Podcast Introduction and Guest Welcome

the way that it's being done today compared to even 10, 15, 20, 50 years ago has changed dramatically. You know, our lab, for example, we're based in Canada.

We're licensed by Health Canada with the drug establishment license. we have a GMP license to do what we do, which means that we are regulated and working on this product as if it were any other.

The end product looks nothing like the starting product in the sense that most of the medical value comes from the microbes themselves. Hi, and welcome to the Lime Bites podcast, where we shine a light on the misunderstood science of Lyme and other vector borne diseases, as well as the truths that many still miss.

I'm Dr. Mariah Hinchy, naturopathic physician and fellow of the Medical Academy of Pediatric Special Needs. I specialize in treating chronic Lyme disease, as well as other complex inflammatory conditions.

In this podcast, we break down what's working and what is not. We share the facts that most people miss, challenge outdated thinking, and give both patients and practitioners the tools to heal smarter.

So let's get into it and change the way we heal Lyma. Welcome back to LimeBites, rebuilding immunity, reversing inflammation, and redefining recovery.

Why Gut Microbiome Matters in Lyme

The gut microbiome is a master regulator of immune function, controlling inflammatory signaling, maintaining barrier integrity, ultimately determining whether the body can restore immune competency and clear chronic infections like Lyme and other vector-borne diseases.

Today, I'm joined by Jason Klopp, founder and CEO of NovelBiome, who brings over six years of hands-on experience using fecal microbiota transplantation, or FMT, and is now leading efforts to advance microbiome-based therapies for clinics and research worldwide.

Welcome, Jason. Thanks so much for joining us. Thank you. Excited to be here. All right, so let's start off with this conversation here. You know, why on a Lyme and complex chronic illness focused podcast and summit, are we talking about fecal transplantation?

Great question. I mean, I think this category of patients and people struggling with Lyme and chronic complex illness as a baseline, all of them are dealing with some immune microbiome dysfunction.

There's an imbalance there. Something is off. And a lot of times that particular audience of patience are the ones struggling to get out of this. cycle of GI problems, symptoms, as well as their immune based ones, which have body wide results.

And so they're just classified in some category of disease, but ultimately there's something deeper going on. There's some keeping them from being able to break out of their sort of locked in symptoms.

Right. They're in this category, they are struggling to get out. For some of them, the key can be fixing the gut microbiome. Right. And the biggest link there, at least in my mind, is a healthy microbiome and a diverse microbiomes is actually going to be able to manage the inflammatory cytokine cascade, so bring down the inflammation in the body.

It's often these various chemicals of inflammation that are actually driving the immune imbalances that we see, whether that is a patient that has a suppressed immune response or those patients that actually tipped more into an autoimmune response.

So I think a lot of people miss that connection that your gut health, and specifically the microbiome, is dictating a lots of the immune function, the immunosurveillance, of all of these immune cells in the body.

And I am always saying to my patients over and over again, this is not something that we can just focus on killing.

Shifting from Kill-Based Medicine to Terrain Healing

These infections change our terrain. I want you to talk about the study where there's actually a signature microbiome in Lyme disease patients without even taking antibiotics.

But you know, it just goes to show how capable these infections are of changing ourselves, changing our terrain. And then we have this downward spiral of various effects.

If we just focus on killing the organism and not healing any of those other things, most patients really aren't going to ever get better. Are you ready to revolutionize your approach to diagnosing and healing complex chronic inflammatory illnesses in both adults and children?

The Lime Bites Symposium is your gateway to cutting-edge education, groundbreaking research, and innovative therapeutic solutions. Join us at LIME BITES SYMPOSIUM.

at the Fort Lauderdale Marriott Pompano Beach Resort and Spa. Lion Bites is the premier functional medicine conference on complex, chronic, infection-driven inflammatory illnesses.

This year's meeting is jam-packed with leading industry experts discussing lung COVID, mycotoxin illness, PANS Pandas, as well as Lyme and other vector-borne diseases.

This conference will arm you with the knowledge, clinical pearls, and practical solutions that you can implement immediately into your practice Monday morning that will literally change your patient's lives and get them on their path to true healing.

So join us at Pompano Beach or virtually from anywhere. Register now at limebites.com. That's L-Y-M-E-B- Y-T- E-S dot com. Right. And I think that's such a key aspect and something when I was treating patients that I really had to have that discussion around.

It's a whole mindset shift, right? Like our whole culture, conventional medicine only thinks about like there's like a bug and, you know, the evolution of antibiotics and the use of, I mean, they're life-saving, and they've been such gift to humanity.

But, it got us to think, like, bug disease. And so, we can just identify the bug, kill the bugs, no disease, and that does work in some context and some settings.

You have C. difficile, in a lot of cases it works, you just take a drug, Bug dead, symptoms gone. Same for like a strep throat. But we're seeing these carry-on effects where that's no longer working, so the bugs are learning to evade antibiotics.

I think that at such a foundational level, shifting the thinking away from the body is this miracle thing. It has this ability to maintain a homeostasis, it wants to be balanced, wants be healthy.

In many cases, that has a memory of what that looks like. And it wants to get back there, but something is getting in the way of that recovery. And what it is for each individual patient, of course, varies.

But if we're only approaching it with the mindset, we just have to kill our way there. So when I was dealing with patients, I'd tell them like, look, We can't just kill her way to health.

Like health doesn't, like health, doesn' have the word kill in it, right? Like it's about balance. If it about peace, it' about happy. There's all these different ways you could think about health and getting to kill herself there is not going to be working.

And so in some cases, a part of the treatment can absolutely include that. But long term, we need to think about, okay, what building blocks does the body need?

To recover to actually do what it's intended nature intended it to do to come back to health. And for some people, the gut and the microbiome is a really foundational piece.

And a lot of times, people sort of forget the interplay between the immune system and that gut, right? Like the majority of our immune systems is actually around the guts, this gut-associated lymphatic tissue.

It totally surrounds the whole digestive tract. and it's having conversations between a gut. So I think, underactive and overactive. Overactive is probably a bigger problem, right?

It's imbalanced. The TH1, TH2 balance is totally off and skewed. And so then when it becomes too overactive for too long, it starts fighting itself and that's where you get this autoimmunity and the picture sort of goes on from there.

But that study you referenced was really interesting because this is the challenge in Lyme, especially is understand how do we diagnose this?

Lyme Microbiome Study and Diagnostic Clues

How do find out who's truly dealing with Lyne? If we've gotten rid of the bug, right? If that's the theory, there's a bug and we get rid it. Now, of course, you know, multiple bugs.

It's not just the burgdorferi bug. But if that is the way of thinking, we got rid the bugs, it's showing up on any of PCR testing or whatever we're doing.

Why is this patient still dealing with anxiety, depression, fatigue, pain, Malaysia, all of these different things? There's something going on. There is something underlying.

And so in that study, was really fascinating. I think it was John Hopkins that did the study and they looked at healthy controls, they look at people with post-line diseases diagnosed by some standard, and then they also looked ICU patients.

And the really curious part about including the ICU patient is because they wanted to rule out this just because the have antibiotics. Of course, someone in the ICU is absolutely on an IV drip.

I don't think you're in the ICU without being on an antibiotic. And so what they identified looking at Lyme disease patients, healthy controls, and ICU patients is A, it doesn't rely just on the fact that there's an antibiotics in place.

The ICU patient sort of proved that point. And then the controls, of course, is just healthy to know, okay, this is what a healthy microbiome is, and this what an unhealthy one was.

And they could identify with 80% accuracy what was a, you know post-treatment Lyme disease patient. There were two bacteria actually that stood out. One was elevated, I'm going to butcher the name, Blaudius.

I am probably saying it wrong. The other one is low Bacteroides. The low-bacteroides one is really interesting because that bacteria, as do most of these bacteria.

They produce something, they make something that's good for us. And in this context they're making GABA. GAB is a neurotransmitter. Too low amount of GABa can cause issues like anxiety and depression.

And so really, really fascinating. A, there's an opportunity for diagnosis here. We could look at their microbiome and understand, okay, who truly fits in this category.

But then it also gives us clues as to the symptoms. The other one they noticed, and I don't know if it was in the study or another one, but actually low amounts of short chain fatty acid production.

which again, our gut microbiome is producing these short chain fatty acids. And if we don't have them, we see increased inflammation. We see leaky gut.

When that happens, you see all of the inflammation that goes body wide, including the brain. A lot of these symptoms, I think, can come from neurotoxicity, neuroinflammation.

Yeah, for sure. So what exactly is FMT? We'll start there. Because I'm sure everyone listening has an idea of what it is. And so I think it's good if we walk through exactly what is and get some of those images out of people's heads.

Right. Yes, exactly. I mean, you know, the branding is definitely not the best. We'd like to call it microbiota transplant therapy. It's much more appropriate to where we are today as far as how the product is made.

Nonetheless, all of the research refers to it as FMT or fecal microbiote transplant. The only accurate part of that is that it does originally derive from a screened exceptionally healthy human stool.

And so there's that aspect. But the way that's being done today compared to even 10, 15, 20, 50 years ago has changed dramatically. So, you know, our lab, for example, we're based in Canada, or licensed by Health Canada with the drug establishment license.

We have a GMP license to do what we do, which means that we are regulated and working on this product as if it were any other drug. which, you know, there's a whole different level of like cleanliness and standards that come with that.

What FMT Is and How Itu2019s Made

And the end product looks nothing like the starting product in the sense that most of the medical value comes from the microbes themselves, right? We talked about this Bacteroides and other butyrate and short-chain fatty acid producing bacteria.

That's in a microbiome, but a lot of weight of a stool is actually fiber and waste products. We're not trying to give someone a prebiotic here. We're not trying to give them fiber, we're trying concentrate for the microbes within the microbiome.

And so there's a lot of filtration and processing that goes into play to get it to that point. Our product is also freeze-dried, and so it's dry powder.

It's basically shelf stable. We do suggest long-term storage in a fridge. But this is what it looks like. It looks like a probiotic. No different than a probiotic, you know, and there's no taste, there is no odor, There's nothing.

So what is left in the capsule when someone is going to take it? What is the final product that is in there? Yeah, part of our release testing, you know, there's a quality department and we do all this different testing standards.

But we're actually looking at anaerobic bacteria, which are the hardest ones to keep alive in a processing environment. And so we are testing for certain bacteria.

it's the whole microbiome. It's not, and this is really the advantage of FMT over something like a probiotic, prebiotic,

postbiotic is it is the WHOLE microbiom.

And so that would include, of course, bacteria. That's mostly what people think about when they think of the microbiomes. But the micro biome also includes viruses, it includes parasites, includes the whole, the fungi, there's a whole bunch of healthy fungi that are involved and then the metabolites that come along with that.

So the microbes themselves produce metabolite, which can be very healthy to reset. And the idea then with FMT is, is that we're trying to the transplant part of the word is what we are in essence trying do.

But again, people think about transplant and they think like, oh, you're cutting someone open and you are putting something new in. No, I mean, it's literally a probiotic type pill that you just ingest.

The transplant idea is generally The treatment does include some pre-treatment. So we're trying to like get rid of the overgrowth, the imbalance, The pathogenic, and the bad microbes.

And you can do testing, you know, there's different stool testing or urine testing looking at metabolites to understand what's all going on. The idea generally, though, is like, let's wipe it out.

Let's clean the slate so that when we do this transplant, we're putting in that whole healthy live microbiome. And that's the real distinction here. This is live.

It's a whole thing. As soon as this powder gets exposed to moisture, they wake up from a metabolic standpoint, because they're basically sleeping now.

When they get exposed the moisture they, wakeup again. And we're then putting in all of these new microbes. And there's definitely an interplay of what the patient's microbiome is and what a donor's micro biome.

Because at the end of all this, the patients microbiomes looks different than when they started. It looks more like the donor, but they develop their own.

Its a unique signature to them. There's a lot of, of course, environmental inputs. What are they eating? Where are living? what is their lifestyle like, we'll define what lives on.

But the core premise or goal that we have for patients is really to expand their diet, to have more diversity in their diets to support these new microbes.

And so one of the biggest differences then between FMT and taking a regular probiotic, like beyond the scope of various genus and species of good bacteria that you're getting, is that these are actually going to wake up and start living in the body, as opposed to most probiotics are just having transient effects.

Correct? Yeah, that's a little bit more about that. Yeah. So, I mean, to be frank, we would love the ability to have a synthetic version of FMT that worked and even half as good.

It just doesn't, unfortunately. And I think there's several reasons for that, like the body just don't recognize the synthetically grown thing. Also, it's just a very small part of like, you know, some probiotics, they may have billions of bacteria there, but it is a few strains.

And the example that I often will use in the context of talking with patients is like, imagine you had to rebuild the Amazon rainforest, but you can only take five trees and start somewhere fresh with five.

Just not going to work, right? There's this whole micro and macro environment. And that's what we're getting and that is what were putting in. And the body has this, you know, this is self.

It recognizes it as, oh this healthy, I know what this. Is and it can start to engraft and take hold. So that really the key distinction is one actually engraphs and can stay there.

The other one is just goes through, has some transient benefit. Like there are studies that do show benefit when taking certain probiotics. It's just that when you stop, the benefit's gone.

And for many of these really chronic patients, it's not going to be enough to shift their microbiome environment or their immune environment in a dramatic way as would be needed to really shift the disease state.

Okay. So for the average patient that's doing all of the right things to prepare for this, like to get the overgrowth of opportunistic bacteria or fungi, back into check.

And we also have root cause. Whether there's vector-borne disease, changing the microbiome, secreting inflammatory cytokines, et cetera. The person that is doing everything right and then they're using FMT as a tool.

Roughly, how many months of therapy What would it take for that sort of like, you know, good enough seeding with the transplantation for it to actually remain inside of them if they continue to do all of the right?

Are you suffering from Lyme disease or another complex chronic illness and aren't sure who to trust when it comes to herbal supplements? Hi. I'm Dr.

How FMT Works and Treatment Timeline

Mariah Hinchey, founder of Lime Core Botanicals. As a naturopathic physician specializing in complex, chronic, infection-driven illnesses like Lyme disease, I needed herbal medicine I could truly trust.

That's why I formulated LIME Core botanicles. where our herbal tinctures are handcrafted in small batches right here in Connecticut. We use the whole herb, never isolates, to preserve the full spectrum of medicinal compounds.

Every single step from sourcing to extraction is done with precision to ensure maximum purity, potency, and consistency. These are the same herbal formulas I used to heal myself and have used for years to help my patients and family members heal too.

And now I'm making them available to practitioners and patients everywhere. Lyme Core Botanicals, herbal medicine you can trust from a doctor who lives this work.

Learn more at LymencoreBotanicles.com In part, the calculus depends on like how long and how severe their illness has been. So that will be a factor. But I would say constantly in two to three months, you're going to see a significant shift and what can be permanent change.

Again, assuming they're doing the lifestyle things to support it. They're avoiding antibiotics and other things. Yeah, but you are going see pretty dramatic shift.

You know, in the context of C. diff, which has the most research, The shift is in days, like we're shifting them very quickly. The difference is though that these patients are, you know, it's a very acute illness.

This is not someone who's had 10, 15, 20 years of total immune dysfunction. And so there is some calculus on that part. they'll absolutely begin observing improvements before then.

So within the first month, someone should have a very clear idea, this is working. You know, I'm seeing improvements in my digestive symptoms, whether that's more consistent, regular bowel movements, you know less gas or bloating, abdominal pain, cramping.

And then as that begins happening, as the theory goes, we're beginning to heal the gut lining. We're getting to reduce the inflammation. And I think that's primarily how FMT is working is shifting the inflammatory sort of cascade that is happening within the got, which then affects the whole rest of the body when it comes to the production of neurotransmitters and all the anti-inflammatory components and the hormonal components, and everything else.

So as happens, then we begin to have an effect on the brain. And so the whole leaky gut, leky brain, I believe in that very strongly. So as the gut lining begins to heal, we can then start to feel this lekey blood brain barrier situation.

And as that heals, were seeing less inflammation in the brain. We start seeing changes there and my background was treating a lot of kids with autism.

who many of them have vector-borne illnesses as well. But it was just dramatic to see first GI improvements, then all of the neurological changes and improvements.

And we're seeing this across other diseases like Parkinson's, which we always thought was a brain thing, you know, until more recently we were starting to realize, well, wait a minute, there's a microbiome signature here.

MS, Alzheimer's. You know. So it really there is a huge GI aspect when it comes to all these chronic diseases. Absolutely. So I have a couple logistical questions.

Number one, is it a one size fits all formulation in the capsule or do you do some matching if someone's had a GI effects or fill in a blank for a CDSA that's done an evaluation of the microbiome?

Is there a matching or is kind of, and I don't mean this in a bad way, but is it like a standard one size fits all? Yeah, currently, that's the approach.

It is a one-size-fits-all. What we do do is that in the course of a patient's treatment, we would try to give product from at least two different donors to get a broader like overlap and broader exposure to the microbes that that patient might need and they'll take on what they need to to, get the benefit.

The future I believe of FMT and very sadly we just recently got turned down for a grant by the government which as you know probably in the US as well is really tightening their belt when it comes to funding science but we really think based on some of the early research, especially there was a study in ulcerative colitis, where a certain group of patients got better outcomes in remission compared to another group and it was donor dependent.

So, you know, there's certain elements of just broad donor screening that would improve one's chances dramatically, like all of our donors are at minimum under 30 years old.

You know, we look at whether they're breastfed, vaginally born, you know. We look all of these parameters that we know contribute to a healthy gut. And then of course we're doing all the screening to rule out anything pathogenic, infectious, inflammatory, and you name it.

However, I do think there's something there. That's been my instinct since the years of starting with FMT. But as a scientific medical community, We just haven't yet identified what precisely that is.

And so it's a matter of time, I mean, we will get there and we hope to play a role in understanding that science. But as of right now, with the success rate generally being very high, it would only hopefully improve the successful rate further.

And again, the safety probe, its exceptionally safe, so we wouldn't really change that. I think the real opportunity, and this is kind of full circle to what we discussed with Lyme, is identifying who would be an ideal recipient.

Donor Screening, Safety, and Manufacturing Standards

Because as of right now, we don't really know. OK, We have microbiome disruption, dysbiosis, too many of some, not enough of others. But how do we really identify who's going to be the most likely responder?

And we're in the context of chronic disease here, but cancer is another use case where there's some really exciting stuff where using FMT and fixing the microbiomes allows the patient to begin responding to a drug they were

previously non-responsive to.

And so how can we then better identify who's going to be the ideal candidate for FMT and almost like predictive of their outcome? That would save people a lot of like, you know, trial and error for any treatment, right?

Like this individual response. And that goes for antibiotics and a whole lot other categories. It'd be great to know before you take it, is this going work?

Right. I mean, and it's also like, you know, the immune system plays a role in inflammation, immune dysfunction and inflammation in pretty much every single chronic disease that exists, whether it is cardiovascular, obesity, autoimmunity, cancer, neurodegenerative, all of it.

is some combination of inflammation and immune dysfunction. But I'm so curious. I have more logistical questions here. If I had them, I am sure that means some of the listeners do.

So, number one, do you screen and make sure your recipients have not been vaccinated for COVID and things like that? What is your screening criteria? Yes, yeah.

So there's the standards, so like Health Canada, FDA, the MHRA in the UK, TGA, they all have different but broadly overlapping standards and because we work with practitioners around the world, we seek to at a minimum comply with the standard as set by these different regulatory bodies.

However, in my opinion, their standards are like very easy to get through. In many cases, a donor could have received an antibiotic three to six months ago and still make it into the donor program.

And so to me, that's just not acceptable. even a really horrible donor can shift someone's C. diff and put them into a cure very quickly. But when you get to these more chronic complex cases, that just isn't going to cut it.

And so there's a lot more on top of that that I think is really important, which does go back to, and I mentioned it briefly, like breastfed, vaginally born.

We're looking at their lifetime use of antibiotics. Many donors have no lifetime of use antibiotics, but we do allow because there's really exceptionally healthy people that might've had a course of antibiotic for a near infection when they were eight and really had no.

Impact on their microbiome or their overall gut health. So we limit the amount of lifetime antibiotics No vaccines at all a minimum of a year before being in the program as well as at All during the course of being a donor in program.

Of course, we want our donors to stay with us long term We do look for COVID vaccine history. We check for spike proteins. Not many, but we do have a few donors who have had a COVID vaccination previously.

And so we've looked at their spike protein and we see, okay, they're in a sort of healthy range. But as a physician, the physician can choose, hey, I don't want a donor who's had, you know, a vaccine with a Covid vaccine in their history, and that's something a, uh, physician could choose and, we would only release in the future any product to them that would come from a unvaccinated donor from a COVID vaccine standpoint.

Oh, that's great. And then, okay, so just to understand a little bit more deeply. So this is not like there was an original donor and you've extracted these bacteria and now you are lab growing these Bacteria, correct?

I wish I was right. No, like every single capsule is coming from bacteria that has come from a real live screened donor that is been for lack of a better like ultra washed purified Yes.

Yeah. We literally have a, I guess he's not technically full time, but essentially full driver that's driving every day, picking up samples. And the majority of our donors are donating daily.

So we're accepting samples six days a week. Wow. Okay. There's just aspects of the microbiome that you can't regrow on a plate. Oh, for sure. We can only grow what we know about, and we can grow with the medium that grows those bacteria.

But the reality is we don't even know all of bacteria and fungi and virus, all the things that actually exist in the micro biome. And I think the microbiome is so much more than the bugs.

Like there's so many more going on. It's just like saying a forest is all about the trees, but not appreciating that the soil has a whole lot more to do with the health of that forest and the tree themselves than actual trees themselves.

So yeah, it's this whole living dynamic, ever changing, daily changing sort of large organism. Its almost its own organ, you know? So it is a fascinating thing.

So what makes novel biomes, your companies, approach different to other FMT companies and products that are out in the market? Yeah, I think that the one part being, i think really key is that, the manufacturing prowess that we have, you know, being regulated by Health Canada, which is probably one of the harder regulatory bodies to get approval from, from a GMP drug manufacturing standpoint.

I, think it's really important having third party oversight and making sure that what we're doing is all above board and being done appropriately. With that with G MP and why I sort of stress the G M P is because there's so many things.

that need to be done to BGMP manufacturer like just as an example you know we're talking about the donors in the screening of course there's all of the donor screen that comes into that and we could talk for half hour just about that but.

Every batch that we make, we're keeping a portion of it as a raw sample. We're a finished product from it, as retention sample, so any product, any pill that have, there's several that can be drawn on to retest in the future should there ever be an issue.

There's checkpoints at every point along the way to even release a product. Everything made between screening is held within in quarantine. So there is no release of product until all of the follow-up donor screening every three months is completed.

We have a microbiology lab run by microbiologists who are doing all the testing on the product to release it at every point along the way. Anything that goes into the products is tested.

This is all being done in clean rooms. Each batch is produced in a clean room that's completely cleaned every time. A new batch is made, so a new donor product comes into it, totally clean.

Then we do environmental testing on it to make sure there's no growth of fungi, bacteria, molds, etc. And that's being done repeatedly. We're testing the water system all the time.

So we're test the city water, we are testing water that comes out of our ultra-pure water. The list goes on and on, binders full of SOPs and documentation and everybody's trained to a certain standard and it's drug manufacturing.

So that to me tells us a lot about the safety of FMT because a part of it comes from the donor and donor screening and the other part comes form the manufacturing, just making sure nothing from environment can come into the product.

Which is really important. And then, you know, I think what makes us unique as well as my background is as a naturopathic doctor. So I spent many, many years treating hundreds of patients.

Pediatric Use, PPI Support, and Pre-Treatment

We bring a lot of that clinical experience as all of the scientific knowledge and our whole role is to try to educate and train doctors to become better at understanding the microbiome.

how to potentially shift it with FMT. And then we have several product types. So we, as I mentioned, we actually treated a lot of pediatrics and so we developed an oral powder and this is, you know, it's pretty magical.

It's substantially colorless, odorless and tasteless. You know it is hard to even see, but it in a small vial and you could just open this up, mix it up with some water, juice, milk, whatever, a parent would normally give their child.

And that will have a similar effect as an oral capsule, which a lot of kids cannot swallow. So several different product types. And again, as I mentioned, basically shelf stable at room temperature, although our stability studies as they stand right now, that's another thing, stability study.

batches every year. We're pulling new batch that we're tracking from a stability standpoint, what's happening over time. And we know we have different stability trials that are running, but just to make sure that the product is at the same standard as when we released it from the bacterial counts and other things.

So it can just easily transport. Fridge temperature is suggested for long-term storage, But that's a huge advantage to many years ago. When it was needing to be with dry ice, And there's, you know, some studies comparing the outcomes when doing like a frozen fresh product versus a freeze dried product, and the outcome are similar.

And then shelf life of minimum is where we're at right now, two years. We've done testing on products that are four or five years from when we made them.

But again, because it's not, we have to start a new stability study on a, new product. So we can't just decipher shelf-life on an old product that didn't have the same testing as the release.

I mean, it. There's a lot that goes into this, but yeah, so it makes it easier for a physician and then of course their patient to be able to travel with it, go home with that.

They don't need a fancy negative 80 freezer at home and so on and forth. That's great. So what about, especially like with the liquid form that you were just talking about with children, like how does it bypass stomach acid?

Yeah, there's a, so it doesn't. What we suggest and what's being done in a lot of the research is using actually a PPI. I hate PPIs as a general statement, as I do antibiotics, unless they can be lifesaving, but in the short term use.

putting a patient on a PPI, we haven't seen any differences. When we were treating autism, We were collecting a lot of data. We've written some of it up.

It's not been in formal publications, but we'vewritten up our own reports. And we saw no difference between a capsule treatment group and an oral powder treatment.

I was convinced in my head like, Oh, absolutely. we're going to see better outcomes for these kids who are doing the oral capsule, which is entericoded.

which we know gets through the stomach acid, we do capsule disintegration testing on every batch that we produce, so we now they don't open up before 60 minutes in that 2 pH, you know, stomach acids scenario.

But we saw no difference in outcomes between the groups, but they would be on 10, 15, 20 milligrams of Prilosec. that would be taken before the FMT dose each day they were going through treatment.

And in our protocol, they're typically doing four months of treatment overall. Then we just have them taper off of the PPI. From our vantage point, we didn't see any negative consequences to that.

Of course, it's a short term. We're not doing this for years, which a lot of patients are doing. PPIs are on them for 10

years in many cases, and the doctor never tells them to go off, even though the label very clearly states this is meant to be a short-term treatment.

So, yeah, that's the way we get around it. Is the PPI necessary to able to do this or that is an optional thing or is that part of the protocol? We suggest, I mean, you know, in medicine, we're always trying to weigh the pros and cons, right?

I think there's an advantage. Just thinking through the physiology and how everything works, there is an advance to doing this. We did have some parents who would say, yeah, really like to avoid this and we would just say hey, why don't you do like one or two teaspoons of baking soda.

That'll lower the pH of the stomach acid and you could do that instead. So there are cases where patients would do as an alternative. But purely looking at what's happening in the research, in research they are using the PPIs.

As an example, when I started this, I was very skeptical on the use of antibiotics as a part of the pre-treatment. I think we can do this better or as good with herbs.

So when initially treating patients back to early 2018, relying more on herbal antimicrobials. But when we started observing patients that would do the antibiotic approach, the outcomes were much better.

And this is anecdotal. This is just my experience. What types of organisms were you targeting? Are you talking about like Clostridium? Yeah, Closteridium is the main thing.

especially in the context of autism. A lot of these kids have a lot clostridium overgrowth, and so we would be using vancomycin common link to deal with that.

And again, it's a pros-cons thing, right? In the absence of FMT, I would very concerned about putting someone who's already vulnerable on an antibiotic just for the fun of it.

But in a context FMD, you're following it up immediately with a full replacement. The example that I often use is like, We're trying to get to the top of a mountain and having too much dysbiosis and overgrowth and pathogenic bugs just increases like how steep the mountain is, how deep the climate.

So we may be able to that, but we're just increasing our odds if we are lowering how hard it is to to top. We are more likely to go there and or get all the way versus part of the lake.

And so part the Lake could still result in really meaningful changes, But it might not be the significant change that we were hoping for.

FMT for SIBO and Complex Chronic Cases

Right. So when someone has something like SIBO, how is this impacting SIBo? Because we all hear that when you have SIbo, you shouldn't be doing probiotics because of the backwards sort of like motility and the intestine being one of, like, the driving causes.

Tell me your opinion on using FMT and people who have chronic SIvo. Yeah, FMT in research and my own clinical experience is actually showing resolution of SIBO, and I've seen this time and again.

I don't think the way we think about SIBo today is really all that accurate. Mm-hmm. And that then translates and sort of migrates up into the small bowel and has it.

If SIBO was purely just an overgrowth of bacteria that made their way into the small intestine, everybody doing oral FMT would get SIBo. Not the case at all.

And this is, again, what I see, but also we'd be seeing all of these people as a side effect of oral FMT treatment,

getting bloating, distention, diarrhea, you know, all of the typical SIBO symptoms.

So yeah, there's a really fascinating study and there has been more since originally where these patients had chronic obstructive bowel disorder. Basically like they're just severe constipation and when it gets so bad, they need to be hospitalized and treated and so on and forth.

And naturally, it's pretty easy to understand that these people develop SIBO. And so they were treating them with oral FMT. Not only did they resolve their current obstructive bowel disorder, they actually on pre-post breath testing resolved the SIBo.

So I think especially in these chronic relapsing cases, the dysfunction or dysbiosis of their microbiome is why they keep relapseing. When I was still treating patients, I would still put them on a SIbo treatment protocol, whether that was an antibiotic one, or an antibiotic herbal or just an herbal one and then we would go into the FMT so I wouldn't just treat them without trying to bring down some of the overgrowth but for many many patients that would be the ticket for them is that we've now fixed their microbiome because that's typically a part of most natural or functional health type protocols for SIBO is like you kill it you then rebuild the microbiom with the probiotics but as we discussed earlier these probiotics in these severe cases where there's just not a lot of my gut diversity to begin with.

There's nothing to regrow because there is nothing there. Like full strains and species of bacteria may have been completely eliminated due to their overuse of antibiotics and potentially diet and other lifestyle things.

So we've gone through the safety of your facility. We've done through safety and screening of the donors. Are there any other safety concerns that one should think about if they are considering using FMT as a piece of their therapeutic puzzle when dealing with complex chronic illness?

Yeah, great question. So I treated kids as young as three and adults into their eighties. I don't think there's like an age thing. There's been research on the use of FMT on newborns, literally like first feeding, comparing like a C.

diff born to a vaginal born and at six months having same microbiome as if they were vaginally born. So in theory, a newborn child could do FMT from the small amounts of studies that we have.

Um, so I don't think age is in any way a factor. I think immune system overall, um, you know, there's been one or two cases now where a patient that was elderly and had no immune systems actually died with FMTs, but predominantly because the donor had an antibiotic resistant bug.

And so now any of the screening, this was years ago, now all of this screening rules out antibiotic resistance to certain bacteria. But there's lots of patients that are humans that're thriving, but they have antibiotic resistant bugs.

They just don't know about it, why would you? Like there are a lot of patient that have H. pylori but no symptoms or B. hominis, actually no symptom at all and it may be beneficial for them.

And to be clear, your screening for all of those things. Yes, yes, so many years ago. But at the same time, there were studies being done that elderly patients, and I'm not talking like low immune function, I am talking these people have no immune system.

And so there was one case study or one report, this was not from our product or anything, it was years And the FDA, you know, put out a notice and this needs to be added to screening.

But there was a person who was elderly and who did die and they assume it was because of this antibiotic resistance, but they had essentially no immune system.

Not essentially, they have no system And so, you know, it's pretty easy to understand that connection. So in that context, like if someone was elderly and, um, had no immune system, they had an immune disease that had required that resulted in no mean system.

I'd be cautious, but this is being done in cancer. This is been done and pans pandas. where they have real immune dysfunction, low white blood cell counts, all of the things, and broadly speaking, no problems at all.

That would be the one caveat.

Safety Considerations, Hope, and Where to Learn More

And when I was treating, I always like cautious of cancer patients. I would more involved in like the post-cancer treatment, but the research now is just gung-ho ahead on using FMT during cancer treatment protocols, which to me is fascinating.

Yeah, it really is. Okay, is there anything else that you would like our listeners to know about novel biome or about FMT in general? Yeah. I mean, I've talked a lot about patients, but we don't treat patients anymore.

So you're going to have to work with someone amazing like Dr. Hinchey or bring your own provider, healthcare provider to the table to, work, with us to collaborate with.

Yeah, the only thing that I would think about is like, get it. You know, this feeling of hopelessness and, you know the daily waking up with, this uncertainty about the future.

And although FMT is not like a magic bullet for everybody, I think for those people that are in that situation, that just have no hope, they have not feeling that there's anything available to them.

There's no doctor, there is no medication, no supplement, nothing that can work. Sometimes an FMC can be life-changing. Of course, as you pointed out, it should absolutely include appropriate preparation and all the lifestyle things that come along with it.

But yeah, I think there's a real opportunity here for those people that are struggling and they don't have anything. There's no obvious disease there, right?

Like they're they, don´t have Lyme anymore. But there is just immune dysfunction, there´s microbiome dysfunction. They're dealing with all of these symptoms.

I think those patients, there's hope here. There's that shifting their microbiome can dramatically shift their quality of life and improve their overall health and wellbeing.

So don't despair, keep trying. And there is a light at the end of the tunnel. The body is magical thing. If you give it what it needs, it can absolutely transform and it doesn't have to take forever.

You know, this doesn' have be 10 years. This can happen in weeks or months. I couldn't agree more. And yes, like hope is such a precious, extremely helpful and necessary tool to getting better when you have a complex chronic illness.

So tell our listeners before we wrap up how they can find more information about novel biome. Yeah, our website has a lot of resources, even for patients who are interested.

But of course, for physicians as well, we do tons of blogs. So novel biome.com. We're on YouTube and all of the different social media platforms where we have our own podcast as Again, at NovelBiome and all of these different places.

Yeah, and if there is a practitioner in the audience who is interested in learning more, we spend a lot of time on education. So whether that's training the provider themselves or their team, if they're certain areas of interest, that there's research available.

We share it all. on the use of FMT in areas where there is a decent amount of research, everything from IBS SIBO

to neurological diseases like autism, Parkinson's, ulcerative colitis, oncology.

And we keep developing more and more resources and tools to give to doctors to help them in helping their patients. So yeah, reach out. Thank you. Thanks so much for your time.

Thank you. This was a lot of fun. It was. Okay. And for all of our listeners at home, thank you for being here with us. If this episode was helpful, please share it with others because together we all heal stronger.

If this episode gave you an answer, brought you new insight, or made you think differently, subscribe to the Lime Bites podcast and share with someone who's ready to take control of their healing journey.

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