Frequently asked questions about fecal microbiota transplant

What is fecal microbiota transplant?
Fecal microbiota transplantation (FMT) is when stool from a healthy donor is made into a liquid mixture and transferred into the colon of a different person to try to reintroduce or boost helpful organisms. FMT is only approved to treat Clostridioides difficile (C. diff) infection that has occurred three times despite adequate antibiotic treatment. FMT for other conditions must be given as part of a clinical trial.

What is C. diff?
Your body has a lot of good bacteria in its gastrointestinal (GI) tract, also called your digestive system. C. diff is an infection from an overgrowth of bad bacteria that can cause GI symptoms, like nausea, watery diarrhea, stomach pain and stomach cramps, that may be severe.

How does FMT work?
Our GI tract has thousands of different bacteria and other microorganisms, or germs, that are vital for good health. Antibiotics can disturb these bacteria and allow disease-causing bacteria, such as C. diff, to grow. FMT involves transferring good bacteria from a healthy donor into a patient with C. diff infection. These bacteria then start growing in the patient’s colon, or large bowel, and stop C. diff from overgrowing.

How is the transplant performed?
Your health care provider will use donor stool and saline to create a liquid mixture that may be transferred into your GI tract during a colonoscopy or sigmoidoscopy. Other methods that have been used with success, and which may be used in select cases, include fecal enemas (given through the rectum) and using a nasogastric (nasal) tube into the upper part of your GI tract.

What is the success rate?
There are more than 500 case reports in the world’s medical literature so far and a recent randomized controlled clinical trial, reporting an overall cure rate of 90 to 95 percent for C. diff using FMT as a treatment.

If your health care provider suggests you have an FMT, ask them to learn more about the AGA Fecal Microbiota Transplantation (FMT) National Registry at www.gastro.org/fmtregistry. If you have received an FMT, you are strongly encouraged to join this community of patients helping us to better understand the long-term safety and impact of FMT.

Is FMT safe?
There are currently no known cases of infection passed from a healthy donor to a receiving patient through FMT. However, feces are a "bodily fluid" and proper donor testing is vital.
Patients are asked to sign a consent form acknowledging the risks of having colonoscopy, if appropriate, as well as potential risks with the FMT (infection, allergic or immune reaction, or other disease transmissions).

How can I find a doctor in my area who performs fecal transplant?
If you are a patient interested in having an FMT, visit Clinicaltrials.gov to see sites participating in the AGA Fecal Microbiota Transplantation (FMT) National Registry. You or your provider can contact the participating sites to learn more about enrolling.

Am I a candidate for FMT?
FMT is performed on patients who are suffering from recurring *C. diff*. FMT is an effective and approved procedure used to treat *C. diff* infection if it has occurred at least three times despite antibiotic treatment. Patients who have had two more severe *C. diff* infections (admitted to an intensive care unit) may also be candidates for FMT. There is ongoing research to determine if FMT may work for other health issues.

Who should be my donor?
The best donor is somebody in good health who has not taken any antibiotics for at least 90 days. Most patients choose a close family member, although the donor does not necessarily have to be related to the recipient.

Your health care provider’s office may have stool from a healthy volunteer available if you do not have a donor.

What kind of screening tests are needed for donors? Are these tests covered by the donor’s health insurance?
Donors fill out a screening questionnaire like those done at blood banks and for organ or tissue transplants.

People are not allowed to donate stool if:

- They are at risk for HIV or viral hepatitis.
- They have major gastrointestinal or autoimmune disease.
- They have a history of cancer.
- Their blood tests positive for HIV, hepatitis A, B, and C, or syphilis.
- Their stool tests positive for bad bacteria (such as salmonella), parasites or *C. diff*.

Donors should be aware that their health insurance may not cover the costs of these screening tests, which may cost several hundred dollars.

How much does FMT cost? Is it covered by my health insurance?
There is no "fee" for the FMT itself. The procedure is performed during a colonoscopy or sigmoidoscopy, which is usually allowed for patients who have recurring *C. diff* infection with chronic diarrhea. Most insurance plans cover the costs of the patient’s laboratory testing and
the colonoscopy. However, to be sure, patients are urged to check with their insurance company to get detailed information about co-pays, deductibles and requirements for referrals, especially for out-of-network or out-of-state providers.

Is FMT approved by the U.S. Food and Drug Administration (FDA)?
Because the long-term results of FMT are not known, the FDA only allows FMT to treat *C. diff* that has occurred at least three times despite antibiotic treatment. Health care providers must have FMT recipients sign an informed consent form, which confirms that the recipient understands the potential risks of FMT. For all other health conditions, the FDA requires FMT to be done as part of a clinical trial.

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