Methods. From 2014 to 2017, environmental swabs were collected from public areas, healthcare settings, and shoe soles. Samples were considered positive for *C. difficile* following growth on CCFA plates and confirmatory PCR testing for toxin genes and fluorescent PCR ribotyping (RT). The rate of *C. difficile* positivity and associated RT distribution were compared between settings, including shoe soles which were investigated for their potential role in environmental transmission.

Results. A total of 11,986 unique isolates were obtained primarily from the US (n=11,002; 92%) in addition to 11 other countries including Taiwan (n=200) and India (n=187). Samples were categorized as being from outdoor environments (n=2,992), private residences (n=2,772), shoe soles (n=1,420), public buildings (n=1,104) or acute care settings (n=3,698). Worldwide *C. difficile* sample positivity was 26% and was similar between US and non-US sampling sites. In the US, private residences (26.2%) and outdoor environments (24.1%) had the highest positivity rate compared to public buildings (17.2%). In a Texas sub-analysis (n=8,571), positivity rates were highest from outdoor samples (27%) and were similar between private residences (24%) and healthcare buildings (24%). The most prevalent RTs overall were F014-020 (16.4%), F106 (14.9%), and FP310 (11%). Shoe soles had the highest positivity rate (45%) with similar RT distribution between shoe soles and environmental samples.

Conclusion. Using a worldwide sample, 26% of environmental samples tested positive for toxigenic *C. difficile* strains from healthcare and non-healthcare sites. Community stewardship efforts will be needed to reduce the risk of CDI in vulnerable patients. Shoe sole sampling may be an ideal surveillance tool to test for emerging epidemic strains.

Disclosures. **Kevin W. Garey, Pharm.D., M.S., FASHP**, **Summit Therapeutics** (Research Grant or Support)

19. The Impact of Investigational Purified Microbiome Therapeutic SER-109 on Health-Related Quality of Life (HRQoL) of Patients with Recurrent *Clostridioides difficile* Infection (rCDI) in ECOSPOR III, a Placebo-Controlled Clinical Trial

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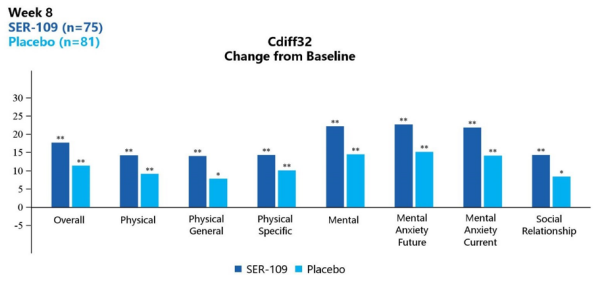
Session: O-04. Challenges in C. difficile

Background. Following standard of care antibiotics, investigational microbiome therapeutic, SER-109, achieved superiority vs placebo (PBO) at 8 weeks in reducing rCDI in patients with ≥3 prior episodes (12.4% vs 39.8%, respectively; p< 0.001). We evaluated the impact of SER-109 vs PBO on HRQoL with general (EQ-5D-5L) and disease-specific (Cdiff32) measures [Garey 2016].

Methods. EQ-5D-5L measures outcomes in 5 domains (mobility, self-care, activities, pain/discomfort, and anxiety/depression) while Cdiff32 measures outcomes in 3 domains (physical, mental, and social) including 5 associated subdomains. Patients completed EQ-5D-5L and Cdiff32 measures at baseline (BL), Wk 8, and at recurrence/early termination. Changes from BL were assessed between SER-109 vs PBO and by clinical outcome (recurrence versus nonrecurrence) in the ITT population and within each treatment arm. The between treatment group comparison analysis controlled for age, gender, prior antibiotics, and number of prior CDI episodes.

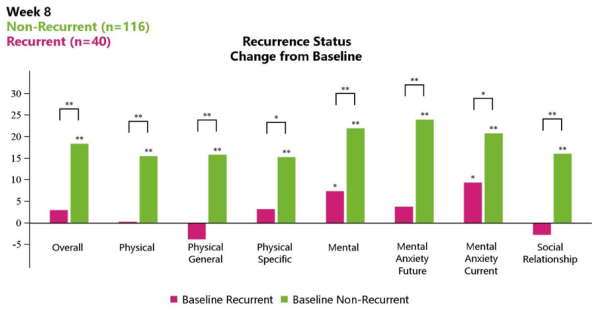
Results. Mean EQ-5D-5L and Cdiff32 scores were comparable between SER-109 and PBO at BL. EQ-5D-5L did not detect differences at Wk 8 from BL between SER-109 and PBO or by clinical outcome. In contrast, Cdiff32 detected significant improvements at Wk 8 from BL within both SER-109 subjects and PBO subjects (Fig1) and by recurrence status (Fig2). Subjects achieved significant improvement in all domains at Wk 8 from BL regardless of treatment group. When examining recurrence status within treatment arms, all PBO subjects with non-recurrence showed improvement in all health domains, while PBO subjects with recurrence had declines in several subdomains (Fig3B). Similarly, SER-109 subjects with non-recurrence showed improvement in all domains compared to BL. However, overall and mental domain/subdomains scores also improved in SER-109 subjects with recurrence (Fig3A).

Figure 1: Change from Baseline at Week 8 in Cdiff32 HRQoL Questionnaire by Treatment Group, ITT Population



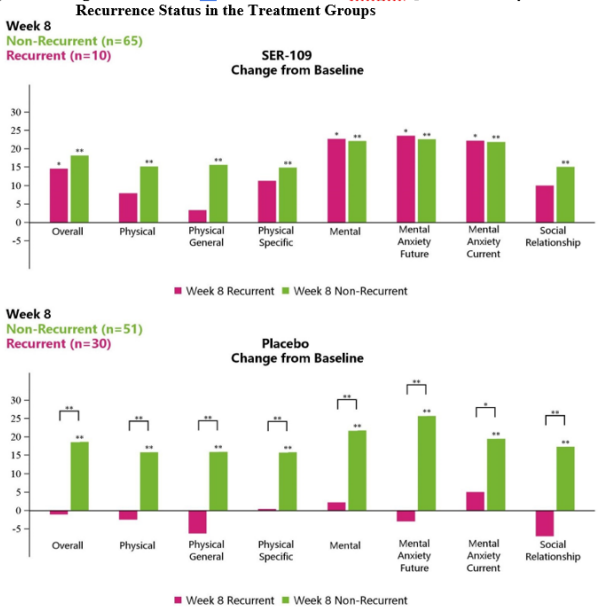
* *P*<0.05; ** *P*<0.001; ⊓ Between group comparison

Figure 2: Change from Baseline in Cdiff32 HRQoL Questionnaire by Recurrence Status at Weeks 8, ITT Population



* *P*<0.05; ** *P*<0.001; ⊓ Between group comparison

Figure 3: Change from Baseline At Week 8 in Cdiff32 HRQoL Questionnaire by Recurrence Status in the Treatment Groups



* *P*<0.05; ** *P*<0.001; ⊓ Between group comparison

Conclusion. Significant HRQoL improvements were associated with CDI nonrecurrence, which highlights the negative impact of this debilitating infection. SER-109 was associated with improved overall and mental scores, regardless of clinical outcome. Further investigation is warranted on the impact of SER-109 on mental health even among those with CDI recurrence.

Disclosures. **Elizabeth Hohmann, MD**, **Seres Therapeutics** (Research Grant or Support) **Paul Feuerstadt, MD, FACG**, **Ferring/Rebiotix Pharmaceuticals** (Consultant, Scientific Research Study Investigator, Speaker's Bureau)**Finch Pharmaceuticals** (Scientific Research Study Investigator)**Merck and Co** (Speaker's Bureau)**SERES Therapeutics** (Consultant, Scientific Research Study Investigator)**Takeda Pharmaceuticals** (Consultant) **Christine Lee, MD, FRCPC**, **Pfizer** (Board Member)**Rebiotix-Ferring** (Board Member)**Rebiotix-Ferring** (Grant/Research Support)**Seres** (Grant/Research Support)**Summit** (Grant/Research Support) **Sissi Pham, PharmD**, **Seres** (Consultant) **Pat Ray Reese, PhD**, **Reese Associates, LLC** (Consultant, Independent Contractor) **Elaine E. Wang, MD**, **Seres Therapeutics** (Employee) **Elaine E. Wang, MD**, **Seres Therapeutics** (Employee, Shareholder) **Lisa von Moltke, MD**, **Seres Therapeutics** (Employee, Shareholder) **Kevin W. Garey, Pharm.D., M.S., FASHP**, **Summit Therapeutics** (Research Grant or Support)

20. Risk Factors for Breakthrough Cytomegalovirus (CMV) Infection and *De Novo* Resistance in Hematopoietic Cell Transplantation (HCT) Recipients Receiving Letermovir Prophylaxis

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