

# FIND YOUR MBC VOICE

## Science of MBC

### Episode Title: Clinical Trial Checklist

Guest: Shirley Mertz, Advocate, President – MBC Network

**DR. COMEN:** Hi, I'm Dr. Elizabeth Comen, a medical oncologist specializing in treating breast cancer patients. When someone is diagnosed with metastatic breast cancer, they're often in a state of shock, especially when they find out it is the most advanced stage of disease. But we want to help you feel both informed and empowered. We are here to help you Find Your MBC Voice. Join me as we speak with Shirley Mertz from the Metastatic Breast Cancer Network or MBCN, a national nonprofit dedicated to the unique concerns of women and men living with metastatic breast cancer. Through her work, she helps educate patients about the considerations for clinical trials, which she is here to discuss with us today. Shirley is here to share her expertise and talk about the ins and outs of clinical trials from her perspective as both an advocate and a patient. This is Science of MBC. Shirley, welcome. We're so honored to have you here.

**SHIRLEY MERTZ:** Thank you.

**DR. COMEN:** So if we could start off by, if you could really just share with us your experience with metastatic breast cancer and how you became an advocate for clinical trials.

**SHIRLEY MERTZ:** Well, my journey with metastatic breast cancer really began 12 years after I was treated for early stage breast cancer. I thought that I had beat the disease after my early stage. And then when I was diagnosed with metastatic disease, I felt the shock that you just mentioned and, after two biopsies, I found out that my metastatic disease was different than my early stage. And fortunately for me, there was a targeted treatment that attacked my cancer. And I went from having cancer that was throughout my skeleton and into my liver, having scans after a year that showed no evidence of disease. So with that, I was very grateful and I decided to use my voice and my experience with the importance of biopsy and knowing your subtype to educating others. And as I talked to other patients I learned that we all have fears that our metastatic breast cancer will progress and we hope at that time when it progresses that there will be another treatment for us. The key, though, to having that other treatment are clinical trials, which are the force that creates new treatments for patients, as well as new options for doctors to review and help with patients to select the next course. So I decided to use my educator background to find out as much as I could, about clinical trials and then to go out into the community and try to dispel a lot of myths about clinical trials and to use my voice to explain their importance and why people should consider them.

**DR. COMEN:** I am just so grateful that you're here to share all of this with us. It's truly quite moving. And I'm again, I'm just so honored to have you share that with us. I think what's so important, particularly as a patient with your experience and your ability as an educator, what would be so wonderful is if you could share with us, really for those who might not be familiar, what is a clinical trial? One of the things I find with patients is, understandably,

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there's a tremendous fear of, "oh my goodness, am I going to be a guinea pig or am I just going to get a placebo? What does this all mean?" And often patients will think that a clinical trial is only when there are no more options left. And those are some of those myths that I'm sure you've encountered, maybe personally and also in your broader outreach. And if you could elaborate on that, it would be really helpful.

**SHIRLEY MERTZ:** Sure. Simply put, clinical trials are studies that seek to determine if a drug might be more efficacious or effective to prevent or treat a disease. It ultimately seeks to find out that perhaps it is better than the current, what we call, standard treatment. So during that trial, patients who join the trial are very carefully monitored for their safety and their metastasis is observed through scans and with blood tests. And so, all of this data is collected on each patient and ultimately analyzed at the end of the study. And if at the end of the study or clinical trial, there appears to be more benefit than say, the current treatment and it outweighs the risk to patients, then the data is submitted to the FDA. And if, after the trial is held and the data is reviewed and it turns out that the treatment is better than a standard, then it becomes another part of the treatment possibility for patients.

**DR. COMEN:** Excellent. Thank you. And we know that there are different types of what we call end points of clinical trials, which can also be a confusing term where we try to understand whether one drug versus the other improved things like progression free survival. How well somebody does before their disease comes back versus overall survival, which may refer to how long somebody lives as compared to getting a different therapy. And these are important terms that patients try to understand in dialog with their doctor when thinking about joining a clinical trial. In terms of the myth about patients concerns that they might not know what drug they're getting or they're gonna be just a guinea pig and that it may not be available to them 'til there are no other options, those are some of the myths that I've encountered in my in my practice. Is that something that you've encountered as well?

**SHIRLEY MERTZ:** Yes. I think patients have those concerns and that, in many ways, just shows the lack of education on all stakeholders part. I think there is an obligation for advocacy groups such as my own and others to share that information that you're not going to be a guinea pig. And with more education, whether it be on the part of advocacy groups or the doctor or nurses, I think we can dispel the myths. And one of the things that my organization and others that are part of the Metastatic Breast Cancer Alliance undertook was to develop a checklist for patients to use when they're considering whether to be part of a trial. And I'd just like to quickly share a couple of things. This checklist doesn't decide for a patient whether they should join a trial, but it says, do you understand the following issues? And our belief is, and this has been reviewed medically, if you understand these issues, then you are in a better position to decide if the trial is right for you or not. And I'll just go through a few of them, like, do you understand what question the trial is trying to answer? Do you understand what drugs or procedures you will be a part of if you are in the trial? Do you understand where the trial will be held? How much time you would have to commit to the trial? Who will be on your care team and what are the benefits that you could reasonably achieve by being in the trial or the risk? And then a few other issues, I don't

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think we have time to go through all of them, but what are the costs that you might incur? Oftentimes costs of a trial are borne by insurance, but not all of them, so you need to ask your doctor. And so, and then the final thing is all patients need to understand, and they do this through the consent form, which is often very long, but they need to understand that they do decide to join a trial, at any time they can decide that, no, they want to withdraw from the trial, so there's flexibility. And, I guess my other comment would be that when I looked at the data that is collected during trials, it is so thorough and people are monitored so carefully.

**DR. COMEN:** Definitely, there's often multiple doctors, or there are multiple doctors, reviewing the data as opposed to a smaller group. There can be research nurses involved and a bigger team providing that oversight. There can be logistical concerns for some patients, namely that clinical trials may only be at certain academic centers or other locations, which may be harder for patients to get to and they may incur costs from trying to get to those places of clinical trials. And the burden, at times, of having to have more appointments than they might otherwise need if they were on standard of care.

**SHIRLEY MERTZ:** There are certainly, as you mentioned, other issues that may be of concern to participants, like if you have small children, you'll have to you know, have childcare issues but, you know, these are the things that a patient should weigh and understand, ask about and if a trial is right for you, you know, you really should give it consideration. Again, I go back. I mean, my key point with everyone that I meet when I talk to patients about trials is if you progress, you are going to hope that your doctor is going to say, OK, you've progressed, but there is another treatment, I think, that is worthy of your consideration. And that only can happen if a clinical trial results in more advanced and more efficient treatments so we really need to think about the benefits that accrue to us in the future.

**DR. COMEN:** Excellent. I think you may raise such incredible points and very thoughtful points. Do you want to just state one more time where patients can find, and caregivers, can find this checklist?

**SHIRLEY MERTZ:** Well, I'll give two immediate sites on the Metastatic Breast Cancer Network, MBCN dot org and then also, the alliance. The Metastatic Breast Cancer Alliance, which is made up of 32 breast cancer organizations. If you go to MBC Alliance dot org, it's also there and also on many member sites. But you know, we don't have time to give every one of them, so just go to the Alliance site.

**DR. COMEN:** I think you raise one other very important point that speaks to a lot of myths and fears that patients have about clinical trials. And one is the loss of autonomy, where the idea is that you're going to join a clinical trial and it's a runaway train. And there's no way to get off of it, if you don't want to be on it anymore. And I think it's very important that patients and caregivers know that if a patient signs up for a clinical trial and for whatever reason wants to get off the clinical trial, they can do that, and it's not that it's etched in stone. And I think that there's a finality to it where patients feel like, "oh my gosh, if I make

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this decision, if I sign this consent, it's over," when really that's not the case as you mentioned. And I wanted to just also cover what do you think are some of the benefits and risks from a patient perspective that patients should think about when joining a clinical trial? One of the things as a physician we do is we go over the potential benefits, obviously, to help a patient and then we have to go through a laundry list of risks about with this drug, with that drug and what it might be. But perhaps from a patient perspective, that may feel different. Is there anything that you'd like to speak to that point?

**SHIRLEY MERTZ:** Yes. And that's an excellent question. I think one of the things a patient needs to share with their doctor really early on in their journey with metastatic disease is what is important to them, what activities are important? What are their responsibilities? Do they have small children? Do they...Are they a caregiver for a parent? And that's really part of what we would call their quality of life. And you want to as much as possible with metastatic breast cancer, maintain your quality of life. So I mention that because as you state a clinical trial is presented and possible toxicities are shared. And so you need to consider, or if fatigue will be an issue that might impact, again, your ability to work or if you have small children, taking care of them. So I think it really needs a frank exchange. And the other factor is that, even with some toxicities, though, they can be managed, it doesn't mean that you have to look for a trial where there will be no toxicity because every treatment has something. It's, I think it's, and I'd love to hear your response, to me, it's like a balance of what can I reasonably handle that still might allow me to have this benefit of a new drug. So, you know, there's no guarantees, but it certainly is worth considering and discussing with your doctor in detail.

**DR. COMEN:** I'm so glad you made all of those points. I will tell you that one of the most sacred, and at times enjoyable, part of my job is tapping into what gives my patients life. Sometimes there's so much focus on the biology of the disease and on months and years and subtypes, that we lose the big picture in all of that. And, one of the most important questions I think I ask my patients is what do you like to do for fun? What's important to you? What does a good day look like? And understanding that from my patients really helps elevate our experience together and hopefully helps me provide better care. And if your doctor isn't asking you that, I think it's important that patients try to advocate for themselves and say, you know, if playing the piano is the most important thing in the world, to me, a study that's going to cause a lot of neuropathy is really frightening to me, and maybe I'm willing to consider it, but we need to really keep a close eye on this and maybe we could loop in a neurologist or someone to help out.

**SHIRLEY MERTZ:** I so want to compliment you for having that approach to your patients, because quite frankly, not all patients are asked about what brings you joy or "tell me a little bit about yourself, what you do and, you know, what activities you participate in." And I often say to patients, well, we all should respect our doctors if they are not caring about us as people first, you know, the human being first and then our disease, then it's time to maybe get a second opinion or quite frankly, find another doctor, because this is a, you know, a journey that is very complicated. I think a key for metastatic breast cancer patients is to know that we need to find joy every day that we live. Everyone is going to pass away.

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But we, as patients, realize that our life has been impacted by a terminal disease, and so, we need to live life fully. And sometimes we need to get crazy and do something that we would normally say, this is ridiculous. And for me, my son told me - we both play the cello - and my son said, "Mom, Yo-Yo Ma is performing in Vienna, a beautiful concert, box suites. We should go." And I said, "Well, jeez, that's like 10 days away. Oh, let's make it happen." And we did. We went, and we arrived on a Tuesday, went to the conference that evening and flew back the next day. Now, how crazy is that to go to Europe and come back in three days? But it's a memory. We held hands and he's 35. I mean, we held hands during the concert, and we had great seats, because he knew someone who could get us tickets. And I'm just bubbling because it's an example of what metastatic breast cancer patients need to give themselves permission to live fully and to do things, that they will make memories for themselves and most of all, for those who love them.

**DR. COMEN:** Shirley I am so moved by everything that you said. And I have to tell you that people often talk about what I give to my patients when the reality is I feel like I gain so much from taking care of them. And you said, you spoke about being crazy. And I will say that one of the immense joys I get from my patients is the daily reminder when they tell me, go live your crazy self. Go live your wild self. Because the reality is, as you said, it throws into high relief all of our fears, each and every one of us about mortality. No one knows what tomorrow brings. And many of my patients give me license to be myself and to do those things. And I think your trip to Vienna was certainly not crazy, but absolutely fantastic, and I'm so glad that you made that journey.

**SHIRLEY MERTZ:** I appreciate your comment. Thank you.

**DR. COMEN:** Actually, even just thinking about it makes me emotional. We always have to remember the humanity in all of this, why we're here, who we're here for, and, on that note, I think it is so important that patients, even when they're participating in a clinical trial where they may be a number, right, they are a number one out of 1000 or one out of 100. But yet they are still a whole and complete person with lots of interests and lots of needs, and to the point about numbers.

**SHIRLEY MERTZ:** Yes.

**DR. COMEN:** And risks and benefits. One of the things that I think is challenging as a physician and you are saying, what was my opinion about this, when you present a clinical trial to a patient and it's an informed consent, the lists of risks can be very long and detailed. And so it is a difficult balance because we don't want to frighten patients. We want people to feel fully and completely informed. And on the other hand, we know that if something is really rare to happen, but a patient hears about it, it can be absolutely terrifying and a barrier. So it is a delicate balance between how you communicate these risks and, and let patients understand that some of them are actually very rare, that could quite happen and differentiate those from the more common ones.

**SHIRLEY MERTZ:** Yes.

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**DR. COMEN:** And I think that that's so critical to the discussion as well. So there's a lot to cover in a doctor's appointments. We can put a little plug for giving the doctors more time to talk to them.

**SHIRLEY MERTZ:** Oh, absolutely right. Yes.

**DR. COMEN:** Right?

**SHIRLEY MERTZ:** And one other thing that's important to me about clinical trials, if I could share with you, is that, when we talk, when we have conferences where the attendance is all metastatic breast cancer patients, we learned that not all doctors bring up clinical trials. And so my mantra all my life, I guess, because I was an educator is, knowledge is power. And so even if you're doing well on your current treatment, I believe that you should be looking at considering what clinical trials might benefit me. And, when I do my advocacy work, I say to patients, if your doctor has not brought up clinical trials, begin by asking, you know, Doctor, I've heard about clinical trials. You know, do you have some clinical trials that you might suggest to me if, if and when I progress? And if the doctor says, well, I don't do clinical trials here, then I think you have the responsibility as a patient for yourself to find clinical trials that might be appropriate and maybe ask another doctor, when you have a progression, would a clinical trial benefit me? So one of the things that happen is one of our organizations within the Metastatic Breast Cancer Alliance has created with our alliance support, the metastatic trials search engine. And it is a search engine where you can input as a patient your subtype. You must know your subtype -

**DR. COMEN:** Let's pause there.

**SHIRLEY MERTZ:** Yeah.

**DR. COMEN:** From a patient perspective, how do you define subtype?

**SHIRLEY MERTZ:** I think society -

**DR. COMEN:** I can help you out if you want.

**SHIRLEY MERTZ:** No that's alright. I think society tends to think that breast cancer is one disease, because we say we're searching for a cure. But what we really are, we're searching for cures, because there are different types of cancer cells, different types of tumors, and within them, the cells are fed by different proteins. Now, I'm not the scientist...

**DR. COMEN:** You're doing great, keep going.

**SHIRLEY MERTZ:** OK. Tell me... stop me if I'm wrong. So if you're cancer, if my metastatic disease is fed by hormones, estrogen and progesterone, which keep us women looking beautiful, then, and you have too much of that, then you are considered to have hormone

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positive breast cancer. But if I have too much of a protein called HER-2/neu, then I, after a particular test, I might be told that you have hormone positive...

**DR. COMEN:** HER-2 positive.

**SHIRLEY MERTZ:** HER-2 positive breast cancer. And then because science has not yet figured out what to call people who aren't, don't have too much hormone or too much of HER-2 protein, the third subgroup is called triple negative breast cancer.

**DR. COMEN:** Exactly. So basically, the absence of the estrogen receptor, the progesterone receptor or the HER-2 receptor.

**SHIRLEY MERTZ:** Yes.

**DR. COMEN:** And we probably know there are many other subtypes that we're still learning about.

**SHIRLEY MERTZ:** Yes. And we're waiting for more definition of triple negative. So that search engine, you will need to know your subtype. They'll ask you, where's your metastasis? Liver, lung, bone, et cetera. Put in your zip code and then if you have some other information about your metastatic disease and then you click send, and what you get back through your e-mail are trials within your area. You can say a hundred miles, with 50 miles, whatever, that you might qualify for. And they are written in language that the patient can understand. So, you could look at it, you can say, well, I wouldn't want to do that. Oh, gee, maybe I would want to do that. And you can take these in, print them off and take them into your doctor for consideration. And I just think that is one way that a patient can be an advocate for themselves. And the point is, then take it to your medical, health care provider and have a discussion.

**DR. COMEN:** Shirley, thank you so much for being your best advocate. But even more importantly, for so many women and so many families out there fighting this disease, you're absolutely extraordinary.

**SHIRLEY MERTZ:** Well, thank you.

**DR. COMEN:** And I really appreciate everything you've shared with us.

**SHIRLEY MERTZ:** Thank you.

**DR. COMEN:** And thanks to Pfizer for sponsoring this conversation. As Shirley stated, while patients may feel vulnerable upon diagnosis, they do have a voice. They can make an active decision to participate in research that can change the course of their own health, as well as the future of those living with metastatic breast cancer.

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Visit Find Your MBC voice dot com for an interactive guide to help you learn how to speak up and have more of an informed conversation with your doctor. Thanks again, Shirley.

**SHIRLEY MERTZ:** Thank you so much.

**END**