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OpenBiome Highlights Donor Screening Program in *New England Journal of Medicine*

OpenBiome published a research letter in the New England Journal of Medicine presenting its donor screening program, which has accepted just 2.5% of over 15,000 potential donors

CAMBRIDGE, Mass. – As the largest universal stool bank in the United States, OpenBiome has screened more potential stool donors than any other institution for material used for fecal microbiota transplantation (FMT).

This week, OpenBiome published a research letter in the *New England Journal of Medicine* presenting its experience screening over 15,000 candidate stool donors. The letter highlights how selection criteria each contribute to an overall qualification rate of 2.5% of all donor candidates.

The screening process includes excluding candidates with antibiotic-resistant pathogens like ESBL-producing organisms, carbapenem-resistant *Enterobacteriaceae*, methicillin-resistant *Staphylococcus aureus*, and vancomycin-resistant *enterococci*, as well as evaluating for risk factors associated with acquisition of these microbes.

“Like blood banks, centralized stool banks help make FMT safer and more accessible,” said Majdi Osman, MD, MPH, OpenBiome’s Chief Medical Officer. “The rigor of screening and processing that we conduct is greater than what is feasible at a physician’s office or hospital.” An [independent study](#) found that it can cost a physician or patient over \$15,000 to find a single suitable donor, including over \$3600 per donor candidate on testing alone.

FMT is an investigational treatment that is recommended in clinical guidelines for recurrent *C. difficile* infection. OpenBiome has shipped out over 50,000 treatments to over 1,200 hospitals since 2013, with no reports of serious adverse events definitively related to OpenBiome FMT material.

“As demonstrated by an FDA safety alert on FMT material from a hospital earlier this year, universal donor screening standards for FMT are vital to help protect patient safety,” said Colleen Kelly, MD, Associate Professor of Medicine at Brown Alpert Medical School, and co-author on the letter. “OpenBiome has developed a model for standardized, rigorously screened FMT material that makes offering this treatment possible for physicians of *C. difficile* patients across the country.”

Insights from this experience can help inform the clinical research and practice of FMT. “Today, there is no universal standard for screening and qualifying human donors,” said Carolyn Edelstein, Executive Director of OpenBiome. “Sharing our findings and learning from the collective experience of FMT is how we will all help advance safety for every patient that follows.”

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About OpenBiome

OpenBiome is the first public stool bank, and a 501(c)3 nonprofit organization, founded to expand safe access to fecal transplantation for patients with recurrent *C. difficile* infections and to catalyze research on the microbiome’s role in human health. OpenBiome provides clinicians with rigorously screened, ready-to-use preparations and supports researchers with a suite of tools to discover how gut bacteria might treat diseases beyond *C. difficile*. Since 2013, OpenBiome has partnered with over 1,200 healthcare institutions across all 50 states to deliver more than 50,000 treatments for recurrent *C. difficile*. Its research portfolio includes 34% of all active and completed trials in the United States exploring the use of fecal transplants to treat disease. For more information, visit <http://www.openbiome.org>.