The Critical Role of Clinical Research in Patient Care

With Todd Nicklas

Episode 84

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Todd (00:00):

The big focus today is to fail early. So what a lot of companies like to do is to do a lot of high throughput, testing thousands of different compounds and various disease processes and targets in the body to understand where they might fail down the road, and there's amazing technology to figure that out, so they can hopefully pick the right one to go down that rabbit hole, shall we say, and hopefully get an approval.

Introduction (00:25):

Welcome to the Healthcare Leadership Experience Podcast, hosted by Lisa Miller and Jim Cagliostro.

Lisa is the founder of VIE Healthcare Consulting and now Managing Director at SpendMend. Lisa and her team has generated over $1 billion in financial improvements for VIE's clients since 1999.

Since 2007, Jim has been a registered nurse working in critical care, perioperative services and outpatient settings at nationally recognized medical facilities across three states.

You'll hear conversations on relevant and trending topics in healthcare and much more. Now, here's your hosts, Lisa and Jim.

Jim (01:05):

Hi, this is Jim Cagliostro and you're listening to The Healthcare Leadership Experience. Today's guest is Todd Nicklas, clinical trial manager at Incyte. Incyte's a biopharmaceutical company based in the Wilmington, Delaware area that focuses on developing medicines to address the critical needs of patients with cancer or dermatological diseases.

Todd has previously worked in a few large academic medical institutions in heart research for over 10 years, and he will pull from that experience to give us a good context of how research can integrate well with hospitals, physicians, and patient's patient care.

Todd, welcome. Thanks for being with us today.

Todd (01:43):

Thank you for having me.

Jim (01:45):

Todd, I know the last time you were with us over a year ago and we had spoken about clinical research and probably more generally, but today we really, at least initially, we want to start off with, at least from the patient perspective, how does clinical research connect with direct patient care? How does being in a clinical research trial work with, how is it compatible with my routine doctor's care?

Todd (02:10):

That's a great question, and yeah, we didn't get to dive into that too much last time, Jim. I appreciate that question. First of all, I do want to say real briefly that I am speaking on today's podcast from my own opinions and my own experience, not on behalf of the company I work for.

So to answer that, I'd like to just phrase it in the context of the fact that we can't avoid research. We've been using the clinical research approach for the

past 300 or so years. We have International Trials Day, which I believe is in May, May 20th if I remember correctly.

Jim (02:40):

I did not realize that there was a day for that, but there's a day for everything. That's good.

Todd (02:45):

Yeah, it celebrates, James Lind did some scurvy studies with citrus fruit versus other different concoctions that he tried in 1747. And then there was some studies that you can go back to even in the 1500s, that people would try various things to see what worked better than others. And we are where we are today. So we understand that there's always ideas that are going to be out there, and there's probably always going to be limitations to care, and there's always going to be better ways to do things. So we have to kind of understand the balance I'd say of, okay, well, we can't avoid clinical research because we're always going to need to make things better and take care of patients. There's always going to have to be a cure for something or a fix for something. But we also can't always say that clinical research is perfect either. Obviously there's a lot of hiccups and safety issues and questions that are still to be answered. So where do we find that kind of middle ground and work together?

Todd (03:35):

So I kind of wanted to start out with that sometimes it is the answer, clinical research for a patient, or sometimes it's not the answer. So I like to give the example... So sometimes it is the answer. I appreciate reading a book by Paul Offit called You Bet Your Life. And what he did was he went through the past few hundred years in some of the early medical interventions in development and when they were very early starting off, the first blood transfusions that were tried or first types of anesthesia. And when he would dive into those stories, I mean, Jim, there was dangerous approaches. We look back today, really wild, crazy ideas or people died or people had maimed arms and legs from radiology exposure and such, but it leads us to where we are today with radiology procedures and blood donation and transfusions and anesthesia. Just a few examples. He did a few others. So it was neat to-

Jim (04:32):

Sorry, Todd, what was the name again, the author?

Todd (04:35):

I think it's called You Bet Your Life by Paul Offit. So his approach was, there's a point, and maybe we'll get to this later, where you can kind of know where the risks are worked out, but you can't just write it off and throw the baby out with the bath water. There might be something still good here that we need to learn. And so sometimes it could be the answer like, look where anesthesia and blood donation is today. But sometimes it's not the answer. You can look back for the past few hundred years and health authority figures or people at various companies thought that lobotomies were a good idea or sterilizing the mentally ill or bloodletting. You can look at some of these things that today we'd say, yeah, they were dangerous or inappropriate or not what they were intending to. So people can be wrong and people can be right. And so you have to understand that balance first and foremost. I kind of wanted to stress that upfront.

Todd (05:23):

And then I think when you are trying to understand clinical research and how it pairs up with clinical care, because every patient or basically every patient you have is not going to be in a vacuum and have one disease and have nothing else. They're going to be 80 years old, they're going to have ten other medications they're taking or four other disease processes that are going on. You need to know what's on board, what's working, what's not working. There are different races, different cultures, different languages. There's so many factors. You have to take a very specific approach and you can't say this is definitely an answer. You have to talk through and balance the risks and the benefits that you perceive from what you know.

Todd (06:01):

But I think the two questions you have to ask when you're trying to balance it is first, does the present, shall I say medication or intervention, does it supplement what is presently trying to treat or help my disease — or does it replace the present? And the reason I wanted to lead with that or categorize

that is because when I was a research nurse for many years in the hospital, you're working with sometimes doctors that really love the research that you're doing and are an investigator with that research. Some doctors could care less and tell you to go away and say, "Don't bother me. Really, you're going to bother me with this research?" Some doctors might have no clue because they're not even connected with your hospital system. And so how do you interact with doctors A, B, and C that I just gave as examples because you're going to have to approach them differently? I think that's probably self-evident.

Todd (06:51):

So you have to say, "Well, listen, it's meant to supplement and here's how it could work already with the present medical regimen that these patients are getting or it's meant to replace the treatment and this is why and this is how you should manage them." So I guess first, does it supplement the present treatment? This is I guess a question that research has to answer: how does the present treatment alone that they're already on affect a certain lab level or an MRI scan or a vital sign that might be concerned about your blood pressure or what have you, versus how much does it affect that measurable point with the two together or the research medication or intervention? We get a lot of time to dive into that, but I just want to leave that hanging out there to think about that.

Todd (07:35):

Those are tough questions because you want to know that downstream to get a true answer of how good and helpful this medication is or is not. You have to know, hey, how many times a day are they taking their medications presently? How many times a day should they take this medication and the half-life of the drug and how it affects the other things that they're taking? Does the research medication have an effect on the present treatment? Does it enhance or decrease? So as an example, let's say you're taking medication A and the research medication might enhance medication A by 50%. Do you have to drop that medication down? Do you have to let it alone because maybe the effects together is actually what you're desiring?

Todd (08:12):

A lot of these things, these factors need to be considered and they need to be communicated to doctors A, B, and C that I referenced because they might just jump at, "Oh, hey, they have a little bit more fluid on board. I'm going to change their diuretic." And they wouldn't even consult you because they don't really understand your research study and what they're on. The patient is the biggest advocate. That's why, I know when I did my 10 years on the hospital side, the thing I really appreciated most was telling the patients the nitty-gritty and really driving home the educational points because then they are there with doctors B and C that might not know or want to be involved in the study and they can say, "Wait, wait, hold up. Don't do this. Or maybe talk to Todd first because this might affect that." They're really good questions.

Todd (08:54):

A couple of times I worked with Entresto, which is a heart failure medication. I'm sure you've probably seen some commercials with it, but it's combination of sacubitril and valsartan. And valsartan is a class of drugs called ARBs that patients take and they can take by themselves, but this now has a combination of an ARB and something else with it. So you have to talk to patients when you're in the clinical trials. "Well, this is what you should do with that ARB medication that impacts your kidneys." How should you taper it or how should you address it or what should I do when I'm in the study or how do I get out of the study?

Todd (09:28):

I also worked with another cool device that would stimulate the left ventricle to squeeze harder. It was called a cardiac contractility modulator. It is FDA approved now and it's been helping patients, but it's like an electrical way to strengthen the heart. But then the question is, wait a minute, if I get this and let's say it makes my heart better by 25%, I'm just going to make something up. It makes my connection fraction go from 25% to 35%, whatever. What should I do with my medications I'm presently on? Will I have to change my beta blocker? Will I have to change my diuretic? When? How do I communicate with my doctor? What do I have to do with watching my blood pressure, my heart rate, my weight?

Todd (10:08):

So there's a lot of different things that you need to figure out when you are supplementing the present treatment. When you're intending to replace the present treatment, well, then the doctors will say, "Well, wait a minute. When does that happen? Is there a washout period? What's the half-life of the drug that they're presently taking and the one that you want them to take in the research study? How quickly can it come on board and give a therapeutic benefit?" These questions, like I said before with the previous point, you need to be very careful in how you convey that to the patient, to the doctors, to the nurse practitioners, how it's in the documentation. Things can get forgotten, as you know. So it has to be clear in the documentation as well.

Todd (10:50):

You and I worked with LVADs, which are the heart pump devices. Could it replace their heart failure meds across the board? Maybe. If they have a really great response, maybe you can get rid of a good bit of them. And then the doctor would say, "Well, when would that occur? And how do we do that in the hospital?" So there are tough questions to ask and you might say... Oh, sorry, I forgot to mention this to you with the supplement. These studies are often with supplements, placebo controlled. Well, how do I handle... If I'm not supposed to know if they're on placebo or not, but it could supplement and have some impact, what do I watch for? What blood levels do I keep an eye on? But with replacement, that doesn't typically happen because they need a therapy, they need to be treated for something. So you have to either be getting the old medication or the research medication. It's not as much. So I wanted to mention that real briefly too, but that is another point I wanted to get across. Did that kind help answer your question?

Jim (11:43):

Yeah. And as you're explaining that, I mean, just the one thing that stood out, there's so many variables, so many variables, and the one study is the patient in terms of the patient is the one that's always going to be there — whether it's with a doctor, whether it's with an advocate or whoever it might be, but really pushing to them or preaching to them that we can be advocates for them, but they have to be their own advocate too, especially if they're involved in a clinical research trial.

Jim (12:10):

The one question I kind of wanted to follow up with those in terms of working with physicians, clinicians, do you see more of a challenge, or maybe it's the same with trying to implement a new drug, a new treatment for that supplemental approach or the replacement approach? Is one harder than the other or does it all depend on the physician's personality? When you're trying to have patients take the new drug or use the new device or whatever it might be, do you see a difference or is there an openness to this with some doctors and others, it's like absolutely not? Does it make a difference whether you're supplementing or replacing?

Todd (12:45):

It's tough to answer across the board because every study is different in every compound. I mean, you might have something like CAR T therapy that's going to cure cancer or something that they're like, "Yeah, come on in, replace what I'm presently doing." That would be amazing. I'd say though that typically I would say the supplement would be easier because I did some studies with some cholesterol medications and if they're already taking a statin or something else, the doctor's like, oh, okay, it could be placebo or something else that might help LDL or HDL a bit, whatever. I don't care. I'm not affected by it. I'm not really seeing much, so I'll just let it ride. And they can figure out the endpoints and the real impact globally on patients. So I would say, yes, supplements are typically easier depending on how the protocol's set up and the compound works. But yeah, I would say probably the supplement.

Jim (13:36):

Sure, thank you. So probably the first question that a lot of people will ask, whether it's patients, whether it's clinicians, is the cost. People often voice their concerns about the money that's spent on research and drug development. It's a lot, I know. I mean, I'm sure you know that much better than I do. And in terms of even until it gets approved, the costs that are spent on it. Can you expound on the why, why is it so expensive? Just kind of lay that out a little more for us.

Todd (14:01):

Yeah, and I forget how much we went into this in the podcast the previous time. I don't think we really did, or if I did mention real briefly, so I'll try not to repeat myself and I'll start out with, I think that people will say that pharmaceutical industry, there's money motives that will push people to say certain things or change data or do certain things and that is the case. And we could see that from time to time. But you know what? We see that in a lot of areas of life that we have checks and balances in a lot of different realms that we appreciate because people might be led by different motivations, but we want to get the true answers.

Todd (14:42):

I want to get a medication approved that actually helps patients and doesn't just fudge the data because what if it gets out there and starts to harm people or just do absolutely nothing? It's no help to them. And that's why you and I are nurses is that we appreciate helping people, but we need to also have checks and balances to make sure we are understanding the data correctly. We have gotten the cleanest, most accurate data. The protocol has been written correctly, and we do understand that. So I do get that money can be a motivator.

Todd (15:10):

Let's say Jim you have a compound, an asset, a drug for your company, and it looks like it could affect a therapeutic area or a disease process that could pull in two million in sales and another avenue that might pull in two billion in sales. Some people might be more led to the two billion regardless of everything else. So I respect that. However, you have to keep in mind, so I've acknowledged that there is some negative approaches to things that are not good and can be shady, but at the same time, research, if you're not in the space, it takes so much money to get a drug approved in the United States with the FDA because the FDA is very careful with understanding all the components that need to be in place and the data that needs to be understood to say this medication should be on the market.

I was just Googling this the other day, the typical cost to develop a drug is $2 billion on average. And the average time it takes from saying, "Here's our

asset in preclinical," which is kind of working with animals and such, to the time it gets approved is about 13 1/2 or 14 years.

Jim (16:20):

We had a guest a few episodes ago, he was speaking more to the medical device side, but the numbers were very similar. I want to say I don't remember the cost, but I remember him saying like 13 or 14 years. So the time it takes is significant too. Go ahead.

Todd (16:37):

Well, yeah, I know devices more on the hospital side and that's a great point. Thank you for mentioning that. But they are pretty similar because they have to do different things and gather different data, which we won't really dive into. But let's take medications for example. You don't have to just do the phase one, twos and threes and bigger studies to see how it affects disease patients, but you also have to do human abuse liability studies for drugs that might be controlled substances like pain medications, what have you. You have to do specific liver and kidney studies to see how it affects your liver and kidneys because those process out and break down the medications in your body. You have to do specific cardiac tests.

Todd (17:17):

And I think the FDA sometimes has, I think multiple study requirements, not just doing one study to make sure the effects on your electrical pathways, like it's called a TQT, a thorough QT test, to understand because that can come up in some fields more than others. I'm just giving you a few examples that have to be done besides those larger studies that, oh, here's the endpoint. We're trying to reduce heart attacks, we're trying to reduce diabetic hospitalizations. Those are obviously the big ones we kind of are aware of, but you have to do all these little studies in the meantime to build up to this is the host of data that the FDA needs.

Todd (17:56):

I guess my point when you sum all this up is, if you have a small company or even a mid-size company and they're leaning on 1, 2, 3 drugs and they have a

little bit of cash on hand, if they make one tiny wrong decision, but even not the best decision on how to structure a protocol or a little bit of data that goes differently, but it still could be a good medication that could help patients, they might drown.

Todd (18:22):

And, Jim, guess what, people might not realize this, but they might have, let's say they have compound A, and let's say it actually could really help diabetes, we're talking about diabetes, let's say it could really help diabetes. If they drown because they didn't do something right and they ran out of money and not enough other companies at that time appreciate the data that they have that's there. Maybe they didn't get to certain points to say, "Hey, this data could be really key with this type of patient population or look at the endpoints that we found with HbA1c levels or what have you. Nobody might buy them and help keep that compound A moving and then suddenly it just disappears into space so it gets forgotten.

Todd (19:02):

That's I think the positive side of what is a motivation of, hey, we might have something that could really help people here, but we have to keep staying alive and keep the lights on and keep things moving. You do that with phase ones to phase twos and then phase twos to phase threes. There's a point where you actually have a sit down and say, does the signal make sense to keep moving on here? Or are we seeing enough that it's maybe not the best, not just financially, but for patients? If it's going to get to the point where it's going to be negative and the FDA is not going to prove it, it's not going to help patients. So let's just cut it.

Todd (19:34):

Because the big focus today, and I think I might've mentioned the last podcast, is to fail early. So what a lot of companies like to do is to do a lot of high throughput, testing thousands of different compounds and various disease processes and targets in the body to understand where they might fail down the road, and there's amazing technology to figure that out, so they can hopefully pick the right one to go down that rabbit hole, shall we say, and hopefully get an approval because we know-

Jim (20:04):

Because it's such a big investment, they want to know that early, right?

Todd (20:08):

It's such a big investment. And, oh, I didn't say this, but I think a compound, once it first gets found to get FDA approved through all the phase ones, twos and threes, it's like 5% or 10%, something really low.

Jim (20:20):

Wow.

Todd (20:20):

Even if things sound really appealing, the amount of drugs that actually get approved after all these things, we talked $2 billion, 13 and a half years, is still pretty small. Because the FDA is trying to be careful, they want to make sure something's safe and effective, that's the big thing. And it is great that we have both of those things that are important. You don't want something that's just one of those things, I mean safe but not effective, or effective but not safe. I mean both of those don't sound appealing to the modern consumer. That's I guess the points I wanted to get at.

Todd (20:53):

I guess the other thing though is, too, and I forget if we talked about this last time, is, and I'm sure SpendMend will really appreciate and has kind of seen this impact, but once a drug gets approved, the transition from clinical research, the bench, the clinical research trials into commercial and clinical care is difficult because you also have to do some real world evidence understanding of, hey, we had this narrow criteria, but now we want to try to give it to a larger population. What are we seeing in the real world space? And you have to kind of do some modeling to say, "Hey, you give Lasix to people and it costs this much a day, this much a month, you have this many hospitalizations, but our new medication will cost this much, but it'll actually save you this much with hospitalizations, this much with ER visits, this amount of money with doctor's visits, urgent doctor visits with fluid on

board." And so you kind of have to show in the data that it will impact your bottom line and your top line, not just help patients.

Jim (21:57):

Absolutely.

Todd (21:58):

Because it has to get approved on insurances and such. So that's an interesting component to watch happen because sometimes you can have a lot of good data to kind of pitch and to show in a slide deck and say, "Hey, look, this will really help you guys out." Or it could be really close to what's already out there and then you're like, "Oh, we have something that's clinically pretty good but doesn't save financially." And then it's up to the hospital committees and such to say if they want it on their formulary or not.

Jim (22:28):

That's a great point. That's a great point, Todd.

Jim (22:30):

If you're just tuning in, you're listening to The Healthcare Leadership Experience and I'm your host, Jim Cagliostro. This show is sponsored by VIE Healthcare Consulting, a SpendMend company, which provides leading edge financial and operational consulting for hospitals, healthcare institutions, and other providers of patient care.

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Jim (23:02):

Todd, you mentioned about risks and benefits, so I kind of want to dig into that a little bit more. How do we know the point or at least to predict when that point would be where a drug or a device is too dangerous or simply not effective versus something that's good that could actually benefit society?

When can patients know this timing, that point, so that they know their benefits did outweigh their risks, especially if it's a blind study?

Todd (23:28):

Yeah, I actually might go back to that book I mentioned by Paul Offit and I think maybe I'll just target one example, and I read this maybe two or three years ago, but blood transfusions. When the scientists at the time thought they understood how to take some person's blood and transfuse it into someone else that needed it, they thought they understood some of the basic points of the science behind and the physiology about it. So they took a certain approach and, if I remember correctly, a few people died and then they were like, "Okay, wait a minute, we need to step back." And then there was, I can't remember the name of the physician, but he essentially was like, "It's just family members. Let's just do family members."

Todd (24:12):

But as you know, if you take family members in more... Because I think he also used extended family members, you might have someone that's an A versus an O versus an AB. As we know today, we're 20/20 vision looking backwards, they might have a blood type that can't take a specific blood type that they're getting. And he didn't understand that at the time, but he kept pushing it because he was like, "No, no, no, it's family members." Or I forget, he had some other links and he started killing more people and were having major safety events from it. It wasn't until they started to understand these blood types and then also the RH positive, RH negative. And I feel like there might've been another point. You started to knock down the big dominoes to say, wait a minute, here's where the big things he was missing are and now they're resolved.

Todd (25:04):

And that's actually the point of his book is early on, the things that he covered that we know and love today and we use today in medical fields, like some of the examples I gave seemed very dangerous and scary and crazy and were way out of the blue and like, oh, how is that going to help patients at that time if you lived in that year that these things occurred. But if you started to see these things start to fall and say, oh, actually now people are

really taking off and doing well and you're not seeing some of the big trends and you're starting to really see a safe approach to it, and if there are safety things that are very minimal and we're understanding it more, that line I respect can be gray.

And I think that he does that, and I think physicians do still today, and that's why they tell the patient, "Hey, look, this is how the drug works. This is how it should work for you, but you haven't taken it yet. So we want to see, and maybe we'll watch you in the hospital or maybe we'll give you a call in a few days and see how you're doing." But we have to kind of take some care but also not back up and say, we're too fearful about such, so let's not even try it. But there is a gray point of where are we in the development process that we truly understand.

Todd (26:16):

So as an example, the other thing is, too, is it a brand new medication in a specific target that has never been used on patients before? So I think I might've used this last time, but PCSK9 inhibitors are a specific type of inhibitor that helps drop your LDL levels, like 40 to 70%. They were just approved a few years ago, got to work on someone that's in the hospital setting, and they're an injection. They're impressive as far as the numbers change, but you have to say, "Well, okay, this is amazing from what we're seeing so far."

Todd (26:50):

And actually I think I might've explained that they actually found certain people in society that had a very low amount of PCSK9 enzyme and some that had a certain high amount, and they understood that those people had very high or very low LDLs, and they started to look into that and they learned more about the enzyme itself and what it does in the system. But until we synthesize it and make it into a medication and know how that works in a patient's body, we can't just say, "Oh, it's safe. Oh, it's perfectly fine. Oh, it's super effective, it's going to be great." So you have to be careful in what you see. The enzyme itself comes up naturally, but how we're inhibiting it does not. So how do we learn that early on?

Todd (27:33):

I think at the end of the day though, and I wanted to drive home is the patient that's in the research trial has a relationship with their doctor and it's their own advocate. I'd have patients that say, "Oh, yeah, I'll just sign on the dotted line. Yeah, I'll do it. My doctor says so." But you have to sense how is the safety going? What do we know so far? Is it enough that makes me comfortable to, I hate to say take a risk, but to take that chance of I could have a good benefit or result and maybe have little to no symptoms or not. But you need to have a doctor that you know well and that knows the studies and the compound well, and also what you're on to really you can trust and say, "Should I do this? Should I not? Are we beyond that gray line that we've talked about? Do you think it's good or if we're before that?"

Todd (28:21):

Because some cancer patients do very early phase one and twos because they have to because of the development process or because of their cancer diagnosis or what have you, you might have to do early on. But are we past that line? Are we not? And what might that line look like? And that's why consent forms nowadays are extremely long because patients have to read all the safety data. We're always updating it to the most recent safety data that's out there. We stop studies early if they are ineffective or if they're extremely effective and they need to get on the market because they're helping a population that doesn't have that yet.

Todd (28:54):

So the line is sensed by the FDA and companies and various things and built into protocols saying statistically we can calculate the power and the signal that we need to see to understand where that line is in the study you are in, whether it be, let's say, phase two or phase three, or in general with the compound that we just say, let's put it on the shelf and forget about it. Or, hey, maybe we'll take it to the FDA right now because the data's so impressive.

So there's a lot of interesting things you can do with math and statistics to understand how many patients you need to see how much of an impact on a certain endpoint to really understand what you're seeing or not seeing to understand what that line is.

Jim (29:36):

Well, it's amazing as you're referring to some of these older, like going back to blood types, and it's amazing how far we've come in terms of patient care and how much we know, and it makes me think about where we're at now, what about 100 years from now. And a lot of these advancements, a lot of it is because of clinical research. But like you said, there are risks involved. And so I maybe follow up with a question like patients will say, "Well, is it worth it?" Is all the hassle for patients and for clinicians, is it worth the potential downstream impact that it could have?

Todd (30:10):

Yeah, I think I might've jumped into that question a little bit on the last one in the sense that it's that patient and doctor relationship that makes that, because patient A and doctor A may be the exact same profile as patient B and doctor B, but one chooses it and the other one doesn't. And it might be for social reasons or for location reasons or for concerns about the safety with something else going on in their lives. So you just never know. And I think that that is going to be hard to predict at times.

Todd (30:42):

But I think when you, let's say you're presented with a medication to take, you can do your own due diligence and Google and look into it that way. You can ask your doctor to maybe see if they can get a hold of some of the data that's out there besides what's maybe in the consent form. You maybe get a little bit more nitty-gritty detail there and talk through it a little bit more. Your consent to get into a research study is able to be withdrawn at any time. So if you start a study and four weeks later you either don't want to do it or there's safety concerns, the physician, the nurses, the whoever are not going to push you in it and you're welcome just to bow out and no one's going to think the worst of you or what have you. So that's also really nice. There were definitely some trials in the last 100 years where that wasn't allowed or that wasn't conveyed to the patients that that could be a possibility. I do appreciate today that the patient's consent is very well respected, for sure.

Todd (31:35):

I'll give you an example. This is probably six, seven years ago now. I did a study with what's now Camzyos, or mavacamten, a BMS drug, and it helps patients that have hypertrophic cardiomyopathy, apologies if I used this last time, but I don't think I did, where it is an overdevelopment of the muscles of the heart to the point that it's typically pushing into the left ventricular outflow tract, which is the exiting tunnel, shall we say, out to the aorta, which goes to the rest of your body and provides blood to the rest of your body. So the muscle as it pushes into that area, it makes the opening smaller and smaller so less blood can go out to the rest of your body to provide blood to your tissues and organs.

Todd (32:21):

And at the point that we were doing the study, the only fixes or treatment were either surgery to cut down that muscle or beta blockers and things to reduce the blood pressure that maybe reduces pressure in that area, but those are difficult to really target long-term or even midterm. It does affect the small muscle fibers and you actually see a reduction in that muscle area. So the reason I say this is because I had a patient that did this and it was a very involved, I think it was early Phase 1b or 2a, pretty early on study where he had to come in weekly for 12 weeks and do echoes and MRIs and a lot of blood work. And some of the visits I remember with him, he was in his 20s, were maybe three, four or five hours long, very busy visits for sure.

Todd (33:14):

So the question is, I mean, he's a young kid, does he want to have this burden on his life to do all this? He had a good relationship with the physicians there that saw him, and I think that he really thought this could help him prevent downstream problems or give him a few years before that muscle was impacting enough that he might need surgery or what have you. So it was certainly his decision and it was inconvenient, like I said, those visits and such. But he had good results and I was able to, I believe it was actually open label, so I kind of got to see how things were going from his echoes and data and such. But even within the first week or two, we saw really impressive results from him.

Todd (34:02):

So it's like, oh, man, he had a really quick turnaround that was great to see from the cardiac muscle that we were watching, but it was a lot of hassle. So how do you weigh that? To each their own. There might be somebody in the exact situation that might say, "It's too much for me and I haven't tried it yet. What happens if I have a reaction to it or what have you?" They might walk away, but this gentleman did it and he did awesome and he was a really nice guy, and we had a good time at our visits because we got to know each other quite well. But I think at the end of the day though, it's a tough call, but I would say it is, but you have to still know what your physicians that are working with you truly understand of what we do and don't know and make that decision for yourself.

Jim (34:41):

Well, thank you, Todd, for sharing even the specific examples. I think the last time we spoke or the last time you were on the podcast, this thought came to my mind and it's come to my mind again about how much we can be thankful for clinical research and we don't even realize it. Just at the bedside, caring for patients and where we are today and how much of that is a result of research. And nowadays, not just any research, but research that is well done, that is well-documented, that the data is good, the results are good, the benefits outweigh the risks. So I really appreciate that and the examples that you're using I think really stick in my mind.

So really to close up here, I know you've worked in a variety of areas and a variety of medications and clinical research. Anything that you would say that has kind of helped you through those different environments that you've been in all related to clinical research, but anything that's really, even just personally, that's kind of helped carry you through your career?

Todd (35:41):

I think that in medicine, and I will say on the pharmaceutical side, I think there's a lot of prestige about what you're doing and you can appreciate your, shall we say, experience and expertise, that there are definitely some that will have the approach of I'm really good at my job, I'm really good at X, Y, Z, know this and know that. And some might say, "Don't tell me what to do." You might have different personalities, you might...personalities.

What I'm actually talking is, what I found to be really helpful for me is respecting and appreciating that I'm working in a team and understanding that it's okay to ask others to do a job that they're really good at because you might work at a small company or a small hospital where you have to wear 10 hats, so you feel like you have to do 12, 15, 20 different things, but at the same time you have other team members that you can...

Todd (36:41):

And I think that what I'm getting at is good delegation is not a negative thing and it doesn't reflect like you don't know what you're doing. I think we as human beings feel like, "Oh, I'm delegating so I clearly don't want to learn that, or I'm not good enough versus someone else." But no, what I found is, and especially now in larger pharmaceutical companies where there's a lot of team members, it's really beneficial to say, "Hey, you're really good at X, you're really good at Y. I should know them a little bit, and I do, and I oversee that, whatever, but I'm not going to jump in. I'm going to let you do it. Can you get back to me in a certain timeframe? Can you help me with this? Can you help me with that?"

Todd (37:19):

It's very beneficial because not only do you kind of know the lines in the sand where people are working and not working, you're respecting your skillset and theirs, and you're working together as a team rather than like, I'm in my own silo. I'm not going to look both ways. I am my own person. I found that to be really, really helpful, and you can learn a lot at the same time. It really helps you learn a lot more than just saying, "I'll do my own thing." I mean, yeah, you might be baptized by fire and learn it kind of, but you might learn it a wrong way, actually. So I think that's probably what I would say and what I've really appreciated in my growth process.

Jim (37:54):

That's great. Thank you. Thanks for being on the show again, Todd. And thank you to our listeners who spent time with us today.

If you have any questions about VIE Healthcare Consulting, a SpendMend company, or if you want to reach out to me or Lisa Miller, you can find us on

LinkedIn. Todd Nicklas is also on LinkedIn. Look him up, connect with him.

We at SpendMend love helping hospitals save money and enhance the patient experience, and we're hoping that the episode today gave you some new insights, some new ideas to consider and use in your own career and your own healthcare organization. Todd, thanks again for joining us today.

Todd (38:27):

Thank you, Jim.

Speaker (38:29):

Thanks for listening to The Healthcare Leadership Experience Podcast. We hope you've enjoyed this episode. If you're interested in learning new strategies, best practices and ideas to utilize in your career and healthcare organization, check out our website at thehealthcareleadershipexperience.com. And, oh, yeah, don't forget to rate and review us and be sure to join Lisa and Jim next time on The Healthcare Leadership Experience Podcast. Thanks again for listening.

MEET LISA MILLER

"It's important for hospitals to have a clearly defined cost savings strategy with purchased services as a component to that strategy. We provide our clients with a focused roadmap to achieve those savings through our expertise since 1999."

Lisa Miller launched VIE Healthcare Consulting in 1999 to provide leading-edge financial and operational consulting for hospitals, healthcare institutions, and all providers of patient care.

She has become a recognized leader in healthcare operational performance improvement, and with her team has generated more than $720 million in financial improvements for VIE Healthcare's clients.

Lisa is a trusted advisor to hospital leaders on operational strategies within margin improvement, process improvements, technology/ telehealth, the patient experience, and growth opportunities.

Her innovative projects include VIE Healthcare's EXCITE! Program, a performance improvement workshop that captures employee ideas and translates them into profit improvement initiatives, and Patient Journey Mapping®, an effective qualitative approach for visualizing patient experience to achieve clinical, operating, and financial improvements.

Lisa has developed patented technology for healthcare financial improvement within purchased services; in addition to a technology that increases patient satisfaction through frontline insights.

Lisa received a BS degree in Business Administration from Eastern University in Pennsylvania and a Masters in Healthcare Administration from Seton Hall University in New Jersey.
She is a member of the National Honor Society for Healthcare Administration – Upsilon Phi Delta. Her book The Entrepreneurial Hospital is being published by Taylor Francis.

MEET JIM CAGLIOSTRO

Jim joined VIE Healthcare Consulting in 2018 and brings to the role over a decade of critical care nursing experience at highly regarded medical facilities across three states.

During that time, he observed both the 'good and bad' of hospital operations in a number of regions, giving him a unique insight and understanding which he brings to VIE Healthcare Consulting's clients.

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MEET TODD NICKLAS

Todd Nicklas, a seasoned clinical research nurse with 12+ years in academia and industry, boasts extensive expertise spanning cardiology, rare genetic diseases, transplantation, and more. His remarkable trial experience ranges from Phase 1 to Phase 4, excelling in both device and pharmaceutical research. A skilled manager and mentor, Todd has led teams, overseen operations, and is dedicated to fostering collaborative, results-driven environments.

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