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Medicine's next frontier: The microbiome



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Four years ago, Natalie Gurchich developed a strange reaction to antibiotics she'd been prescribed for strep throat: horrible stomach problems, no matter what she ate, up to 20 times a day.

The diagnosis: Clostridium difficile, known as C. diff. It's a bacterial infection that affects as many as half a million people in the U.S. each year, causing almost 30,000 deaths.

Often acquired in hospitals, it's both related to antibiotic use and treated with antibiotics. Gurchich said her case cleared up after two courses of the bacteria-killing drugs.

Earlier this year though, after she took antibiotics again for an unrelated condition, the C. diff returned. This time, even three courses of the medicines didn't help.

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"Once I started investigating on my own, I realized the next time I take antibiotics—even if I recover this time—I would have a 65 percent chance of developing C. diff again," Gurvich, a registered nurse, said in an interview. "I really did not want to become a hostage to this condition."

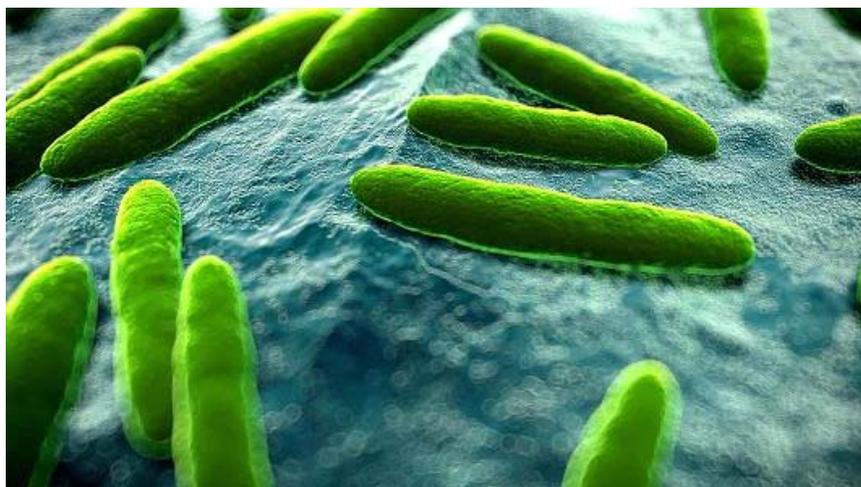
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In April, Gurvich had a procedure known as FMT: fecal microbiota transplantation. It's exactly what it sounds like.

"It involves the infusion of one person's fecal material—it's a fecal suspension that we make—into another person's gastrointestinal tract," said Dr. Caterina Oneto, the gastroenterologist who performed Gurvich's FMT.

"It works very quickly," said Oneto, a clinical instructor at NYU's Langone Medical Center. "For the most part, patients start to feel—and everybody's of course different—but most patients start to feel better within the next 24 hours after the procedure."

FMTs are some of the earliest ways medicine is employing a growing understanding of what's known as the microbiome: the trillions of microbes that live in and on us.



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For centuries, it was thought that bacteria could only be harmful to us. But recent research has yielded insights into the microbiome's role in everything from our immune system to our metabolism.

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Last decade, the National Institutes of Health began the Human Microbiome Project to study those trillions of bugs and their implications for human health—as it turns out, microbes make up the majority of cells on our bodies, outnumbering human cells 10 to 1. The average 200-pound person is covered in 2 to 6 pounds of microorganisms, according to the NIH.

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Investment from companies has followed. Late last month, microbiome-focused drugmaker [Seres Therapeutics](#) (ticker MCRB) filed to raise \$100 million in an initial public offering.

Seres is working on a pill version of FMT for C. diff. It showed in an early trial to cure the infection in 29 of 30 patients, and started the next stage of studies in May. The experimental medicine, SER-109, was just granted breakthrough therapy designation by the FDA, designed to streamline a potential path to market.

It's not just start-ups pursuing the microbiome. Health giant [Johnson & Johnson](#) in February established a microbiome institute, which partners with academic researchers and biotech companies working in the space.

"The science around the microbiome is very quickly emerging, but at the same time is demonstrating some very essential links with some specific diseases such as autoimmune diseases, cancer, diabetes," said Dirk Gevers, global head of the project at J&J. "At the same time it's also opening up an entirely new way of looking at drug development."

Gevers said a better understanding of the root cause of diseases may enable an approach, through the microbiome, to prevent them. He cited the potential to monitor development of the microbiome in newborn babies, "so when you see the microbiome going off track, you actually are in a position then to intercept and change the microbiome to put it back toward a healthy track."

Diabetes and allergy are potential targets for that kind of disease interception, Gevers said.

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Sue Dillon, J&J's global therapeutic head for immunology, listed conditions from autoimmune diseases including plaque psoriasis and rheumatoid arthritis, to inflammatory bowel diseases like Crohn's and ulcerative colitis, asthma, diabetes and even cancer as potential targets for microbiome therapeutics.

"I think the list is very long," Dillon said. "This is the very, very early stages of what's really going to be a revolution in science and medicine."

J&J is partnered with companies [Vedanta Biosciences](#) and [Second Genome](#), as well as the Icahn School of Medicine at Mount Sinai in New York and others.

Companies are also mining the microbiome for uses beyond therapeutic ones. Cambridge, Massachusetts-based [AOBiome](#) is pursuing a consumer route, having developed a live bacterial spray it says can help users cut back on deodorant and soap. The product, AO+ Mist, contains ammonia oxidizing bacteria that the company calls AOBs.

"They convert ammonia to nitrate and nitric oxide," CEO Spiros Jamas

said in an interview at AOBiome's offices, which are decked out in gear touting the benefits of bacteria, including shirts that say "bacteria is the new black; wear it every day."

"The company's hypothesis is that humans evolved with AOBs as a natural component of our skin," Jamas said. "And really only in the last 50 years, with the advent of cleaning and hygiene routines and antibacterial products, we've lost AOBs from our skin and also lost a key regulatory element from our skin microbiome."

The company has thousands of customers using the product, said Jasmina Aganovic, general manager of consumer products. It was backordered for several months after *The New York Times* magazine [featured a story about it](#) on its cover in May 2014. A one-month supply costs \$99.

Sunny Bates is a regular user. She says the AO+ Mist has enabled her to cut out deoderant.

"It took a couple of days to adjust," Bates said in an interview in her Manhattan apartment.

Therese Lichtle, a self-proclaimed germaphobe, is also a convert. The 50-year-old said she feels she doesn't sweat as much after using the spray and no longer uses cosmetic products. AOBiome is also pursuing uses in acne and other skin disorders.

As for Gurvich, she says she hasn't felt any symptoms of *C. diff* since her transplant procedure two months ago. Oneto is planning to start a clinical trial of FMT in irritable bowel syndrome, in concert with Montefiore and Yale medical centers and the nonprofit OpenBiome, which facilitates donations for FMT.

"I didn't expect to be doing this after my Ph.D., mailing poop out to hospitals," OpenBiome founder Mark Smith said by phone. The company has a stringent screening policy for donors, whom Smith says have now helped treat more than 4,500 patients at more than 300 hospitals in 47 states and five countries through FMT.

To be sure, the field is young and the science is still evolving. The FDA has tentatively given the green light for FMT in *C. diff*, and OpenBiome says it's involved in other clinical trials for ulcerative colitis and Crohn's as well. Plus there's the yuck factor—which Gurvich dismisses.

"I was not grossed out by that," Gurvich said. "The truth of the matter is that when you're sick, you would take any means of getting better."

—With reporting by CNBC's Jodi Gralnick.



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Reporter



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