Lauren Hixenbaugh:

Welcome to Living Beyond Cancer. I'm Lauren Hixenbaugh, your host for today's episode. Living Beyond Cancer is a series of podcasts created for cancer patients, survivors, and their caregivers. This series is brought to you by the WVU Cancer Institute's Cancer Prevention and Control in collaboration with the West Virginia Cancer Coalition Mountains of Hope. And today I'm really excited to introduce Dr. Tina Bhatnagar. She's here today talking about clinical trials and questions relating to that. So if you just want to start us off by telling us a little bit about yourself and your role.

Dr Tina Bhatnagar:

Well, thank you Lauren for having me on the podcast. I'm really excited to talk with everyone about clinical trials. It's a topic I'm very passionate about. I am the medical director of hematology and medical oncology at WVU Cancer Institute Wheeling Hospital, which is the largest regional affiliate of the cancer center. I've been there for about three years almost. It'll be three years in May and my area of specialty is blood cancers. So I have a special interest and expertise in the management of patients with acute leukemias and other blood disorders. So I consider myself to be mainly a hematologist. I came to WVU after serving as an assistant and later an associate professor at the Ohio State University where I specialized again in the care of patients with acute leukemia and had the opportunity to participate in a number of clinical trials for those patients. And I'm hoping in my new role to really grow the access that patients in our region have to clinical trials across all malignancies.

Lauren Hixenbaugh:

Definitely. And that access is so important. And so to start off today, let's just start with a super broad question of what is clinical trials and then we'll get to some more specific questions.

Dr Tina Bhatnagar:

Yeah, it's an important question because you'd be surprised by what people understand about clinical trials. But the way I generally explain clinical trials to patients is that these are studies that are being conducted to answer certain questions that we don't know the answer to. So clinical trials, the whole reason we do them is for that purpose- to find out how best to care for our patients. And clinical trials come in all different shapes and flavors. However, the ones that I think people are most familiar with are trials that involve the use of an investigational drug for the management of some type of a condition. So in our case, cancer of course, investigational drugs are not FDA approved. They are under development. And the whole question regarding the clinical trial is whether or not those drugs work and whether or not they help patients. And we call those trials interventional trials because we are planning to actually do something with respect to treatment for the patient. There are a lot of other types of trials out there which don't necessarily involve giving patient drugs, things like observational studies where you're just trying to get a sense of how patients do on a certain treatment, but you're not actually treating them. There are quality of life studies which look at the way that patients are affected by certain symptoms. So there's a whole host that's sort of a topic for another podcast. But I think what generally people think

about with clinical trials are the interventional ones where patients are trying to receive a new treatment.

Lauren Hixenbaugh:

So what you're saying is there are trials beyond treatment and that patients don't have to actually be sick to participate.

Dr Tina Bhatnagar:

Correct. They do not. Clinical trials are really open to anyone who is interested in them. So you don't have to be at a specific point in your disease course to really consider a clinical trial. So I think that's one misconception that a lot of patients have is that clinical trials are considered kind of a last resort, when in truth they're considered the standard of care. That's the best care that you can offer a patient.

Lauren Hixenbaugh:

And so during the trials, patients are receiving the standard of care or beyond that, and what type of care are they receiving during that?

Dr Tina Bhatnagar:

Yeah, so if we're talking about interventional trials where you're trying to determine if a specific drug or therapy works, these trials have multiple phases before they're actually brought to patients. So they are studied in cell lines and a lot of the time they are studied in animal models. We call those preclinical studies, and we do those upfront to even see if a particular drug has any particular benefit or if there's a side effect that tells you about how well or safe this drug is going to be. So the drugs that are selected to go into clinical trials have sort of more or less gone through the wringer before they're officially brought to patients. And ethically, when you're doing something called a randomized controlled trial where some of the patients are going to receive either the standard of care versus the treatment, that ethically has to be approved by the institutional review board and whatnot. So in other words, it's not going to, a patient is not going to encounter a situation where they're not offered the best treatment upfront.

Lauren Hixenbaugh:

We hear a lot of concerns from patients about that, the benefits versus the side effects, and especially if patients are always worried about that they're not going to receive care if they participate. I think that's what we're trying to convey to people as they're listening today is that they are going to receive at least the standard of care. Correct. When they're a part of a clinical trial.

Dr Tina Bhatnagar:

Yeah, absolutely. And sometimes the standard of care is nothing. So we don't know, or we're in a situation where there is no standard of care. So there are still placebo controlled trials, but it's only because that's the best we have at that point. But a patient is not necessarily going to be denied what is considered the frontline standard treatment because at the end of the day, I've had several mentors say this to me, and it's something that resonates with me, is that the trials are for the patients. The patients are not for the trials.

Lauren Hixenbaugh:

So I guess talk about a little bit patients worrying about the particular side effects of something that they're undergoing. And then we hear a lot about how will the trial help me? Will it definitely help somebody or maybe not.

Dr Tina Bhatnagar:

Yeah, I think that is an important question that often comes up. And the truth is that we can't guarantee that an investigational drug is going to help hurt or do nothing for a patient in their disease. And I make that very clear to my patients when I'm discussing clinical trials with them. At the same time, I also make it clear that pretty much all of the drugs that are currently available for us, were initially only available through a clinical trial. So it does allow them to have early access to treatments that could potentially help them. As far as the side effects of these investigational drugs go, there are some side effects that we definitely know about, but I think it's also important for patients to know that they could encounter a side effect that is new and that has not been reported and upfront we don't know that information right away. So while there are a lot of unknowns and there's a little bit of a gamble when you go into a clinical trial, particularly an early phase clinical trial, like a phase one or a phase two study phase, especially though that ultimately the hope is that this treatment will help you and if it doesn't help you, it will at least advance the field in terms of understanding that drug better.

Lauren Hixenbaugh:

And I think that's what you said right in the very beginning is the whole importance is answering questions that we don't know the answers to. So I mean, that is what we're trying to do and maybe talk a little bit more about why trials are important. So we're answering those questions, but why is it important to patients?

Dr Tina Bhatnagar:

So as I mentioned, they do represent a standard of care for our patient population. So they're actually considered the best quality of care that a patient can receive. Obviously from a larger perspective, you are advancing the field. You're also offering patients access to treatments that they otherwise would not

have that could potentially help them. And so I think those are the two biggest reasons. I will say that clinical trial participants are monitored very closely too because they are on a study and we have to really keep an eye on them to make sure that they're doing okay. So in some ways they have more eyes on them as they're receiving treatment, and I think that does enhance their care as well. And so I think clinical trials have advantages for patients and for the scientific community at large and also for other patients in the future who might become afflicted with certain cancers. So that's all really important information to know. It's important to know what drugs work. It's also really important to know what drugs don't work so that we don't continue to look into them.

Lauren Hixenbaugh:

And and I talked earlier about the importance of access and making sure that we are getting those underrepresented populations involved in clinical trials so that our drugs are meeting different genetic makeups of all sorts of people. And I think that's really important as well from our perspective is just making sure that we're providing access to people. So on that note, how do folks find out about clinical trials and participate?

Dr Tina Bhatnagar:

So the first place is really to ask their physician about them. I've had patients, so some patients especially in our region, are not even aware of clinical trials and what they are and how they're supposed to help. So I think talking to their doctor is a good first step. There are some patients who are very aware of clinical trials and clinical trials.gov is a publicly available website where you are obligated, it's a federal law to have your clinical trial registered there. So you can search clinical trials.gov and see what trials are available in your area or according to a certain disease group. So I would say those are the two biggest avenues that patients can find out whether they're eligible for a clinical trial and where there might be one for them to enroll in if they are interested.

Lauren Hixenbaugh:

And is there any advantage to being a part of a particular health system? Like if we have WVU patients that are interested in clinical trials?

Dr Tina Bhatnagar:

So most clinical trials are done in an academic or we sometimes refer to them as a tertiary medical center. So places that are affiliated with a university, WVU is certainly one of them. And so by virtue of having more resources and personnel, because running a clinical trial involves a lot of different types of people from different areas. So it's a heavy lift and sometimes community practices don't necessarily have the infrastructure to support trials, but the conundrum is that the majority of patients live out in the community. So how do you provide access to the people who sort of need it the most? Not everybody can make it to an academic medical center. And to that end, there has been a huge push to

provide community centers and community practices with the necessary resources and personnel to support clinical trials in the community. So we are working on that in Wheeling and across a lot of the other regional sites as well, because that's where most of our patients are seen.

Lauren Hixenbaugh:

So I think that's really interesting for patients to kind of understand the difference in participating, maybe looking at a national trial versus more specific to our state. So could you kind of walk me through, I know there's lots of different trials, testing for different types of things, but maybe just very basic and broad of what it would look like for a patient to begin the clinical trial process through maybe some basic interaction and then that survivorship piece.

Dr Tina Bhatnagar:

Sure. So for simplicity's sake, we'll talk about a patient who's interested in going on an interventional trial, basically wanting to know whether drug X works. And so if such a patient were to show up, then that initial discussion would happen with their treating oncologist. And then if the patient expresses an interest, what usually happens is that they are screened for the trial. Each clinical trial has specific eligibility criteria to make sure that appropriate patients are being enrolled. So there's inclusion and exclusion criteria. And so if the patients meet all of the eligibility criteria, then they can officially move forward with trial enrollment. Once they're officially in the study, they are going to be monitored by their treating physician at specific intervals specified by the clinical trial. Some trials have patients monitored very, very frequently. Others are a little more lax, and some are in that middle ground where patients are monitored really closely for the first few months and then you sort of back off as far as their monitoring goes.

But they go on the study. In addition to seeing the physician, they will interact with a research nurse or a research coordinator who will follow those patients for the duration of their trial and ask them about what types of side effects they are experiencing on whatever treatment they're on. It'll be up to the treating physician to determine whether the side effects that a patient is experiencing are acceptable or not. There are specific definitions of acceptable side effects in each protocol. So if patients are getting really sick or if they are having a major issue with a specific drug, that will either require stopping the medication completely or temporarily stopping the medication until that side effect becomes more manageable. And again, depending on the trial, patients can either restart treatment with an adjusted dose of the medication or they would come off the study completely. So they're monitored at different intervals like that throughout the course of the study.

And again, depending on the trial, the trial either mandates that they have to come off at a certain time point or it doesn't. And so we try to follow the protocol to the letter of the law. And pretty much any time we deviate from what the protocol says medically, we have to report it and we have to report all side effects that all of our patients are experiencing. So in addition to being monitored by their local physician, the trial itself has study oversight from larger organizations, whether that is, if the trial is being done from say a pharmaceutical sponsor, they will have their own team watching the conduct of the study. The FDA will be watching the conduct of the study. If the trial is being done by one of the larger

cooperative groups, they will be monitoring the conduct of the study and then eventually when people come off trial, either because they want to.

So I think it's really important for patients to know that you're not wed to the clinical trial and that you have the freedom to come off whenever you want for whatever reason, even if it's just, I don't feel like being on the study anymore. You're not committed to it in any way. Although I would say that we try to discourage that, but that it's completely within their right to come off at any point, and it's without any legal, financial or personal ramifications. So they don't have to worry about the consequences of coming off study so people can withdraw at any time. I have seen people do that, especially when they are taking a medication that has a lot of side effects and is affecting their quality of life, or they come off when the study mandates that they come off and their information is stored for many, many years while it's analyzed and compared to how other people have done on the trial.

And the hope is that ultimately the results of the study will result in a publication or some type of a large public presentation of the results. And personally, I know I've had a lot of patients inquire about the status of clinical trials and how the drug ended up working and if a drug got FDA approved, we see that a lot with Imatinib or Gleevec, which was approved for CML back in 2000 for chronic myelogenous leukemia. And I have patients that I take care of today who were on the original trials with that drug and they're very proud of it. And that disease, CML, which used to be uniformly fatal, is now very treatable and people are living a completely normal lifespan because of this drug that became available in 2000. So I think hopefully that answers your question about the sort of trajectory and how patients, what a patient can expect at on a high level as they're going through the clinical trial process.

I will say that clinical trials involve more than standard of care, so patients come more frequently to the clinic for follow-up appointments if the trial is far from where they live. There are transportation considerations to think about as well. Sometimes it's a big deterrent, and that's why I think it's all the more important to have community centered clinical trials that are kind of in the patient's own backyard so that they can sort of offset that inconvenience. A lot of patients ask about cost and what the financial ramifications are at most centers, if not all, when a patient is interested in a clinical trial, we do make sure that their insurance company is aware of it and that they would be willing to cover the costs related to the clinical trial that are not covered by the trial itself. So if anything, in my experience, I actually think participating in clinical trials is cheaper because a lot of these medications are covered by the trial or by insurance, and so patients oftentimes do not have to pay out of pocket. And a lot of trials too are offering some additional funding and stipends for travel and incidental expenses as well.

Lauren Hixenbaugh:

So you did, thank you. I think that's great for people to understand the whole continuum. The only question I think I have from that is, so we talked about where to find the trial now, do you need any kind of doctor referral or your PCP or specialist or anybody to refer you to a trial? Or is that something that you can just do on your own

Dr Tina Bhatnagar:

As a patient? So I would say to get a referral for it, because I think the nuances of the clinical trial and communicating information from one place to another can be complicated. So I think if there's a clinical trial that is not available at your treating institution and you want to go somewhere else, I think it's better to get that referral from your primary oncologist.

Lauren Hixenbaugh:

And then we talked a little bit about cost, and of course there's always some, like you said, transportation costs that might be on the periphery of the trial. And then what about how long the trial lasts? We talked about being able to opt out that it's voluntary, but how long do they typically last or how long does the clinical trial follow you into treatment and then into survivorship?

Dr Tina Bhatnagar:

It's variable, but in general with research, the longer you can follow people, the better. And so you can't say a whole lot about how well a drug works and how long the response lasts if you're following patients for a short period of time. But if you follow them for say five, 10 years, which a lot of studies will do, they will follow patients for the rest of their natural life, then you can sort of say more about the durability of the response that a particular drug has to offer. So I hesitate to answer your question because it is so variable how long these trials last, but I think a patient can expect to be on them for years, either actively receiving treatment or in follow-up.

Lauren Hixenbaugh:

I think it has been great. We've answered lots of questions that are common to our patients, and we'll look towards wrapping up today. And usually what I like to do is just kind of take a minute to revisit a few points for our listeners. And so if there was one tip out of today's podcast that you really hope that would resonate with folks, what do you hope that it would be?

Dr Tina Bhatnagar:

So I would actually ask for two tips. Sure. Yeah. So my first tip is to ask about clinical trials because a lot of people don't even know that they're out there and there are so many resources that are available, but I think it always sort starts in your own backyard, talk to your doctor about clinical trials. That's tip number one. Ask about how they can help you. The second tip is that clinical trials are the best form of care that you can receive. They are not a last resort. They are not intended in any way to treat patients as guinea pigs. Because I hear that a lot and sometimes it's a big reason why patients don't want to participate is because they'll say, oh, there's that mistrust element to it. And I think it's important to highlight that everything that we know about cancer care and all of the advances that we have made in the field are because of clinical trials and because of the patients who participated in them.

Lauren Hixenbaugh:

I love that, and I'm so glad you talked about mistrust. That is definitely a big piece that we see. And all the information you provided helps to dispel some of the myths related to clinical trials. So hopefully people will see the major value in the information that we're providing today. So if people have more questions or would like to have to find out more information about Living Beyond Cancer, our podcasts and our support groups, they can go to moh.wvu.gov or wvu cancer.org. And then we also have a Facebook support group that is related to our Living Beyond Cancer Group. Just go to Facebook Search Living Beyond Cancer, and you can find out additional information. Are there any other websites that we should provide as a part of the podcast for our folks to look at relating to clinical trials?

Dr Tina Bhatnagar:

Just clinical trials.gov. You mentioned that, correct. So no, I think that's it. I know the Leukemia and Lymphoma Society as well has a lot of information on clinical trials for blood cancer patients.

Lauren Hixenbaugh:

Great. Thank you. Well Live and Beyond Cancer, we'd love to thank you for joining us today as well as our listeners. We hope that everyone will continue to join us.