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.
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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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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