

Fecal Microbiota Therapy: Information for Recipients

What is fecal microbiota therapy?

Fecal microbiota therapy is a simple procedure that treats recurring or severe cases of an infection called **clostridium difficile** (usually referred to as *C. diff*).

Most infections of *C. diff* can be treated with antibiotics, but sometimes the infection doesn't go away. Fortunately, there's another option. Introducing healthy bacteria from the digestive system of another person can break the cycle of *C. diff* infection. This is done by transferring a small amount of fecal material from a healthy person (donor) to the infected person (recipient).

Does it work?

Fecal microbiota therapy is highly effective. Although the therapy is considered investigational by some regulatory agencies, studies show it gets rid of *C. diff* about 90% of the time.

For many, symptoms go away immediately after the procedure. In rare cases, more than one treatment with fecal microbiota therapy is needed to eliminate the *C. diff* infection.

Why does my provider recommend it?

You may benefit from fecal microbiota therapy if the *C. diff* infection recurs two or more times, doesn't respond to antibiotics, or is severe.

Who donates the feces?

Doctors prefer the donor to be an intimate partner, someone you live with, or a family member.

A nurse will ask the donor some screening questions, similar to the ones asked when donating blood. These questions identify anything that would disqualify a potential donor. Certain illnesses and behaviors disqualify donors — it's very important to not expose you to additional problems.

Any of the following can disqualify a donor:

- Certain infectious diseases, illnesses, or recent exposure to them, such as HIV, AIDS, hepatitis, and chronic gastrointestinal (GI) conditions.
- Certain **activities**, such as high-risk sexual behaviors, drug use, and recent tattoos or piercings.
- Recent use of certain **medications**, such as antibiotics, immunosuppressants, and cancer medications.
- Travel or residency in countries with risk of certain diseases, including Creutzfeldt-Jakob disease ("mad cow disease"), diarrheal illnesses, and traveler's diarrhea.

Potential benefits	Risks and potential complications	Alternatives
 Diarrhea reduced or eliminated Abdominal pain greatly reduced or eliminated C. diff infection eliminated 	 The risks associated with fecal microbiota therapy include: Transmission of an infection (donor screening and stool testing reduce that risk) Risks associated with NG tubes, colonoscopy, and enemas Diarrhea, cramping, and belching for a short time after the procedure 	AntibioticsProbiotics ("good" bacteria)Watchful waitingColon surgery

What happens before the procedure?

In general, a gastroenterologist (a doctor who focuses on the digestive system) and his or her staff will work with you to complete these steps, but other healthcare providers may be involved as well:

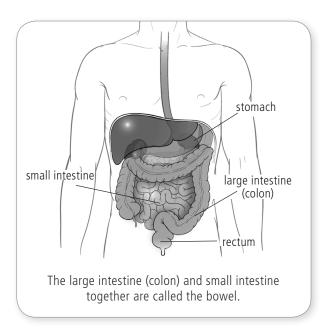
- **Complete screening tests.** You and the donor will be screened for certain illnesses and bacteria. You will give blood and stool samples to be tested.
- Receive directions. Doctors and nurses will educate you and the donor on the procedure and give you directions for the day of the procedure. You'll also sign a consent form.
- **Take medications.** You may be given a laxative to take before the procedure. You may also need to stop any antibiotics you're taking for the *C. diff* infection.
- Prepare your colon (if you're having a colonoscope or an enema). Your colon (bowel) needs to be clear before the fecal material is infused. Your doctor will give you a laxative before the procedure. Also, you will need to stop eating for at least 24 hours, stop drinking for 4 to 6 hours, and possibly stop some medications before the procedure.

The hospital or medical facility prepares the stool for infusion. This includes diluting the feces with a solution of salt and water, and filtering it to remove any solid material.

What happens during the procedure?

During fecal microbiota therapy, the doctor transfers a small amount of fecal material from the donor into your intestines using one of these methods:

• A **colonoscope** (a long, flexible tube) inserted into the rectum to the colon (like a colonoscopy). This is the most common method. You will receive IV medication, and you may be sedated during the procedure. The colonoscope is inserted into your rectum, the material is infused into your colon, and the scope is removed.



- A nasogastric (NG) tube or an endoscope inserted into the nose or throat and into the bowel. You may be sedated during the procedure. The material will be infused into your small intestine through the NG tube or endoscope, but you will not taste or smell it.
- An enema bag inserted into the rectum. You will be awake during the procedure. The enema infuses the fecal matter into your colon using pressure.

What happens after the procedure?

- You will be observed for 30 to 45 minutes while you recover.
- You need to keep the fecal material in for as long as possible. You may be given a medication to keep you from going to the bathroom. The longer the fecal material stays in your body, the better.
- If you respond well to the treatment and don't have other health concerns, your doctor will send you home.
- You may have further testing. Depending on your response to the procedure, your stool may be tested for *C. diff*.

After discussing the risks and benefits with my healthcare provider, I consent to fecal microbiota therapy. I have had an opportunity to read the information in this document and ask questions.		
Patient Signature:	Date of Birth:	
Printed Name:	Today's Date:	

To be retained in the patient medical record



Provider: Place or scan this signed document into the patient file and give a copy to the patient.

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