Safety Alert: Fecal Microbiota for Transplantation and Risk of Transmission of Multi-Drug Resistant Organisms

An immunocompromised patient died from invasive infections after an investigational fecal microbiota transplant.

June 13, 2019 By Food and Drug Administration (FDA)

Important Safety Alert Regarding Use of Fecal Microbiota for Transplantation and Risk of Serious Adverse Reactions Due to Transmission of Multi-Drug Resistant Organisms

The Food and Drug Administration (FDA) is informing health care providers and patients of the potential risk of serious or life-threatening infections with the use of fecal microbiota for transplantation (FMT). The agency is now aware of bacterial infections caused by multi-drug resistant organisms (MDROs) that have occurred due to transmission of a MDRO from use of investigational FMT.

Summary of the Issue

- Two immunocompromised adults who received investigational FMT developed invasive infections caused by extended-spectrum beta-lactamase (ESBL)-producing Escherichia coli (E.coli). One of the individuals died.
- FMT used in these two individuals were prepared from stool obtained from the same donor.
- The donor stool and resulting FMT used in these two individuals were not tested for ESBL-producing gram-negative organisms prior to use. After these adverse events occurred, stored preparations of FMT from this stool donor were tested and found to be positive for ESBL-producing E. coli identical to the organisms isolated from the two patients.

Information for Health Care Providers and Patients

In July 2013, FDA issued guidance stating that it intends to exercise enforcement discretion under limited conditions regarding the IND requirements for the use of FMT to treat Clostridium difficile (C. difficile) infection in patients who have not responded to standard therapies. The guidance states that FDA intends to exercise enforcement discretion provided that the treating physician obtains adequate consent for the use of FMT from the patient or his or her legally authorized representative. The consent should include, at a minimum, a statement that the use of FMT to treat C. difficile is investigational and a discussion of its potential risks. FDA is informing members of the medical and scientific communities and other interested persons of the potential risk of transmission of MDROs by FMT and the resultant serious adverse reactions that may occur.

Patients considering FMT to treat C. difficile infection should speak to their health care provider to understand the potential risks associated with the product's use.

Additional Protections for Investigational Use of FMT

- Because of these serious adverse reactions that occurredwithinvestigationalFMT,FDA has determined that the following protections are needed foranyinvestigational useofFMT:
  - Donor screening with questions that specifically address risk factors for colonization with MDROs, and exclusion of individuals at higher risk of colonization with MDROs.
  - MDRO testing of donor stool and exclusion of stool that tests positive for MDRO. FDA scientists have determined the specific MDRO testing and frequency that should be implemented.

Reporting Adverse Events

FDA encourages all health care providers administering FMT products to report suspected adverse events to the FDA at 1-800-FDA-1088 or http://www.fda.gov/medwatch.

This announcement was originally published on the Food and Drug Administration website on June 13, 2019.
