Transcript Details
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An Outlier Survivor's Story: Confronting Systemic Barriers in Breast Cancer Care

Announcer:
You're listening to a special focus on breast cancer from *Advances in Women's Health*, sponsored by Lily.

Dr. Birnholz:
Coming to you from the 42nd annual San Antonio Breast Cancer Symposium, this is ReachMD. I'm Dr. Matt Birnholz. I'm joined by Marina Kaplan. She's a retired epidemiologist, cancer survivor, and volunteer with Living Beyond Breast Cancer, the Hear My Voice Metastatic Breast Cancer outreach program, which is a program that trains people living with metastatic disease to become advocates in their communities. Maria – Marina, welcome to the program.

Ms. Kaplan:
Thank you very much. Thank you for having me. I appreciate it.

Dr. Birnholz:
So, you've presented a poster here that is called Hear Our Voice: Patient-Driven Solutions to Increase Participation in Clinical Trials. It almost goes without saying, but why move in on this study now?

Ms. Kaplan:

Well, I think there's a huge problem with participation rates in clinical trials. It slows down the research, it makes it more expensive, it takes longer for drugs to get to market that people need. So I've always been passionate about clinical trials and about promoting clinical trials. I personally have actually been on six different interventional clinical trials in the metastatic breast cancer setting. So I think that I could say that I'm a huge fan. So for my Hear My Voice project, they have been percolating in my brain that I wanted to do a study looking from the patient perspective of what exactly are the barriers. So the literature is full of attitude barriers. So people are saying that patients don't want to participate in trials, they're scared of trials, they don't want to be seen as a guinea pig. And my experience with people I've spoken to was very different. So I actually wanted to do like a proper mixed methods research study that involved interviews and a survey to figure out what is it that metastatic breast cancer patients are saying about the barriers and the solutions to participating in clinical trials.

Dr. Birnholz:
It certainly makes perfect sense as to your background and motivations. This is a huge gap area in terms of access to clinical trials, patient understandings, their feeling of comfort around enrolling in or even looking for and when to do so. How is this painted by your own experience? You yourself mentioned you had undergone six clinical trials. What was your experience like that helped lead you to feel motivated to move in on this study?

Ms. Kaplan:
So for me personally, getting access to clinical trials gave me the opportunity to try innovative treatments that I wouldn't otherwise be able to try in about six years' time. So it often takes about six years for someone to start in a clinical trial until it's FDA approved. So selfishly, I was thinking this is a way of getting to, you know, treatments that aren't out there yet, but they have promise. Also in the back of my head, I was thinking let me promote the science, as well, while I'm at it. So that was the more altruistic method, but I have to be honest, it was more the selfish reason of how can this help me with my disease. And as it turns out, I am an outlier of being with metastatic triple-negative breast cancer for six years. And I was old the median survival when I was first diagnosed six years ago was 9-10 months. So I've been an outlier. Is it because of the trials? It could possibly be.

Dr. Birnholz:
And I think that's a perfect segue way to then discuss some of the outcomes of your – your study because there are many other outliers in waiting there. And it's a very inspiring story that you talk about. Maybe we can discuss some of the reasons for and against participating in trials from the patient standpoint.

Ms. Kaplan:

Wonderful. So the thing that made me most excited about the findings of this trial is that patient's attitudes in the metastatic breast cancer setting, because that was my sample, are really not barriers. You can see from the study, people were saying they really wanted to participate in trials, it gives them access to innovative treatments, they get close monitoring when they're on a trial, the drugs they may get might be more effective, it helps others with metastatic breast cancer, and it contributes to research. So there's like lots of compelling reasons people gave me during this survey, and there were very few like serious concerns about the typical barriers in terms of patient attitudes. So people were not very worried about data being misused, which I thought might be a bigger thing. People were not worried at all about being a guinea pig or a lab rat, which I thought they would be. So what this says to me is that patients in the metastatic breast cancer setting are very willing to participate in clinical trials. So the next part of my survey is, well what's preventing them? Because we know we have a very low accrual rate in clinical trials. And what came out of that dataset was the system level barriers. So that's the way the trials are set up. Those people in my study reported some significant system level barriers that prevented them from participating in trials. So one of the biggest examples is the exclusion criteria is too broad, and the eligibility criteria is too strict. Sometimes centers offering trials don't take people's insurance, so that cuts out a huge segment of the population. People are also concerned about the washout period being too long. The washout period is the time from one drug to when you can start the trial drug, and it's usually about 30 days, which is a very long time. And then people were saying also it's hard for them to get to the trials because there aren't a lot of trials that they would qualify for near to where they live.

Dr. Birnholz:
Fascinating. And it's a little bit eye opening, maybe a lot a bit eye opening, considering the overwhelming willingness to become involved in clinical trials, given the sobering prognoses that many patients are given. You yourself said you were given a prognosis that would have taken down many of the reasons for not participating, naturally. And yet many of these system level barriers do exist. It's a little bit premature to ask this, but where do we approach this? And how do we put these – this awareness of system level barriers into action from a clinical perspective on the healthcare side to enable the patient voice to be heard to get involved in clinical trials?

Ms. Kaplan:
I think that's a really good question. I think one of the big things would be education. So, you know, educating oncologists, working with scientists to develop protocols where the exclusion and inclusion criteria is absolutely critically necessary, not just for the science of the study, but also for patient safety. So if an exclusion criteria is there just sort of because, it's felt like well maybe we should add that, it shouldn't be there. It should be there only if there's a really compelling reason. The other thing too that I

found from this, and I got a lot of solutions from the people who participated in my interviews, so solutions to the barriers. And another big thing that came up, a lot of people reported that their oncologists don't bring up clinical trial opportunities at the first restaging visit or at the second restaging visit; they often wait until the patient has progressed a lot, which then in turn makes them excluded from the trials because they've been heavily pretreated. So one of the things we're proposing is the oncology field as a whole should be talking to patients at every restaging visit about clinical trials, and the oncologist themselves doesn't have to do it, but have like a navigator do something like that, um, to give them access to what trials are available for their particular disease.

Dr. Birnholz:
So a liaison of sorts through this navigator role, uh, to be able to address some of these barriers. I find it particularly compelling when you refer to education because the first thing people often think about, especially in our field of healthcare when we refer to education, we think, oh, educate the patients on how to better access trials. You're finding it's not just the patients that need to be educated, it's those who are designing the studies really need to think through, how do you make these accessible to patients and actually fill out your trials?

Ms. Kaplan:
Exactly. And what we would like to see is a patient advocate who is informed and educated, you know, on the science of trials and the methodologies, have them sit in on designing trials. So right now there are a lot of pharmaceutical companies and study sponsors that do engage patient advocates, and that's a fantastic thing. I think it's something that should be across the board, is having someone sitting at the table saying, you know, 'Why is this exclusion criteria there? Is it absolutely essential?' or 'How can we, you know, speed up recruitment for this trial by making the eligibility criteria a little broader?'

Dr. Birnholz:
Now, Marina, you yourself are an epidemiologist, health data runs in your DNA. Where next? What are the next data gaps that need to be addressed to help enable the patient's voice in clinical trial participation?

Ms. Kaplan:
That's a fantastic question. So for this particular study, I did it via social media, so I went to the metastatic breast cancer support groups on social media, but a wonderful response rate. But my response rate from minorities was not high enough to make any statements about minority patients. And we know from the data that minority participation in clinical trials is excruciatingly low. And that means that treatments aren't really designed for that population specifically. So I think that's a terrible thing. So that's where my next step is going to be, is to collaborate with the minority community and to

replicate the study as far as it makes sense in that community and get some data that's actionable for our minority populations.

Dr. Birnholz:
That's a perfect message to cascade to clinical trial designers, as well. It seems like a message that – a problem that is pervasive on both sides of the coin here.

Ms. Kaplan:
Exactly. That's exactly right. You know, I couldn't have said it better myself.

Dr. Birnholz:
Well, Marina, it's been a pleasure talking to you. We've been focusing on patient-driven solutions to increase participation in clinical trials. I hope to have you again sometime to interview you about the next project that you're working on to help enable the patient voice.

Ms. Kaplan:
Thank you very much. And thank you for the great work that you do. You know, this is an honor for me.

Dr. Birnholz:
To access this and other episodes devoted to better management, treatment research of breast cancer, visit reachmd.com where you can be part of the knowledge. I'm Dr. Matt Birnholz. Thanks again for listening.

Announcer:
You've been listening to this special focus on breast cancer from *Advances in Women's Health*. To revisit any part of this discussion and to access other episodes in this series, visit reachmd.com/advancesinwomen'shealth. Thank you for joining us.