	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%)	
вмі				
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

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) <sup>1</sup>	95% CI aRR <sup>1</sup>
Week 4	SER-109 (N=89)	5 (5.62%)	0.004	5 (0.056)	0.256	0.006.0.603
Week 4	Placebo (N=93)	18 (19.35%)		20 (0.215)		0.096, 0.683
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 

Adjusted for treatment, age, sex, antibiotic type, and person-time

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-109treated 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

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## **Presentation Type:**

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

Pathogen	Number of CLABSIs
Bacteroides sp	22
Clostridium sp	14
Lactobacillus sp	11
Fusobacterium nucleatum	4
Actinomyces sp	3
Prevotella sp	3
Cutibacterium acnes	1
Veillonella sp	1
Peptostreptococcus sp	1

Fig. 1.

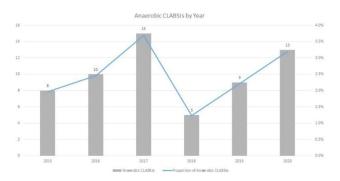


Fig. 2.

in the 53 community hospitals over the 6-year study period. Of these 29 anaerobic CLABSIs, 23 (79%) were clinically consistent with secondary bloodstream infections (BSIs) due to gastrointestinal or genitourinary source, but they lacked appropriate documentation to meet NHSN criteria for secondary BSI or MBI-LCBI based on case reviews by infection prevention physicians. The other 6 anaerobic CLABSIs did not have a clear clinical etiology and did not meet MBI-LCBI criteria. In addition, 27 (93%) of 29 anaerobic CLABSIs occurred in patients who were either solid-organ transplant recipients, were stem-cell transplant recipients, or were receiving chemotherapy. Lastly, 27 (93%) of 29 anaerobic CLABSIs were treated with antibiotics. **Conclusions:** Anaerobic CLABSIs are uncommon events, but CLABSI may disproportionately affect large, academic hospitals caring for a high proportion of medically complex patients. Additional criteria could be added to the MBI-LCBI to better classify anaerobic BSI.

Funding: None Disclosures: None

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**Presentation Type:** 

Poster Presentation - Oral Presentation **Subject Category:** COVID-19

Genomic investigation to identify the source of SARS-CoV-2 infection among healthcare personnel

Sarah Sansom; Hannah Barbian; Evan Snitkin; Christine Fukuda; Nicholas Moore; Lahari Thotapalli; Elias Baied; DO Young Kim; Mary Hayden and Michael Lin

**Background:** Contact tracing alone is often inadequate to determine the source of healthcare personnel (HCP) COVID-19 when SARS-CoV-2 is widespread in the community. We combined whole-genome sequencing (WGS) with traditional epidemiologic analysis to investigate the frequency

Table. Epidemiologic Criteria for Source of Healthcare Personnel (HCP) COVID-19 within Genomic Clusters

Source	Criteria
Healthcare associated: Patient source	Clinical or patient-facing HCP Patient diagnosed with COVID-19 before HCP diagnosed with COVID-19 HCP exposed to COVID-19 patient 2-14 days before HCP tested positive
Healthcare associated: HCP source	Clinical or patient-facing HCP and non-patient-facing HCP     Source HCP diagnosed with COVID-19 before recipient HCP diagnosed with COVID-19
470.00	HCP exposed to source HCP 2-14 days before recipient HCP tested positive
Not healthcare associated	Inconclusive evidence to support a patient or HCP source within the healthcare setting

Abbreviations in table: healthcare personnel (HCP)

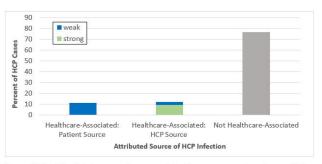


Figure. Epidemiologic links supporting transmission from symptomatic patients and/or staff to healthcare personnel (HCP) was uncommon. Genomic clusters were independently evaluated for valid epidemiologic links using metadata extracted from the electronic medical record. Most HCP infections were judged as not healthcare-associated (88/115, 76.5%). We did not identify any strong linkages for patient-to-HCP transmission. Thirteen HCP cases (11.3%) were attributed to patient source (weak linkage). Fourteen HCP cases (12.2%) were attributed to HCP source (11 strong and 3 weak linkages).

with which patients or other HCP with symptomatic COVID-19 acted as the source of HCP infection at a large tertiary-care center early in the pandemic. Methods: Cohort samples were selected from patients and HCP with PCR-positive SARS-CoV-2 infection from a period with complete retention of samples (March 14, 2021-April 10, 2020) at Rush University Medical Center, a 664-bed hospital in Chicago, Illinois. During this period, testing was limited to symptomatic patients and HCP. Recommended respiratory equipment for HCP evolved under guidance, including a 19-day period when medical face masks were recommended for COVID-19 care except for aerosol-generating procedures. Viral RNA was extracted and sequenced (NovaSeq, Illumina) from remnant nasopharyngeal swab samples in M4RT viral transport medium. Genomes with >90% coverage underwent cluster detection using a 2 single-nucleotide variant genetic distance cutoff. Genomic clusters were independently evaluated for valid epidemiologic links by 2 infectious diseases physicians (with a third adjudicator) using metadata extracted from the electronic medical record and according to predetermined criteria (Table 1). Results: In total, 1,031 SARS-CoV-2 sequences were analyzed, identifying 49 genomic clusters with HCP (median, 8; range, 2-43 members per cluster; total, 268 patients and 115 HCP) (Fig. 1). Also, 20,190 flowsheet activities were documented for cohort HCP and patient interactions, including 686 instances in which a cohort HCP contributed to a cohort patient's chart. Most HCP infections were considered not healthcare associated (88 of 115, 76.5%). We did not identify any strong linkages for patient-to-HCP transmission. Moreover, 13 HCP cases (11.3%) were attributed to patient source (weak linkage). Also, 14 HCP cases (12.2%) were attributed to HCP source (11 strong and 3 weak linkages). Weak linkages were due to lack of epidemiologic data for HCP location, particularly nonclinical staff (eg, an environmental service worker who lacked location documentation to rule out patient-specific contact). Agreement for epidemiologic linkage between the 2 evaluators was high  $(\kappa,\ 0.91)$ . Conclusions: Using genomic and epidemiologic data, we found that most HCP COVID-19 infections were not healthcare associated. We found weak evidence to support symptomatic patient-to-HCP transmission of SARS-CoV-2 and stronger evidence for HCP-to-HCP transmission.