

Wonder cure for gut: FDA allows fecal transplants

October 31 2013, by Carol M. Ostrom

Conventional wisdom says it takes 15 years for a medical therapy, once proven safe and effective, to be widely accepted by the medical profession.

In the case of one particular treatment, however, a growing cadre of doctors and [patients](#) turned conventional wisdom on its head, enthusiastically adopting a [procedure](#) before the evidence was in - so enthusiastically, in fact, that the Food and Drug Administration was recently forced to rescind its restrictions.

The treatment, now widely employed against recurrent attacks by a nasty intestinal bug known as *Clostridium difficile* and tested on Crohn's disease and colitis, is one you'll likely never see advertised on TV: the fecal microbiota transplant, politely known as the FMT.

Acronym or no, a rose is a rose is a rose, and a poop transplant, likewise.

Born of desperation on the part of patients and their doctors, an infusion of fecal material from a healthy donor has risen from folk wisdom to near-mythical status. Despite a certain "yuk" factor, an increasing number of patients have undergone the procedure in top hospitals, clinics and even in their homes, doctors say.

In a first-of-its-kind research study just concluded at Seattle Children's, the treatment significantly helped kids with Crohn's.

So far, the transplant's biggest success has been against the bug commonly known as *C. diff*, which now strikes upward of half a million people a year in the U.S. With the emergence of a particularly virulent strain, it has been deemed a "global public health challenge" by the Centers for Disease Control and Prevention.

The infection can cause relentless diarrhea, a potentially life-threatening complication, particularly for older people. This notorious bacterium typically proliferates when a person's natural intestinal bacteria - which normally outnumber and marginalize such bad actors - are laid low, most often by antibiotics.

In theory, FMT repopulates the compromised intestine with a healthy mix of fecal bacteria that kicks the bad bugs' butts. But until recently, with scant first-rate research, doctors intent on helping their patients had to rely mostly on anecdotal evidence.

"I became one of those desperate doctors," said Dr. Christina Surawicz, a gastroenterologist at Harborview Medical Center, who first used the treatment in 2004. No conventional medications were working for her patient, who had been miserable for nine months. "I took a leap of faith."

The transplant, taken from the patient's husband and given via colonoscopy, worked. Surawicz, long a researcher of *C. diff*, wasn't the first locally to do such a transplant, but became known as a pioneer. Around town - and the country - a small underground of gastroenterologists and infectious disease specialists began experimenting with the procedure, making up protocols as they went.

There was indeed a "yuk" factor, particularly in the early years. "Most people would say, 'You're going to do whaaaat?'" recalled Dr. Francis Riedo, an infectious-disease specialist at EvergreenHealth in Kirkland.

"But by the time we saw those patients, they were so miserable, so desperate, they would try anything."

Some hospitals wouldn't allow the procedure, so doctors instructed their patients on home administration through an enema - likely a less-than-ideal method. And there was wide variation in methods, with some doctors favoring tubes through the nose to deliver a slurry to the upper gastrointestinal region, while others favored the lower route.

Early this summer, the FDA firmly declared poop a "biologic" and warned doctors they must acquire an "Investigational New Drug" research permit to administer it.

Doctors pounded the FDA. They complained that having to go through a cumbersome research process threatened to add costs and limit access for seriously ill patients. Also, more might be tempted to try the procedure on their own, without such safeguards as donor testing.

Just two months later, the agency relented, saying doctors didn't need a permit to administer a fecal transplant to patients with recurrent *C. diff.*

"It's clearly the single most effective therapy for *C. diff.* Nothing comes close to the rate of fecal transplantation - nothing," says Riedo.

Who woulda thought a poop transplant would become so popular?

Linda Bollen, 71, of Bothell, would like a chance to explain why.

Her bout with *C. diff* began in April 2011, when she contracted pneumonia and ended up in intensive care and later a rehabilitation facility. Throughout her ordeal, she needed multiple doses of antibiotics.

When she came home, *C. diff* got the best of her gut.

The diarrhea began in June, and then came doctors and more doctors, drugs and more drugs - including very expensive drugs. She ended up in the hospital again, dehydrated from the diarrhea. Then pneumonia, again. And C. diff, again.

Finally, nearly a year later, her infectious disease doctor at Evergreen proposed a radical shift in treatment.

Desperate, she agreed. "I said, 'Hey, I'll do anything to get rid of this,?'" she recalled.

"I've been fine ever since - not even a cold," says Bollen. "I would totally recommend this for anybody - 100 percent. You feel better immediately."

Another doctor told her some patients say they'd rather die than have "that" done. "I don't understand that. If it's from a loved one, what's the difference?"

Her husband, she said, was happy to donate. "He'd seen what I've gone through."

And she couldn't resist making the obvious joke to her doctor about what she was finally happy to take from her husband.

The idea of recolonizing a troubled intestine with someone else's "good" bacteria is far from new. In *The American Journal of Gastroenterology* last year, a researcher in China noted evidence of its use there in the fourth century, for patients near death from food poisoning or severe diarrhea.

At about 100 trillion per person, the microorganisms making up the "gut flora" vastly outnumber the body's cells. New recognition of their power

has prompted research into their relationship to obesity, allergies, asthma and a variety of inflammatory and autoimmune disorders.

At Seattle Children's, Dr. David Suskind has just finished the first FDA-approved studies of fecal transplants in children with inflammatory bowel disease. Those with ulcerative colitis didn't see much improvement, but seven of 10 Crohn's patients went into remission - results similar to those of drug treatments with more potential side effects.

Now, Suskind says, "I think there are very many more important questions to answer."

For *C. diff*, the broad acceptance of fecal transplants - and the successful results - have been steadily building. In 2008, an episode of "Grey's Anatomy" featured a transplant.

In 30 years of practice, Surawicz said, no other treatment has spurred so many patients to tell her "You saved my life." One mother kept emailing about her daughter, a former patient who is now 19. "She says, 'She is so happy. ... She can go camping now. She's moved on with her life.'?"

Research on fecal transplants has moved on, too. By 2011, combined results from scattered studies showed 92 percent success in patients with recurrent infections that had failed to respond to drugs. In January, a study in the *New England Journal of Medicine* seemed to tip the scale, reporting FMT was "significantly more effective" at treating recurrent *C. diff* than the most powerful drug.

At this point, there are many unknowns, and some experts have urged caution. There is little agreement on best methods for the procedure, and long-term consequences are unclear.

The proliferation of websites with DIY instructions, such as thepowerofpoop.com and fecaltransplant.org, also worries doctors.

Most have no doubt dangers lurk: A would-be donor, typically a family member, might harbor unrevealed disease, for example, or a do-it-yourself job by someone with *C. diff* might contaminate surroundings. And for some patients, infusions could be dangerous.

Even in medical centers and research studies, different routes of administration - top and bottom - have been used, and volumes of transplant vary, as do preparation methods. While matching isn't required for this transplant, most centers test donors for HIV and hepatitis. But there's no standardized list of tests.

Like [doctors](#) elsewhere, Dr. Michael Gluck and Dr. Margot Schwartz of Virginia Mason Medical Center had to develop their own protocols to ensure safe preparation, adequate donor screening and consistent procedures.

For now, the FDA's recent decision on *C. diff* treatment opens the door to experimentation with a simple caveat: Doctors must tell patients the procedure is investigational and could have risks.

Of course, the best thing would be to never get *C. diff*. And maybe the next best would be to take a pill instead of getting a transplant.

At Bastyr University, Joshua Goldenberg led a team analyzing previous studies of probiotics for *C. diff* prevention, covering more than 4,000 patients. The work found probiotics significantly reduced the risk of [diarrhea](#), although patients still had *C. diff*. And he can't answer the question he's most asked: Which of the gazillion probiotics on the market is best?

Goldenberg, who graduated from Bastyr's Doctor of Naturopathic Medicine program in June, is not anti-antibiotics. But as a former microbiology student, he believes human guts need a good supply of microbes to be healthy.

It seems, at least in this regard, the conventional and alternative worlds of medicine are coming together. To foster that collaboration, Goldenberg will soon open a practice with an M.D.

In the research world overall, poop is gaining new respect. Surawicz notes the development in Canada of a synthetic stool mixture called "RePOOPulate," and a fecal pill, a gelatin-coated capsule containing donor bacteria.

Poop as a [treatment](#), it seems, is gaining traction, and Surawicz is hopeful that newer methods will replace the "very crude" procedures used today. "I don't think in five years we'll still be doing this," she predicts.

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