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AGA establishes NIH-funded registry to track fecal microbiota transplants

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Today, the American Gastroenterological Association (AGA) announced that it has received funding from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) to launch the first national registry assessing short- and long-term patient outcomes associated with fecal microbiota transplantation (FMT).

Rapidly accumulating evidence suggests that modifying gut microbiota may promote health or treat disease, with FMT for *Clostridium difficile* infection being the first successful clinical application of this concept. Researchers are now exploring FMT for conditions beyond *C. difficile*, such as inflammatory bowel disease. However, the early adoption and expansion of FMT in clinical practice has outpaced scientific study, resulting in a lack of understanding of the potential health risks from human-to-human transfer of stool.

The AGA Fecal Microbiota Transplantation National Registry—a program of the AGA Center for Gut Microbiome Research and Education—will enable researchers to identify potential short-term adverse outcomes and to search for long-term safety concerns, such as development of chronic conditions like irritable bowel syndrome, obesity and diabetes.

"We are in a unique position in which the responsibility to protect the safety of patients receiving FMT is combined with the opportunity to gain tremendous new insights into the biology of the human gut microbiome," said Timothy C. Wang, MD, AGAF, president of the

American Gastroenterological Association. "AGA is eager to put a formal infrastructure into place for physicians and patients to report information that will standardize best practices for FMT, while offering insight into the gut microbiome and its role in human health and disease."

The AGA Fecal Microbiota Transplantation National Registry will prospectively enroll patients who undergo FMT at sites throughout the U.S. Information on FMT methodology, FMT indication, as well as baseline data on donors and recipients will be collected from each site. Patients will be followed at regular intervals for up to 10 years after FMT for pre-defined and spontaneously reported adverse events and for pre-defined outcomes of effectiveness. The registry is led by principal investigators Colleen Kelly, MD, Loren Laine, MD, AGAF, and Gary D. Wu, MD, who are also members of the AGA Center for Gut Microbiome Research and Education scientific advisory board.

"The immediate goal of the FMT registry is to protect patient safety by providing a central place in which to collect patient outcomes and monitor potential issues that we may not even know about yet," said Dr. Kelly. "Long term, the data we collect will be of enormous value, offering the scientific community a rich resource of information about manipulation of the gut microbiota in humans to promote health and treat disease."

The AGA Center for Gut Microbiome Research and Education thanks the Crohn's & Colitis Foundation of America (CCFA), the Infectious Diseases Society of America (IDSA), and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) for their partnership in this initiative. AGA also extends its gratitude to the members of the registry steering committee: Colleen Kelly, MD, (AGA) Loren Laine, MD, AGAF (AGA) Gary D. Wu, MD, (AGA) James D. Lewis, MD, MSCE, AGAF, (AGA) Ashish Atreja,

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Provided by American Gastroenterological Association