Clinical Trials In A New Age: Part 1
What You Need to Know

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Presented by:

SHARSHERET
Your Jewish Community Facing Breast Cancer

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Jackie: Good evening, everyone, and welcome to today's program. At this time all participants are in a listen-only mode. Later you will have the opportunity to ask questions during the question-and-answer session. You may register to ask a question at any time by pressing star, one on your touch-tone phone. You may withdraw yourself from the queue by pressing the pound key. Please note this call may be recorded; and we'll be standing by should you need any assistance.

It is now my pleasure to turn the conference over to Ms. Shera Dubitsky. Please go ahead.

I. Introduction

Shera Dubitsky: Thank you, Jackie. Good evening to everyone. As she said, my name is Shera Dubitsky and I want to welcome you to Sharsheret's National Teleconference, Clinical Trials in a New Age: What You Need to Know. We'd like to thank AstraZeneca and Provectus for their ongoing support, and for sponsoring tonight's program.

Sharsheret is a national not-for-profit organization supporting young Jewish women and their families facing breast cancer. Our mission is to offer a community of support to women of all Jewish backgrounds diagnosed with breast cancer, or at an increased genetic risk, by fostering culturally relevant individualized connections with networks of peers, health professionals, and related resources. As most of you know, in the general population one in 345 individuals carry the BRCA positive mutation.

For those of Ashkenazi Jewish descent, meaning those whose ancestry is traced back to Eastern Europe, that number is 1 in 40. This is astounding. Those of Ashkenazi Jewish descent are 10 times more likely to carry the BRCA mutation than those in the general population. Given these numbers, Jewish women and their families qualify for and benefit from clinical trials where the focus is on the BRCA mutation.

A study published in the Journal of Medical Ethics in 2013 looked at the attitudes of Jews towards clinical trials and whether they are influenced by Jewish teachings. The research showed that participants' attitudes were influenced in a variety of ways by Jewish teachings, such as the overriding importance of preserving life, the need to avoid risks affecting life and health while taking risks to preserve life, and the Jewish value to help others.

In Judaism, *Pikuach Nefesh* describes the principles in Jewish law that emphasize the value of preserving life. This refers to our own lives, as well as the lives of others. There have been women before you who participated in clinical trials and the medical field has come a long way in offering more options in the prevention, testing, and treatment of cancer. Many of you have benefited from the generosity of these women, and now you can impact the next generation of women and their families. *L'dor Va'dor*, from generation to generation, we are improving health and health options for Jewish families and the Jewish community.

We have two speakers this evening. Our first speaker will discuss the history, myths, and truths about clinical trials, and our second speaker will share her personal decision-making process about participating in clinical trials. Following our second presenter we will have time for question and answers.

Without further ado I will introduce our first speaker. Margo Michaels is the Principal of Health Access and Action. Ms. Michaels is the Founder and Former Executive Director of the Education Network to Advance Cancer Clinical Trials. She is considered a national expert in improving clinical trials accrual through community engagement. Bringing 16 years of progressive leadership in patient advocacy organizations, the National Cancer Institute, and consulting to oncology care providers, Ms. Michaels has a strong commitment to social change through effective community engagement around health care issues.

Ms. Michaels serves on advisory panels and is a member of community campus partnerships for health. She has co-authored nine peer review publications, and holds a Master's in Public Health from University of North Carolina Chapel Hill School of Public Health. Ms. Michaels, the floor is yours.

II. History, Myths, and Truths about Clinical Trials

Margo Michaels: Great. Thank you so much. I'm really happy to be here tonight. I'm going to be talking about a number of issues around clinical trials.

What we are going to talk about today are a few important things that are really critical for us to consider when we think about clinical trials. One is why they are important, the second is how clinical trials have helped us, as we heard a little bit about earlier, but we may not realize how we are helped everyday by what has been learned in clinical trials in the past. We are going to talk about myths because many of us believe those, or think we know what

the facts are, when we might not. We will talk about why clinical trials are different than the treatment that your doctor may offer you, which is called standard treatment, and patient protection.

If we think about what we want, and I'm talking about "we" as sort of national advocates, what we want, if we think about advocacy around clinical trials is three things. One is whether we find out that we are at high risk, whether we find out we've been diagnosed, or whether we found out that we've recurred, we want to make sure that every eligible patient is actually offered the opportunity to participate. That every patient can actually make a decision that is informed, including the ability to say, "Hey, no thanks." Every patient feels confident to say, "Hey, doc, is there a trial for me, and if not, why not?"

I wanted to put this out there, because that's the perspective with which I'm going to be presenting this information about clinical trials. They are not right for everyone, but we don't want anyone to make any assumptions about our interest or disinterest in participating.

Here are some common myths that we often hear: they only are offered at the big cancer centers; it's the treatment of last resort; what they are testing is better than what I could get from my doctor right now; you are just a guinea pig. One of my personal favorites is, "If it were right for me; my doctor would have told me about it." Hopefully by the end of today's presentation you'll have a little bit more information about why none of these are true.

Cancer clinical trials, simply, are research studies with people to find better ways to screen, prevent or detect, or treat diseases like cancer, and of course they help find ways to improve cancer care.

When we think about who participates, it's really all over the place when we think about cancer clinical trials. On one side you see people who have cancer, such as treatment trials, with some people being treated for their disease within a clinical trial. Genetics trials, looking at things like BRCA1, BRCA2, and how that impacts treatments. Quality of life for supportive care studies; these are studies that are looking at diet, or yoga, or exercise to help with things like fatigue, nauseousness, or other kinds of symptoms.

There's also trials for people at higher risk for getting cancer, which are actually around prevention and genetics as well, so some of your daughters or your sisters who share some of the genetic mutations that you have may be interested in participating in a

prevention clinical trial, or a genetics clinical trial. Then, of course, there are also cities where people are being screened for cancer. For example, I just had a series of mammograms and biopsies for something they found on my breast, I could have decided to participate in a clinical around some of that screening. That could have been an option for me.

People don't often think about high quality care and clinical trials in the same sentence, but I want to offer you two quotes from some national experts, boards, and panels that really put this in perspective. One group, the National Comprehensive Cancer Network- they produce national guidelines for how to treat all kinds of oncology patients- has stated, "The best management of any cancer patient is within a clinical trial," and the Institute of Medicine has said, "Therapies offered through a clinical trial should ideally be considered the preferred treatment choice for patients and physicians if they are available." Some of you may be surprised to hear those quotes, but I hope that by the end of the presentation, these quotes may not be surprising.

Let's talk about standard care. Some people say the word "standard" and they say, "Oh, that just means average or okay care," but standard care is treatment that experts agree is appropriate, accepted, and widely used. It's also called standard therapy or best practice. If we go to our doctor, we assume that our doctor is going to be giving us options for care that are standard, that are widely accepted, and that have been shown in research to be effective for our type of disease.

The picture I have there on the corner is a picture of my grandmother who, in 1975, did not get mammograms regularly because that wasn’t done, and when she was diagnosed with stage three breast cancer, had something called a radical mastectomy, which in today's day and age, would not be done.

At that point in time she received the standard care, but it is care today that we would consider barbaric or inappropriate. Hopefully, as we move forward in time, perhaps 20, 30 years from now, the treatments or approaches we have for treating cancer, or for prevention of cancer, will also be considered strange or unusual because we will have even better ways to treat or prevent the disease.

If we look at cancer survivor rates again, looking at 1975 to 1977, for breast cancer specifically, when my grandmother was diagnosed, you can see that we weren’t doing so well around five-

year survival rates. Okay, but still not great. You can see how much that's improved over the years. We still have many more improvements to go, certainly in areas like pancreatic cancer or lung cancer, but you can see that many women have survived breast cancer because of the better treatments that are available and that have been achieved through clinical trials.

In fact, even the identification of BRCA1 and BRCA2 was not around more than 25, 30 years ago. They were not even identified as a risk factor for Ashkenazi women who may be at high risk for breast cancer. That was done through research and through repeated research. Things like Tamoxifen which many women are taking now as a preventative for avoiding breast cancer. Those studies were shown through clinical trials to be effective to prevent breast cancer in women who were at high risk for developing the disease.

One important myth about cancer research is that you get a sugar pill or placebo, that you really don't get treated for your cancer. One thing that's important to know is that in treatment trials, patients are always treated for their cancer. No one receives a placebo or sugar pill, instead of appropriate treatments. Now placebos may be used in prevention trials, and that is ethical, because someone does not have cancer, so we are not actually withholding treatment for someone.

It's important to know that if placebos are used, a patient will always know that is a possibility, it's not going to be a surprise for that patient. I will show you in a little while how that works.

In most clinical trials you can't choose your treatments. In the most common type of study, patients have an equal chance to be assigned to groups. One group gets the most widely accepted treatments, that's the standard treatment, and one group gets the new treatment being tested which doctors hope will be better than what is the most widely accepted treatment right now.

Let me show you how this works in real life. Sometimes the cancer treatment being studied is much different than what is currently used. Here we have two types of treatment, and I'm using the word treatment, but please know that you can very well here talk about prevention agents, drugs that are prevention. The green illustration look is standard, that's the medicine that we know works, it may not work for everyone, but it's the best we have right now. The blue is the treatment being studied, so in this case we could say, later-

phase trial, we know that it's safe, we know it's effective, we just don't know how it compares to what is currently being used.

We see a bunch of people here, let's imagine they are all very beautiful Jewish women and these are all Jewish women who were diagnosed with breast cancer. Let's say half of these women are going to be assigned to the standard group and half of them are going to be assigned to the new treatment. In this case, if these women decided they wanted to be in a clinical trial, they can't choose which treatment they are going to get, and they have to be okay with the idea they are going to get either the standard or the treatment being studied.

Let's look at another way a trial can be designed, this time with a placebo. Even though I already told you that placebos are never used instead of appropriate treatment, this shows you how they can be used in ethical and appropriate manners.

Let's look again at the options here. Here we have standard plus placebo, and the next we have standard plus zing. Zing is something I made up, but zing is the new treatment that they are studying, and in this case everyone is getting standard treatment. Some people are getting standard treatment plus zing, which is what we think maybe better than standard treatment by itself, and some people are getting standard treatment plus a placebo.

Now you may say to me, "How is it ethical that we are giving some of those people a placebo?" It is ethical because no one is being denied appropriate treatment. If you look at the picture here, you can see that half of the women have been assigned to this one group and half of them have been assigned to another.

It may be they would know that they were on a placebo, or it may be that they would not know. It depends how the trial is designed, but they all would know it's a possibility that they are not getting both drugs, and just getting one. The reason it is ethical is because we don't know if zing is better, worse, or the same as standard treatment. We are talking about, when we say better or worse, it might not only be how fast the tumor grows, reducing the growth of the tumor, but it may be more tolerable.

For example: less nauseousness, fewer rashes, fewer episodes of neutropenia, or other kinds of things that may result from treatments. They may be measuring many different things when they want to see what works better.

Another favorite myth of mine is, "If it were right for me, my doctor would tell me about it." In fact, my uncle who was a veterinarian and diagnosed with lung cancer told me this about a year before he died. I think this is probably one of the biggest myths that I want to make sure that you all know is, in fact, a myth.

We know that only about 3% of cancer patients receive treatment through a clinical trial, and even when we think about prevention trials, the number of people participating is also relatively low. 20% of us are eligible, so not all of us who have cancer would be eligible for participation, but 20% of us would be. That means 17% of us are eligible but are not being offered that opportunity; and so we need to think about why that is, and there are many, many, many research studies talking about why this is. It's important to know that just because a trial is out there doesn't mean your doctor knows about it, and doesn't mean the doctor participates in clinical trials, so he or she may not even be able to offer it if he or she wanted to.

Only about 15% are ever told about the option, and that number varies according to the study. Sometimes people say as low 6% or as high as 20%, but not that many of us are ever told about the option of participating. Some groups, like older people, African-Americans, Latinos, or Asians, may be even less likely to be offered participation in trials. That's why our proactive questioning and exploration is very important, and to not make assumptions that the doctor always knows what's out there and what's best.

Another myth is that you get treated like a guinea pig. There are many protections that we have in place today, because of abuses that have happened in the past, and one of the biggest reasons that we are not guinea pigs is because we have the ability to give consent. In fact, it is required to give consent to participate in a clinical trial. This is due to atrocities in the past that we are all familiar with, including what happened in Nazi Germany, at Tuskegee with African-American men, and even the 1960s at institutions that were treating mentally handicapped children and older people.

Patients are protected in four different ways. One through this thing called Informed Consent, which means that the person understands everything that's going to happen in the study, the reason for the study, and has a good understanding of the risks and benefits.

There are also scientific reviews so that no study can go forth unless it has scientific merits. Local institutions must review the

research that’s being done to make sure that it's ethically appropriate and meets the values and norms of the community. There are also data safety monitoring boards that look at data nationally, so that, for example, if we find there is a benefit early on in the study, and it's so striking that it would be unethical to continue the study, they would cancel the study and let everyone take the new drug that shows such extensive promise.

As I said, informed consent is an important procedure that really ensures that a person understands exactly what they are getting into. Many of us don’t even get that with our regular medical treatments, so there are even added benefits. There are things that the physicians, the nurses who are involved with the clinical trial need to tell us about, including the ability to drop off of the study at any time for any reason without prejudice for future care.

I'm often asked this question, and I think it's important to point out the differences. "What is the difference between the treatment that my doctor provides for me, versus the treatment that I might receive through a clinical trial?" The way we can explain this is the following. Treatment is medical care that your doctor gives you to improve your personal health and to enhance your well-being as an individual patient.

He or she may be making adjustments because you may prefer a certain drug or another, or she may prefer a certain drug or another. Or because you’re having a hard time getting back and forth to the clinic, so she may decide that the times of the treatments are different. It's care that’s really personalized to you, based on your doctor's sole decision and judgment, and expertise as to what she or he believes is the best option and courses for your care.

When we think about the clinical trial it really is different. The primary purpose of the clinical research is to develop new knowledge. Remember, we talked about the purpose of a clinical trial being to improve care, but it's not necessarily to benefit you as an individual. That means that there's a national protocol or a local protocol that has to be followed; you have to have this medication the third day, this test on the fifth day, this exam on the twentieth day, and there's not a lot of wiggle room that you or the doctor has to veer away from that protocol.

Some people find that protocol very reassuring because they know there's no deviation from what national experts have recommended and have actually outlined in this recipe for caring for a patient.

Some people also like the fact that they know about everything that is going to happen, including all the questions that are going to be asked. Every sneeze, every cough, every fever; it's going to be recorded and asked about, and some people find that extra attention very reassuring.

What are the reasons why those national experts believe that care within a clinical trial is actually better than care that's in a treatment? Because of that extra attention that is done by someone being in a clinical trial, that's required really; that's the difference between treatment that one would receive as an individual, versus treatment one would receive being in a clinical trial.

It's important to note that if you are not doing well on a study, that it would be unethical for a doctor to keep you on that study. I know of many people who were on a clinical trial who weren't doing well for one reason or another, the tumors weren't responding. They were getting ill, they felt it was too much of a burden. Then they are removed from the study and placed on another treatment that is not on a clinical trial.

It would be unethical, again, to say, "Oh, you are not doing well but we'll still keep you on the trial to see how long you are not doing well." That would be unethical, and it's not a part of how we do research in this country. As I said, you can drop out of a trial anytime and for any reason without prejudice to your care.

As I said earlier, your doctor may not offer trials, may not know about trials, or he or she may feel a trial is not appropriate for you. This may or may not be true, and that's why in the next webinar that Sharsheret is going to be doing, they will be talking about how to find out about clinical trials. One of the things we are going to be talking about is resources to learn about clinical trials, and resources to actually put your name into databases to make sure that you learn of new clinical trials when they come up.

These things are important. In fact, I was once told by someone, "Well, you should say that. You shouldn't say that your doctor may not offer clinical trials." Well, but it's true, it's not sort of saying that your doctor isn't a good doctor, there are many good reasons why that doc may not be aware of clinical trials or may not offer them. It doesn't mean that it shouldn't be an option for you to pursue.

One other myth that's important to think about is that what is being tested in the clinical trial is better than standard treatment, or what I can get from my doctor right now. That's also not necessarily true.

We know that new agents being tested in clinical trials are asking different kinds of research questions. As I said, most clinical trials that people participate in, there are three clinical trials, but which at that point we know the new drug is safe and effective. We just don't know how well it compares to standard treatments. Again, it may be better, it may be worse, or it may be the same, and so that's why we are doing a clinical trial. It would not be ethical, if we knew the answer already to do a clinic trial. If we knew that one was better than the other, then we wouldn't have to do the clinical trial in the first place.

There are benefits to participating which I think I've talked about already. In most trials patients get at least the best treatment available. In other trials, phase one and two, all people get the experimental drug and no one is given the standard treatments. In these trials everyone is treated the same, there's no comparison.

As I said earlier, patients are closely followed by doctors and nurses. Some people find that reassuring, some people find that annoying, and that would be a personal preference from you all. If Nuetrim has proven to work, patients maybe among the first to benefit. That's also a reason why patients do participate in clinical trials because as soon as they can get access to a new treatment that isn't commercially available.

There are also risks. Even if a new treatment has benefits, it may not work for everyone. That's true, by the way, for standard care. Even the care that we get from our doctor today. If we had very, very effective treatments, no one would die or have side effects from their treatment. Of course that's not true. So until we have a cure, until we have the best ways to treat cancer where no one dies or suffers from side-effects of treatment, we still have to do research that can make lives better and longer and healthier.

We also know that new treatments are not always better than what's currently used to treat the cancer. There can be unexpected side effects, but again, by the time something gets to a phase three study we know about many of the side effects. We don't know about all of them, but people find that reassuring that they will know about most of the potential side effects that could happen and that they are being monitored carefully.

Another myth that's important to know about is this one. "They only take place at big cancer centers." This is untrue. Although they are taking place at places like Memorial Sloan Kettering and other big cancer centers around the country, they are also taking place at

small community oncology practices around the country as well, or even smaller cancer centers that may not be the prestigious ones. So don't be alarmed to think that just because you are not being treated at one of those large places means that it's the only place that you have access to studies. In fact, many times those large institutions have satellite relationships with smaller institutions, and would, say, offer the exact same study that's happening at those larger, more prestigious institutions. I want to leave you with a couple of talking points, because even though you are on the phone today, you are certainly going to be speaking to and seeing other women who are at high risk of developing cancer, or are dealing with cancer right now. One: I'd like to ask you to be an advocate for clinical trials, and correct the myths when you hear them. When you hear someone say, "Well, no one wants to be in a clinical trial because they don't want to get a sugar pill," correct that myth. Your knowledge now can be very influential for other people.

Know that clinical trials can be a treatment option for many people. That's true for not only treatment, but for prevention or even for genetic studies as well, regardless of the state that someone is in, and whether they have the disease now, or whether they are concerned about the disease because they are at high risk. That's something important to know and to advocate for.

The last talking point is this one. It's that we want to make sure everyone knows about all of their options for care, and treatment is just one kind of care, obviously. Including care through a clinical trial, and that assumption should not be made about someone's interest or disinterest based on their age, or the color of their skin, or the fact that they had to travel to get to that location, or because they appear to be disinterested in learning about medicine or science. I think that's often the assumptions that people make about someone's interest or disinterest, and that's something that we should be making the decision for, "No. Thank you. I don't want to learn about that," rather someone else making that decision for us.

I'll leave you with that same little quote I started with, about what we want, and I hope that you all were convinced a little bit from my comments about what we should want. At every point during treatment or when someone has been told that they have a BRCA genetic mutation, we want to make sure three things happen. One, that everybody who is eligible is offered the opportunity, that everyone who is interested can make an informed decision about participating, and not a knee-jerk decision, "No way," but actually

say, "Hey, you know what? I thought about it and I don't think I'm interested, or I do think I'm interested."

Then everybody feels confident to say, "Hey, doc, is there a trial for me? If not, why not, and where could I find more information about that?" We will continue this series of conference calls in the early part of next year, and we'll be answering those questions about how to find information about clinical trials. I believe that is my last slide, and I think I'm right at time, so I will turn it back over to you all.

Shera Dubitsky: Great. Thank you, Ms. Michaels. As you were speaking I was imagining the women on our call tonight all across the country universally nodding as you were going through each one of the myths. I very much appreciate your answering and responding to those myths in a way that was very clear and easy to understand, and when you talk about the talking points, about telling other people, I think sometimes you may need to go back to the talking points for yourselves; if those voices of doubt start whispering in your ears again.

Our next presenter is Rachel, and she is a Sharsheret Caller. Rachel participates in Sharsheret's Embrace program for women living with advanced cancer, and will share her thoughts and attitudes towards clinical trials. Go ahead, the floor is yours.

III. Participating in a BRCA Clinical Trial

Rachel: Okay. Good evening everyone. I'm participating in this evening's webinar, because I would like to share my inspirational story with you, and illustrate how clinical trials have played a part in my treatment. My name is Rachel, and I will be 48 years old next month. My friends all bemoan their birthday every year, and they just discuss how old they look and which lines they need to fill in their face. I, on the other hand, I celebrate each birthday with awe and cheer in complete gratitude. I've been given another year, and that's the best gift of all. I've been blessed with life, and the ability to live and experience this beauty of watching my children grow into young adults and share more quality time with my husband.

I've been involved with Sharsheret for six years. I had the great privilege to meet Rochelle Shoretz in the waiting room of Memorial Sloan Kettering in 2009, and we instantly connected. She had powerful advice then that changed by life forever. I hung to every word she uttered, and when I was diagnosed again in 2011, I again

clung to every bit of advice which has given me clarity, strength, knowledge, and hope.

This evening I realize that some of you listening to this webinar may not have been diagnosed, or could have early-stage cancer, you might be a survivor living with advanced breast cancer. What I want to share with you is that no matter where you are in your journey, there are clinical trials out there that can offer you options and hope.

As Rochelle said to me in one of our many conversations, "You need a bag of tricks. The more tricks you have the better," so I began my metastatic journey looking for what Rochelle called a bag of tricks. After meeting with my local oncologist, I decided I would get another opinion. My oncologist helped me set up an appointment in Boston with a colleague, and I never looked back. I left New York without hope and in tears, only to return the same day with the name of a potentially new drug trial that had just received FDA approval, and was beginning within a matter of a couple weeks.

My seedling of hope has been everything to me, and that has helped me blossom and gain strength over the last three years. I travel to Boston on Amtrak several times a month. It hasn't been easy at times. Even this week, I've had different issues with different blood levels, and it's been costly, but it's my full-time job. Just like the business people who travel on the train each week with the laptops, dressed in business suits. This is the most important job of my life.

I'm willing and able to make the sacrifices needed because I can financially, and I have family there to support me when I'm treated. These are both very important aspects to consider once selecting a location for clinical trials, as well as standard treatments.

Standard chemotherapies are offered in most hospitals and clinics, the combinations may change slightly from hospital to hospital, but generally they are always available, and always a part of your bag of tricks. In my experience, clinical trials had been more specific to my BRCA gene mutation, and incorporate my triple negative status in unique proteins that I have been tested for.

Thanks to clinical trials, I have increased my bag of tricks from a few options to many more. As I mentioned before, I've been living with advanced breast cancer for three years, and I haven't had standard chemotherapy as of yet. My disease has responded to the

drugs and I've had success. Many of these trials, as Margo mentioned, can be phase three. The trials that I've been involved in have been phase one and phase two. Some hospitals share the same clinical studies, and others are only offered at a couple of sites. Most teaching and research hospitals have their own studies going on as well, others are offered by drug companies.

It's up to you to ask your oncologists questions about clinical trials, and probe and push your doctor to share information about these studies with you, by showing your genuine interest. My oncologists aren't even familiar with some of the studies themselves, because there are so few people participating in them, or they don't have enough data or results from the studies to share with patients. Needless to say, studies are available, and if you are willing and able to be a part of something, if you qualify, based on a biopsy or a blood test, then all the more reason to do so.

Why am I participating in clinical studies or trials? The short answer to the question is as follows: trials give me options and hope. They open my eyes to a world of research and science and medicine that I hadn't witnessed the first time around. I didn't ask questions then the first time, I just prescribed to what my oncologist suggested for me. Now we talk about trials and make decisions together, and think outside of the box.

We always sort of have the left column, which is standard care, and then we have the right column, which is the list of trials that are available with my different status, whether it is the BRCA gene, the triple negative, or a particular protein. Instead of thinking about trials as a last resort, as chemotherapy alternatives, I think of them as a first resort. I was going to mention that if you are a candidate where, perhaps, wherever you are in your diagnosis, but in my particular situation, I don't have anything particularly weighty, meaning substantial, but I do have more than one site; I am a good candidate for these types of trials.

If you are considered a good candidate by your doctor and you are willing to participate, why not consider cutting-edge science and medicine as a first choice? As I said before, I began my journey with a trial; at the time, it was the very best option for me. Several oncologists agreed the trial had a significant impact on my cancer, and I was very pleased with the results. I actually was on that particular trial for over two-and-a-half years.

As long as there are acceptable trials out there for me, I do believe I will continue on this path, because I have had a positive

experience. But I also participate, and most importantly, because I want to help other patients living with BRCA mutation, or with BRCA cancer-related disease. I want to help patients that are triple negative status, which is a rare type of breast cancer. I want to give them hope. I want to find a cure. I want to find little nooks and crannies that can help doctors decode and come closer to solutions to help us find the answers to some of these questions.

If I can help in a small way, or help myself, and help in a small way, I am committed to that. By contributing to science and research, by helping doctors in understanding my results and potentially improving the medicine or dosage for others, I can help others that have these diseases. I feel great satisfaction by partaking in clinical trials, I really do. I like to think that I'm making a difference by participating in trials.

I also want to mention that I do feel like, in this particular case too, because there are so few patients sometimes on some of these studies, that I get extra special care. That there are fewer numbers, and I have doctors looking over me and studying my results and findings, and I might be on a clinical floor where the nurses know me extremely well, because I'm one of the few that are on that particular floor being treated for my specific case.

Also, I'm not shy about sharing my study information and results with oncologists, not only at Dana-Farber, but at Memorial Sloan Kettering where I've been treated, the University of Pennsylvania, Basser Center, the University of Michigan, the good people at Sharsheret, and at the Breast Cancer Research Center, to name a few.

I want to share the positive and the negative aspects of my clinical trial experience, with as many doctors and women that will listen, so that there is a dialogue among doctors, it's so important. A sharing of information, a connectivity among the medical and support communities, so that BRCA patients will benefit from the information. If I can inspire just one person out there to consider a clinical trial and give them a thread of hope, another option to extend their life, or enhance their quality of life, then I feel I have done by job. I have given a gift.

Hope is what gets you out of bed each day, and gives you the strength and purpose to live each day. When you are battling cancer, whether you are surviving it, coping with the next steps, or living with a metastatic disease, from my vantage point, there is hope when you have a bag of tricks. Thanks.

Shera Dubitsky: Thank you, Rachel, for your insights, and for so generously sharing your decision-making process. I suspect that your thoughts about clinical trials will resonate with many of our callers.

We will now begin our question-and-answer period. Jackie, can you please instruct our participants on how to ask questions?

V. Question & Answer

Jackie: Absolutely! At this time, if you would like to ask a question, please press star, one on your touch-tone telephone. You may withdraw your question at any time by pressing the pound key. Once again, to ask a question, please press star and one on your touch-tone phone, and we will pause for a few moments to allow questions to enter the queue.

Shera Dubitsky: We actually received several questions before tonight's teleconference, so while some of you are posing your questions, I'll begin with the ones that came earlier. First of all, for Ms. Michaels, a question came in, "What is the relationship between your primary care doctor or oncologist and the physician that's heading the clinical trials? Do they speak with one another? Do they share records?"

Margo Michaels: It's a good question. First I want to say that you do not need a referral from your oncologist or primary care physician to get in a clinical trial. Often they will want to have those records, so they don't have to repeat tests that have already been done, and the protocol varies in terms of how frequently there is contact between the clinical trial, your regular treatment oncologist, and your primary care provider.

Usually there are regular updates, at least saying that your patient is now on this clinical trial 1, 2, or 3, and here is more information about the study. Sometimes the contact is more frequent because of information needs that the clinical trial has. Or, vice versa, that the primary care provider or the home oncologist would have. What is important to know is that, even if you are on a clinical trial, you would likely still be followed by your home oncologist once the trial is done, and so that information about your trial is really important for both your primary care provider and the local oncologist to know about. That you are on that study, and what that study is about.

It does vary, how frequent that contact is, and if you were to go on a clinical trial you would want to ask how they will keep your

doctors informed about your progress on the study, and be satisfied with that answer.

Shera Dubitsky: I think that's a good suggestion.

Rachel: Both of my doctors. When I signed on to my clinical trials, the hospital took care of that information. You list the doctors that you want to receive the information, so both my oncologist and my primary both know.

Shera Dubitsky: Okay. Another question came in. "Are there clinical trials for people who have an extended family history of breast cancer or ovarian cancer and have all tested BRCA negative?

Margo Michaels: To be on a prevention study one has to be designated to be high risk in some way, and while we often thing about genetic mutations as, "the highest risk," that is not the only way one can make that designation. For example, the breast cancer prevention trial that I talked about earlier, looking at Tamoxifen and a later study called STAR that was looking at Raloxifene, did not look at BRCA1 or 2 sets. It rather looked at other things like family history, and age, and some other issues in order to construct what a woman's risk is.

The short answer is, yes, there are, and I would suggest that you go on Cancer.Gov to look at clinical trials at the national level, data looking at prevention and genetics and what their criteria is for determining high risk, because that varies. As you know, even though we talk often about people at high risk, about 80% of women who get breast cancer have no risk history at all, but there are many studies that are looking at high-risk women.

Shera Dubitsky: I think a continuation of that, and perhaps maybe the answer again is Cancer.Gov, is that another question that came in is, "What is available for prevention trials for those who are triple negative BRCA1, for those who had breast cancer, and for those who have not?"

Margo Michaels: Right. As the previous speaker said, the triple negative, unfortunately, is more rare and for many years they didn't really have much available. Once they discovered issues about triple negative breast cancer, they didn't really have very good answers about what treatments were going to work more effectively and what were not, simply because there hadn't been a lot of research on women with triple negative.

The short answer is you should look at ClinicalTrials.Gov to search for clinical trials around this issue, because the answer is, yes, there are. Then I would also say that they are not going to be as common. Triple negative is not going to be as common as other things, like BRCA positive for example, but they are still there and you should be checking them out.

Again, on the next call that we do we are going to be talking about resources, not only to find clinical trials but to sign up for potential clinical trials that are going to come down the line. I know a lot of people are interested in that as well.

Shera Dubitsky: Indeed. Rachel, you talked about the gift of being a clinical trial participant, but what were some of your biggest concerns before deciding to participate in a clinical trial?

Rachel: Obviously, the side effects. I think the amount of time that it will take to participate in it, meaning travel, how many times a month I would need to be present at the hospital. If I did have side effects, how many more times. In the beginning, sometimes, if you are in a phase three, even phase two, more patients obviously have partaken in them, and so the side effects are known.

Just like breast cancer treatments, from week to week the symptoms are pretty much the same, they don't change much, but everyone responds differently, so you don't know how you, in particular, are going to respond to a treatment. I was on the same treatment, as I mentioned, for two-and-a-half years. That particular treatment required several different biopsies which, in the beginning, were not fun, but they gave me two-and-a-half fabulous years of excellent results. Then I started another treatment, and we are working out the kinks right now, but I've had excellent results in terms of shrinkage.

I think within, if you don't mind me mentioning the details, but within a matter of a week I think some things shrunk like 81%, so there's really interesting things like that. However, getting my blood work in order, getting my enzymes in order, little things like that we are still working out, which required a lot of blood work. It's more an issue of time; time, side effects, flexibility. You have to have those things in order, I think, to be a participant.

Shera Dubitsky: It sounds to me certainly, Rachel, that you keep coming back to the gift again, so I guess that's the hopeful message.

Rachel: Absolutely.

Shera Dubitsky: Ms. Michaels, a question came in, "Why are there so many exclusions in the participation criteria?"

Margo Michaels: Great question. It's also a source of a lot of frustration, because people say, "Well, I want to participate but I can't because I don't meet the eligibility criteria." The standard answer I will give is that it's for patient safety so, for example, if someone has a heart condition or has uncontrolled high blood pressure, if the medication could cause that to get worse, it would not be ethical or appropriate for that patient to be on a clinical trial.

My more cynical answer is that sometimes those eligibility criteria are not always as thought out as they could be. For example, we've always restricted on high blood pressure, so we are going to continue to restrict on high blood pressure. Those rigid designs, I think, are changing now that more of the advocates are more involved in the design of studies. But the silly reasons, I think, are becoming less. You are right, that only 20% of us will be eligible to participate in the clinical trial, doesn't mean that all of us can be, but it is for patient safety rather than for other reasons that you might think.

Shera Dubitsky: Okay. We have another question, "Where would a patient go if they need help with logistics?" for example, Ms. Michaels, if they have a question about a clinical trial, or if they need advice or mediation.

Margo Michaels: Well, 1-800-For-Cancer is probably the one that I would recommend the most, it's the telephone number for the National Cancer Institute so they can answer questions around clinical trials. They are trained to answer these questions from all walks of life, from all over the country and for all cancers, so I think that's a really good place to start. There are also places like CancerCare, which is in New York; which can provide resources to address some funding or insurance issues. The same is true for a group called the Patient Advocate Foundation, which is in Virginia; you can also look them up on the Web. They can also help you with some advocacy around clinical trials and payment issues.

Just so you know that the ACA, otherwise known as Obama Care, has actually legislated nationally now that insurance companies cannot discriminate against you if you participate in a clinical trial, and if your network providers offer clinical trials they cannot make you pay extra costs associated with that clinical trial. It's a new law that was really state-by-state for many, many years, it's now national.

IV. Conclusion

Shera Dubitsky: Okay. I just want to say that all of this information that we've gotten this evening will be available on our website in the next coming weeks, so all those numbers and websites, you'll be able to access once we post the transcript of tonight's webinar.

I want to thank both Ms. Michaels and Rachel for their time, their expertise, and their insights and I believe that tonight's discussion demystifies the idea of clinical trials, and I hope that this is a springboard for further discussions with your doctors and treatment teams.

You will be receiving an evaluation by email, please take a few minutes to complete the survey. Your feedback is valuable to us, as we are committed to staying relevant by enhancing our programs to reflect the growing and changing needs of the women and families of our Sharsheret community.

Sharsheret expertise is in young women and Jewish families, though our 12 national programs are opened to all women and men regardless of background. I want to remind you to save the date for Part 2 of our Clinical Trial Series, what Ms. Michaels was referring to. Clinical Trials in a New Age: How You Can Connect, researching, accessing and participating in clinical trials, on February 25th of next year, 8:00 PM EST, and it's featuring Dr. Susan Domchek, who is the Executive Director of the Basser Research Center.

I would like to, again, thank AstraZeneca and Provectus for generously sponsoring tonight's teleconference, and for recognizing and supporting the needs of families who are at a higher risk of carrying the BRCA mutation.

Please visit Sharsheret's website at www.sharsheret.org, or give us a call at 866-474-2774, to discuss tonight's topic, or any other concerns that you are facing. Finally, all of us here at Sharsheret want to wish you a very happy Hanukkah and Holiday Season. Good night.

V. Speakers' Biographies

Shera Dubitsky, M.Ed., MA, is the Director of Navigation and Support Services at Sharsheret. She is a graduate of Columbia University and a doctoral candidate of Adelphi University Institute of Advanced Psychological Studies. Shera supports and connects newly diagnosed young women and those at high risk of developing breast cancer or ovarian cancer with suitable peer supporters, advances and develops programs addressing the unique needs of the young women and families of Sharsheret, and counsels individual members of the Embrace program.

Margo Michaels, MPH, is the Founder and former Executive Director of the Education Network to Advance Cancer Clinical Trials (ENACCT), Michaels has extensive experience in adult education, health professional education, program planning, strategic planning and management/administration. She is considered a national expert in improving clinical trials accrual through community engagement. Bringing 16 years of progressive leadership in patient advocacy organizations, the National Cancer Institute, and consulting to oncology care providers, she has a strong commitment to social change through effective community engagement around health care issues. Michaels serves on PCORI's Advisory Panel on Clinical Trials, CTTI's Patient Leadership Council, and is a member of Community Campus Partnerships for Health. Michaels has co-authored 9 peer-reviewed publications, and holds an MPH from UNC Chapel Hill School of Public Health.

VI. About Sharsheret

Sharsheret, Hebrew for “chain”, is a national not-for-profit organization supporting young women and their families, of all Jewish backgrounds, facing breast cancer. Our mission is to offer a community of support to women diagnosed with breast cancer or at increased genetic risk, by fostering culturally-relevant individualized connections with networks of peers, health professionals, and related resources.

Since Sharsheret’s founding in 2001, we have responded to more than 40,000 breast cancer inquiries, involved more than 4,000 peer supporters, and presented over 250 educational programs nationwide. Sharsheret supports young Jewish women and families facing breast cancer at every stage—before, during, and after diagnosis. We help women and families connect to our community in the way that feels most comfortable, taking into consideration their stage of life, diagnosis, or treatment, as well as their connection to Judaism. We also provide educational resources, offer specialized support to those facing ovarian cancer or at high risk of developing cancer, and create programs for women and families to improve their quality of life. All Sharsheret’s programs are open to all women and men.

Sharsheret offers the following national programs:

The Link Program

- *Peer Support Network,* connecting women newly diagnosed or at high risk of developing breast cancer one-on-one with others who share similar diagnoses and experiences
- *Embrace*™, supporting women living with advanced breast cancer
- *Genetics for Life®,* addressing hereditary breast and ovarian cancer
- *Thriving Again*®, providing individualized support, education, and survivorship plans for young breast cancer survivors
- *Busy Box®,* for young parents facing breast cancer
- *Best Face Forward®,* addressing the cosmetic side effects of treatment
- *Family Focus*®, providing resources and support for caregivers and family members
- *Ovarian Cancer Program*, tailored resources and support for young Jewish women and families facing ovarian cancer
- *Sharsheret Supports*™, developing local support groups and programs

Education and Outreach Programs

- *Health Care Symposia,* on issues unique to younger women facing breast cancer
- *Sharsheret on Campus,* outreach and education to students on campus
- *Sharsheret Educational Resource Booklet Series,* culturally-relevant publications for Jewish women and their families and healthcare professionals

VII. Disclaimer

The information contained in this document is presented in summary form only and is intended to provide broad understanding and knowledge of the topics. The information should not be considered complete and should not be used in place of a visit, call, consultation, or advice of your physician or other health care professional. The document does not recommend the self-management of health problems. Should you have any health care related questions, please call or see your physician or other health care provider promptly. You should never disregard medical advice or delay in seeking it because of something you have read here.

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