		0.55	
Catheter 72,335 5,170,262	1.40	0.97		1.74		1.45		1.44		1.38	

Figure 1. Rates of total (Panel A) and unsupported (Panel B) IV antibiotic starts (IVAS) per 100 patient-months stratified by access site in outpatient hemodialysis facilities reporting to NHSN, 2016-2020.



decrease did not differ significantly by vascular access site. The total IVAS rate was lowest in 2020 (2.17 per 100 patient months; 95% CI, 2.18–2.17). IVAS rates in 2020 were greatest for patients with catheter access (4.79 per 100 patient months; 95% CI, 4.75–4.83), followed by graft (1.71 per 100 patient months; 95% CI, 1.68–1.73), and lowest for patients with fistulas (1.30 per 100 patient months; 95% CI, 1.29–1.31). The overall pooled mean rate of unsupported IVAS was 0.64 per 100 patient months (95% CI, 0.63–0.64), which did not significantly change by year (Fig. 1). **Conclusions:** Total IVAS rates among outpatient hemodialysis patients have decreased since 2016, and rates among catheter patients remain highest compared to patients with fistulas or grafts. However, unsupported IVAS rates did not change, and the proportion of facilities reporting an unsupported IVAS increased annually. Targeted efforts to engage facilities with unsupported IVAS may help improve accurate reporting and prescribing practices.

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Poster Presentation - Oral Presentation
Subject Category: C. difficile

Comparison of fidaxomicin to oral vancomycin for the treatment of Clostridioides difficile infection in hospitalized patients

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Background: *Clostridioides difficile* infection (CDI) is a major source of morbidity and mortality. Even after recovery, recurrent CDI (rCDI) occurs frequently, and concomitant antibiotic use for treatment of a concurrent non–*C. difficile* infection is a major risk factor. Treatment with fidaxomicin versus vancomycin is associated with similar rate of cure and lower recurrence risk. However, the comparative efficacy of these 2 agents remains unclear in those receiving concomitant antibiotics. **Methods:** We conducted a randomized, controlled, open-label trial at the University of Michigan and St. Joseph Mercy hospitals in Ann Arbor, Michigan. Patients provided written informed consent at enrollment. We included all hospitalized patients aged ≥18 years with a positive test for toxigenic *C. difficile*, >3 unformed stools per 24 hours, and ≥1 qualifying concomitant antibiotic with a planned treatment of an infection for ≥5 days after enrollment. We excluded patients with complicated CDI, allergy to vancomycin–fidaxomicin, planned adjunctive CDI treatments, CDI treatment for >24 hours prior to enrollment, concomitant laxative use, current or planned colostomy or ileostomy, and/or planned long-term (>12 weeks) concomitant antibiotic use. Clinical cure was defined as resolution of diarrhea for 2 consecutive days maintained until the end of therapy and for 2 days afterward. rCDI was defined as recurrent diarrhea with positive testing within 30 days of initial treatment. Patients were randomized (stratified by ICU status) to fidaxomicin 200 mg twice daily or vancomycin 125 mg orally 4 times daily for 10 days. If concomitant antibiotic treatment continued >10 days, the study drug continued until the concomitant antibiotic ended. Bivariable statistics included *t* tests and χ^2 tests. **Results:** After screening 5,101 patients for eligibility (May 2017–May 2021), 144 were included and randomized (Fig. 1). Study characteristics and outcomes are noted in Table 1. Baseline characteristics were similar between groups. Most patients were aged <65 years, were on a proton-pump inhibitor (PPI), and were not in the ICU. The mean duration of concomitant antibiotic was 18.4 days. In the intention-to-treat population, clinical cure (73% vs 62.9%; P =.195), and rCDI (3.3% vs 4.0%; P >.99) were similar for fidaxomicin and vancomycin, respectively. **Conclusions:** In this study of patients with CDI receiving a concomitant antibiotic, a numerically higher proportion were cured with fidaxomicin versus vancomycin, but this result did not reach statistical significance. Overall recurrence was lower than anticipated in both arms compared to previous studies in which duration of CDI treatment was not extended during concomitant antibiotic treatment. Future studies are needed to ascertain whether clinical cure is higher with fidaxomicin than vancomycin during concomitant antibiotic exposure, and whether extending the duration of CDI treatment reduces recurrence.

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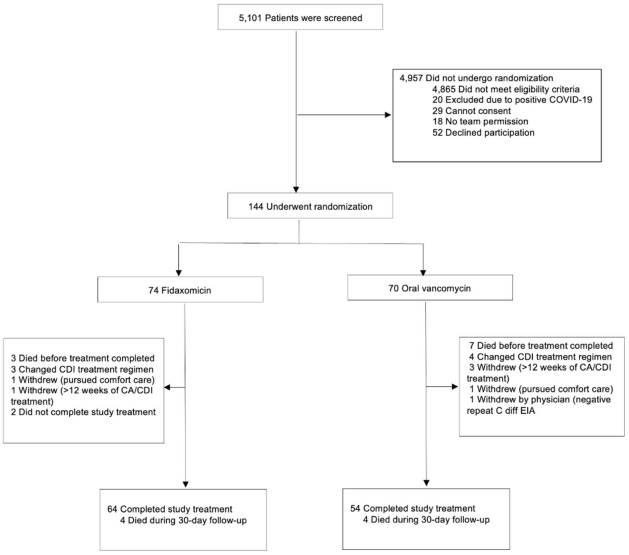

Fig. 1.

Table 1. Patient Characteristics and Outcomes

	Fidaxomicin (N=74)	Oral vancomycin (N=70)	Overall (N=144)
Patient Characteristics			
Age			
<65	51 (68.9%)	40 (57.1%)	91 (63.2%)
65-74	15 (20.3%)	20 (28.6%)	35 (24.3%)
>74	8 (10.8%)	10 (14.3%)	18 (12.5%)
Gender			
Male	34 (45.9%)	35 (50.0%)	69 (47.9%)
Female	40 (54.1%)	35 (50.0%)	75 (52.1%)
BMI			
Mean (SD)	26.7 (6.77)	28.2 (7.36)	27.4 (7.08)
Median [Min, Max]	25.1 [15.5, 48.2]	27.0 [15.2, 51.3]	26.2 [15.2, 51.3]
ICU			
No	62 (83.8%)	59 (84.3%)	121 (84.0%)
Yes	12 (16.2%)	11 (15.7%)	23 (16.0%)
History of CDI			
Yes	16 (21.6%)	8 (11.4%)	24 (16.7%)
No	58 (78.4%)	62 (88.6%)	120 (83.3%)
History of cancer			
No	40 (54.1%)	32 (45.7%)	72 (50.0%)
Yes	34 (45.9%)	38 (54.3%)	72 (50.0%)
History of stem cell transplant			
No	70 (94.6%)	60 (85.7%)	130 (90.3%)
Yes	4 (5.4%)	10 (14.3%)	14 (9.7%)
History of IBD			
No	71 (95.9%)	68 (97.1%)	139 (96.5%)
Yes	3 (4.1%)	2 (2.9%)	5 (3.5%)
PPI			
No	45 (60.8%)	40 (57.1%)	85 (59.0%)
Yes	29 (39.2%)	30 (42.9%)	59 (41.0%)
WBC at enrollment			
Mean (SD)	9.46 (7.37)	7.93 (6.90)	8.70 (7.15)
Median [Min, Max]	7.65 [0.100, 33.5]	8.05 [0.100, 36.3]	7.85 [0.100, 36.3]
Missing	12 (16.2%)	8 (11.4%)	20 (13.9%)
Creatinine at enrollment			
Mean (SD)	1.11 (0.703)	1.36 (1.04)	1.23 (0.890)
Median [Min, Max]	0.885 [0.260, 3.27]	1.02 [0.420, 5.36]	0.920 [0.260, 5.36]
Missing	8 (10.8%)	6 (8.6%)	14 (9.7%)
Patient Outcomes			
Duration of concomitant antibiotics			
Mean (SD)	16.5 (13.1)	20.6 (19.7)	18.4 (16.6)
Cure at EOT			
No	20 (27.0%)	26 (37.1%)	46 (31.9%)
Yes	54 (73.0%)	44 (62.9%)	98 (68.1%)
Recurrence during follow-up (per protocol)			
No	58 (96.7%)	48 (96%)	116 (96.7%)
Yes	2 (3.3%)	2 (4%)	4 (3.3%)
Excluded from per-protocol analysis	14	20	34
Death during follow-up			
No	60 (93.7%)	50 (92.6%)	110 (93.2%)
Yes	4 (6.3%)	4 (7.4%)	8 (6.8%)
Withdrew, protocol deviation, or death before follow-up	10	16	36

Presentation Type:
Poster Presentation - Oral Presentation
Subject Category: ***C. difficile***
Healthcare resource utilization in a phase 3 trial of SER-109 in patients with recurrent *Clostridioides difficile* infection
Stuart Cohen; Thomas Louie; Charles Berenson; Alpesh Amin; David Lombardi; Sissi Pham; Shirley Huang; Elaine Wang; Brooke Hasson and Barbara McGovern, Lisa Von Moltke

Background: The estimated economic cost of *Clostridioides difficile* infection (CDI) is $5.4 billion annually, primarily attributed to acute-care costs. We previously reported data from ECOSPOR III that SER-109, an investigational oral microbiome therapeutic, was superior to placebo in reducing recurrent CDI (rCDI) in adults at 8 weeks after treatment, with a 68% relative risk reduction. Adults with rCDI have more hospitalizations and emergency room (ER) visits (defined herein as healthcare resource utilization, HRU) compared to those without recurrence. Thus, we evaluated incidence of HRU. **Methods:** Adults with rCDI (≥3 episodes in 12 months) were screened at 56 US and Canadian sites and were randomized 1:1 to SER-109 (4 capsules × 3 days) or placebo following resolution of CDI with standard-of-care CDI antibiotics. The primary end point was rCDI at 8 weeks. Exploratory end points included cumulative incidence of hospitalizations through 24 weeks after treatment. Here, we report cumulative incidence of all-cause HRU through 8 weeks after treatment. **Results:** In total, 281 patients were screened and 182 were randomized (59.9% female; mean age 65.5 years; 98.9% outpatient). Overall, 31 patients (17%) had 38 hospitalizations or ER visits through week 8 (11 events in 10 SER-109 patients and 27 events in 21 placebo patients) (Table 1). The cumulative incidence of HRU was lower in SER-109–treated patients compared to placebo at both weeks 4 and 8 with most events (65.8%) recorded within 4 weeks after treatment. The adjusted HRU incidence rate (by person time, age, sex, and antibiotic use) was also lower in SER-109–treated patients compared to placebo at weeks 4 and 8 (0.256 [95% CI, 0.096–0.683] versus 0.417 [95% CI, 0.199–0.873], respectively). **Conclusions:** SER-109–treated patients had less HRU compared to placebo patients through 8 weeks after treatment in this mostly outpatient population. These data suggest a potential benefit of SER-109 in reducing HRU, thus lowering the healthcare burden of rCDI.
Funding: Seres Therapeutics
Disclosures: None

Table 1. Cumulative Incidence of All-Cause Healthcare Resource Utilization (Hospitalizations and ER Visits) through Week 8 (ITT)

		Number of Subjects Analysis		Number of HRU Analysis		
Study Week	**Treatment Group**	**Number and (%) of Subjects with HRU**	**p-value**	**Total and (Mean) Number of HRU per Subject**	**Adjusted Incidence Rate-Ratio (aRR)[1]**	**95% CI aRR[1]**
Week 4	SER-109 (N=89)	5 (5.62%)	0.004	5 (0.056)	0.256	0.096, 0.683
	Placebo (N=93)	18 (19.35%)		20 (0.215)		
Week 8	SER-109 (N=89)	10 (11.24%)	0.020	11 (0.124)	0.417	0.199, 0.873
	Placebo (N=93)	21 (22.58%)		27 (0.290)		

Abbreviations: HRU = healthcare resource utilization
[1]Adjusted for treatment, age, sex, antibiotic type, and person-time

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Poster Presentation - Oral Presentation
Subject Category: CLABSI
Central-line associated bloodstream infections secondary to strict anaerobes: Time for A definition change?
Jessica Seidelman; Sarah Lewis; Ibukun Kalu; Erin Gettler; Sonali Advani; Deverick Anderson and Becky Smith

Background: Central-line–associated bloodstream infections (CLABSIs) arise from bacteria migrating from the skin along the catheter, by direct inoculation, or from pathogens that form biofilms on the interior surface of the catheter. However, given the oxygen-poor environments that obligate anaerobes require, these organisms are unlikely to survive long enough on the skin or on the catheter after direct inoculation to be the true cause of a CLABSI. Although some anaerobic CLABSIs may meet the definition for a mucosal-barrier-injury, laboratory-confirmed, bloodstream infection (MBI-LCBI), some may be not. We sought to determine the proportion of CLABSIs attributed to obligate anaerobic bacteria, and we sought to determine the pathophysiologic source of these infections. **Methods:** We performed a retrospective analysis of prospectively collected CLABSI data at 54 hospitals (academic and community) in the southeastern United States from January 2015 to December 2020. We performed chart reviews on a convenient sample for which medical records were available. We calculated the proportion of CLABSIs due to obligate anaerobes, and we have described a subset of anaerobic CLABSI cases. **Results:** We identified 60 anaerobic CLABSIs of 2,430 CLABSIs (2.5%). Of the 60 anaerobic CLABSIs, 7 were polymicrobial with nonanaerobic bacteria. The most common species we identified were *Bacteroides*, *Clostridium*, and *Lactobacillus* (Table 1). The proportion of anaerobic CLABSIs per year varied from 1.2% to 3.7% (Fig. 1). Of 60 anaerobic CLABSIs, 29 (48%) occurred in the only quaternary-care academic medical center in the database. In contrast, an average of 0.6 (SD, 0.6) anaerobic CLABSIs occurred