Introduction and Lorraine Johnsonu2019s background

Hello, everyone. My name is Dr. Richard Horowitz and we are here today with Lorraine Johnson for DrTalks for the Healing From Lyme Summit. it's a great pleasure to have Lorraine here today.

We're going to be discussing patient led research using the MyLymeData patient registry. For those of you who don't know, Lorraine, Lorraine Johnson is a lawyer and CEO of LymeDisease.org, which reaches millions of Lyme patients and LymeDisease.org has launched one of the nation's largest patient driven research projects.

It's a patient registry and research platform that allows patients to pool their data to help find a cure. And Lorraine, it's really a pleasure. You and I have not had a chance to connect for a while, so it's really great to see you.

Why don't you tell people a little bit about yourself, how you got into this, right. your story a little bit. And then let's dive into the Lyme. The Lyme data and the great information that you've gotten from it.

Yes. It's great to be here with you, Rich. I, you know, I came into Lyme like a lot of people do. I was a reluctant volunteer, meaning I came down with Lyme disease.

And as I was going through the diagnostic process and the treatment process and finding out how difficult it was, you know, and I had been misdiagnosed for five years, which I don't think is uncommon.

And, finally getting the treatment that I needed to get back on course, I thought, this isn't right. We really need to step in and do something for the patients.

And so I joined LymeDisease.org and got on their board, and we started doing a lot of advocacy and advocacy work. But then, you know, somewhere along the Lyme, I just figured out that, you know, you can say things that are right or that are ethical all you want.

What really matters is do you have the data, can you back it up? Do you have solid facts? Because honestly, public policy makers, they don't want to hear about your opinions on anything.

They want you to show them the data. And patients just really didn't have a way to put together data. and at the time, I was doing a lot of public speaking and engaged with a lot of large government organizations like, well, the, the internationally I would have been the Cochrane Collaboration, but but locally, I would have been the, the Patient Centered Outcomes Research Institute, which was just conducting some groundbreaking research.

And they had funded 35 patient registries. And so they asked me to be on their advisory committee. and then they asked me to be on their executive committee.

So I was really learning from the best folks around about how to do patient led research. And I thought, I'm going to launch a registry. So we launched the registry while I was at Pcori, and it was initially part of the Patient, you know, Centered Research Outcomes Institute.

So, you know, it was we were breathtakingly lucky that we had people who just sort of held our hand and tutored us. And till we got it launched and launched correctly.

And then we were just amazed at the success for it. Yeah. No. That's great. In fact, this is your quote. I'm, I'm attributing this to you. And I have to tell you, because you just mentioned this and I think it's an amazing quote "In God We Trust, but all others bring data." And I think it it is a fabulous quote because ultimately we've always known that it is big data, ultimately, right, that we need to help really solve the problem because otherwise we all see things from our own lens.

But we've got to create that big data registry. So. So tell us exactly what is the MyLymeData? MyLymeData, what does it do? Why is it important and what types of patients have you included?

Give us a little background on it. Well, MyLymeData in order to be enrolled in it, you simply have to be, clinically diagnosed by a clinician and be in the US.

That's all we, we require. and so it's a really broad registry. We have, people who have acute Lyme disease, people who have late, untreated Lyme disease, people who have, treated Lyme disease that's become chronic, you know, six months or more after their initial treatment.

And then we have patients who are, well, so, you know, when we launched the registry, we didn't expect to get a lot of acute patients, and we didn't expect to get a lot of, well, patients.

But we probably have the largest registry of patients who have acute disease and also patients who are well, because they came and they filled out the questionnaire.

Why patient-led research needs data

And so now they're part of the database, which means we can compare people with acute disease to people with chronic, Lyme disease, to people who are well, and find out how they differ, you know, and how are they alike.

So I think we're just really fortunate with the breadth of people who are enrolled. And we have 18,000 people who've enrolled now, and it just keeps growing. So, it's it's it's hard to under it's hard to overstate the importance of having data and vast quantities of data.

So the data that we collect is both deep, meaning we ask all of the questions that you would think to ask of Lyme patients. and we do it. We do it in a way that's very credible.

We use government questions to the extent that we can't. So we really want to be able to compare ourselves to other diseases, to the general population.

And we're able to do that because we ask the right questions. And the other thing is it's very broad. It includes all of these different types of patients.

So that means that we can divide people into subgroups. We can say, how does how the treatment responders compare to treatment non-responders. And what's different about those two groups?

What was it that the responders did that that made them more likely to get well? And I think everybody wants to know that. What, what, treatments have people found to be the most effective?

and that is the type of information that is not being collected by it's not being collected by anybody because nobody has that type of resource to do that.

And because, you know, clinical trials are usually very narrow. You know, maybe they are maybe they're, a convenient sample of people who walk in the door from somebody who you respect, like you, you've done research and maybe it's, maybe it's a randomized controlled trial where you eliminate 89 to 99% of the people who apply.

So then you take those results and you say, okay, well, those results, those results are not going to apply to most patients because you excluded most patients. Right?

So now what are those patients to do and what are clinicians to do. And how are we guiding people. So I think that collecting the type of data that we're able to collect allows us to do things that other resources can't do, even big data resources.

So if you look at, say, like an Insurance Database or EHR records, they're only as good as the information they

collect. And the fact is that those, databases are created to collect and assist in billing practices so they don't ask the questions that you want to know.

What treatments have you tried, what's been successful, you know, so you you have to have, a registry that's actually vast in terms of what is asking.

And you have to have the right people working on it. Right now. That's it's excellent. And and, you know, if you've told me the public policy requires data, I mean, how do you have public policy without adequate data?

And I guess the question I would have is because you have the largest database at this point than anyone has on these, you know, acute and chronic Lyme patients.

Do you think it's actually moving the needle a little bit? Because I think a lot of us have been frustrated. Of course, with how slow the process is. Right.

You I was on the HHS Tick Borne Disease Working Group on the first round. You know, Pat was there. We've all put our time in with this. And yet we look at how slow the process is.

I mean, do you think the database is starting to move public policy a little bit in the right direction? I really do I mean, I think, okay, so in the the tick borne disease working group, you know, which was initiated under the 21st Century Cures Act.

So it was really, you know, that that act was intended to start engaging in innovative research. It was really intended to break open the doors of traditional, slow paced plotting research. And, so that was what really sort of opened the doors for these sorts of things.

And we've been able now when we go into, say, the tick borne disease working group and I've been on I've been on a subcommittee for every working group, you know, to provide information, to search our database to make sure that they've got the tools that they need to point them to the, the you know, we published six studies that are peer reviewed to point them to those studies so that they have research that they can cite.

And, we have been cited over 100 times by the Tick Borne Disease Working Group and were, you know, by other researchers. We've been cited over 100 times.

So, yes, we're we're getting cited. We're getting noticed. In fact, our the journals that publish us, we're in the top 5%, influencers in terms of those journals, in terms of what we publish.

And these are different journals with different standards. You know, I just pulled it together for the board the other day, and I went, whoa, you're kidding.

You know, in the top 5%. I got an A, you know, this registry got an A in terms of its research. So I feel really good about the reach that the articles have had and how they're being used by other advocates in the community, because you have to be able to cite something.

And so if somebody is working on a research project, they call me and I tell them, here's what you can cite, here's what we've done, here's what we know.

and when it's a tick borne disease working group, I'm typically, you know, informing the person who's the head of the committee here's, you know, here's an approach, here's what we've tried, here's what we found out.

Here are some items we have to rate. And, and it's made a difference. I mean, for example, we we one of the things that, I was involved in was writing, proposal that they start funding innovative research.

So research using patient registries, research that's a little bit out of the box. Right. And and that got included and that got included. And then it got funded by the CDMO, you know, which is the Department of Defense's grant arm.

So they they proposed a grant that was essentially the innovative research, concept that I had worked on in the subcommittee. So I think we're making a difference.

But it's it's excruciatingly slow because patients don't have they just don't have treatment options. And they don't have they don't have time to wait because their life is just it's just going by.

Right. So I think, one of the things that really slowed us down is the legacy systems of research. You know, we enroll 36 patients or 120 patients and we call that a study.

And it it is a study, and it does provide some information. But but we're going so slow. And you know, each of those studies takes, you know, five years to conduct.

What MyLymeData is and who enrolls

And so how are we going to get from point A to point B. And I'll give you an example. So let's say that you're talking about what are the treatment options that work for patients.

And we did a study that showed that, patients who were, well, or who were high responders. So people who are doing really well on, you know, in treatment, we said, you know, what was it that worked for you?

How long were you on treatment? what type of physician was treating you? And the answer was they were, on and how biotics they were on them for a long time.

They were on them for for over four months. Over 12 months. so these are not even time periods that are being included in any of the trials, right. And they were on varying, you know, various drugs and the type of clinician that they were seeing that was improving their health care was an alarmed.

So, I mean, like you, you know, you you you put out questions. You don't know what the answer is going to be. You know, sometimes you're surprised, you know, people, refer.

You know, I thought, for example, when we ask, are you on antibiotics that almost all people would say, yes. But the answer to that is 52% on antibiotics, 52%.

I was I was stunned, you know, only 52%. And so then you wonder, well, why is it why, you know, what are the factors that are getting in the way of these people being on antibiotics?

And then you start looking at structural barriers to care. I can't find a physician. I've got to travel 200 miles to get to a physician. I'm on a waiting list for six months.

Nobody will give me the diagnostic tests. I've had the tests done and they don't believe me. They're telling me it's all in my head. I'm being gaslit. Right.

That's that's a typical patient journey. Right? And then. And then you flip that on its head and you say, well, what's the journey for the physician this treating?

Well, the physicians, that are treating, you know, their journey goes something like I'm having trouble finding, partnerships. I'm having trouble working in practices.

I can't accept insurance because I may get sued or I'm making it a target of myself. I may come up for charges of malpractice. Right. So. And and, you know, so the path on both sides for physicians to provide care and for patients to receive care is just it's just extraordinarily difficult.

So, you know. We we address this thing, we address the same things. And and in fact, you're on those committees. But when I was in the first round of the HHS Tick-Borne working group, we actually had discussed this as part of the problems of that.

The patients were unable to find care, and the doctors were afraid to give the care. And what a horrible situation that you have, a worldwide epidemic where the numbers every year just keep going up and up and up and they've created, you know, a platform where the patients can't get the care they need.

The doctors are afraid to give the care they're not trained to keep. And, of course, you to keep up with the medical literature on Lyme. You know, I'm reading it an hour every morning right before I even go into the office.

I mean, it's a lot of work to keep up with it. So we we did show and I think a lot of that came from my Lyme data that, yeah, there were a lot of obstacles and that that was one of the things Congress was told about.

so, so question for you, the my Lyme that what exactly has it come up with? Because the controversies on why people are still sick, right. What did it show us about persistent Lyme disease, why it develops?

I mean, what were the biggest factors that all of this data actually showed? Well, I thought it was very interesting because we've been working with the data now for, you know, nine years going on ten.

And we have we have a really solid teams. We have some academic researchers involved. We've got a biostatistician involved. And as we've gone through it and done, you know, conducted these studies and, you know, there are six of them and they're they're on different factors.

What we've found has been that there are common themes. So the biggest themes are delays in diagnosis, misdiagnosis and co-infections. And when you look at people who have persistent Lyme disease, what you find is that they have those things in spades.

And people who, who I have acute disease. Why they don't have that going on. I mean, by definition, they were they were diagnosed early. They were treated early, you know, how did they do on treatment compared to the people who were delayed in their diagnosis?

So, you know, delayed diagnosis is is so common. It's about I think it's, you know, it's it's up near 70% of people are they have a delayed or misdiagnosis and co-infections are like 60% of patients with persistent Lyme disease.

So, you know, what is it that's making it so difficult for people to get, diagnosed and to get treated well for diagnosis? We just have a lot of people who are being misdiagnosed with chronic fatigue, fibromyalgia, psychiatric conditions.

I mean, those are like the common ones, right? So, you know, and. Long-Covid, of course, now comes into play with all of it now. So. Yeah, long coat. Well, all these conditions all have similar, you know, overlapping symptoms.

Right. And you know, I mean speaking of long Covid, you know, we're working one of the things that arose out of the the last, quasi government work that I was doing was for the National Academy of Science, Engineering and Medicine, and they did a forum that included long Covid, Emmy, CFS and, persistent Lyme disease.

And so here in this room, you had people from these various diseases talking about similarities, approaches. People were trying what works, what doesn't work, and the need to accelerate the pace of research.

So we're now, you know, I headed committee. I was on the working group, so I formed a committee that was patient led research. And so we had, you know, somebody from, long Covid.

That was, Lisa McCorkle with some of, you know, me, CFS. And then I was on it. And then Liz Horne from the Line Biobank was on it, and it was just. I think it was a breath of fresh air for people sitting in that room.

You know, they had just they had just never they first of all, they didn't know that patients did research. And second of all, they didn't know that patients were so enthusiastic about what they were doing that they that they had so much data to share.

So it was, it was an extraordinary event. and I do think we need to see more of that, because when you talk about barriers to, you know, to accelerating the pace of research, some of these, some of these diseases have got things in common, things in common that aren't obvious.

So, you know, John Arkadin and his group published a paper yesterday that was included in it, a lot of a lot of things on neurology and a lot of a lot about the overlap.

Peter Rowe, who was involved with me. CFS was also on the paper. And one of the things he started talking about was small fiber neuropathy. I mean, and it's a it's a funny thing because I that's, you know, ten years ago people weren't talking about small fiber neuropathy.

And I remember, you know, when I was on one of the patient panels that's, they now have something called the backpack, which is infection associated chronic Conditions advocacy group.

Right. So I'm a part of that. And one of the things they said is and nobody's talking about small fiber neuropathy. And I remember when the woman said that I thought, you know, it is it's really a problem.

You know, you know, it's it's funny you say that because there was there was a young girl in Colorado and somebody sent me the link for this. And she was diagnosed with small fiber neuropathy and gastroparesis with the diagnosis of long Covid.

And I contacted her just yesterday and I said, listen, I'm not looking for business. I'm just here to help. I'm just letting you know if you have small fiber, interrupt me with gastroparesis. With what? Anomic dysfunction.

If your doctors have not checked you for lemon co-infections, please have your doctors do the following and please feel free to contact me. Just yesterday I did this because it is.

It's one of those, you know, very, very clear things you see in the chronic Lyme population all of the time. Lorraine, I'm sure people are going to have a lot of questions after they listen to this, including, by the way, how do they enroll?

And I would encourage everyone who is listening to this. You know, we're hoping to get 50,000, 100,000 people on this summit. That would be amazing to get them all to enroll.

How the registry is influencing policy and research

So how do they enroll and contact you and get a lot more information and help the Lyme community? Well, they go to, my Lyme data.org to enroll and to contact me.

They would go to info at Lyme disease.org. And the both of the process is very quick. it takes very little time to fill out, you know, patients who have, completed the survey say, you know, look, I was really sick.

I really couldn't do much, but this was the one thing I could do. So that's why I think we've gotten 18,000. We would love to get 20,000. So I just put that number out there so that people feel inspired.

It's not going to take much time. Do it while you're thinking about it. Oh, I'm. I'm going to go even higher, Lorraine, since we're expecting 50 to 100,000 people, I'm hoping everybody who watches the summit is going to go, I want to sign up right for Lorraine and get this, that.

And honestly, wouldn't that be fabulous if we got another 20, 30,000 people to sign up or listening? Yeah, it would, it would be, you know, it would be enormous because these large samples allow you to look at things that you can't look at in small samples.

So, you know, like if you have a sample of 20 and you ask them a question that's got five choices, you know, you're down to a sample of five for anyone choice.

It just the, you know, is when you're asking, deep levels of questions, sample size matters more than ever. So it's it's really important to sign up. And it's really important that we get the data from everybody, including patients who have acute disease, including patients who are well and including, you know, of course, people who have late untreated Lyme disease and people who have, chronic Lyme disease, all of them.

And of course, this is a way for people to take their illness. Right? All the suffering and difficulties they've had and contribute to science, right?

Contribute to something that will help other people along the way so that, you know, their journey is basically one that's going to benefit a lot more people.

And and it really doesn't take a lot of time, right, to fill this out and to do this. No, no, it's it's, you know, 20 minutes. It's really no big no big deal.

And it just, contributes so much to, our understanding of science. You know, we've got six papers that we publish. We have two more that we're working on.

And the list from there just goes on and on, because you can see that, every time you do a study, you see. Oh, well, we haven't asked about, you know, we haven't looked at this carefully.

Let's, let's look at, you know, one of the things we're going to be working on is, is, is neurological ion. So, you know, like, like, you know, rich, I mean, a lot of the early studies, neurological Lyme, you have to have objective symptoms.

But, you know, finding objective symptoms is pretty invasive. You know, it might involve a, you know, a, a spinal tap, you know, and, and it's they're extremely rare.

So requiring them is like, you know, requiring a needle in a haystack. But we see that most patients they're complaining with persistent Lyme disease are complaining about neurological symptoms, that those are their worst.

Right. Oh, and then, you know, in in the daptone studies that we've been publishing, because we're up to eight studies, we published neurological improvement with 68%.

That was the biggest improvement we had, because that's only penetration into the brain is enormous. It has great CNS penetration. It's anti-inflammatory.

You know, it works against malaria parasite. It works for autoimmunity. And it's a persistent drug. Right. So I mean we are seeing that the neurological improvements are great.

But you're right. You're not going to get people with a lot of Bell's Palsy showing up or, you know, other cranial nerve palsy, which is the definition the CDC is using.

Right. Even the psychological issues in the paper we just published, we were highlighting this and it's in peer review right now. We did three case studies, that we just took from the last paper we published, microorganisms.

And it was really amazing the psychological symptoms these kids who suicide, the ones who are at risk, they're talking about it now with Covid. This is massive.

I mean, this needs to be highlighted. It's such a risk for the young population that it's not just, you know, neurology, it's psychological. Also. And of course, Bartonella makes it way, way worse, as does Bbca.

So so, you know, let me use that as a stepping stone. The percentage of co-infections. But these micro, these uncanny Bartonella species, and even persistent Lyme.

I'm curious, when you were pulling the data, how many of these people had positive PCR has had positive fish is

can you, can you give me a little bit of the details, like how how much you're finding in this population.

Well yeah. So I mean we ask patients, have you been diagnosed with and we, you know, by Basia, Bartonella or Ligeia? Anna. Plasma, mycoplasma, Rockies, but Rocky Mountain spotted fever.

And then we ask, has your diagnosis been confirmed by a laboratory test? So that, you know, that's about the level of detail you can get into with a patient.

So it could be as you start losing patients, when you start talking about fish, I say when a fish swims in the ocean, you know now. So but at any rate, with laboratory confirmed, co-infections, there were 32% who reported ABC, 28% Bartonella or Licky, a 15% and a plasma 5%, Mycoplasma 15%, and Rocky Mountain spotted fever 6%.

And a lot of the patients were reporting that they had, you know, a third, so they had two or more co-infections. I was one of those lucky candidates. Right.

And those people are, of course, harder to treat. Right. Because the you know this better than anybody, which I mean, the agents that you're going to use to treat people with depend on what they're infected with.

You know, what this organism is going to respond to. So, that's another reason why you see a lot of patients with, persistent Lyme disease having co-infections.

And, you know, the CDC used to say, and I'm not sure that they do anymore, but they used to say, you know, co-infections are rare. You know, they're rare.

They don't happen, they're rare. And, you know, everybody kind of thought that they were rare. But when we did this survey, one of our first publications was, not so rare.

You know, 60% of patients with persistent Lyme disease have a co-infection. And perhaps that's the defining feature of developing, persistent Lyme disease or one of the defining features.

Right. And so if you're only looking at the acute population, you're not going to see those co-infections. But when you start, they won't mean they may not even be tested for to try.

Right? I mean, the line docs do it. I mean, in the publications we've been finding the the busier for me has been around, you know, somewhere between 66 to 80%.

And the last paper we published a few months ago, Bartonella, was 84%. But the interesting part was the only way we were able to find it with a lot of these species, we had to do a Bartonella immuno blot right, to at least get those species or had to go to galaxy to get all that.

Right. It wasn't just Bartonella, Hensleigh or Quinton or Bexhill to form is. So that's the problem. Of course, you got 18 different pathogenic species of Bart, right?

It's very difficult to know. I think a lot of the times in the earlier patients we were saying, I think the Bart patients were probably a lot higher than we realized.

We just didn't have the tools to be able to diagnose it. And I think I think you'll find over time, as more and more patients enroll, I'm seeing the co-infection at least.

I mean, maybe it's and it's different in my practices than others, but I think it's going to be pretty similar. It's over 50% and we're seeing a lot higher, at least in our patient population.

Yeah. You know, the thing is, Richie in in the survey, we you know, we say were you diagnosed. So think about that.

That means a clinician may not have asked may not have done the test, may not have looked a patient may have a co-infection. It's not reported in the survey because it wasn't diagnosed.

Maybe nobody even suggested it. Right? I mean, that's really common, I think, for patients to be sick for 2 or 3 years, maybe somebody's diagnosis of Lyme, but then maybe it's two years later.

The doctor says, you know what, let's do a Bartonella test. Right? And the thing that's a little sad about the BCA is, I mean, not that everyone gets the malarial symptoms, but, you know, they sweats, night sweats, chills, flushing.

I mean, the joke I have from men when they come into my practice in their 20s and they're complaining of sweaters. I'm sorry, are you in menopause? It's like, well, what did your doctors think?

You know, you don't have malaria. You don't have hypothyroidism, you're not in menopause. You didn't. You've not been to India to get this. You don't have to Burkitt losses. You're non-Hodgkin's lymphoma.

It's like the basics in medicine is differential diagnosis. And taking a proper history and taking your history in a Lyme patient, and, you know, malarial symptoms, air hunger, cough.

I mean, it's basic. And honestly, even doing a physical exam for Bach, the more times you look for those Bartonella story, the more you start finding it in these patients.

And I'm not even sure the doctors are always looking for it. Yeah, I think I think by and large they're not. So I mean, I think, you know, it's it's really unfortunate.

But among among physicians are clinicians who treat the ones who are sophisticated enough to know this level of, understanding about the disease. I think I, I think it's a handful, two handfuls, three handfuls.

It's really not a lot. And so, I mean, that's partially why patients who are really sick, will take the extra effort and travel to find an experienced clinician.

It just and by the way, it's the same reason that when we publish, I try and put every detail of everything we do so any doctor can pick up the paper and say, these are the supplements he uses.

These are the drugs he uses. These are the just so that, you know, I'm trying to share it as much as possible. In fact, a woman from Mexico contacted me on on LinkedIn and said, my boss is 24 year old daughter sick.

And I said, listen, if she's got a Mexican doctor, you know, I can help the doctor. It's all in the paper. I mean, I'm encouraging these doctors to learn the protocols, not to come to me, but to learn the protocols so that they can get the patients better.

Right? Right. I mean, that's that's really what has to be done. And there are some people who are doing some fabulous work in clinician education. But unfortunately, most, doctors and clinicians are graduating without really any basis for understanding this or how common it is.

You know, I was on a committee not long ago where people were talking about and it was just just infuriating people from California. They were talking about, you know, we're only going to consider endemic states, and California is not considered endemic because we have a really I know we have a really large population and we have a lot of different ecosystems.

And this isn't a disease. It's driven by ecosystems. So you take the state of Connecticut and you put it in California 14 times seriously. That's how large California is compared to Connecticut.

And if you did that, would we be endemic? Oh yeah, we would be endemic in, you know, numerous counties,

numerous areas. Right. But that's not how it's measured.

And people, people who read guidelines without thinking, well, say, well, it's not an endemic area, but there was a study that came out from Fair Health a number of years ago that was published in the Wall Street Journal, and they have a vast insurance database.

And when they looked at claims the submitted California was among the top five. So how can we be among the top five in terms of raw claims committed and not be considered an endemic state?

You know, it's just, you know, and why do we need a criteria that's endemic? Why does it. Make, you know, even the quest data, the quest data that came out a couple of years ago that showed the numbers jumped from like 6% to 11, 12% right over a period of time.

And that was the US, right? I mean, so it's definitely growing and it's, you know, it's getting worse. Now let's go back to the data again a little bit.

The worst symptoms that people showed up with in the my line that a registry. What were the worst symptoms on top of the list. Well the worst symptom by far is fatigue, which is, you know, shared by long Covid.

And it's also shared by me CFS. So 54% have you know, report having that. And that's followed by sleep impairment, 38% muscle aches, 38% joint pain, 38%, neuropathy, 34%, and then in addition, between 20 to 30% report cognitive impairment, memory loss or psychiatric symptoms, GI complaint, headache, twitching.

So I mean, that's just, the the the thing with symptoms is they really vary by the individual. So it does seem like some people more likely have the joint and muscle aches, and some people more likely have the neurologic.

And and those patients seem to be in different profiles, which is why we're looking into, neurology right now, because we think it's a very big deal. And when you look at when you start looking at clusters of symptoms, what you find is, the leading cluster is neurology.

So you start combining things like memory loss with neuropathy and some of these other things. And pretty soon you're dealing with you know, large percentages of patients, in fact, the largest percentage of patients having neurological symptoms.

But, you know, this is the disease is mischaracterized across the board because the CDC takes acute patients and then they apply it to chronic patients.

And it's just not the same disease. You know, we looked at there's a simple question you can you can ask and the government asks this and a lot of their surveys, how would you rate your health currently.

Would you rate it as excellent. Very good, good fair report. And people who report that their health is very poor, that that's really uncommon in the in the normal population that's about 16%.

But you know, in Lyme disease it's like in persistent Lyme disease is 77%. You know, oh my. You know, oh my goodness. You know this, these people are really, really ill.

And then when you start diving in and saying how many severe symptoms do you have. Well a lot of patients have they have very severe page, symptoms. How does that affect your work?

People have to quit work. People have to go to part time. People have to change the neighbor nature of their work. So it has this profound effect. And then, well, how does that affect your family economically?

How does that affect your community? Your community's not, you know, collecting any taxes on income you're not earning. Right. So it's affecting really everybody.

and it's just it's a problem. It's not being addressed because we have this old way of looking at the disease, which is under the model of acute disease.

Now, you know, I speaking about the disability when, because Holly and I are both working on the, New York State tick borne disease working group, and I looked at disability in New York State, and I was surprised to find, you know, that the level of disability in New York state was actually in the country.

By the way, it's one out of two people, has one chronic disease. At least 50% of Americans suffer from one chronic disease. But I was surprised to see, like, you know, it's at least a third of New Yorkers, you know.

We're oh yeah, that's that's interesting. That we're we're talking disability. And when you look at what it is, it's like it's fatigue. It's arthritis.

You know, it's cognition. It's like, how do we know that all of these people in New York, in a very highly endemic state, have not been exposed? And all the money that the health care system is spending on disability payments, again, they're not productive members of society.

How it affects their family. You're right. I mean, I don't think people understand, like the full scope of how this is. And with the climate, the tics are just getting worse and worse every year.

And I don't think, you know, we're taking enough precautions at this point. I, I know most of my patients, I tell them about prevention all the time. But, you know, you've really got to drill this home for people because once you're sick, it's not so easy.

Yeah, I think that's right. I mean, we we ask an open ended question. That's, you know, what, how would you describe your current employment status? So full time, part time, you know, whatever.

And, one of one of the answer choices is disabled.

Symptoms, disability, and disease severity

And the people who select disabled is 38%. It's really it's kind of this remarkably high. and, you know, the, the, the point that you're making about this many people having chronic conditions, and most of these diseases that we're talking about are other conditions like Long-Covid or me CFS, they have no cure.

The thing that's so frustrating about Lyme disease is there are some cures that work for some people. They don't work for everybody, but there are some cures that work for some people, and people's hands are being tied from providing those cures.

So patients are remaining ill and some patients just give up on the system. Yeah, right. It's so hard to find a doctor know. And you know, I. Didn't have a great. Injury.

And this is why later this year if I, if I have the energy and I get the support, after we publish, hopefully this next paper that went into peer review, I'm going to try and do a multicenter, placebo controlled randomized trial on that, some combination therapy, because we've as you know, the last randomized trial was done by Brian in 2008.

I mean, my God, it's over 15 years ago, we've had a randomized trial. And when the NIH did it, they weren't they didn't know about biofilms at the time.

They didn't know about persistent bacteria persist or drugs. We didn't address co-infections. And in my case, none of the variables. Right. We're address like plots, dysautonomia, etc..

So we learned a lot in the last 15 years. And yet some of the agencies are just making believe, like, you know, the science is the same as it was, but it's not.

We've learned a lot. and I think that brings up the point. You know, since you're looking at the data, there's a lot of people, you know, one size fits all treatment recommendations.

Can you address a little bit how do people vary in the treatments like that. They've been given by different doctors. Well they they they vary quite a bit.

I mean, one one of the things, one of the myths that we wanted to dissolve was just this notion that there's you use one treatment approach and it works for everyone.

And, you know, when you look at the studies that have been done, they have been really they've been so small, 36 to 120 patients. So when you're looking at those studies, you know that they can't distinguish between people who are responding to treatment and people who are not.

And let's just say you took a a simple system and you said if you respond I'm going to give you a plus one. And if you don't respond, I'll give you a negative one.

Will you add those two together and you're going to come up with zero, which is no treatment effect. And that's what happens when you use treatment averages in small samples.

You know, there are people who are saying that it is, that there are as a matter of ethics, you need to size your sample large enough in order to be able to detect treatment effects that are moderate to, to small that patients would consider important.

And that's, that's simply not being done. So we found, one of the patients papers that we published was, was about, about how people vary in their treatment response and was.

So one of the things that was so fun about doing it was just sort of other people who worked in this area that aren't in, in Lyme disease, but, you know, like you draw a normal curve, right?

Like we're all aware of the normal curve distribution. And you take a randomized control trial and it is very selective in who gets in. So it could be at any point that it's drawn out and sample.

That sample is not representative of the patients who have the disease. Right. So what we found was we found that patients were able to be categorized as treatment responders.

So those were patients who said that they were moderately to a very great deal improved. And, or they were capable of being, characterized as well. So, you know, those two groups, you can put them together in a category.

And then you had people who were responders, but, you know, not at a really high level, but, you know, they were getting some success out of the treatment that was over 50%.

And then you had some people who were non-responders and, you know, that's important to know because then you can go a step further and say, okay, well, if we have responders and we've got, well, patients, all right.

We got people who are really doing well, what did they do and what worked? And what we found was that those patients were using antibiotics, using them for a long period of time, you know, over four months, over 12 months.

And, and you could see, you know, you could see that the duration of therapy was linked to how well they were doing, how they characterized their health.

You know, without that question, you know, excellent. Very good. Good. Very poor. You could see that the other thing you could see is, you know, people talk about does Lyme disease progress.

And I remember asking that question very early on. Do we know that Lyme disease progresses. And the answer was nobody knows. You know that because nobody had done the study.

We all everybody knew, but we hadn't done the study. Right. So, when we look at patients in these various categories, you know, you look at acute patients and then you look at patients who are diagnosed at six months to a one year, and then you look at patients who are diagnosed after that, or at ten years.

And you see that this quality of life. So I'm talking about excellent. Very good good fair poor fair poor just skyrockets. Right. So like in acute disease, you know, it's like people are doing pretty well.

You know, there are there is a percentage that report their health as being fair or poor. But most people are reporting that their hair is their health is good, very good or excellent. Right.

But as you progress, you just see it goes right up a slope. So, you know, like catching this disease early, there's no more important thing that we can do.

And it just seems to me that nobody's even trying. And so for us training. Yeah. You know I in the, in the paper, we just, we just published I have to do a PubMed search every time I'm doing this.

I was looking at early Lyme disease. I was trying to figure out when you look at the Wormser paper from antimicrobial agents and chemotherapy, like 35 years ago, 80 to 90% responded with early.

But if you looked at the 10 to 20% that didn't, it was usually because they either had peripheral nervous system symptoms tingling, numbness, burning, stabbing the extremities, Lyme neuropathy.

Right. Got into the peripheral nervous system. Oh that's really interesting. For central nervous system light sensitivity sound sensitivity memory concentration sleep disorders mood disorders etc..

So it had clearly either gotten up into the sea in the scorpions. But then I looked recently at the biofilm data and didn't realize there are biofilms that are being found in ticks in the gut in some of these ticks.

So it's like, well, hold on, is it possible because no one's looked at this, should we be using biofilm agents? Because the reason the antibiotics aren't working in that subset who take antibiotics early on is we needed to be opening up the biofilms because the bugs are protected from day one, that they're forming biofilm aggregates.

Not even later. No one has looked at it. We put this in the last paper we just did because they thought, wow, that's something somebody's got to look at.

So yeah. And this there's a lot of data I know we can pull out. And and by the way, these people that did well and long term I'm obviously trying to create protocols now that are not long term that the adoption protocol is nine weeks followed by two week pulses.

And we are having success. But I need to prove it to the world. In a randomized trial, did you pull out of the data the people who are doing well and long term?

And then they stopped the treatment and they were not on persistent drugs. They were on a cell wall, drug like kept intravenous after penicillin or whatever.

They're almost all on doxycycline, just FYI. Okay, so did it show that the relapses were happening when they stopped the antibiotics, even if they were on long term?

No. You know, this is this is a really interesting question. I know there are. So I think it's interesting, you know, I consider myself well and there are people who say nobody can be cured of Lyme disease.

I don't consider myself to be completely free of all symptoms, but I consider myself well at this point. and what surprised me is we asked the question casually, are you sick or are you well?

And we ended up. We have like a thousand people who consider themselves well in our registry, which is

phenomenal. Right? Like where do you find people that.

But that's only 1000 out of 18,000 in the registry. But but we don't even we aren't even trying to get people who are well to register. I say everything we're doing is, is geared towards people with chronic Lyme.

Treatment patterns, alternatives, and sex differences

So to us it's kind of like, oh really? And now we've got that larger sample for that. But we do ask those people, were you, were you treated with a common course of antibiotics?

did that work? what did your clinician do afterwards and how did you respond? So, you know, for the, the that early piece where it's like, okay, 30 days and then no treatment, did you relapse or did you come back?

We do ask it there. And we haven't analyzed that data. I mean, it's an example of, you know, we're drowning in data. We have a ton of data to analyze.

And that's one of the things we want to get to. But we haven't gotten to yet. So you can't just put in your phone ChatGPT and just say, can you please go on the site and, and tell me the answer to this question?

you know, it's real interesting. We are working with artificial intelligence. We have been working with artificial intelligence since we launched the registry in 2015.

So that is kind of remarkable. All right. Because right now is the heyday of AI. But we've been working in it since 2015. So we actually and we have a great partner at UCLA, UCLA doctor Diana Nadal.

And and we have just learned an extraordinary amount. So, so what AI is really good at is taking vast quantities of information and saying, looky here, looky here.

That's what it's really good at. And then you go in and you look and at that particular item and you say, okay, well, what is it about this item that AI is telling us they're telling us is important?

But why? Because you and it's still you still have to apply common sense, right? If you don't have common sense, AI is it's not it's not useful. So, you know, we've seen it used in situations where, oh boy, you know, they really needed to have somebody who knew something about the disease and well, you know.

So yeah. So so we're lucky with our studies. We we always have a clinician. We have a biostatistician. We have an academic researcher. I mean I see, you know, and then we've got, you know, I'm involved.

So we have a really great team of people who've worked together now for a very long time. You know, I'm feeling really, really fortunate about that. And I just I.

Just I just I just I just want to dive in because we've got about ten minutes left. I want to make sure we get these questions in, okay, about alternative therapies.

What did you pull out of the data? Because a lot of people, I think, have questions on the efficacy of alternative therapies. What have you found? Well, so we ask, we ask we have a set number of, different alternative therapies that we considered something like 15.

And we ask patients which ones were effective, how effective they were and whether they had side effects. And, that is that was a that was a really interesting question to ask because the the top ones that were identified are ones that you would suspect they were the herbal protocols, a lot of which are anti-microbial in might address the bugs.

Right. So they might actually, you know, the mechanism by which they're working may be that they're targeting, you know, critters that shouldn't be in your blood, or shouldn't be in your tissues.

but the other the other thing. And then Sorna comes next. Okay. So, I mean, science got a really long history, being effective for many, many, many things, you know, in terms of how it works with the immune system and, and what it allows a human body to do, by recovering, by detoxing and by, just, just, improving the immune system.

So that one's not a surprise. The one that was surprising to us is we asked at the time, stem cell therapy was very, very popular. And so we asked about stem cell therapy.

And we were just shocked that we got 300 people at that. And that was early on. So we had about 2000 people who were wrong. So 300 people had tried stem cell therapy and only 3% said it was effective.

So, you know, there's a lot of different ways they do stem cell. It could have had to done with that. But you know, when patients see that they say, okay, so 60% are are saying that they're improving on antimicrobials and 3% are saying they're improving on stem cell.

I gotta make choices. I think I'm gonna go on antimicrobials. And, you know, a lot of patients can't get antibiotics, period. So the treatment they can get is an anti-microbial.

So we have you know the samples for anti microbial herbal treatments are really pretty big. Great. And what about the differences between men and women as far as treatment response severity of illness persistent Lyme disease.

Can you talk a little bit about sex differences. Oh yeah. That that was that was very interesting. So we we decided to do a study of the difference between, men and women in, men in persistent Lyme disease, primarily.

And, and we compare it with acute, but, what we found was that women reported more two more in co-infections, worse symptoms, longer diagnostic delays, more missed diagnosis and worse functional impairment than men.

And, there were no differences reported in antibiotic treatment response, which I thought was interesting. And then we took the broader lens, right, because a lot of studies have been done, you know, including your studies.

Right? We have so we have studies by clinicians who are using different criteria for enrollment. We have randomized control trials that the NIH funded.

And then we have studies, you know, like that are larger databases. So my Lyme data, where you've also got the Lyme Biobank, they have really expansive entry criteria.

Anybody can get in. If you've been clinically diagnosed essentially. And so what you see when you look at those categories is you see that with acute disease.

So studies of acute disease showed that women were, you know, pretty much on par with men. And there was a slight difference. It wasn't great. But then with, persistent Lyme disease, if you were looking at randomized control trial, it went up quite a bit.

But then if you were looking at a trial that was done by a clinician or would that what I would call real world data, so a clinician, a patient registry or a Lyme Biobank, it went up enormously.

Right. So, it does seem that women are, contracting more persistent Lyme disease. I if I had to take a guess as to why that might be, because there's a lot of reasons. It could be right. It could be hormones.

It could be biology. Women really are different than men, on so many levels. And they reacted. That's a that's a whole nother hour, a talk that we could be doing on this one.

By. No, I. Mean, it's so it's so interesting because people have always just put them together as one group and really only done the studies on the men and so then they apply them to the women and then find out that they're not true.

You know, so women were having heart attacks, you know, but when we knew how to treat men, but we didn't know how to diagnose women, but, we I really think it has a lot of it, to the extent you can control it.

I think a lot of it has to do with misdiagnosis, diagnostic delays. You know, women are gaslit all the time. It's just the usual the women goes in and they think, oh dear, it's in your head.

You're just stressed at home with your children. Don't worry. Right. You think that's probably paying a big part. And by the way, when women have come in and told me that the they've said it was in their head, you know, my usual response as well.

It is in your head, you've got spider kits in your head, you've got toxins in your head. It's like, oh, he was right. Just not for the right reason of why they told it to you.

But that's I mean, that's I mean, honestly, in this day and age, it's it's beyond it's beyond the beyond for me that there's still those kind of sexism differences at this point in time.

It amazes me. Well, I think it's I think it's really large, you know, I mean, there's a lot of advice includes things like bring a man with you to your appointment, you know, so you bring your husband or your spouse or your partner and or a friend and they can say, yeah, I've seen this.

It's it's just this credibility issue. So, you know, it's it's the same thing which with, you know, self-reported data versus clinician reported data.

so if I say something to you and you write it down suddenly it's good. It's good information, it's clinical information. But if I say it directly, if it's self-reported, oh, it's questionable.

It's questionable may not be true. You know, she may not understand her symptoms or, you know, there's a verity or, you know, whatever, right. You can discount the individual.

But and that just unfortunately that happens a lot more with women.

How to enroll and support MyLymeData

Yeah. So, let's just finish up because you only got a couple more minutes. So, Lyme disease comparing to other diseases out there with severity. what did you find with the data?

Because usually we hear, like, excessive fear of chronic congestive heart failure. Right? I mean, this has been reported in the literature even by other researchers.

You finding that in the data, like that's how severe people are. That's how severe it is. I mean, it's really it's kind of staggering because, you know, that simple question that I told you, which is how would you in general report your health?

How are you? Excellent. Yeah. Very good. Good therapy for that simple question. Many diseases use it. The government is used in many surveys. So in general in the population it's 16% are reporting their status as being fair or poor.

with persistent Lyme disease is 77%. And that's higher than other chronic illnesses also. So for instance is higher than lupus, higher than multiple sclerosis, higher than congestive heart failure, and higher than fibromyalgia.

So it's hard to find a disease has got a greater amount of people reporting their health status that poorly. And, you know, as I said before, that progresses, as the disease progresses, people report, more, poorer, less health status, I mean, less quality of life.

So they also report more severe symptoms. So you'll see them going from you know, this is staggering. You know,

patients on an average are reporting three severe symptoms.

That's a lot of severe symptoms to be dealing with right. But you know patients for for mental or fair or poor health status. Well they're reporting four or more severe symptoms.

So these people, you know, are really, you know, have a large severity of symptom load and it's going to affect whether they can work, is going to affect how often they go see doctors.

They see doctors five times as often as, you know, other patients, the general population, and, they're more likely to be hospitalized, you know, two times more likely to be hospitalized than the general population in over a year.

So, you know, it's like we just count these things. We say, oh, you know, this is the yuppie flu. This is not the yuppie flu. Yeah. Know. Yeah. No, this this this is a very severe disease.

And it's all across all strategies of society and age and sex. And I mean, it's it's it's just terrible. So, so listen, where believe now this was in our conversation that we've had so we're kind of out of time.

So I just want to finish up with people and say, for those of you listening, I would encourage everyone who is coming to this Lyme Summit, please contact Lorraine and MyLymeData and get your information.

As you heard earlier today, it does not take that long. It's 20-25 five minutes to fill out these questionnaires and get your data into the big data so you can help other people.

Lorraine, again, as we're finishing up, tell people how they can contact you. MyLymeData and anything you're working on in the future that we can expect, you know, some some great research, just like all the great stuff you've been putting out. So.

So if you want to enroll in MyLymeData go to, MyLymeData.org is all one word. MyLymeData.org. If you want to contact me, send an email to info@LymeDisease.org and we'll be sure that we get right back to you.

we, we would really love to see these numbers 18,000 is a lot. But as you know, Rich was saying it can be a lot more. Let's make it a lot more. We can aim for the sky and just kind of see what happens.

But as I said, I think we're going to have a great turnout. during the Summits, I mean, we'll see what the figures are. But, so, so again, everyone, I just want to thank you so much for attending the Summit.

you've been hearing from myself and Lorraine Johnson of Patient Led Research and MyLymeData, really the only big data set that's out there. And again, I encourage people to contact Lorraine and and get your information in there.

Again, my name is Dr. Richard Horowitz. I've been co-host for the Healing From Lyme Summit from DrTalks. Thank you everyone for attending the Summit. It's been great.

We've got a lot of great information and we look forward to seeing you also soon. please look forward for another episode. Thank you so much.