Interview with Dr David Shepard M.D.

RDS Infusions is a gastroenterology clinic that assists patients with Fecal Microbiota Transplantation (FMT). R. David Shepard, MD. Is the head of RDS Infusions. He is Board Certified in Gastroenterology and has been practicing in Tampa, Florida, USA for 25 years specializing in Inflammatory Bowel Disease.

What kinds of patients does your clinic see?
Our clinic treats patients with C. Diff, UC, Crohns, IBS, Heartburn, Liver Disease, and Pancreatitis. FMT comprises 20% of the practice and is increasing. We use FMT for the treatment of drug resistant C. diff., ulcerative colitis, IBS, and chronic diarrhea.

How long have you been doing FMTs and how many have you done?
We've assisted with more than 100 FMTs over a two-year period. C. diff. and UC make up the vast majority of our FMT patients.

What kind of successes and non-successes have you seen with FMT?
We've had excellent results with C. diff. and UC. Our success rate for the treatment of C. diff. is nearly 100% and for ulcerative colitis it is in the range of 70 to 80%. We've also seen IBS-D predominant patients reduce their diarrhea significantly. The use of FMT to treat Crohn's patients has been disappointing.

We've assisted patients with FMT to tackle conditions such as MS and constipation, but the numbers are too small and it's too early to know if its will be successful. We've also received enquiries regarding Autism, Parkinson's disease and obesity.

What has been your most striking success?
The most striking success has been a young woman with UC. She was at university and quite debilitated by the disease, which was causing social issues. She has now been in remission for two years after receiving only one FMT from her mother. She has gone from 15 bloody bowel movements daily to one or two normal BMs. Her father reports the treatment has been "life-changing."

We've successfully treated a 60-year-old man who had been on and off antibiotics for C. Diff for 9 months. He couldn't sleep; he was underweight, ashen and gray. When I met him he'd been hospitalized on multiple occasions. He said to me: "If you can't cure this I want to die." Yet he achieved remission after a mere two FMT treatments, and is still well six months later.

These kinds of success stories keep us going.

What kind of donors work better?
We like to use donors who have previously been successful with other patients. We like our donors aged 20-50, free of antibiotics for six months, and ideally medication and gluten free.

Do you do FMT Top-down or Bottom-up?
Both. Some resistant cases of C. dif. and UC require top-down via gastroscope infusion.

Does Top-Down aggravate SIBO?
We have not experienced this yet.

Have you used Frozen FMT?
Yes, we've seen good results from frozen FMT. We freeze it in a small cylinder, then cut it in small pieces to fit in a capsule.

What is your view on antibiotics prior to FMT?
We feel it is important to reduce bacteria in the gut before infusing. That's with first infusion only. After you've done FMT it is very important to avoid them.

How long should a patient continue FMT?
C. diff. generally only requires one or two treatments. UC needs more depending on the individual. We recommend to gradually decrease to weekly, then monthly over a couple of years until a normal colonoscopy is achieved.
How long should medications be continued once symptoms subside?

We try to slowly wean the medications. Everyone is different. Not everyone with UC can completely come off of all medications.

Is it ok to do FMT during a flare?
During a mild flare it's ok. But with a severe flare we prefer to control it with a short course of steroids.
Where FMT doesn't work in a patient or only works for a while, what factors do you believe perpetuate the dysbiosis?
With UC it can be the severity of the disease, or the FMT comes onboard too late and too much damage has been done. Unfortunately with UC, some people seem genetically programmed to lose their colons and there is nothing we can do to help.

What side effects have you observed from FMT?
Bloating is the only side effect I've seen to date.

What do you see as the risks of FMT?
The biggest risk I see is from untested donors. I had a patient who did home FMT and picked up a parasite from his spouse. She was very healthy and had no outward symptoms of infection. We had to treat both of them before starting the FMT again.

This is why we offer a supervised self-infusion protocol. Desperate patients will do FMT anyway regardless of the FDA. It is better that we offer the testing with advice on how to do FMT safely.

What do you think about the potential long-term risks of FMT?
FT has been used since 1958 without any documented serious side effects. However, more research needs to be done.
Why is the mainstream medical profession so dismissive of FMT? Given the success with C. diff. what's wrong with trying it for more difficult chronic gut conditions? Where's the harm?

No. 1 deterrent is the "gross factor." Without question it's the stigma.

No. 2 deterrent is the lack of controlled clinical trials. There is no incentive for pharmaceutical companies to fund them. In fact, Big Pharma will lose money if FMT becomes widely available. So that leaves the universities and not-for-profit sector and the reality is that it's a huge investment and years before anyone will recoup any money, if ever.

No. 3 deterrent is patient resistance. Patients want a pill. Although once they're really sick they don't care.

Why don't the insurance companies take on the research?

I suspect that it's not on their radar compared to cancer, heart disease, etc. However, sooner or later they'll have to pick up on this. It costs around $2,000 to have FMT compared to tens of thousands of dollars on treatments for C. diff. and IBD. One hospitalization can cost 20-30 thousand dollars, not to mention lost wages.

Do you know much about the fake poop being developed?
They sound like a fancy probiotic to me. Even with the best science we have identified only 20% of the bacteria in the gut. I have not seen any clinical trials on synthetic stool yet.

What research is on your wish list?
I would like to know if infant donors are as good as adults as they would be a safer option. I'd also like to know which stool filtration methods work best.

What have been some of the challenges of running a FMT practice?
Finding donors. Staff acceptability.

How has the recent FDA ruling affected your practice?
We've now stopped doing FMT except for C. Diff. For other conditions we have a protocol for patients to self-infuse under medical supervision. This is done in my office.

What's the best way for patients to get assistance from you with FMT?
Visit our website at RDSInfusions.com

Interview with Dr Mark Davis N.D.

In November 2011, I ran into a friend of mine, GI Dr, Glenn Eisen. He asked how my UC was. I replied that it was under control, but had really not gone into remission for four years, despite Remicade infusions and many other meds. He was not my MD, but was familiar with my case. I had had IBD since 1978. I asked him "What are the odds that I will need to have my colon removed at some point?" He did not answer directly, saying "there is hope for a new treatment being studied, fecal microbiota transplant." I went home and hit google.

My HMO Doc was open minded, but could not directly support me per company protocol. I knew that I could order screening tests on my own – but didn't want to. Like 99% of patients, I wanted a professional to guide me. I was very relieved to find Dr. Mark Davis in my hometown of Portland, Oregon, USA and was among his first FMT patients in January 2012. The procedure was a great success as I have written in my success story. Dr Davis specializes in naturopathic treatment of IBD. Up until the recent FDA suspension of FMT 75% of his practice involved FMT. I am grateful that I met him and that he has agreed to be interviewed for the launch of PoP.

How did you end up doing FMT for a living?
As a student at the National College of Naturopathic Medicine, one of my favorite professors was Dr. Seven Sandberg-Lewis, an ND with over thirty years of clinical practice. I did as many clinical rotations with him as I could, just because I liked his approach to medicine. For some reason, about a quarter of his practice is people with inflammatory bowel disease, so I got used to working with that patient population.

He usually saw particularly complex patients who were referred to him by local gastroenterologists or primary care naturopathic doctors, and I saw a lot of them have really improved quality of life under our care. We mostly used dietary interventions, botanicals, supplements, homeopathy and probiotics. Although we were able to help a lot of them, we certainly weren't able to help all of them, and so I was always poring through the literature to see if I could find anything else that could help our patients.

One of the things I happened upon was Thomas Borody's 2003 paper, "Treatment of Ulcerative Colitis Using Fecal Bacteriotherapy." It described six patients with active ulcerative colitis who had "failed maximally tolerated standard UC therapies" but who became asymptomatic and able to withdraw from all meds after five fecal slurry retention enemas preceded by antibiotics and an oral bowel lavage. After we confirmed with the Oregon Board of Naturopathic Medicine that FMT was in our scope of practice, we tried it with an ulcerative colitis patient who saw a lot of benefit. When I got my degree and could practice on my own, I realized that (at that time) literally no physician in North America was offering FMT for IBD, so I wanted to fill that niche.

What conditions have you treated with FMT and what were the results?

C diff colitis, post-*C diff* colitis, UC (including ulcerative proctitis all the way through ulcerative pancolitis), Crohn's disease, microscopic colitis, IBS-C, IBS-D, IBS-A, chronic constipation, intestinal candidiasis, multiple sclerosis, autoimmune lymphadenopathy, idiopathic abdominal pain following long-term antibiotic use, probably others. I've pretty carefully tallied my results with colonic inflammatory bowel disease (see table) but haven't carefully recorded results for others.

I've used FMT with about twenty-five patients with colonic IBD and about thirty-five patients with other indications. I used to cite a higher number because I would count people whom I'd just sent my protocol without having met, but since they aren't my patients and I don't follow their outcomes very well, I have stopped doing that.

	total #	complete no relapse	complete with relapse	partial no relapse	partial with relapse	none	no symptoms to start
Ulcerative Colitis	18	5	2	3	3	2	3
Ulcerative Proctitis	3					3	
Micro Colitis	3		1	1		1	
Crohns Colitis	1	1					
Total #	25	7	3	4	3	6	3

How do you control the quality of your donors? What risks do you see with donor banks?
Before I was put on hiatus by the FDA, I was using four active donors (and had screened many more). I started out screening people according to the Fecal Microbiota Transplantation Workgroup protocol, and after a few months added on a PCR stool test that looks for and measures relative amounts of certain organisms by looking for their DNA.

I remember when I got the test back for my first set of donors – despite having been screened with a normal parasite test (an O&Px3), one was positive for *Enterobius vermicularis*, the human pinworm! I had to call up the three patients I'd used that donor for thus-far and offer to screen them

for free. Pinworm is generally harmless, and none of the three patients turned out to have it, but it highlighted that there is so much going on with the fecal microbiome and we cannot realistically test all of it.

The risks I see are that there could be an organism in the donor feces that we don't test for or don't find despite testing, which could be harmful to the patient. Some people use family members and don't screen them using labs as long as they have a clean health history and no risk factors, but I had someone screen a healthy young friend who turned out to be positive for *C diff* despite having no GI symptoms (which occurs in about 3% of young people if I remember correctly). I tried to control donor quality by not only making sure they had a clean health history and no risk factors, and doing the lab testing, but asking them to let me know if they acquired any risk factors (a new intimate partner, travel abroad) and re-testing relevant factors sooner than I otherwise would have if indicated.

When people around the world have contacted me interested in treatment, I've generally encouraged them to seek out a local eligible donor, work with a local provider to provide antimicrobial pretreatment if it's indicated, and try self-preparing and self-administering at home. Dozens of people have come to see me largely because they simply do not have a healthy person who is willing and able to be a stool donor for them. It's been really rewarding to have maintained a donor bank for the sake of those people.

Prior to the FDA suspension I was administering FMT via enema, so aside from the clinical experience & knowledge I've accumulated and the training and scope of practice to prescribe antibiotic pre-treatment, I wasn't actually doing anything that someone with an eligible donor can't do at home.

The only other North American provider I know of who's used a donor bank system is Alexander Khoruts, who has published about using his system to treat *C diff* colitis. Dr. Khoruts has run his as a volunteer donor system, whereas I've been compensating my donors. I figure I'm asking them to eat certain foods, avoid certain foods, get regular testing, keep me in the loop about new intimate relationships, international travel, etc. I think his system does avoid certain ethical complications, but my system worked well for me before I suspended the program because of the FDA.

Which is better, fresh or frozen?

For most people I think frozen is fine (although I personally have only banked fecal slurries at significantly below -30C, so there isn't a lot of crystal formation and most home freezers only go to about -20C). For some people I think fresh may be necessary or better, but I don't know how to identify those people.

How long is frozen good for?

According to a paper by Alexander Khoruts, fecal slurries that have been centrifuged and reconstituted, frozen at -80C and thawed seem to be just as effective for *C diff* colitis as fresh ones. I've used quite a bit of frozen in my practice (without the centrifuge part, but stored at below -70C) for up to eight weeks, and I've seen frozen give UC patients a lot of benefit.

What is your view on anti-biotics prior to FMT?

It's really hard to know the answer and we simply don't know without an RCT to tell us. My clinical feeling is that not everybody needs antibiotic pre-treatment to have a durable good result but some probably do.

Which is better? Colonoscope or enema?

I've seen enema-administered FMT be a complete life-changer for some of my IBD and *C diff* colitis patients, so that method (which is the lowest cost and lowest risk) seems effective for at least some. I worked with one man with UC who didn't seem to respond to enema-administered FMT at first, and the fiber foods I was recommending really seemed to flare him up. I referred him to a gastroenterologist who delivered an initial bolus of fecal slurry via colonoscope, then he followed up with enema-administered infusions, and he had a great outcome. For him I think the colonoscopic dose was a necessary part. For some of my patients who didn't respond to enema-administered FMT, I wonder if they would have responded to colonoscopically administered FMT.

Does donor diet matter?

The donor is donating his or her colon flora, so we want him or her to have good quantities of healthy, diverse colon flora. I encourage donors to eat moderate to high amounts of a diverse range of fiber foods at all or most meals, and to stay well-hydrated.

If a recipient has allergies should the donor change diet?

Any foods that provoke true allergies (an IgE reaction, characterized by hives, swelling, redness, shortness of breath) in the patient should be

strictly avoided by the donor for at least five days before the first donation. Foods that provoke a food hypersensitivity reaction (usually an IgG reaction, characterized by a flare of symptoms in other organ systems) should probably be avoided for five days before starting to donate. Carb and fiber foods that cause symptoms due to their effect on the patient's gut flora do not need to be avoided.

How long should a patient continue FMT?
For IBD I say until symptom free then at least weekly for eight weeks minimum, or until colonoscopy with biopsy shows no macroscopic inflammation and no microscopic inflammation in the unprepared tissues. My protocol states ten consecutive days with eight subsequent weekly infusions.

How long should medications be continued once symptoms subside?
Opinions differ and it depends on the condition and the medication. Although I use some pharmaceuticals in my practice that is not my area of focus and I prefer to let gastroenterologists take the lead on those kinds of issues.
Some doctors say colonic IBD patients should continue with oral mesalamines for life to decrease chance of colon cancer, even when they are asymptomatic and there is no inflammation apparent through endoscopy. Other docs say that the colon cancer risk comes from inflammation so if there is no inflammation we can decrease the meds. Patients who seem to be benefitting from regular Infliximab (Remicade) infusions are particularly hard to take off, because if they go off then on again there is less chance of it benefitting them and more chance of them developing an allergic reaction to the drug.

Where FMT doesn't work in a patient or only works for a while, what factors do you believe perpetuate the dysbiosis?
There are several possibilities: the symptoms aren't caused by an underlying colon dysbiosis, the donor doesn't have the necessary microbiome to benefit the patient, there are errors in preparation or administration, or something is preventing the donor microbiome from taking over (large amounts of retained stool in the colon, redundant colon, etc.)

In my experience and in the literature, FMT for a simple infectious *C diff* colitis is generally long-lasting or permanent. The fact that the durability

of the treatment is much more variable for UC, Crohn's colitis, and other conditions speaks to the different nature of those conditions. Infectious colitis is largely about the pathogen and somewhat about the rest of the microbiome. With UC, Crohn's disease, certain types of IBS which seem to respond, I think there's not only a microbiome component but mostly likely a genetic and/or epigenetic component as well, so a variety of external factors could trigger this predisposition to disease. There are stories about a round of antibiotics or an acute gastroenteritis triggering relapse after successful FMT, and there are stories about it seeming to just… wear off after a while. In those cases I imagine that there's a remnant of the sufferer's native colon microbiome that was originally suppressed, but re-grows and triggers the immune response.

Why is the mainstream medical profession so dismissive of FMT? Given the success with C Diff what's wrong with trying it for more difficult chronic gut conditions? Where's the harm?

In my experience the mainstream medical profession has been quite interested in FMT, particularly gastroenterologists. The reason to question the use of FMT is that it hasn't been rigorously studied in large randomized controlled trials (RCTs). That's generally the route to getting a therapy accepted for mainstream use. Remember Rofecoxib (Vioxx)? It was an NSAID that was pulled from the market for increasing the user's chance of a heart attack. There was an increase of three heart attacks per thousand people that were on Rofecoxib for a year.
What clinician sees enough people and is scrupulous enough about their record-keeping to be able to notice that of the thousand people they've put on Rofecoxib in the past year, a few more have had heart attacks than otherwise would have? That kind of information can only come out through large RCTs. I've used FMT with about 100 people. Dr. Borody has used FMT with maybe 2,000 people over his career. Would we as clinicians be able to pull out some tiny increases in a bad outcome? Doubtful.

The FDA thinks it's their job (and I applaud them for this) to ask clinicians to keep information in a very systematic way about who they are treating, how they are performing the procedure, what kinds of benefits they're seeing, and what kinds of adverse events they're seeing, so they can tell the American people how effective or dangerous this procedure is. The FDA regulation of FMT has been crippling to my personal practice (which was

about 75% focused on FMT), but I think they're really just trying to do their job.

What's the harm? I can only report one detectable adverse event from my own practice. A young man with IBS-A (alternating between diarrhea and constipation) came to see me at a time when he was maybe leaning a little bit towards constipation but still having a BM most days. His chief complaint was constant abdominal pain. He had five consecutive infusions which did nothing to improve his abdominal pain but sent him into a round of 10-15 urgent, watery BMs per day, which apparently self-resolved over the course of about three months. That's the only adverse event I've been able to detect in my practice, but are there more subtle adverse effects that I was unable to detect? Who knows!

Now, all that being said, if I had my druthers, I'd still be able to perform FMT without FDA oversight, not only because it's how I make a living but because I personally as a patient am willing to take (apparently) slight risks when there is (quite possibly) a lot to gain. I know others have the same medical aesthetic and I wish that I could legally work with that group of people, but I can't because of the type of mandate the American people have given the FDA, or at least the way the FDA interprets that mandate.

What are the potential long term risks of FT?

No one knows. None have been hypothesized so far as far as I know.

It seems that the only therapies promoted by gastroenterologists for IBD are drug therapies. Are they really that brain-washed by the drug companies?

I don't think of it as brain washing, it's just their medical culture. If you want your bicycle fixed, you go to a bike shop, not an auto mechanic, because that's what they do. Gastroenterologists are primarily trained to diagnose disease and heal and/or palliate using drugs and surgery, maybe a few dietary interventions. So if you want that, you go to them.

If you want more in-depth nutritional suggestions, try a nutritionist or an ND. If you want more extensive natural therapies like botanical medicines, supplements, hydrotherapy, etc, go see an ND. As for FMT, its modern usage has been pioneered by gastroenterologists and other MDs – that minority who prioritize potential benefit over unknown risk.

What research are you following right now and when will results be known?

I periodically go to clinicaltrials.gov and search for “fecal microbiota transplantation” and “fecal transplant.” As of this interview there are over a dozen studies the FDA has approved using fecal slurries or standardized fecal microbe culture slurries to treat UC, relapsing *C diff*, Crohn’s disease, and Type II Diabetes.

Christine Lee is an infectious disease MD in Toronto who is asking really interesting questions–one trial she’s doing is comparing fresh to frozen fecal slurries for *C diff* colitis, which I’m particularly interested in because her freezing technique is almost identical to mine. She’s also comparing fecal slurry enema vs. placebo enema for UC, with a well thought out double blinding technique.

There’s a Dutch group looking at inserting fecal slurry into the small intestine of people with UC, prepared either from a donor or from the patient’s own stool. If I had been on their institutional review board I might have questioned the safety of placing bacteria from the large intestine of others (or one’s self, since they are hypothesizing that there may be a problem with the patient’s large-bowel flora) into the small intestine, which has a totally different bacterial community.

What research is on your wish list?

Antibiotic pre-treatment vs. placebo pre-treatment for UC, FMT for metabolic syndrome, studies for IBD with long-term follow-up, FMT for *C diff* colitis as a first-line intervention.

Are you collaborating with other FT providers, if so, how?

I had talked with Christine Lee in Toronto about some collaboration, but since I’m not affiliated with a large teaching hospital I didn’t have the resources to be a site in her multi-site trial. I’ve corresponded with Thomas Borody, Lawrence Brandt and Alexander Khoruts about their techniques, but haven’t done any collaborating with them.

As a practitioner working in a fringe area of medicine, how do you manage liability in your practice?

I have (very expensive) malpractice insurance that specifically states I am covered to perform FMT via enema and colonoscope.

What do you enjoy about your work? What are the frustrations?

The thing I enjoy about my work is the extent to which people get better. I love it when people go from intense symptomology to feeling great as a

result of my interventions. The converse it true, too – it can feel really frustrating when I'm doing my utmost to help someone get better and they just don't improve at all.
What do you tell people you do when they ask you at a dinner party? What do your kids tell their friends Dad does for a living?

At dinner parties I say I'm a naturopathic physician, and if they ask for more detail I tell them we should talk about it after dinner. All kidding aside, although I try not to talk about my work over meals I'm usually quite eager to talk about what I do for a living.

I just went and asked my eight year old son and my six year old daughter what I do for a living. They both said "you're a doctor!" I said "what kind of doctor?" and my son said "a poop doctor!" and my daughter said "I don't think he's a poop doctor anymore." In reality they both know that I'm a naturopathic doctor who uses (or used to use) a lot of fecal slurry enemas as part of my practice.

Dr Mark Davis offers consulting in naturopathic treatment of digestive health issues and specialises in IBD. For further information and pricing contact The Bright Medicine Clinic

Interview with Taymount Clinic's Glenn Taylor

Glenn Taylor is Clinic Director & Food Bacteriologist at Taymount Clinic in Hitchin, Hertfordshire, UK. Taymount is a natural medicine clinic that specialises in health conditions influenced by the functions of gut flora.

What's your background, and how did you come to run a fecal transplant clinic?
Firstly, could I make a distinction – at the Taymount Clinic we perform fecal microbiota transplants, and not a fecal transplant – which I will expand upon later.

My personal history is in engineering and it was through my wife's work as a Doctor of Naturopathy, specialising in food and digestion, that my interest in biology was re-kindled. I should at this point stress, that I am a microbiologist and not a medical doctor. The reality is, that were I a doctor,

I probably would not be able to be involved with FMT – and more about that later, too.

I first got involved with digestion and colon health back in 2002 and trained up to the level of Instructor and we ran a therapist training school. From the very beginning, I was aware that cleansing a colon was not a complete treatment. It made no sense to me to be completely removing bacterial colonies from patients who had digestive problems. It did not seem reasonable to expect the gut to regulate the restoration of the microflora unaided.
I worked with various probiotics, both as manufactured and naturally occurring forms in an attempt to create a favourable environment so that bacteria would re-establish in what we would call a normal fashion. It was not too long before I realised that manufactured probiotics were only useful *whilst* they were being consumed and they didn't perform any lasting improvement.

One day we received a phone call from a young man who apologised for his enquiry, almost as if he knew it might cause offence, and he asked if we performed fecal transplants. We explained that we didn't but for the rest of the day, my mind was completely restless and I threw myself into research of how to restore the whole microbiome to an imbalanced gut. The answer was quite plain and obvious – there is only one way to fully restore the human gut microflora – the microbiome – and that is to do exactly what happens at birth, the gut is inoculated with a living microbiome from a healthy donor.

What services do you offer patients?
We specialise in FMT so that is the main service we offer. We offer lab tests relevant to gut health and food allergies.

What kinds of patients does your clinic see?
We are seeing an increasingly broad range of patients from all walks of life and from all over the world. They all have dysbiosis in common, but for a variety of reasons and in a variety of expressions. From IBS, to IBDs, to Neurological conditions and even TMAU. The more we learn, the more we realise that we simply do not know the limits of conditions that may be influenced by changes in gut microflora. So when I receive an enquiry for an obscure condition, my initial response is "Why not?" We are in a

pioneering developmental stage and who are we to decide what the limits are.
How long have you been offering FMTs and how many have you done?

We have been quietly working to provide FMT for almost three years on a very limited basis. Then word of our existence hit the internet probably from chat forum sites and word of mouth. We started slowly and we are now treating between 6 and 8 patients per month. We have seen over 40 patients so far this year alone, of varying lengths of programs, but this roughly equates to some 400+ procedures.

What kind of results have you seen with FMT?
It ranges from no effect whatsoever to complete remission. But the outcome depends on the patient's presenting condition. It ranges from disappointing to truly rewarding and remarkable. Some are slow to respond, some respond very quickly. As well as symptom relief, we have seen great changes in mood, behaviour, aspect and energy. Appetites return and food allergies seem to resolve sometimes very quickly.

What has been your most memorable success?
The one that sticks in our mind most of all is the 84 year old lady who by her own admission, was on her last legs with recurrent C.diff infection at 6-weekly cycles which were getting progressively worse each time. She had actually asked her doctor not to resuscitate at her next flare of this completely debilitating disease. Her next flare was due the week after her clinic booking.

She was carried into the clinic by her family and expressed very poor communication; little eye contact and very pale and weak.

We carried out 3 implants over three consecutive days. Each day her energy and activity increased in leaps and bounds. On the third day, she came up the stairs unaided and said we had to hurry up as she was off to the pub for lunch afterwards! Her son said she would not stop talking now, what had we done?! She had improved eye contact, energy levels, colour in her face and brightness of eye. The staff on our front desk remarked on her dramatic and noticeable improvement.

She remains free of c.diff and in her own words, is "…thrilled."

Where do you get your donors and how do you screen them?
You have to kiss an awful lot of frogs to find the Princes. It is purely by word of mouth. The testing is extremely expensive because it is not just a case of finding them, but to ensure that they remain appropriately clear to continue being donors. So we have to test, every one to two months to check levels and to sometimes swap transplants between donors to make sure that they are all producing the maximum amount of beneficial bacteria. We should point out at this stage that we use the Standardised Donor system, we do not support patients using their own donor. Our experience and research shows that filial and spousal donors carry the risk of already having the same deficiencies in their microbiome as the patient.

We take stool and blood tests. We utilise very respectable main-stream testing laboratories using the latest qPCR assay techniques. There is a formidable list of the communicable conditions that we test for rigourously.

Do you think donor diet matters?
Absolutely. Our donors are coached to eat the best organic diet, high in fruits and vegetables and pasture-fed animal products. They eat high fibre and eat natural sources of probiotics, supplementing with kefir and probiotic yogurts on a regular basis.

Without the right diet, the beneficial bacteria would not thrive. The microbiome is like the most exotic pet shop in the world; if you bought a pet, you would ensure that you were feeding it properly. The same goes for the gut microflora, which individually thrive on particular food groups; absence of these food groups results in the absence of a bacterial group.

Along with the diet, it is important that the donor does not smoke – all the pathogenic smoking debris gets transferred into the swallowed mucus and ends up in the digestive tract to be excreted in the feces.
We would also not use a donor who drank a lot of alcohol for obvious reasons.

Do you do FMT Top-down or Bottom-up?
We do bottom up. The top-down application via a naso-gastric tube is somewhat risky in our opinion. Once a stomach is loaded with something it might not want, it has a habit of contracting and sending the contents back p through the throat and mouth. Vomiting in this case would be

extremely unpleasant and in the event of choking and inhaling some fecal matter, this could be potentially fatal. I know the naso-gastric tube is intended to pass through the stomach and out through the pyloric sphincter, actually into the duodenum, but there is a chance the stomach could back-fill anyway, and then want to empty. These are colon-resident bacteria, so we feel that they should be deposited directly into the colon. We just feel that it is safer going into the sigmoid and descending colon and depositing the implant in that area instead. We don't like to describe our actual method as we fell this to be a clinically confidential matter (a trade secret if you like).

Have you used frozen FMT? Do you think it is as good as fresh?
We initially used fresh stool, recently processed and refined and extracted, but we found that the timing was fraught with possible problems, and our donors cannot always perform to a tight patient schedule. An element of performance anxiety even crept in! Seriously, we feel that the only safe implants are ones stored in laboratory Ultra-Low Freezers (-86°C) between two tests. Once you take a battery of screening tests, you know your donor material is starting off clear of disease, but it is an unknown just when a disease or infection can step in. So the only safe implant is one which is taken and stored between an opening test and a closing test after an interval – say one to three months. If the donor fails the closing test, then all those implants are scrapped. How else can you be sure your donor material is completely free of any communicable disease? Using fresh is just not reliably safe, in our opinion.

How long does stool stay fresh once exposed to air?
We do not expose our donor material to air. It is delivered into a de-oxygenated saline solution (another trade secret) and is processed using nitrogen to keep the obligate anaerobes safe from their undesired oxygen environment. We then centrifuge and rinse the bacterial "pellet" with more de-ox saline, which allows us to extract the bacterial colonies almost clear of debris and waste products. If you consider that fresh donor stool contains things like: mucus, bilirubin (old red blood cell debris), epithelial cells (old digestive tract skin cells), metabolic liver waste as well as old food debris, nasal and bronchial mucus laden with environmental pollution… there is a lot that you would not want to have implanted. So we have perfected this refinement procedure to extract the Microbiome itself; we then add a special safe anti-freeze protection fluid and place it in the Ultra-Low freezer. This is then stored at -86°C to await the closing tests for that

period. It can safely be stored at this temperature where it will stay good for up to 5 years. This microbiome extract actually doesn't even smell very much, unlike the raw stool, so this is a much more aesthetically acceptable entity altogether.

What is your view on antibiotics prior to FMT?
We feel that it is only really necessary for patients where they have C.diff infections and then only to reduce the microbial load so that the FMT implants don't have quite so much to do. It does seems that it is antibiotic over-use which eventually leads many patients to seek FMT to restore their somewhat ravaged microbiome.

If we feel that a patient is suffering from an active infection, we refer them to their doctor for the appropriate treatment first as we see FMT as a restorative rather than a curative.

Again, it is an individual case-by-case situation.

What side effects have you observed from FMT?
During the program, there are a lot of changes going on in the gut and this can be experienced as increased gas, diarrhoea or other disturbances. We often warn patients that they may feel a little strange as the "germ warfare" going on in the gut settles down with the new microbiome.

As for side effects from the treatment in terms of unwanted effects, we have not experienced any adverse effects from FMT and to date there remains no reports on such side effects. It is currently regarded by its medical proponents as one of the safest treatments available.

How long should medication be continued once symptoms subside?
This is a matter strictly for the patients and their prescribing doctors. We can never tell patients to reduce or stop their prescribed medications. Obviously, if symptoms start to subside as remission occurs, then the prescribing doctors can decide if the dosage can be reduced or discontinued, but this is not for the clinic to indicate.
What do you see as the risks of FMT?

The only risks we can see is that people will expect it to be the instant miracle salve which will end all their problems. So over-expectation is a real risk. It is totally safe, *providing the proper donor testing is done at*

intervals and implants used from the period between successful tests. We just worry that people expect this to act like a medicine or a magic salve to heal in short times. This is a gentle, non-dynamic and normalising treatment. It is not a miracle cure, it simply resets the bowel flora to that which should be there and which would have been there in a healthy person.

It takes times to get chronically sick, with all its attendant changes and degeneration, so it takes time to gently and naturally re-establish the normal environment and rebuild healthy tissue where previously there was damage and inflammation. It takes time, and we never know how much time as each person is an individual and their condition will respond individually.

Speaking of the risks in a more general sense, there is the worry that colon hydrotherapists, beauticians and hairdressers will regard FMT as a great money-making adjunct to their colon hydrotherapy business. We dread the awful mistakes that will be made when people try to cut corners, save money and increase profits by reducing the testing or eschew it altogether. Then someone will catch something unpleasant and the whole FMT treatment program will come under strict regulation. If this makes it safer, this will be a good thing, but if it makes it harder for patients to find and obtain and harder for dedicated and conscientious clinicians to provide this much-needed service (like it has in the US), then this will be a shame for the people who need this and for the clinics who are providing a quality and safe procedure. Also this will threaten the future acceptance of FMT as a main-stream medical procedure.

Be aware that one particular international colon hydrotherapist member organisation (based in the UK) is offering a "Crash Course in Fecal Transplant" as an A4 laminated education card with information directly garnered from Wikipedia, and given away free with colonic disposables orders. Advice to use a family member, mix the stool with milk and use as an implant enema – just chills the blood. No mention of the removal of the unwanted waste products that raw stool contains. Until suitable licensing comes into force, it is very much a case of "buyer beware".

Why is the mainstream medical profession so reluctant to investigate and offer FMT? Given the success with C.diff, what's wrong with trying it for more difficult chronic gut conditions?

With many articles that we have seen written by mainstream medical doctors, we have found repeated reference to the “Yuk” factor. It might just be that doctors just don’t want to get involved with something as basic as feces. Doctors, during their extensive medical training, do not get enough training in the basic biological and microbiological world of the gut microbes and what feces really contain. All the while our attention is turned to the drug companies to come up with a pill for every ill, the doctors will continue to study medicine and not biology.

It might also be a factor that the major pharmaceutical companies would not want a relatively cheap and effective solution to be used to replace expensive and on-going pharmacological drugs and they will not be in favour of doctors trying anything so natural and freely available as feces to bring about the drug-free remission called health.

What’s your view on DIY FMT?
Mainly for the reasons described beforehand, we are against DIY FMT where there is not enough research or testing done. It is not safe to assume someone is a healthy donor just because they look healthy and perform daily bowel deposits. A donor may be a carrier of a disease of which they are asymptomatic and usually people with gut problems are immuno-compromised or may even be on immuno-suppressant drugs, which will make them dangerously vulnerable to infections from untested donors. Also, in the clinic, we do opening and closing tests to ensure that a whole batch of implants is safe. After all, supposing a donor unknowingly catches sometimes nasty on the way home from having their testing done? Only when two batches of tests are done are the implants safe from that period alone.
Having said all that, we do issue kits for physicians’ use. Once a patient has been to the clinic and experienced the whole FMT procedure, we are happy to let them take kits to their doctors or other health professionals for them to use to continue the treatments. This is the only DIY method we endorse.

Where FMT doesn’t work in a patient or only works for a while, what factors do you believe perpetuate the dysbiosis?
We find that often people want to be fixed so that they can go home and continue a detrimental lifestyle once more. We often tell them that if they continue to do what they have always done, they will continue to get what they have always got. It is the true definition of madness to repeat an

action and expect a different outcome. We try and educate them to realise that they hold their health between their knife and fork. What goes into their mouths will dictate their gut health.
Where there is compliance and a conscientious adherence to a sensible eating regime, relapses can occur for many reasons. Sometimes we wonder if there are some microbes who go into zygospore (like a hibernation) when conditions are not favourable to it, and then they re-emerge and begin a life-cycle all over again a bit later on. Some parasites are known to do this and we can order up specific stools tests to identify suspected parasites. The treatment for these varies according to what species is featured.

We would also repeat what we said earlier – that this is not an instant cure and it takes time for people to get sick, so it takes time for the body to heal and become well again.

Sometimes there are outside factors that will overwhelm the new gut flora, such as extra stress, bad food choices, food poisoning, travel bugs, antibiotic use, viruses etc.

We often recommend top up sessions at intervals which are individually agreed with the patients, depending on the progress they are making. Some of out patients come back for top ups every couple of months or so, just as a reassurance, like a reinforcement.

What do you think of the efforts of some to manufacture their own fecal microbiota?
Synthesized or “farmed” probiotics lack the protein marking, like tagging, that the immune system does to recognised and accepted microbes. When a microbiome is extracted from a healthy donor, his or her immune system has marked these bugs as approved and safe. They enter the host and even if they are a species which has never been in that gut before due to lifelong dysbiosis, somehow the immune system “recognises” the tagging and will respond favourably. This does not happen with the synthesized microbes, although they do some good whilst they are passing through, their failure to be accepted means they are unlikely to colonise and cannot stick around to do long term beneficial changes.
Freeze-dried probiotics also have the disadvantage that the freeze-drying process can damage their fine finger-like extrusions (pili) and this is what they use to hang on to their new hosts. They can take up to 24 hours to

“imbibe” or rehydrate and wake up and then with their pili damaged, they cannot stop themselves being excreted unceremoniously with the next bowel movement. Again, we need colonising microbes which will bring about long-lasting beneficial changes which are sustainable.

Lastly, we are aware of “Robogut” from Canada, which is the most sophisticated system yet for trying to mimic the human gut. The human gut consists of some 1150 different strains of bacteria; Robogut consists of 33. When trying to normalise the gut, should we use 33 strains or 1150?

What research is on your wish list?
This is obviously something I can’t talk about without risking spilling my candy in the lobby. We are looking at more aesthetic
delivery systemsand that is all I am prepare to say on the matter at this point!
In view of the decision of the US FDA to stop doctors offering FMT for non-C.diff conditions, where do you think the regulation of FMT is headed in the UK and Europe?

I am not going to get drawn into regional politics and the future is very difficult to predict. At this moment in time, the UK is known to have a refreshingly laissez-faire attitude towards alternative therapies. There is no doubt that with increasing success of the treatment, FMT will fall under the purview of the authorities and regulation will become a necessity. I can see this only as a good thing; I only hope that Draconian measures are not applied before sufficient meaningful research is completed.

As a practitioner working in a fringe area of medicine, how do you manage liability in your practice?
The UK market is well-served for specialist insurance companies offering cover for alternative and non-conventional health professionals
and offerboth professional indemnity and public liability insurance.

What do you enjoy about your work? What are the frustrations?
The frustrations are the patients who come to us quoting things they have read on the internet, mostly without scientific foundation. As useful as the internet is for gathering information, it also has its fair share of absolute rubbish!
What we enjoy about our work is seeing the improvement in patients, hearing them report how many different foods their previously tricky gut is

now tolerating, how well they feel and how they can hold down a job now, how they can carry out a journey without planning toilet stops, how it has changed their personal relationships, etc.
What is there for international visitors to do in Hitchin?

Hitchin is a charming and ancient market town, dating back to 1100 or even earlier. It is something of a cafe society, with many different bistros, restaurants, bars and it is lively all day and well into the evenings. It is a lively place to be and nice to walk through or sit in the cobbled town square and just watch the people go by. There is a general market on Tuesdays, a flea market and antiques on Fridays and another general market on Saturdays. So it bustles and buzzes on many days of the week. There are lots of little individual boutique shops as well as the usual large high street chains, but lots of character and history.

For entertainment, there is the delightful Market Theatre, in Sun street, it is the tiniest theatre I have ever seen, seats about 50 but has pretensions and murals to suggest that it holds many more – it doesn't! It has a charming upstairs bar with painted murals of rows of seats and theatre-goers that just aren't there! It is simply charming and the plays are good quality and it is just extremely intimate and exquisite. There is also the larger and more mainstream Queen Mother Theatre with a much larger capacity and still great live theatre, great value for money. On the Cambridge Road, the south west side of Hitchin. Hitchin is home to the Benslow Music Academy and can boast the origin of the first ladies college in UK
– the Girton (Cambridge) college started its life in Hitchin:
.
Stevenage is one train stop away and the railway station opens straight into the Stevenage Leisure Park, offering 16-screen cinema, bowling alley and lots of popular restaurants like Ask, Frankie & Benny's, etc., night clubs and meeting places. It is the hub of Stevenage. Shopping is well served by both Hitchin and Stevenage. 3 miles away is the world's first Garden City, Letchworth Garden City; founded 1903 by Ebeneezer Howard, co-social reformer and friend of William
Pryor Letchworth (from Letchworth State Park, Upper New York State, USA). Offering a museum and a calming and country-side feel to a small town. Again, one stop on the train, in the opposite direction
from Stevenage.

As for places to stay, Hitchin has a lovely old manor house hotel called The Priory, which has very nice grounds, riverside and lots of ducks to feed! Nearer to Luton airport but still only 12 minutes away is the delightful Offley Place, which people have described as a small Downton Abbey! La Bella Vita in Sun Street is a gorgeous Italian restaurant which is also a boutique hotel, featuring 8 – 10 rooms with heavy wooden four-poster beds and exquisite furnishings, each room totally unique in style and character. There is also pub/inn style accommodation with the Sun Hotel, the Lord Lister public house and other B&B nearby.

Hitchin is a lively town and as the clinic is situated on the upper floor level, facing a busy junction of the High Street, Brand Street and Bancroft, we often look out the window and watch the world go by and chuckle at the parking antics of some of the drivers trying to wedge themselves intoparking spaces outside their favourite shops!
How can someone make an appointment to see you?

Visit our website, contact us and make an appointment. We also do (paid) phone consultations

How to talk to your doctor about fecal transplant: a doctor's perspective

Dr. Arnab Ray is a gastroenterologist at the Ochsner Clinic in New Orleans, Louisiana, USA. He has performed over 20 Fecal Microbiota Transplantations (FMT) to treat Clostridium difficile and is currently enrolling patients in the Rebiotix Punch CD clinical trial. He is also starting a clinical trial for FMT using Ulcerative Colitis.

Background

Fecal microbiota transplantation (aka stool transplant, fecal transplant) has been getting a lot of attention in the media recently. Patients have many questions, and physicians do not always have the answers. Just to give a little background to the conversation, fecal transplants have been around in various forms since the 4th century as documented in Chinese writings of Ge Hong. They reappeared in Western medical literature most notably in 1958, when Eiseman successfully treated 4 patients with what was likely Clostridium difficile (C. diff) colitis (the infection was not named until the 1980's). It disappeared again until C. diff started becoming more common, more virulent, and more resistant to standard antibiotics regimens at the turn of the century. Physicians rediscovered this treatment and began using

it, but concerns about safety soon arose and the FDA became involved. Earlier this summer, the FDA released a statement requiring a research protocol in place in order to use FMT for the purposes of tracking adverse events. After an inundation of research applications, they reversed their position and simply requested that physicians follow minimal standards of safety when performing a FMT.

In this article I discuss FMT for the treatment of C. diff infection. The reason that we are restricting this discussion just to C. diff is that FMT is currently only FDA approved for treatment of C. diff infection, and it is still considered an experimental therapy. That means that doctors are not supposed to use it as a treatment for other diseases unless they are doing so within the supervision of an approved research trial. In order for the FDA to approve a treatment for a disease, it must be proven both safe and effective. We have a good number of studies showing this to be the case for C. diff, but not as many for other diseases. As a result, your doctor is technically not legally allowed to use FMT to treat other diseases, and can get into trouble for doing so, especially if something goes wrong.

That being said, there are a large number of clinical studies currently underway across the country to investigate the use of FMT in other gastrointestinal diseases. For example, our department is interested in studying the effectiveness of FMT in patients with mild to moderate Ulcerative Colitis. If you are interested in being a participant in one of these trials, please see here. Finally, if you are interested in performing FMT on yourself for a condition other than C. diff, you may run into different reactions from your doctor. It is reasonable to ask him to test your donor for safety purposes, but keep in mind that insurance companies are under no obligation to pay for such testing, and your doctor will be hard pressed to help you if your condition worsens.

Treatment Options

Once you have been diagnosed with C. diff diarrhea, your doctor will likely treat you with an antibiotic such as Metronidazole (flagyl), Vancomycin, Fidaxomicin (dificid), or Xifaxan (rifaximin). When these antibiotics do not work, a fecal transplant is typically considered. Often, it is the patient who will raise this, as they are looking for anything to give them their life as they knew it back. Many patients who are wary of the side effects and overuse of antibiotics ask for fecal transplant as an alternative to antibiotics. As the use of fecal transplant in modern medicine is still considered experimental,

a lot of questions typically arise between acknowledging this as a treatment option and actually receiving it.

Which doctor do I ask?

Although this seems like a simple question, the answer can actually be quite complicated. Physicians typically try to stick with treatments within their field of expertise, and C. diff qualifies as both an infectious disease and a disease of the gastrointestinal tract. As a result, both infectious disease (ID) specialists and gastroenterologists (GI's) tend to get consulted for this disease. Sometimes a colorectal surgeon will be consulted if the colitis is so severe that the colon needs to be removed to save the patient's life, but they typically do not continue management of the disease beyond the surgery. In my experience, I have seen both infectious disease doctors and gastroenterologists perform fecal transplants.

Infectious disease doctors typically will administer the fecal transplant via an enema or a nasogastric tube (a temporary tube from the nose down to the stomach), and gastroenterologists have the additional ability to administer the transplant via colonoscopy or upper endoscopy (a lighted camera guided into the stomach and small intestine). I personally prefer the colonoscopy approach as I can see what the colon looks like, and make sure there is not another reason that the patient is sick, such as inflammatory bowel disease (Crohn's disease and Ulcerative Colitis). I also think that patients have an easier time retaining the fecal transplant material when it is administered 6 feet into their colon, as opposed to an enema which is just infused in the bottom portion of the colon, but both approaches have proven effective.

As far as which doctor to ask, it simply depends on the personal experience of the doctors in your town. This is typically not handled by primary care providers or family practitioners, but I would not be surprised if some have tried to take this on. Many doctors simply refer patients who need a fecal transplant to a larger university hospital or tertiary care referral center where physicians are more familiar with the required testing and have experience with performing the procedure.

How do I talk to my doctor about fecal transplant?

With medical advances changing from day to day, it can be hard for a doctor to keep up with all the new treatments, especially the treatments which are not officially FDA approved and still considered experimental, such as fecal transplant. The best way to get your doctor's attention is to

show them the evidence. Every doctor in the world has heard of the New England Journal of Medicine. If your doctor has not, then I suggest you find a new one. A landmark article came out in January 2013 which tested fecal transplant versus vancomycin treatment and concluded: “The infusion of donor feces was significantly more effective for the treatment of recurrent C. difficile infection than the use of vancomycin.” Physicians nowadays are taught to practice evidence based medicine, and this is about as good evidence as you can provide. Once your doctor agrees that you need a fecal transplant for your C diff infection, you need to find a GI or ID doctor who can perform one.

Here is a list to get you started in case your doctor does not know who to call:
http://www.fmtscience.org/for-patients.html
http://thepowerofpoop.com/epatients/where-to-get-fecal-transplant

Where do I find a donor?
Some doctors may be hesitant to perform fecal transplants because finding a donor takes a lot of work, and no one knows what makes a perfect donor. There is some consensus as to which tests to run at a minimum to screen the donor, but locating a donor and having them available for your appointment to discuss fecal transplant goes a long way towards making the process smoother. A donor can be anyone who is generally in good health, has not had antibiotics in the last 3-6 months, has not had a cancer of the gastrointestinal tract, has not traveled to an area where diarrhea is endemic, and does not have constipation or diarrhea. A doctor experienced in FMT will perform a more thorough questionnaire and testing of the donor’s stool and blood to make sure that they are suitable. Most people typically use a spouse, family member, or close friend. As a doctor, I am always glad when a patient brings their donor to their appointment so that I can take a good history face to face and explain the testing to everyone (all confidentially of course).

Within the last few months, some companies such as Open Biome and the Taymount Clinic in England are making screened stool commercially available, so there are options available if you cannot find a suitable donor, or are too shy to ask!

Doctor’s Perspective

There is understandably a lot of frustration from patients who are seeking fecal transplant when they talk to their doctors, because many doctors do not perform this procedure. Here are some reasons that your doctor may give for being hesitant to move forward with a fecal transplant.

Is it safe?

Primun non nocere. One of the first things a doctor is taught in medical school is “first, do no harm”. Can we guarantee that fecal transplants are not harmful? Right now, we think fecal transplants are safe, but we just don’t know for sure. The only way to know this is to follow a large number of patients in standardized research protocols and patient registries over a number of years. A large number of studies are currently underway with FDA supervision to try to answer this question. So far in the medical literature, there have been no documented cases of transmitting infection by fecal transplant, but it will almost inevitably happen at some point. It is important to realize that there are thousands of bacteria and viruses in the colon that we do not even know how to grow in culture, so we cannot routinely test for all of them. Bacteria which may be completely happy and content in one person’s colon may cause havoc and disease in another colon, especially someone who is already sick. We are learning that everyone’s gut microbiota is unique, just like their fingerprint.

What are the long term effects?

Again, we don’t know the answer to this question. There have been studies following patients from a few months to a few years, but there are only case reports beyond that. There have been reports of patients gaining weight after their fecal transplant because they have taken on some of the metabolic characteristics of their donor. The truth is, we are just beginning to understand the interaction of our gut bacteria with our bodies. Until we have a better grasp on the long term implications of manipulating gut bacteria, a lot of practitioners feel like we are playing with fire. Medical history is filled with examples of medications and vaccines being brought out with good intentions before they were fully understood, but with lethal consequences. Just look no further than the history of the polio vaccine, or more recently the use of an adenovirus vector for gene therapy at the University of Pittsburgh. We may find out in 10 years that people who undergo fecal transplants develop colon cancer at greatly increased rates due to the manipulation of the gut microbiota that we do not currently fully understand. Although unlikely, If that happens, then the only ones who benefit will be the lawyers.

How do I do it?

If you are a doctor who takes care of patients 60 to 80 hours a week and then spends your “extra” time fighting insurance companies, there really is not much time to learn how to do a new experimental procedure, especially if there are other doctors who are willing to do it. Fecal transplant is not something that they teach everyone in medical school or residency, and there is no standardized or “right way” to do it, which makes it even more difficult to learn how to do. On top of that uncertainty, all it takes is one case to go wrong to bring on a lawsuit. Unfortunately, that is the reality of practicing medicine in our litigation happy society. It is extremely difficult to defend yourself against a bad outcome when the rules of the game are so unclear, and for a lot of doctors who have gone into considerable debt to train and then spent their lives building their practice, an experimental procedure with so many unknowns is simply not worth the risk, so they pass it on to someone else. The good news is that more and more doctors are becoming familiar and willing to perform this procedure to help battle the epidemic of C. diff.

The Future

The good news is that FMT is gaining more widespread acceptance, and the doctors who are performing this effectively are getting their names out. I treat patients from across the state and the entire Gulf South region. There is also no hotter topic of interest than the human microbiome among gastroenterologists. You could not attend a single discussion at the recent American College of Gastroenterology conference without FMT coming up. I anticipate that as more cost effectiveness studies emerge and treatment protocols become standardized and more feasible to the average practitioner, FMT will eventually replace antibiotics as first line treatment for C. diff.

As the volume of research done on the human microbiome increases, we will get further clarity on the use of FMT for other gastrointestinal diseases such as ulcerative colitis, Crohn’s disease, and irritable bowel syndrome. We will even begin to see its potential application in non gastrointestinal diseases such as depression, obesity, and autoimmune disorders. Keep in mind that research does take time and patience to perform. Not every study comes back positive and unforeseen complications arise. There is limited funding for this sort of research because there is very little incentive for a pharmaceutical company to

develop something as readily available as stool! The big trick will be to standardize stool and mass produce it in pill form. In the meantime, keep the lines of communication open with your doctor so that you can continue to have a mutually respectful and honest discussion

Dr Gary H. Hoffman on FMT for C. diff

The following guest post is written by Dr. Gary H. Hoffman, a board certified surgeon of Los Angeles Colon And Rectal Surgical Associates. Dr. Hoffman has experience with fecal microbial transplantation and is attuned to the nuances of c. diff colitis and its treatments. The surgeons of LAcolon.com work closely with referring doctors and infectious disease specialists to individualize the evaluation and treatment of patients with resistant C. Diff.

Fecal Microbial Transplantation. Time To Call A Specialist.

The final part of the gastrointestinal tract involved in handling our waste is the colon. The colon serves as a storage area and a place where excess water can be resorbed into the body. Although remarkably resistant to infections given the large number of bacteria inhabiting the colon, occasionally an infection with a virulent bacteria known as Clostridium Difficile (also know as C. Diff.) may occur. If this infection, C. Diff., does not respond to antibiotics, a technique known as fecal microbial transplantation (FMT for short) must be used. Fecal microbial transplantation, performed by a specialist known as a colon and rectal surgeon, or proctologist, reintroduces normal bacteria into the colon, and this normal bacteria replaces the abnormal bacteria such as c. diff.

Fecal microbial transplantation is a relatively new procedure, and has been developed in an effort to combat the growing problem of antibiotic-resistant strains of bacteria beginning to inhabit humans on a worldwide basis. Because of increasing ease of worldwide travel, these resistant strains have moved around the globe. Some bacteria may cause an infection and inflammation of the colon, known as colitis. When a patient develops c. diff, colitis, strong antibiotics are needed to combat this inflammatory condition. However, c. diff. is becoming increasingly immune to the drugs used to treat it. This is where fecal microbial transplantation is needed.

In the United States, FMT is only performed by physicians. Colon and rectal surgeons have been trained to diagnose resistant cases of C. Diff.

They are also trained in FMT. Equally important, much thought, planning and technical expertise are used in what may appear to be an easy procedure. In other words, do not try FMT at home.

Fecal Microbial Transplantation for Clostridium Difficile (C. Diff)

Drugs used to treat clostridium difficile colitis include metronidazole and vancomycin. Increasingly, C. Diff is becoming resistant to both of these drugs. The theory underlying fecal microbial transplantation is simple: replace the pathogenic, resistant bacteria with healthy bacteria from a healthy donor. How is this done?

The first, most important step in the treatment is to find a specialist familiar with both the disease and the treatment. Surgeons who perform fecal microbial transplantation are few and far between. Once you have found an FMT a physician, you will be asked a thorough list of questions evaluating your health, your travel, your contacts and your symptoms. Past failed treatments protocols will be discussed. Stool cultures may be taken to establish the correct diagnosis. At this point, if you are a candidate for fecal microbial transplantation, you will be asked to find a healthy stool donor. The donor does not need to be a relative. As long as your donor is healthy and willing to give a stool sample, anyone may donate and testing of the donor stool begins. Infectious diseases are ruled out and the donor stool is tested for clostridium difficile as well. If you are unable to find a suitable donor, a pre-screened, healthy stool sample may be purchased from a laboratory, specialized in this area of treatment.

Once the stool is obtained, you will undergo a standard colonoscopy. Colonoscopy is a test normally used to screen the colon for polyps and tumors. It is usually performed on patients over the age of 50 as a cancer screen. You will be asked to clean your colon by drinking clear liquids and then taking a strong laxative. On the morning of your procedure, you will receive a mild anesthetic to allow you to sleep while your surgeon performs the colonoscopy. At this time, the donor stool will be placed into your colon and “sprayed” along your colon wall. The entire procedure may last only a few minutes. You will be awakened and allowed to return home shortly thereafter.

Does Fecal Microbial Transplantation Really Work?

The short answer is a resounding YES. Up to 98% of cases of c. diff colitis are cured by fecal microbial transplantation. Rarely, two treatment

sessions are required. Patients report a cessation of symptoms such as diarrhea or abdominal bloating, almost immediately. Treatment is gratifying for both the physician and the patient.

FMT Treatment for Other Medical Conditions

Using FMT as a treatment for Clostridium Difficile colitis has become a therapy that is now endorsed by the medical community. However, many patients have turned to FMT as an alternative form of treatment for diseases other than c. diff. colitis, such as various autoimmune diseases. The medical community prides itself on using proven therapies whose success and safety are based on evidence-based studies. Hence, patients looking for support for the use of FMT in various conditions other than c. diff colitis, must turn to non-medical sources for education and support. And, these patients run the risks of using improperly tested stool administered in the home setting. While these patients are desperate for help, they may inadvertently worsen their conditions, or develop new conditions caused by the unsupervised use of FMT. Few medical doctors are willing to participate in clinical fecal transplants for other, unstudied and unapproved diagnoses, and alternative uses for FMT cannot be recommended. Wider use of FMT awaits the study and confirmation from large, supervised randomized clinical trials.

What to do next?

The most important first step is to schedule a confidential appointment with your colorectal surgeon to gather more information. They will provide you with additional information about your treatment options as well as answer any questions you may have

Interview with Dr Silvio Najt

Dr Silvio Najt runs the Newbery Clinic in Buenos Aires, Argentina. Newbery Clinic specialises in the treatment of inflammatory illnesses, through restoration of gut health through nutrition and FMT.

What's your background? How did you become a FMT specialist?

I specialize in Internal Medicine and am board certified in Cardiology and Emergency Medicine. Around 2005 I became interested in the link between inflammation and the human microbiome. Since then I have devoted most of my practice to a diversity of inflammatory diseases, initially with a

pharmacological approach and then incorporating a number of other sources to deal with the phenomena, including nutrition, supplements, enteral and parenteral nutrition, and finally FMTs.

How did you become a FMT practitioner?

When I first heard about the method I thought it was just hot air; witchcraft. However it stayed in my mind as a treatment for Clostridium difficile and I eventually started using it in some desperate cases of IBD, used only when patients learned that their last remaining option was surgical. An infection control nurse and I did the implants in patient´s homes, and we saw they all improved, some recovered but all the patients we treated got some sort of benefit from the implants. That was the beginning of the learning curve. We have since teamed up with a high quality biochemist and microbiologist to minimize the risk of transmission of disease from our donors.

When did you open your clinic? What kind of patients do you treat?

We opened Newbery Clinic in February 2014 in the heart of Buenos Aires, and we slowly started treating patients, mostly IBD -Crohn´s and Ulcerative colitis. Our goal was to start slowly with very few cases so that we could devote sufficient time to evaluate the patients, measure before and after results, refine preparation of the slurry and learn how to choose our donors.

We focus our practice in IBD, Crohn´s and Ulcerative colitis. However, any patient with chronic diarrhea seems to benefit by replacing their microbiota. Our results are good, we are collecting data and as we are in such close contact with many of the patients we see, we expect to draw a magnificent perspective of the clinical evolution of every case, including nutritional and pharmacological interventions alongside treatment with FMT. We are getting requests to perform FMTs on many other diseases like primary sclerosing cholangitis, bad cases of psoriasis, etc.

What kind of results have you seen with FMT?

Every day when I enter the clinic, I have a certain feeling that we are performing some kind of magical procedure, that I never came across something like this in my 40 years of medical practice. We see good results in all the people we treat, some enter in a state of relapse, many don´t, but all improve their quality of life, their symptoms change, they gain energy and are able to recover control over their lives. I do not use the word “cure”,

it is out of my vocabulary, as nobody is entirely healthy, nobody is entirely sick. There is always something with us that bothers our health. So my approach is, if we can reach a better situation and not jeopardize your health in any way, it is worth trying. Every time I write down a prescription for any (any I say any) drug, I know somewhere in this action, there is a risk, sometimes small, sometimes big.

What has been your most memorable success?

A young boy treated with FMTs, one of the first we saw at Newbery Clinic, he had a mild to severe ulcerative pancolitis, always with diarrhea, with bloody stools on and off, he did a very strict SCD diet (since then he developed a catering service for Celiacs) but was always in need of some sort of medication that never took him into a full recovery. He could not gain any weight, anemic, lack of energy, and something that always called my attention, his grayish skin color. His initial Fecal calprotectin was above 1100 units. He decided he did not want to get any more medication, that he wanted to try this “new” (very new those days) approach. We did 30 days in a row of daily implants, then a month of three times a week then a month of two a week, then we did them once a week and we stabilized the implants to two a month for about eight months. Now he comes to the clinic just once a month. Results, he has no symptoms whatsoever, his skin color dramatically changed, and his last Calprotectin level is 80 units, he gained some weight but is full of energy devoting all his time to this Celiac catering business with great success.

What makes a good donor?

Someone who is healthy (with the limitations of the definition of healthy in our society). Decide that the donor is apt after performing a medical examination and blood and stool tests. Also that he/she has a stable life, somehow stability (steady couple, steady job, place to live, good eating habits, some exercise, no drugs, little alcohol, etc.). And finally we “test” their stools against others, after “using his stuff” we kind of measure if his bacteria make a difference in the receptor, that means an “inclusion” parameter, we still have no way to know if a donor is a “good one” before using his stuff on someone. An those we take good care they stay healthy and willing to continue to donate!

Where do you get your donors and how do you screen them?

We need donors within a close distance from the clinic. We tend to use fresh specimens and only in special occasions we use material from our frozen bank, we are working with a microbiologist to improve the anaerobic process, and then we will test if that makes any big difference, we developing a bank of frozen stools for our facility and for some colleagues that are just starting to use FMTs in Argentina. In the meantime we stick to what we know works: fresh specimens within a certain amount of hours, then we discard them and use another batch. So we have a good number of donors, that live closeby. We discard they sample if we find out that they are sick or had a “bad night”. We keep a tight medical control over our donors.

What percentage of donors do you reject?

I would say we discard about 30-40 % of the potential candidates, maybe less, before we send them to the lab to get their blood and stool testing, we perform a very thorough interview and physical examination -don´t forget that we are a medical group and that is what we do, medicine and in some patients we recommend FMTs, not the other way around.

Do you think donor diet matters?

Yes, we are convinced that our bacteria need a huge amount of fiber, probably two to three times the dietary recommendations, so we elaborate a diet for our donors that include a fantastic and healthy combination of nutrients, fiber and fermented foods. They are part of the team and they share this view of “magical” stuff they are giving us to improve the life of people that suffer from very sad diseases. We share the spirit of sharing their good health with others. Many of our donors learned how to follow a “healthy diet” after starting collaborating with us.

Do you use enema or colonoscopy delivery?

We do not do colonoscopy, we prefer to preserve the flora as is and replace it gradually instead of “cleansing” the field with antibiotics and bowel preparations and stressing an already sick gut further. That way we get good results and see less gut reactions.

We use a long and thin silicone cannula to make our implants.

We take advantage of a normal gut movement called “peristalsis”. Peristalsis refers to the smooth muscle gut contraction, which occurs in

sequences to produce a wave. It forces a ball of food (bolus) to move from the esophagus to the anus. This automatic movement is highly efficient and coordinated until the end of the small intestine. However when the bolus enters the colon, peristalsis exists but is not as coordinated. The colon content moves back and forth like a washing machine to extract energy from the undigested fibers. We can take advantage of this physiological movement to send new microbiota to the ascending colon, simply by implanting good bacteria in final sector of the sigmoid. Peristalsis will take care of seeding the whole organ and beyond. So only bottom-up techniques, our group think that the Top-down (nasogastric approach) is highly risky and we do not sense we need to go that way.

Why don't you support top-down FMT?

Top down vs bottom up is a controversial area that has polarizes FMT practitioners. I am very concerned about these magic FMT pills that are receiving so much publicity. The small intestine is essentially sterile when compared with the colon (1000 vs one trillion bacteria) yet there seems to be a "crosstalk" between both communities. I believe 'bottom-up' is a much better approach than carpet bombing the entire gut. From a theoretical point of view there is a very strong argument against "infecting the small gut". One of the most feared complications of Ulcerative colitis is primary sclerosing cholangitis (PSC), which is a situation that can lead to liver transplant, high incidence of colon cancer and premature death. One of the experimental ways of provoking PSC in experimental animals, is to surgically perform in their guts what is called a "blind loop". It consists in contaminating the small gut with colonic bacteria, over and over. So if there is the slightest or remote possibility of developing a PSC or any other complication in the small gut (SIBO) this approach should be avoided.

What side-effects have you seen from FMT?

We have seen a few but very mild side effects, our approach is to minimize rejection of the new implanted bacteria so we generally use some amount of steroids a few days before we start and we then slowly tapper from it, this way we have seen almost no side-effects, other than some bloating or a mild exacerbation of the symptoms the patient already had.

What do you see as the risks of FMT generally?

My feeling is to perform the technique without medical knowledge and medical supervision. It is very brave to see this mothers and dads that are left without options when they are faced with surgery and they have to do FMTs by themselves because the medical community can´t do them yet in some certain countries. The main risk is by using the wrong donors, or hurting the already damaged gut with very aggressive techniques as are described over the internet. The gut is very delicate and can be teared down by inappropriate maneuvers, and the worst part of this is that those complications may not even be realized by the operators as they lack the medical experience of evaluating a punctured gut and its clinical manifestations. That concerns me a lot.

How long does stool stay fresh once exposed to air?

We tend not to “expose the stools to the air”. We collect the materials in a low oxygen receptacle, then we manipulate the sample with a vacuum devise to preserve it until we blend it. It usually takes no more than two, max three hours from the moment the stools are emitted until they are implanted.

How do you preserve anaerobic microbiota?

We do our best not to expose feces to oxygen and light, and our results so far are very good. We are starting to use a new technique to make the atmosphere more anaerobic, but it’s still under experimentation. There is still a lot of room for improvement. We are working side by side with a very enthusiastic group of Doctors in Microbiology to organize the first South American Stool bank.

Have you used frozen FMT? Do you think it is as good as fresh?

We have a frozen bank and we use them as a back-up. Even though we use the best techniques known in this area, we tend to use them occasionally as we see better results with the fresh specimens, as I said we are still in the phase of developing a professional bank of frozen stools. We expect to have it up and working by July/August 2015.

Have you treated anyone with a J-pouch?

No we have not yet treated anyone with J-pouch yet, although I have some local patients with that intervention. Our biggest experience is with Colitis and Crohn`s with intact guts.

Have you treated constipation with FMT?
We find FMTs extremely useful for constipated patients, however our experience is that it should be used along with other interventions such as diet and habit changes. We find there are many patients that are constipated and feel OK with that as they will not use their office or school bathrooms, so there is a lot to do to treat constipation, it is the other side of the coin, colitis patients would use *any* toilet, constipated would only use just a few.
What are your post-FMT support recommendations?

It depends on the case, we always recommend and customize a diet for each and every patient. We are all different. Then we use some, not many supplements, we have to be very cautious, every day we learn about more "vitamins and supplements" that can harm our microbiota. So good food, fresh, non processed, lots of good fats, low starch, low sugar, lots of exercise, and no stress is what we try to inculcate in our patients. We may sometimes use medication, we know how to use them and we have seen some cases improve when we combine the best of all these different worlds.

Why is the mainstream medical profession so reluctant to investigate and offer FMT? Given the success with C.diff, what's wrong with trying it for more difficult chronic gut conditions?

I do not know, there mixed interests, one of the most profitable group of drugs in the world right now are the anti-TNF – biologics, billions of dollars are spent on this drugs. In IBD cases the best results ever reported do not exceed 40% remission of the treated cases. Usually associated with azathioprine. So as long as the medical leaders are so strongly influenced by the pharmaceutical companies, they will not change horses. We will see the clinical trials that are about to be reported quite soon, some of them will start showing what we see in our daily practice. We improve the life of the people and we cause no harm. The worst that could happen is that the patient see no changes, which is unusual, with drugs you may see no change but you know they are quite dangerous.

What's your view on DIY FMT?

As I said, when you are left aside by the medical community you are compelled to do something for you or someone loved beside you. Not the best way to go, I think medicine has advanced in many ways, and has a lot

to offer to the people. And I am not talking about technology, I am talking about been better people, listen better, be closer to the one that suffers, not become the savior -that we are not, but after 40 years of listening to lungs and hearts and palpating abdomens you acquire a certain skill that can be useful for the patient, you may advise them how to have a healthier approach to their daily life, how to eat better, how to relate with others is a less stressful way. I think DIY is a failure of the medical system and of the community as a whole, I would expect governments to take care of our health in a proper way. This is a clear and ever increasing demand the PUBLIC is demanding. So they should be listening as FDA did with Catherine Duff.

What research is on your wish list?

We want to develop some kind of devise that could help the people get access to good bacteria in their houses, not pills or capsules but something safer than that. Also improve our technique and laboratory processes, something we do every day. This is all so new that every day we find new ways and new equipment to improve the technique. As I am originally a cardiologist, I have had a huge exposure to catheters, cannulas and monitoring equipment that I am reconfiguring to use them a little lower than the heart, the gut. We still need to learn a lot about the microbiome, we ignore which is the “normal” bacterial map, although by now millions of people´s microbiota has been studied. Lot of room to improve. And of course devote most of our attention to build a very consistent bank of frozen stools.

Do you think it will soon be possible to transplant specific strains of microbiota depending on what is missing in the gut?

We are still too far away to understand what goes on in the gut microbiome. This “diagnosis” of lack of one particular family of bacteria is still futuristic medicine, as we are just at the beginning of this science. It is therefore risky and uninformed to emphatically state that something is “missing”. The accuracy of such microbiome tests are yet to be proven and what appears to be “missing’’ might just be that people are different. What we do know is that the fecal microbiota is an “organ” and should be transplanted as that, as a whole. All attempts to depurate or extract the good ones, have failed or showed poor results. It is like attempting to implant a certain part of a kidney or a liver, Can´t be done today, maybe sometime in the future.

What do you enjoy about your work? What are the frustrations?

I am totally fascinated with the results we see. We are treating very young kids, babies already suffering from IBD, cases we did not see a few years ago, so on one hand we get more severe cases but on the other hand we see them improve without exposing them to dangerous drugs, but there is something very wrong this society as a whole is doing to put so many people sick. When I started practicing medicine celiacs were estimated to be 1 in 10,000. Today, 40 years later the estimation is 1 in 80. What is that we are not doing well?

How can someone make an appointment to see you? Do you do Skype consultations for international patients?
Yes, half of our patients are international, Buenos Aires is an easy city, most of the people speak English and we are located in a very friendly neighborhood. We do a lot of Skype consults and we supervise many people from around the world that can´t move to Argentina to do the technique in their own place. Not the best scenario, we prefer to treat them and follow them here in Buenos Aires, but somehow we may offer our medical skills to help people go through this challenging therapy in a remote fashion with a system that has already helped people in places like Poland and Hong Kong. You can , Skype us via *newbery.clinic* or call +1-315-519-9636.

Visit the Newbery Clinic website