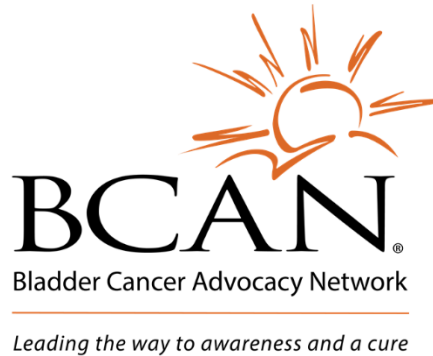


TREATMENT TALKS

What you need to know about clinical trials as a treatment option for bladder cancer.



What You Need to Know About Clinical Trials As a Treatment Option for Bladder Cancer

Stephanie Chisolm:

This is a Treatment Talk program from the Bladder Cancer Advocacy Network and tonight's topic is "What You Really Need to Know About Clinical Trials as a Treatment Option for Bladder Cancer." I'd like to welcome Dr. Peter O'Donnell from the University of Chicago and Dr. Neil Shore from down in South Carolina. We have two patients with us today, Bob Wrenn and Kevin Williamson. I'm just going to start by welcoming you all for being here with us. I wanted to talk a little bit about clinical trials as a treatment option because a lot of people don't always think about this. The difference with Treatment Talks, these different types of webinars that we have, is that we're bringing in the patient voice into the conversation. We wanted to make this a little bit comfortable for both patients and the doctors to talk about these things. When we did a little bit of planning we thought it would be really helpful to do a little bit of myth busting because I think that there are a lot of myths about clinical trials. What I thought I would start to do is give everybody a chance, on the panel, to address the issue about, "I have to go to a big research hospital to be involved in a clinical trial."

Myth busting Clinical Trials as Treatment

I have to go to a big research hospital to get access to a clinical trial.

- I'll be getting a "sugar pill". I don't want to be a guinea pig.
- Clinical trials are for when I run out options.
- Clinical trials use outrageous or unapproved treatments.
- Once I sign up, I have to stay on the trial till the end.
- Costs are all covered. I won't have to even provide my insurance information.
- The cost of being on a clinical trial will be very high.
- Is genetic testing required to be in a trial? Who pays for that?



Stephanie Chisolm:

Dr. O'Donnell, I'm going to ask you a quick question to get us started. You're in a large academic institution at the University of Chicago and you do many clinical trials, right?

Dr. O'Donnell:

Correct.

Stephanie Chisolm:

Is that the only place in Chicago that people can get into a clinical trial?

Dr. O'Donnell:

I'm sure it's not. Sometimes patients have that myth that clinical trials are only happening at the big academic centers. While it might be true that academic centers have maybe access to more clinical trials on average, one of the big pushes is actually to get these clinical trials out into the community so that all can have access. I think that certainly over the past decade or so we've done a good job of that in bladder cancer and Dr. Shore might be able to speak to that as well.

Stephanie Chisolm:

Dr. Shore, you're there in Myrtle Beach, South Carolina, in a large urology practice, and you do clinical trials in your practice. I think because that makes it a little bit more convenient, you're in the community. Just making it easier for people to get involved in the clinical trial so that they don't necessarily have to drive a long distance, because you're kind of a long distance from some major cities in South Carolina. For people who live on the shore that might be hard for them to get to. Why do you do clinical trials in your practice and do all urologists or medical oncologists do clinical trials in the community?

Dr. Shore:

There's a lot of things there that I think are really important. I'm really looking forward to hearing both Kevin and Bob talk about their initial impressions when a physician would say to them, "Hey, we've got a clinical trial," what was their initial reaction. The bottom line is, I've been in community practice now since 1990 and I've done over 400 clinical trials. I'm really proud of the work that we've done at Carolina Urologic Research Center. I started the facility in the '90s. I have 18 full-time employees. It's all we do with clinical trials. Prostate cancer, at least in the world of urologic oncology, was getting all the attention the last 15 years and in the last five or six years bladder cancer's really come into its own. In fact Stephanie, and I think Peter would agree, we have more trials than we can find the right patients. We have this sort of embarrassment of riches. We have so many great trials. Why are trials important and why do I do it? It's the same reason why anybody does research. It's because we have unmet needs. At our core, whether you're a community practitioner or you're a researcher in academia we're all physician scientists and when we have patients who are still dying of advanced cancer or we need better diagnostics to identify early stage bladder cancer or better markers to understand who's going to respond or not, this is what makes precision based therapy and makes us all better.

Dr. Shore:

I know I think I speak for Peter and everyone at BCAN, we are 100% committed to bladder cancer research because that's the only way we, number one, up our excellence in the approved therapies. The

approved therapies by FDA, CMS, and commercial payers, but more importantly it's always about trying to find new diagnostic tests, new biomarkers whether it's blood based or urine based and new therapies so that we don't have patients succumbing to bladder cancer. Those are all the reasons. The answer is, is that we're getting more community based sites involved both medical oncology and urology. I think combining the excellence and the expertise of BCAN, the AUA, the SUO, ASCO, LUGPA we're all really working together now to say we all need to be doing clinical studies. In fact, being a clinical study option is in the guidelines for all of the leading organizations throughout the US and the world. Being involved in a clinical trial is a standard of care, frankly. I think this is a very, very important message.

Stephanie Chisolm:

It is and I'm really glad that you're here and have an opportunity to share that message. I know that some people are a little bit anxious about being in a clinical trial. **Why did you participate in a clinical trial?**

Patient Advocate Kevin W.:

Well, it was the third thing that I did after chemotherapy and a targeted therapy. We were definitely looking for answers and happened to be in the right place at the right time. This is eight years ago. I don't think the trials were quite as plentiful back then. We were with Dr. O'Donnell. He had access to the trials and made them available to us, talked about it, asked questions. At my stage, for me, it kind of felt like, I'm not sure it was, but it kind of felt like it was my last chance. I had tried other things that were available prior.

Stephanie Chisolm:

Okay. So why did you do a clinical trial? You're not in a big city. Kevin is closer to Chicago.

Patient Advocate Bob W.:

Why did I do a clinical trial? Well, quite frankly, Dr. Shore said to me, "You have bladder cancer," and then he said, "But I got this program I want to put you in... A test program." And he says, "But I'm going to take care of you." So I said, "Well, you know what? Let me think about that." And about five minutes later I said, "Well, you know, I'm 80..." At the time I was 87 or 86. I said, "You know, maybe God put me here to do this clinical trial and maybe it will help somebody else." That's kind of where I came from because it seemed to me I had to have some kind of treatment so I might as well do this clinical trial while I'm doing it.

Stephanie Chisolm:

That's a good reason to do that. So, Dr. Shore: **Tell me about that in terms of is there an age limit for clinical trials?**

Dr. Shore:

I would just say that my friend Mr. Bob Wrenn who just gave you an answer, he's 87 going on 47. He is a prolific exerciser and he's a proud graduate of Virginia Tech, which is a beautiful university. I would encourage everybody to go and take a look at that. It's all about performance status. Meaning, how is a patient living their lives? I don't think there is any limit on an age. Of course we have some men and women who have a lot of health issues and they're frail and they're even, arguably, in their 40s and 50s. Maybe they're severely obese and have bad poorly controlled diabetes. Maybe they've had vascular problems. Maybe they've even had an amputation, in their 40s. And then you've got a lot of men and

women, like my friend Bob here, who is extremely active. I do not hold back on patients because of a chronologic age. It really comes down to how fit they are, their performance status and very importantly their desire to keep going.

The will to make it to another milestone of life. A child's graduate, a wedding, a trip once COVID simmers down. My answer, Stephanie, is unabashedly I don't let age get in the way. That's just a number.

Stephanie Chisolm:

Dr. O'Donnell, **when we're looking at clinical trials isn't it important to test a treatment option in the actual population that will be using it?** Isn't that also why it would be important to ensure that older people are a part of a clinical trial?

Dr. O'Donnell:

Of course. A lot of people wonder about that and they want to say that doctors want to be able to use the results of the trial to generalize to other patients, but even beyond that I want to remind folks, and I know Dr. Shore believes this too, we're doing these clinical trials to help the patient that's sitting in front of us, right? When Mr. Williamson came to me he's the one that needed the treatment and I actually believed that the clinical trial was the best option for him to help his situation. Not to try to generate some research down the future. Yes, we hope to generate new treatments for thousands of patients to come, but really the doctors first obligation is to try to find the best option for that patient there. I'll address maybe one of the things that you've shown on the slide here Stephanie and a lot of patients feel that, and Kevin even said it. He felt like in his case it was the last option for his situation. At that time there weren't a lot of options but we have a lot of clinical trials now that are trying to compare newer options to the existing standard of care. It could be the frontline therapy. This could be the first line treatment that you're going to receive for your cancer and we're trying to still improve upon that to cure an additional percentage of patients. It's not as if clinical trials are only when you feel like you're out of options. You might be actually appropriate for a clinical trial much earlier in the course of your disease and it does not mean that you're getting a sugar pill. It doesn't mean we're trying to experiment something on you. It might actually just be a way to get a treatment earlier than might be available to the general population.

The FDA, the government, have a requirement that doctors test these therapies often in all settings of the disease. You can use an approved drug and then just use that in a different earlier setting of the disease and that still has to be tested.

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