Introduction to MyLymeData

Hello everyone. My name is Doctor Richard Horowitz and I'm the co-host of the Doctor Talk Killing Lyme Summit 2.0. It is my great pleasure to introduce to you a long term friend of mine, Lorraine Johnson.

Lorraine is CEO of Lyme disease.org and principal investigator of my Lyme data. And we're going to discuss today the My Lyme data, which is the largest at this point internationally nationally driven registry for patients.

I'm talking about how they do with treatments outcomes. Lorraine, thank you for joining us today. It's going to be I know, a fascinating conversation.

It's my pleasure, Rich. Yeah. You know, I want to add a few things about my background that I think most people won't know. And one is that I am a recovered, patient who had persistent Lyme disease.

So I was one of those people, was misdiagnosed for five years, and then ended up on some fairly aggressive long term treatment to get well. And the other is that my background is that I.

I'm an attorney who has an MBA. So when I became involved with Lyme disease, I started getting involved in health care policy matters and started working with the national, you know, national government organizations like the Patient-Centered Outcomes Research Institute, the Cochrane Collaboration.

So a lot of, you know, sort of high level government positions. And I learned quite a bit about that, about how the health care policy arena works and what was needed for us to do in Lyme disease.

Yeah. No that's great. So, tell me what inspired the creation of my Lyme data and what what are the primary goals. How did you get into this. Well, the main thing that inspired my Lyme got it.

Aside from the fact that I was working for the patient centered, you know, Research Outcomes Institute is and their focus is on was on patient registries.

So I actually was on the executive committee overseeing, you know, the patient registries there. So I learned a phenomenal amount about patient registries.

But it was clear that there were at this time in history where the patient voice can actually matter in terms of research. It didn't used to matter much, you know, used to just be researchers in a lab.

But there were more and more patient registries being put together. And a lot of them were put together by rare diseases because nobody had done the research.

But, in Lyme disease is not the problem that we're a rare disease. The problem is that nobody was doing the research. So we had this 20 year gap where nobody was really looking at, you know, at research projects.

It's 25 years now, I think. So the last NIH project was over 20 years ago, and it was really clear that patients don't need to wait, you know, patients can't wait, and they don't need to wait in order to have some research going on.

That's really important and to be building a knowledge base. So those were really sort of the primary reasons that we got involved with, putting together the registry.

Why the Registry Was Created

Right. So you're bridging this critical gap between patient experience and scientific research, which really doesn't

get done. And you have over 18,000.

Did I get the number right? People who've now registered. Yeah. And what's interesting about that, which is, you know, academic research is, is typically top down driven.

So they're going to have entry criteria that's going to exclude a lot of patients. And when you do that, you're just you're not dealing with real world data.

You're not dealing with the type of patients that a clinician will see in their practice. And so these are the patients who are misdiagnosed or that have co-infections or they had a delayed diagnosis.

So this bridging this gap between academic research and what patients experiences, which, by the way, is the same thing as bridging the gap between academic research and and clinic and clinicians, because the patient experience reflects the clinical experience, of course.

Right, right. So you're able to just sort of, leapfrog over and gather a lot of data that you just couldn't get in any of these, you know, government funded trials.

Right? And so, for example, if the prior NIH trials didn't really show that well, there actually was some benefit with antibiotics in the study with fatigue and Brian, study with, neurological symptoms.

But if the word on the street through the NIH was there's really no sense in getting longer term antibiotics, right? They don't work. But then we come to your registry and we read it.

It's like patients kind of say actually the opposite, right. As far as what they're reporting. Yeah. I mean, it's you know, it's over 50% are having treatment response.

But either they got well or they improved, you know, significantly or they improved mildly. So these are these are all people who are on their diagnostic journey and treatment journey.

So it's not a point in time study where you know, somebody has had just 30 days of treatment. And of course, we're including long term outcomes. Right.

Which I think is a really critical piece. So, you know, like in our registry, what we found was that the people who did really well, those were patients who had been on antibiotics, they'd been on them for a long time.

That means over four months, we don't have any trials are over four months. And, most of them had been on them for over a year. So if you're looking at what is it that makes a patient get well, the factors were antibiotics long term and working with a clinician who specializes in tick borne diseases.

Those were going to be the factors that were going to be predictive of whether patients got well right. I know, of course, what I'm trying to prove. And I know you know, this.

I'm in the process of trying to apply for a multicenter, placebo controlled, randomized trial of DAPs, some combination therapy which is less than four months.

And in fact, it's a 8 to 9 week oral generic protocol, no. IV, but also looking at overlapping factors of inflammation. So what I'm hoping to prove right is that the reason these people have needed longer term antibiotics to stay well is the older treatments that were done in these old NIH studies, they were not looking at the biofilm persist or forms of Bergdorf.

Right. They were not addressing Bartonella, which also has Bartonella, biofilm persistent forms. They weren't addressing pots, dysautonomia, viruses. Right. Long Covid wasn't around.

We're finding all these overlapping factors keeping people sick. Now in this in the registry, are people kind of listing

these things that they're finding that are overlapping, that are causing them to be ill?

Oh, yeah. I mean, we we gather information about, you know, the number of patients who've got co-infections. And that's, you know, that's about 70%, or higher than 70%.

So 76% are reporting co-infections, and the major ones are BBC and Bartonella. So those are both over 40%. And a lot of patients are reporting to or more.

So if you have clinical trials that exclude everybody who has a co-infection which the clinical trials have done, you're not going to get a sample. See, one of the things that may predict who develops persistent Lyme disease, maybe these co-infections.

So you leave all of these people out and you're not going to get any of the data back. That reflects how those people are doing. Yeah, I mean, this is the problem we face is we're we can't avoid it.

I mean, in my patient population, I mean, it's at least 80, 90% have BBC of Bartonella and overlapping factors.

Patient Diversity and Real-World Data

The problem of course, when I try and get this trial going is almost everyone is going to be exposed with BBC, a titers or an immuno blot or Barton or a BBC or a Bartonella immuno blots titers.

But I hope to have fish negative, meaning they're not active. And that's going to be, I think, the only way I'm going to be able to enroll people, because I don't think you can exclude people at this point when we call it chronic Lyme.

The reason I like calling it Limited's is I'm referring to the fact that it's Lyme with all these overlapping co-infections and mole toxins and pots and all these variables, right, that are keeping them ill.

You know, one thing you might consider, which is if you're looking at co-infections, is to do subgroups. So you may have a you know, we asked the simple question, have you been diagnosed with a co-infection.

And then we ask with supporting labs without supporting them. So we do it that way. But but you can take the the people who are not your fish and you know, positives and put them in a subgroup and see is it really any difference in these people because, you know, it's sort of a way of looking at how valuable is clinical diagnosis with these co-infections.

And I think sometimes it's extremely valuable, you know, do you have night sweats, you know, do you have a lot of neurological symptoms? I mean, having psychiatric symptoms, those are really, you know, clues that that patient may have a co-infection.

Right? Yeah. So, you know, I, I agree and I and that's of course, we're showing up in our practice also. So, so the patients that have enrolled in this registry, how does chronic Lyme disease compare to these other chronic diseases that are out there like a CFS, Me and fibro?

How chronic congestive heart failure is the one that people usually talk about their sick. How does it compare? Well, we're you know, it's it's much more severe than most illnesses I think 77%.

This is the this isn't such an important question. How would you in general how would you rate your health stacks. Excellent. Very good. Good. Fair. Poor.

So 77% of patients in our registry say that they're they have fair or poor health status. And that's actually that's a really large number. You don't see that type of number.

Ordinarily the general population has got 16% reporting fair or poor health standards. And, you know, the, the the impact on patients life using that question, because it's a government question and it's been used across multiple

diseases where it's been compared.

We see that Lyme patients have a far worse quality of life than patients with CFS, patients with fibromyalgia, patients with congestive heart failure.

So it's really it's an extreme debilitating disease. And, you know, aside from that, the other place you see a really big impact is on people's ability to work, you know?

So that's a really blunt instrument. You can you work or not? I mean, usually you don't walk into a doctor and say, hi, can you work? You know, if you can't work, you're really in trouble.

Yeah. Well, we have like. The rain. What were the ability rates? What were the disability rates that you found on the average in this population? It was it was 25% about 20.

And that's been pretty consistent over a number of studies that we've done, 25% and approximately 40% say that they have either had to reduce their hours or, adjust the type of work they do.

So maybe they're working at home. Right? So remote work and, you know, people don't necessarily think of those factors. I mean, you might ask somebody, what is your activity level been the last two weeks or one month?

And that may not reflect how the disease has impacted them, because maybe two years ago they had to quit their job. And that's not going to be captured in that to, you know, that two year period.

And they may still be not working, you know, so you have to actually if you're looking at things like limitations on function, you have to actually look at what's happened to the patient over the course of their illness.

Are they are they dealing from a place of a new normal? Have they now decided that it's normal not to work? Have they now decided that it's normal to work part time, or it's normal to have to work at home?

So those are factors that a lot of researchers aren't looking at. And it's it's an important factor. And what are the most common severe symptoms you're seeing in this patient population?

Well, the most common is, you know, fatigue, of course, but then we have sleep impairment, muscle aches, joint pains. But the ones that you see gathering together are the neurologic symptoms.

And they're it's about 80, 84% identify as having neurological, symptoms as among their three worst symptoms. So that's another question we ask. What are your three worst symptoms. Right.

Because that's not telling questions. Somebody might have severe psychiatric symptoms but those aren't their three worst. They're going to tell you their three worst or something else you know.

So you really have to you know, look at these, measurements of symptoms differently. I think in order to capture the information you need. Right. So fatigue is there.

But of course cognition, brain fog, neuropathy you do when you collect the data on neuropathy, tingling, numbness, burning, stabbing sensations.

Treatment Outcomes and Long-Term Antibiotics

One of the things we found when we validated our questionnaire, years ago at State University of New Paltz researchers, is that it migrated, are you collecting at all the migratory aspect?

Is that being asked or. It's not specific? Because even now when steer was finding it early on and, you know, early Lyman, we see it quite a bit in our patients.

Yeah, yeah. You know, you you have one of the things you have the benefit of is you have the benefit as a clinician of having longitudinal data. Yes, our data is a point in time data.

So we, we, we, we gather a really vast array of data. But it's on a single point in time. So we're not seeing those fluctuations. But we do ask patients whether they vary.

And the the answer is yes. Okay. So how does my Lyme data is different from the traditional clinical research approach like explain again, like why? And again for people listening I'm speaking to Lorraine Johnson who's CEO of Lyme disease.org.

When we've done our prior podcasts, by the way, I've encouraged people to please sign up if you are a Lyme patient and has not, at this point contacted Lorraine and my Lyme data and Lorraine tell them how they can do this, because really, everyone who is suffering from this really should be in your registry at this point.

Because the more people that register the more information we're getting, the better. Obviously, we can diagnose and treat patients. How are they going to sign up for this?

So you go to my Lyme data.org and you simply input your information. It it's not a long process. It's something that almost any patient can do. I mean, a lot of patients can't work, but they can do this, and, it just contributes so much to the body of knowledge that we have.

So I think it's really important if you or somebody you know, has Lyme disease, please, join up for my Lyme data at my line data.org. Great. And again, how does this vary exactly from the traditional clinical research approaches that have been done before?

Well, it's really interesting research because, you know, it came at a time when big data was just emerging as a type of research that you would do right.

But big data is new. It's a it's an emerging type of research. And, so it, it, it goes are the people who are doing big data research are typically very different from those who are doing traditional randomized controlled trials, traditional randomized controlled trials weed out a lot of patients, and then they look on a single variable like maybe it's one treatment and it's, for a course of time.

And that's it. It was either successful or it wasn't successful. And it took five years, by the way, to do this study. And it cost a gazillion dollars. Right. And, the results aren't applicable to most patients.

So, you know, the, the, the critique of traditional research is it costs too much, takes too long, and doesn't apply to most patients, you know, when you're excluding and, you know, the NIH study is excluded between, I believe it was 93 and 98% of patients.

When you're excluding that many patients, what is it that you're studying? You know, you're not studying patients who have Lyme disease. You're studying something.

It may be important to someone, but it's not important to most patients. And it doesn't apply to clinical practice. And it's such a big problem that we actually did a study, that's pending publication right now, actually.

And it is, taking a look at, the patients who are clinically diagnosed. So you start with 100% of the patients who are clinically diagnosed, and then you say, what is the effect of a positive Western blot or a rash positive or, you know, a history of a rash?

What is the effect of, you know, co-infections? What is the effect of having a prior diagnosis of CFS offense or a psychiatric addition? Right. Because those are all exclusions in the standard, you know, protocols for randomized controlled trials.

And what you find is that when you go through this list, it's a short list. It's just for, you know, we just looked at four

items. You end up with a sample size that just, you know, not is 10%.

So you've excluded 90% of the patients by applying these, you know, generally used standards. So it's not that we don't need standards. We need standards, but we need to be very careful about which standards we're using and why.

And, a good example of this is, you know, if you're going to exclude patients who have been previously diagnosed with CFS, FMS or psychiatric conditions, that's about 53% of patients who've been clinically diagnosed.

Okay. That one requirement is about 53% because those patients were misdiagnosed. So most patients before they're diagnosed with Lyme disease are misdiagnosed with another condition.

And the most common ones are CFS, FMF, and the psychiatric condition or so you know, you're not, gathering the information that you need in order to be able to, you know, to make valid conclusions that apply clinical practice.

And I just I just want to say one more thing. I just really encourage when this study is published, I really encourage clinicians, research tours, anybody who's doing research, take a look at the effect of each exclusion criteria before you apply it and ask yourself, is this scientifically justified?

Do I have a good reason for excluding patients who had a prior misdiagnosis? I mean, I don't think so. I think that's an error that occur. No.

Co-Infections and Overlapping Conditions

And in fact, and in designing the randomized trial I'm trying to do right now, I never thought of actually of excluding these people because just as you said, the majority of people who come to see me, who end up with the diagnosis of chronic Lyme, PTSD and all these overlapping factors, right?

They have a chronic fatigue, musculoskeletal, cardiopulmonary, neuropsychiatric illness. But yeah, symptoms of chronic fatigue and fibro long-covid and chronic Lyme are basically all the same, right?

With fatigue and pain and neuropathy. And I can't sleep and I have Pots disorder, Nami and psychiatric issue. The symptoms overlap. I mean, the only difference I see with Lyme is the symptoms come and go, good and bad days, right?

Migrates with the pain, which is the hallmark of Lyme, which you don't necessarily see in long-covid. But from what I'm getting from Bruce Patterson and other people in Long-Covid, they're going to find that a lot of these long Covid patients have live in Bartonella, as well as mold and everything else overlapping the you can't, you know, it's a mishmash at this point in time to think that you're going to live in a bubble and just find pure Lyme disease.

You have to take patients in the real world with these conditions and see, this is what I'm trying to do. Apply the model. How many these 16 factors are theoretically keeping a mill, adjust them, give them DAP zone and then following them over time.

And so I'm not planning on excluding them. I just have to figure out how to exclude active but easier barred because otherwise it's going to get a little bit tricky trying to prove the efficacy of that zone for chronic Lyme.

But ultimately we may have to have secondary, you know, pulse effects afterwards or using other things. We'll have to figure out how to do it down the line.

What do you I mean, with gaps on do you give it to your Bartonella patients? Oh, yeah. In fact, the thing about Bartonella. Is why are you going to exclude them exactly.

Well, no, but but the the reason is, is because if they have like, leave, you know, my beloved wife is now six years in full remission from some combination therapy.

But she tested positive for Bard. But she wasn't active when she finally did. Double dose stepson. The problem with Bart is if people do the nine week protocol and the Bard is active and I've addressed mold and I'm pulling the toxins and pots and low adrenal, I have to give them pulses of DAP.

So in roughly two week pulses every two months, at least four pulses over a year. So that would mean extending the trial child to two years with one year follow up.

It just. Right. Right. It's a much longer follow up. Yeah. It's cost. This cost. Well, I mean and you know, cost is an important factor because you don't want the perfect to be the enemy of the good.

You know, you actually just want to get some of this stuff done. It's just really important. Yeah. So, so getting back to what we've learned so far from the my Lyme data about persistent Lyme disease, what what have we learned so far from this that we didn't know from the traditional research?

Well, okay, I think that some of the most important things that we've learned are how patients vary, how different they are. You know, all of the NIH studies assumed that patients were a monolith.

I mean, they used to treatment averages. They didn't have a large enough sample to say, okay, well, these people, you know, were, had co-infections, but they didn't they weren't able to actually parse out the data.

So you ended up with a mishmash, you know, if you look at it this way, Rich, if if one person tests negative and that's a negative, negative one and one person tests positive and that's a positive one.

And now you average them together, you get zero. So it's not useful information. You know, it's it you want to be able to actually know how patients vary.

So one of the studies we published was on treatment heterogeneity. It was on how patients varied in their treatment response. That's a really important study because it shows that, patients are not all the same, that you actually have to look at these different subgroups.

And, you know, if you have a large enough sample, you can look at subgroups, but you can't do it with a really small, clinical trial. So that's that's one of the things.

And the other thing is we learned that patients really vary in how they respond to treatment. You know, it used to be that what you heard was that everybody's on I. V.

antibiotics. Well, that's that's not true. I mean, I think it's something like 2% on IV antibiotics. But if you listen to the CDC and the NIH, you're going to believe, well, everybody's on IV antibiotics, and we have to do everything we can to shut down treatment.

I mean, the fact of the matter is, the patients being treated most almost all are being treated uncommon oral antibiotics, you know, so that's another thing that we were able to discover that wasn't known before symptom severity.

So you say does a person have a symptom or not? We started asking how severe are your symptoms. That will really distinguish between the general population.

That's got an itsy bitsy little bit of fatigue and the Lyme population, they can't get out of bed. Right. It's you have to ask about severity. So if you're if you're really focused on your patient population and you understand what's driving this disease, you're able to get it information that it isn't known.

And the other thing we're doing is we're we're kind of, you know, completely, blowing up the house of cards that the only way to do research is traditional randomized control trials.

It's one way to do research, but it's not the only way to do research. And so you need to be bringing together all of

these different types of ways of approaching research.

Yeah, I'm and we talked about a little bit before we came on today. It's like since I plan on enrolling hopefully a couple of hundred people in this trial, I'll make sure also that we connect with my Lyme data so that they're feeding it in, and maybe you can even do a subgroup analysis to see, because you've got AI running.

I mean, you've got would you even have one? I, I was like several AIS running to do subgroup analysis of the data at this point. Right. Well, I mean, we're working with UCLA.

So, you know, if you're working with a professor, Professor Deanna Needle, who is, by the way, fabulous and who joined in our efforts the very first day we started, it was kind of remarkable.

She gave me a phone call I want to be in. So we've been working with AI for a long time.

Symptoms, Disability, and Quality of Life

We've learned an enormous amount about working with AI, and it's so fortunate that we've developed all of our protocols and how we analyze data, you know, in step with AI, because you actually need AI to start sifting through vast quantities of data.

There just is. There just isn't any substitute. You can't do it manually, you know, one calculation at a time, or I think or I think it's this I think this is the important thing.

And then you do that analysis and you find out, oh, that wasn't the important thing. Okay. And I can tell you look at these five factors. And so the most important thing, rich in, you know, in putting together that type of the study for where you're going to be using in some subgroups is to make sure that you ask the right questions for identifying the subgroups.

And it would be lovely if you were asking some of the same questions that we were, so that we had comparable. But I will definitely speak to my statistician.

Her name is Nicole. Nicole Close is the one we're going to be using. She's done multiple randomized trials. I will make sure I put Nicole in touch with you so that when you eventually start collecting the data she can use, I mean, your extensive experience here, obviously, we want to learn from what's already been done, and I'd have to, you know, reinvent the wheel at this point in time.

Yeah. I mean, you know, it's it's interesting too. I mean, the other thing that I think is a really huge accomplished method for my Lyme data is we're now on like our eighth publication, our a peer reviewed publication.

You know, it's it's extremely uncommon to have patient led research to begin with and then to have that many publications in coordination, in partnership with academic researchers, bio statisticians.

It's really remarkable. And it's changed. I think the the way we look at research. Well, I mean, we're in the middle of a worldwide epidemic. I mean, somebody who's got to care at some point in time with everybody doing this.

I mean, I mean, even if it wasn't compassion, the place where you were coming from is, oh, my God, we have to get sick people better. They would do it for financial reasons alone because of the disability rates and all right, insurance costs and everything that's happening associated with it.

Yeah. Yeah it's it's a big deal. And you know, the the point that you were making earlier about co-infections and about how a lot of these symptoms overlap.

I'm not sure you're aware of the efforts of, you know, infection associated chronic conditions and illnesses. I Aki is kind of the moniker that it used.

But the National Academy of Science and Engineering and Medicine put together hosted a workshop which, I was fortunate enough to be on the planning committee for.

And it brought together all of these diseases at the same time. And so for the first time I have ever seen, we had clinicians who treated each of these individual diseases, researchers who treated these individual, well researched, diseases, and they were talking to each other and you were seeing the symptom overlap, and you were saying that some of the mechanisms that might be at play there, there could be commonalities there, and that it was important to understand how these diseases were working in general, where they overlap, and then also to do individual research where, you know, where it makes sense.

So, you know, I mean, I had somebody ask me, have you ask people in my Lyme data whether they have, you know, covet or long covet and we have it. Yeah. But we will.

But even if you did, it's kind of like almost everybody has had it. So, I mean, is it is it a factor that's going to distinguish, you know, how small is that population going to be that didn't you know.

Yeah. And it's a little tricky with long Covid because of the definition of long Covid. And whether you want to use, for example, Radiance Diagnostics and Bruce Patterson's 14 cytokine panel to meet the official criteria, it gets a little bit tricky, but but certainly if you've had Covid, you're much worse, which we've seen of course happened to patients.

And we started using a little bit of pravastatin to see we're still evaluating it. The only part I have difficulty, I think it's great that all these people are coming together for different diseases.

And by the way, so my third science book, I don't know if you know, I'm writing this, but Simon and Schuster gave me a contract. My third science book I'm writing is on why We Stay Sick.

And what I found is when I did an I dive into all these major diseases from autism, ALS, Alzheimer's disease, allergies, cardio. It doesn't matter what the name of the disease is, cancer.

All 16 points on the since model are showing up in the medical literature on a PubMed search. The only problem I have with associated infection chronic illness of calling it that is that there's of course been this problem in the Lyme community for a long time that they don't like calling it chronic Lyme disease.

Or some people don't like TLDs. I don't mind chronic Lyme disease because it is a chronic infection, but I prefer Lyme message or non Lyme message only because the 16 points on the message model are showing up in chronic fatigue syndrome, in fibromyalgia in Lyme in long Covid I, the article we published this year, all 16 factors on the message model that I published in 2018 and health care showed up long Covid before the virus was even around.

Yeah, we need a common denominator, all these chronic diseases. You probably know this, but roughly one to Americans suffers from a chronic illness. Right.

And if you if you add up long Covid and CFS me you're talking over 14% of the the US population. It's a big problem. So I'm glad the researchers got together.

I just wish that they would use at least take some of the research we have done and look at it. Maybe after the book is out, it'll, you know, it'll get a little bit more traction of using the model we're using because the PubMed search shows up in all of these different chronic diseases.

Yeah, I mean, it's it's interesting because, you know, just terminology or definitions of a disease, right? I mean, that's interesting.

Research Limits and Exclusion Criteria

I don't know, I mean, I think CFS is ten different definitions have been developed for CFS. And so which one are you going to use. Becomes an issue. Right.

And so, you know, the thing with chronic Lyme is it is it is chronic Lyme. You can you know, everybody knows that from 30 years ago. Right? The CDC, when they're doing a survey, they say chronic Lyme.

And you ask them why. Why do you do that. You know, as they put it they explained it in one of their papers. And the reason they do that is I say, this is what the public knows the disease is. So is you got to reach people in both places.

One way you have to have people understand the similarities and the overlapping nature of these diseases. And on the other hand, you have to have people be able to understand this is what we're talking about in common, right?

But by the way, when you're doing these subgroup analysis and I don't know if you've looked at this, have you looked at any of the persistent drugs like rifampin, methylene blue.

Have you been able to or can it be done eventually with AI to look at these subgroups, to see how these people have used persist your medications do compared to the other group?

Yeah. I think, you know, the question is it's it's really interesting. You have this really large sample and then that sample 52% are taking antibiotics, and now you've eliminated just about 50%.

Right. And now you're looking at what antibiotics are they using. And the primary antibiotic I'm going to just let you tell me what the primary antibiotic is that used to treat Lyme.

Because it's the one that shows up in like, you know, I don't know, 90% say 90% of people like Doxy cycling is within answering. Right. And and then you get down to some of the other more common IV zero seven.

But eventually you make your way down to methylene blue and you make your way down to downtown, and we've got people who've tried DEP, so who are in our registry and people who've done methylene blue, we don't have large numbers.

So I'd love to see, hundred people or more that have tried one of those, you know, one of those drugs. And that's why we need more people to, sign up and enroll.

In my, you know, you know what I think I'm doing now that we're having this conversation, I'll speak to Heather from my office to actually see if we can blast out, and tell them at this point that it'd be great.

Yeah, because these are all people in my practice have used it. Right. And and maybe if enough people sign up, you can do a subgroup analysis with the I.

Yeah. That's right, that's right. Yeah. I mean, this thing about working with clinicians, which it's so important because clinicians have so much to offer.

And, the registry has a lot to offer, but the two together really can make, I think, big progress. Yeah. Is there something really surprising that came out of the data?

I mean most of us expected chronic fatigue and neurological issues of course to be there. For those of us like myself in there, I'm not surprised that longer term antibiotics help people because people would come in to see me and say, I stopped them.

My symptoms came back before I started using more of the persistent drug regimens. Was there anything surprising that came out of the data you weren't expecting?

Well, I, I will tell you that I was I have been completely floored by how much variation there is in the disease. It's

the. Variation. Yeah. How much variation there is in the symptoms that people present with how much we even if you if you look at, you know, gender, you see that there's huge differences in males and females.

With this disease. And, you know, we published a paper on, biological sex based differences in Lyme disease. And there's a lot there was some research that was done before it, and there's some more research that's being done now at Johns Hopkins.

So, you know, a part of this is getting conversations going about topics nobody's talked about, you know, on a robust way. But that's, you know, all of that variation in the variation in treatment response, I think are really, extraordinary in this population, particularly considering that we were told that everybody was the same, that they all had a Western blot, but they all had the rash, that they were all treated timely.

You know, none of that stuff is true. And, and and the variation in treatment responses, at least what we find, if people, for example, have more toxicity, they don't respond to the treatment as well.

And whether it's because the more toxins themselves cause similar symptoms of fatigue, brain fog rapidly, or because the glial toxins are suppressing the immune system or all of the above, we're finding there are certain specific key factors like mold long-covid, horrible Potts disorder, Nami, affecting your fatigue, your dizziness, your brain fog.

I mean, some of these are well known, but we're seeing these factors, like, if we don't address these overlapping factors of inflammation and downstream effects, the effect that we're seeing from our nine weeks alone protocol and pulsing.

It's not going to be as robust because it's like going into a doctor's office with 16 nails in your foot. You pulled out one nail and you still got 15 to go.

Right? So I, I. Are you able to see in the subgroup analysis the same type of thing. Or again, it's not yet been completely looked at. Well, you know, we ask the questions about mold and parts but we haven't, we haven't, turned our resources to developing that or taking a closer look at it.

But we well, I mean, I have a question for you. When you treat the patients that you have that have heart with the, do you believe that the daptone, has an effect on the part?

No. Not specifically. That's interesting. No. And as an example, my wife has no more chronic Lyme symptoms, but she still has some residual parts. But that's from kind of limbic vagal issues from trauma as a child, the vagus nerve being affected.

Persistent Lyme, Subgroups, and Trial Design

You know, we find I have o over 50% of my patients are doing vagal Olympic retraining because the limbic system, you know, a lot of them have been abused in many different ways.

The vagus nerve gets affected by mold by Lyme, by Bart, by long Covid. We find we have to do vagal retraining, Olympic retraining. Otherwise we don't get the same robust responses.

So no, the dapt zone will help with layers of fatigue and brain fog and pain and neuropathy. But if your fatigue and your brain fog is due to pots and you're not treating the pots properly or getting to the cause of it, you still might see that the fatigue and brain fog is somewhat better, but you're not going to get the full result of the protocol until the Pots has been addressed.

Okay, I have another question for you. Yeah. So what is vagal limbic retraining. Everybody's going to want to know rich. So so the autonomic nervous system, the part of your body that does the involuntary movements of, of breathing and heart rate and digestion and moving your bowels.

And this, this is the autonomic nervous system. It's kind of the silent part of your nervous system that's not volitional. It's in the background that it's doing all of what needs to do.

So there's two branches. The parasympathetic which uses primarily the vagus nerve. Vagus nerve is has a big role actually in inflammation. But it's the people who, for example, come in that are very anxious.

They have the parasympathetic is kind of decreased. They have an auto sympathetic increase where they have fight or flight reactions. They're putting out epinephrine and norepinephrine.

In those patients, they're not easy to get better because of this imbalance in their autonomic nervous system. So we find that between the emotional trauma that they've had in the past, either from being gaslighted, going to 30 doctors, telling them there's nothing wrong with or for abuse earlier in life, or because they've actually had mold or other factors making them ill.

We find that getting their autonomic nervous system back in balance, meaning you're not overstimulated, with your auto sympathetic fight or flight or too much parasympathetic.

It's got to be in balance, right, for the body to work properly. When that happens, we find people feel much, much better. So there are techniques. Some are like meditation techniques, some people wear like these devices on their wrists, like the Apollo neuro stim is one that people love that I just ordered one for Lee and a friend of ours.

I'm even going to try it myself to see what it is. I'm getting some great results from patients doing these things, because they don't always have time to meditate and do some of these techniques, like the anti hopper dynamic neural retraining, the gutter amygdala, insula retraining, primal trust.

There are all these techniques that work. They do a great job, but you got to stick with them for a half hour, hour a day. And it takes months. So people are accessing these things, but it takes time to do the healing.

But I can tell you the reason it's important in people is when you look at the 16 point M6 model, from my perspective, mitochondrial dysfunction, where you've got all this free radical oxidative stress and inflammation, damaging the cells in the joints, the mitochondria gets stuck and it what's called a cell danger response.

So if you are in an unsafe environment, if you're in California and you have frequent wildfires or floods or mudslides, your system is in a state that no matter how many antibiotics you take or how much multitask you take, you're not going to go back in balance and you're not going to be well, because the mitochondria is getting stuck in the cell.

Danger response the limbic retraining by addressing mold and addressing Lyme and co-infections and pots and doing all this and then doing the limbic vagal retraining, it kind of resets the system so the healing can then take place.

And we really see, for some people, absolutely essential, especially the people that have had abuse and have been gaslighted before coming to see us like that.

The mind body connection, I mean, you really see the results of it, that you can't just give them antibiotics and treat. You've got to really do all of this to get patients better.

I think it's so important. And I know you recently did an article on that mentions meditation. You know, as one of the things it's important for patients to be involved in.

The other thing I just wanted to mention that it's really striking about what you said is, you know, the innovation aspect of your patients coming to you and saying, you know, we're using the Apollo, you know, neuro stem, you know, and so now you're saying, okay, I'm wondering about the Apollo neuro, so maybe I should look at that.

Maybe that's actually something I should be using with my patients. Right. But there's this piece of innovation that

gets lost when you're just doing top down academic research.

It's the innovation piece. And the people who know the innovation are the clinicians and the patients, and that's what we need to be capturing. So I'm really glad to hear, you know, that you're moving in those types of directions.

Well, I mean, whatever innovation I've had comes from the great researchers, because if John Hopkins, researchers like Doctor Yunxiang have not talked about biofilm, persistent forms of bacteria, that's true.

I wouldn't have said, oh, hold on. Oh, you mean persistent bacteria like TB? Oh, maybe I should look at mycobacterium drugs for leprosy and TB. And then I use them around. Oh my god. Home run out of the park.

It's because of them. It's the innovation really came from just reading the literature. And thank God the Lyme groups were funding Hopkins and Stanford and ever Shopee's group.

And now all of that research is so important, is so important. Yeah. I mean, I would say the thing about the academic model, but I don't really I don't really mean it as a broad, sweeping thing because the fact of the matter is, like you point out, we've had some terrific research that has come out in the last, you know, particularly the last five years, I'd say.

Yeah. And, you know, it's just one way that we need to be thinking about this is we need to be thinking about how do we capture innovation, how do we capture innovation of patients who've been told they can't do this or they can't do that, or they don't have access to this?

You need to be able to capture that innovation, because is what informs us what we can do. Right. And and the Gold Standard of Medicine is a randomized, multicenter, placebo trial, which is why I'm now right, because even though I know it's working, the rest of the world is not going to know until I prove it in that model.

Yeah, right. Well, I'm I'm really I'm really grateful that you're going to do that. I think it's such an important thing to do. A lot of people do things that they think work and they don't put it to the test.

Alternative Therapies and AI Analysis

But you know, you're you're walking the walk in terms of here's what I believe. And here's what we're going to do to demonstrate it. I think that's so important.

Yeah. Now, you know, in our group, of course, I mean, we see and this is the reason I'm doing the study is we see superior results using persistent drugs and biofilm agents in your group.

When you're looking at the My Lyme data, are you able to tell why some patients respond differently to antibiotics, like why some do better and some don't?

There's the subgroup analysis able to to show that at this point. You know, we're not looking at biological data. So we're not able to actually say okay was there a persist or are there what we're able to do is we're able to say, you know, what seems to be working for people?

And that's like a really in-depth analysis that needs to be done. I'm waiting for there to be a larger sample in things like gaps or in methylene blue.

Some of the more, you know, recent treatments that I think may be really making a difference so that we can actually take a look at, you know, the population as a whole.

But a lot of times if you ask a patient, you know, what medication they're taking, it's going to be toxic cycling because that's what their physician is prescribing, either because it's the first step in their treatment journey or because that's all their physician prescribes.

And, you know, they maybe take it for a longer term or shorter term. But the persistent issue is a really big issue. I don't think we can get at that through survey data.

I think that's going to have to come from clinicians who can, you know. Look at, know. And I realize now, speaking to you, I really need to tell Heather from my office to send out a blast.

In fact, I'll have her contact you if there a specific. I realize they can just go on and my Lyme that a.org and fill it out. But if there are specific questions you even want them to answer.

Yeah, on the my Lyme data, you should let me know before I send out a blast. And hopefully I'll get you enough patients, even from our practice. Oh yeah, we definitely want them to answer the antibiotic questions.

So I mean, the bottom line is we need for them to answer the, you know, the full bank of questions. It doesn't take that long, but it's important because you can't do your subgroup analysis unless you know, when were you diagnosed, were you previously misdiagnosed?

Did you have a positive Western blot? Did you have a rash? You actually need to know that information in order to be able to do things like, say, how or how is this group different than that group to identify your subgroups?

Right now, apart from the antibiotics that you are finding effective in the longer term, even if it's, you know, doxy because Monica members, you know, the studies you just published last year, of course, Doxy cycling alone was not enough to eliminate Borelli in the mouse.

But if you've used rifampin dapt some to persist or drugs, it did eliminate it. Which is great for me because now when I go to the NIH for, you know, the trials, I can say I have an animal model.

I have a culture model, I have retrospective, you know, semi we'll see what other great research. Yeah. No. Really fabulous. What other alternative therapies have people found helpful in the my Lyme data research.

Well, people have found using antimicrobials. So herbal supplements seem to be effective. And the other thing that we're seeing a lot of is there were a number of people who tried this did not work very well.

Who tried, stem cells and stem cells, you know, only 3% said that they were effective. So, you know, but we were able to look at both the side effects and the efficacy of different alternative treatments where we've gone back in and we've beefed up that section since then, too, you know, to ask about specific herbal supplements, because I think, you know, a little bit the devil is in the details, you know, in terms of which supplement where you're taking, what was the effect that it was having.

And, but that's information that we've gathered a lot of, and we need to go back and do analysis. I'm telling you, Rick, we have so much data. It's it's an embarrassment of riches.

There's so many studies that it's like we sit there and we say, oh, yeah, well, we have to do that study. We have to do that. So we need to do that saying, oh yeah, that brings up another study because, you know, it's great.

When it. Helps. I think that the patients are making this happen. Right. So it's that so obviously getting more patients to sign up again. Yes. My Lyme data.org is where they're they're signing up for this.

Right. But apart from getting patients to sign up will eventually like conditions like myself be able to go to the I and ask a question. I mean, this would be the ideal, right?

Go to the data, ask the computer. It's like I have a just like right now I got my new iPhone 16 with eye on it, right? So I'm using right. I'm using the Gemini from Google.

And I'm asking and it's you know, it's fun to ask it. Yeah. Well eventually we might eventually have that ability as clinicians to ask questions from the data back.

Yeah. Wouldn't that be great? Wouldn't that be great? You first you have to know ground truth before you start, you know, allowing sort of little little questions because and you have to know what a question can answer and what its limitations are.

So in order to train, I mean, we are working with somebody on a high, but in order to train that AI to do something like that effectively, that you're, it's that's years away, but it's, it's not off the table because, you know, AI is just, growing exponentially.

Future Collaboration and Registry Growth

I mean, we use it quite a bit, too. It's it's extremely helpful, in certain, in certain aspects. I would I wouldn't use it as a primary source for some things, but for other things it's just extraordinarily helpful.

But you have to read it carefully. I mean, where it's been helpful from my perspective is like doing PubMed searches and stuff and having it bring out like multiple scientific articles at once and adding that's been very helpful.

Yeah, right. Well, there's some really great tools for that. That so so what's your next steps for the my lab did a project. We're actually I knew we were going to come to an hour almost before we knew it.

Then what are the next steps and anything else by the way you feel important that you'd like to share with with the audience? Well, we're in the process of developing a comprehensive treatment survey.

We think it's just really, really important to know what patients are using and what's working. And so that's going to be you know, what we're queuing up is sort of our next, survey is going to be, really in-depth focus on treatments and treatment response and treatment side effects.

Were, interested in collaborating with clinicians like you mentioned. And we're also working on academic, collaboration. So we're working with UCLA. We worked with the University of Washington.

We're excited about a new collaboration with Sherry Marvel at Johns Hopkins that were, beginning and this is working with students, which when you're dealing with academic, a lot of us is working with students.

And then we've spoken with researchers at Stanford, and we're hoping that relationship will develop further. So, you know, there's a lot of opportunities for people to collaborate right now.

Yeah. As I said, I'm going to speak to Nicole, close to the statistician we're using for our trial, and I'm going to have her contact you about not only what questions to ask in the study, but also getting the data right, so we can all kind of combine the data and, and use it and have the AI take a look at subgroup analysis.

I think that'll be fascinating. Yeah, it'd be great. Yeah. Lauren, anything else you want to share with people that you think? Or did we cover the big points?

You think we've covered the big points? I just want to say one last time, if you are online patient or you know somebody who's an online patient, please make sure that they sign up for my Lyme data.

You can do that easily by going to my Lyme data.org. Right. And I would please encourage people who are listening. Have we did this last year right when we did the summit and did you did you get a good response from some of the people?

Oh yeah, people. People love. This. Yeah. So so again, I mean we're looking and because this is a world I mean, the CDC, when they talk about roughly a half a million cases, but then they come out later in the year and say, oh, by the way, the Medicare rates were seven times higher.

It's like, what are we talking 3.5 million people a year? It's like, if you have 18,000 people and over 3 billion are getting. It's like, hey everybody, please sign up for my Lyme data.org and let's get that data in there.

Because the more data you have with big data, the faster we're going to have solutions for this. Yeah that's right. Lorraine, you're doing great work.

You're doing great work. I want to I want to congratulate you on sticking with this. And, I'm really happy you've stuck with it because it's such an important project.

And again, we'll encourage our, our patients in our practice to sign up and try and get you some of that, that also. You know, I really appreciate it.

It's been great talking to you. Yeah. So for those of you again who've been tuning in, my name is Doctor Richard Horowitz. I'm co-host of the Doctor Talk Healing Lyme Summit 2.0.

We've been discussing my Lyme data, the largest online patient registry for chronic Lyme disease. Lorraine Johnson has been running that project now for years, doing a great job with eight publications, more than anyone's ever done in this.

Please sign up for my line data.org and again to stay tuned soon for your next episode of Healing Lyme. Thank you so much for joining us.