weeks. Virologic response, adverse events (AEs), and laboratory abnormalities were evaluated.

Results. Across the two trials, 152 patients without cirrhosis and 16 with compensated cirrhosis received glecaprevir/pibrentasvir for 8 and 12 weeks, respectively. Baseline demographics are shown in Tables 1 and 2. The overall intention-to-treat (ITT) SVR12 rate was 98.2% (165/168), with no virologic failures among non-cirrhotic patients treated for 8 weeks; mITT rate (excluding non-virologic failures) was 99.4% (167/168). Reasons for nonresponse were breakthrough ($n = 1$; patient with incomplete study drug adherence), premature study drug discontinuation ($n = 1$), and missing SVR12 data ($n = 1$). Safety analyses included the additional 18 non-cirrhotic GT1-infected patients treated for 12 weeks (all achieved SVR12). AEs occurring in ≥5% of patients were fatigue, headache, nausea, and nasopharyngitis. Serious AEs and AEs leading to discontinuation were rare; none were related to study drug. Grade 3 or higher laboratory abnormalities were infrequent. All patients maintained HIV-1 suppression (<200 copies/mL) during treatment.

Conclusion. Glecaprevir/pibrentasvir was highly efficacious and well tolerated in patients co-infected with HCV GT1–6/HIV-1 without or with cirrhosis following 8 or 12 weeks of treatment, respectively, and could be the first 8-week pangenotypic treatment option for HCV/HIV-1 co-infected patients without cirrhosis.

Table 1. Baseline Demographics and Disease Characteristics

Characteristic	Without Cirrhosis 8 Weeks N=152	With Cirrhosis 12 Weeks N=16
Male, n (%)	127 (84)	15 (94)
Age, median (range) years	45 (23–74)	50 (35–62)
HCV genotype 1/2/3/4/5/6, n	102/9/22/16/0/3	10/1/4/1/0/0
HCV treatment-experienced, n (%)	31 (20)	2 (13)
HCV RNA, median (range), Log_{10} IU/mL	6.23 (3.98–7.37)	6.05 (4.41–7.03)
CD4+ cell count, median (range), cells/mm^3	595 (154–2103)	545 (222–1806)

Table 2. Baseline Antiretroviral Therapy

Characteristic	Without Cirrhosis 8 Weeks N=152	With Cirrhosis 12 Weeks N=16
Antiretroviral therapy-naïve, n (%)	9 (6)	0
Raltegravir anchor ARV, n (%)	46 (32)[a]	6 (38)
Dolutegravir anchor ARV, n (%)	67 (47)[a]	5 (31)
Rilpivirine anchor ARV, n (%)	30 (21)[a]	5 (31)
ARV = antiretroviral. [a]Denominator excludes patients who are ARV therapy-naïve.		

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1966. Evaluating a Prototype Microbiome Health Index (MHI) as a Measure of Microbiome Restoration Using Data Derived From a Published Study of Fecal Microbiota Transplant (FMT) to Treat Recurrent *Clostridium difficile* Infections (rCDI)

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Background. There are efforts to develop FDA-approved microbiota-based drugs to restore the microbiome, notably for recurrent *Clostridium difficile* infections (rCDI). Given the lack of established biomarkers for microbiome restoration, we are evaluating unidimensional Microbiome Health Indices (MHI™). We previously presented a prototype MHI for clinical trials of RBX2660—a standardized microbiota restoration therapy in Phase 3 clinical development. Herein we assessed MHI for a published study of fecal microbiota transplant (FMT) for treating rCDI.

Methods. The prototype MHI is based on the associations of *Bacteroidia* and *Clostridia* with colonization resistance, and *Gammaproteobacteria* and *Bacilli* with dysbiosis, and Receiver Operating Characteristic analysis of pooled RBX2660 trial data indicated that rCDI participants before treatment (baseline) are distinguished from the healthier RBX2660 profile with an odds ratio of 121 (AUC = 0.99, sensitivity = 0.96, specificity = 0.99, cutpoint = 8.2). MHI data for the published FMT cohort were calculated using publicly available data derived from pre- and post-treatment fecal samples (Khanna S, et al. *Microbiome* 2017 **5**:55), and this study included patients with or without a co-diagnosis of inflammatory bowel disease (IBD).

Results. At baseline, 92% of patients in the FMT cohort were below the MHI = 8.2 cutpoint, consistent with a rCDI diagnosis. Among FMT responders 7 days after treatment, 91% of patients had shifted to MHI>8.2, ($P < 0.0001$ compared with baseline). Likewise, a significant shift was observed from baseline to 30 days ($P < 0.0001$), with 83% having MHI > 8.2. There were insufficient patients to support a statistical comparison of IBD vs. no IBD, but MHIs trended lower at all time points among patients with IBD.

Conclusion. MHI parameters derived from RBX2660 trials were predictive of pre- and post-treatment states for a published cohort of FMT-treated rCDI patients, suggesting that this prototype MHI represents a useful dysbiosis measure beyond RBX2660 trials. Lower MHI among patients co-diagnosed with IBD suggests the potential utility of MHI beyond rCDI. Collectively our results continue to support the utility of MHI and its prospective evaluation in ongoing Phase 3 clinical trials.

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1967. Study of the Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) When Co-administered with Other Vaccines in Healthy Adolescents

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Background. The MenACYW-TT conjugate vaccine is a quadrivalent meningococcal vaccine candidate intended for global use in all age groups. This pivotal phase II study evaluated the safety and immunogenicity of the vaccine when compared with a licensed quadrivalent conjugated meningococcal vaccine (MCV4-CRM) when co-administered with tetanus, diphtheria, acellular pertussis (Tdap), and human papilloma virus (HPV4) vaccines in meningococcal vaccine naïve adolescents (10–17 years of age).

Methods. A randomized, open-label, multicenter study (NCT02199691) was conducted in 1,715 healthy subjects in the United States, who were randomly assigned to receive MenACYW-TT conjugate vaccine, MCV4-CRM, MenACYW-TT conjugate vaccine (co-administered with Tdap and HPV4), or Tdap and HPV4 vaccines. Serum bactericidal assay with human (hSBA) and baby rabbit (rSBA) complement was used to measure antibodies against serogroups A, C, W, and Y test strains at baseline and 30 days after vaccination. Safety data were collected up to 6 months post-vaccination.

Results. Noninferiority of immune response was demonstrated between MenACYW-TT conjugate vaccine and MCV4-CRM, and MenACYW-TT conjugate vaccine when co-administered with Tdap and HPV4 vaccines vs. when administered alone, based on percentages of study participants achieving hSBA vaccine seroresponse at Day 30 fromD0 baseline. The proportions of individuals with hSBA ≥ 1:8 after MenACYW-TT conjugate vaccine administration were higher than those after MCV4-CRM administration for all four serogroups (A: 93.5% vs. 82.8%; C: 98.5% vs. 76.0%; W: 99.1% vs. 90.7%; Y: 97.2% vs. 83.2%). Co-administration of MenACYW conjugate, Tdap and HPV4 vaccines did not generate any results suggestive of immune interference. Reactogenicity profiles were comparable across study groups. Most unsolicited adverse events were of Grade 1 or Grade 2 intensity. No vaccine related serious adverse events were reported.

Conclusion. MenACYW-TT conjugate vaccine was immunogenic and well tolerated when administered as a single dose to meningococcal vaccine naïve adolescents along with Tdap and HPV4 vaccines. Such a vaccine will offer an alternative for the prevention of invasive meningococcal disease in susceptible populations across the world.

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1968. Procalcitonin-Guided Antibiotic Therapy for Lower Respiratory Tract Infections in a US Academic Medical Center

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Background. European trials using procalcitonin (PCT)-guided antibiotic therapy for patients with lower respiratory tract infections (LRTI) have resulted in significant reductions in antibiotic use without increasing adverse outcomes. Few prospective studies have examined PCT-guided antibiotic therapy for LRTI in the United States.