

FDA warns of infections from fecal transplants after 1 death

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Fecal microbiota transplant is a still-experimental procedure, as yet unapproved by the FDA. It's been primarily used to treat serious infections of antibiotic-resistant forms of the *Clostridium difficile* (*C. difficile*) bacterium.

The transplant involves taking stool from a healthy donor and placing it in the ill patient's colon. The aim is to help replace an unhealthy "[microbiome](#)"—the trillions of bacteria that reside in the human gut—with a more robust, disease-fighting microbiome from the donor.

Once delivered via the fecal transplant, this new microbiome repopulates the patient's microbiome with healthier microorganisms, which effectively crowd out dangerous *C. difficile*.

Researchers are also looking into the use of fecal transplants to treat chronic gastrointestinal illnesses such as ulcerative colitis or irritable bowel syndrome.

But every therapy comes with risks, and the FDA said that two patients who received fecal microbiota transplants as part of a clinical trial developed life-threatening infections from multidrug-resistant bacteria delivered in the transplants. One of the patients has died.

Both patients had weakened immune systems, making them more vulnerable to germs that are resistant to multiple antibiotics. So, the FDA is now mandating that special screening and testing of the stool used in these procedures be done, to ensure that no drug-resistant bacteria are in the donated material.

Also, when fecal microbiota transplants are used, doctors need to have adequate informed consent from the patient, the FDA said. Patients need to be warned of any potential risks associated with the [treatment](#) and be told that the treatment is still considered experimental.

(HealthDay)—Fecal transplants—transferring fecal matter from a healthy person into an ill person with a compromised "microbiome"—is an increasingly used new treatment for a variety of ills.

But on Thursday federal health officials announced that a patient died after such a procedure, highlighting the potential for severe infections linked to fecal transplants.

"While we support this area of scientific discovery, it's important to note that fecal [microbiota](#) for transplantation does not come without risk," said Dr. Peter Marks, director the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration.

After reports of serious, antibiotic-resistant infections linked to the procedures, the FDA wants "to alert all health care professionals who administer FMT [fecal microbiota [transplant](#)] about this potential serious risk so they can inform their patients," Marks said in an agency news release.

Marks stressed that the FDA still supports research into fecal transplant therapy.

"The medical community is actively engaged in exploring the potential uses of fecal microbiota for transplantation," he said. Although the therapy isn't approved by the FDA, the agency supports the use of this treatment and is looking to "strike a balance between assuring patient safety and facilitating access to unapproved treatments for unmet medical needs," Marks said.

To that end, "we will continue to aggressively monitor clinical trials to ensure [patients](#) are protected when safety concerns arise," Marks said.

More information: The nonprofit organization OpenBiome has more on [fecal microbiota transplant](#).

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