Understanding Your Risk:

A Guide to Breast Cancer Recurrence Testing

National Webinar Transcript

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Presented by:

Aimee Sax:

So good evening and welcome. Thank you so much for joining us for tonight's webinar, Understanding Your Risk: A Guide to Breast Cancer Recurrence Testing with Dr. Noam Drazin. I'm Aimee Sax, Sharsheret's support program manager. I want to give a special thank you to tonight's sponsor, Cooperative Agreement 24-0061 from the Centers for Disease Control and Prevention and to Veracyte, Foundation Medicine and Novartis, and our Embrace sponsors Pfizer and Lilly. Before we begin, a few housekeeping items. Today's webinar is being recorded and will be posted on Sharsheret's website along with a transcript. It will also be emailed to everyone who registered. Participants' faces and names will not be captured in the recording. If you'd like to remain private, you have the option to turn off your video and rename yourself by clicking the three dots in the corner of your screen, or you can call into the webinar.

We also have closed captioning available, so to display live captions on the bottom bar, click on captions and then click on show captions. You may have noticed that you were muted upon entering the Zoom. Please stay muted during the call. We received so many questions in advance of tonight. We will hold a Q&A at the end of the presentation and quite honestly throughout. If you have additional questions, you can type them in the chat box and we'll get to as many as we can. I want to remind you that Sharsheret is a not-for-profit cancer support and educational organization. We do not provide any medical advice or perform any medical procedures. Our full medical disclaimer is going in the chat box now.

Two quick Sharsheret program spotlights I'd like to share. First, Sharsheret offers monthly virtual support groups for those personally affected by breast cancer and ovarian cancer. We have one group for those in survivorship diagnosed stages zero to three, one for our Embrace community, those living with metastatic breast and advanced ovarian cancer, and starting this week, we have a new support group for those newly diagnosed or in active treatment for stage zero to three breast cancer or ovarian cancer. So that's really geared towards people planning for or going through surgery, chemotherapy, and/or radiation. The signup link for all three of those groups is in the chat now. You can also register now for part two of this webinar series, Risk of Recurrence: Coping with Fear, Anxiety, and the Emotional Weigh of Survivorship. So tonight is going to be a little bit more medically focused and that is going to be more emotional focused. That will be on August 27th at 10:00 AM Pacific, 12:00 PM Central and 1:00 PM Eastern. The link to register for that is going in the chat now as well.

Most importantly, please know that if you are currently facing a breast cancer or ovarian cancer diagnosis, Sharsheret is here for you and your loved ones. Sharsheret provides one-on-one emotional support as well as programs and resources designed to help you navigate the cancer experience. Everything we do is completely free and confidential. If you're not already connected to one of our social workers, please get in touch using the contact information going in the chat box now.

Now onto tonight's webinar. So at Sharsheret, we know that cancer is so much more than just a diagnosis. It's an experience that takes lots of twists and turns, often depending on the results of different tests, both at the beginning, before treatment planning begins, and after active treatment ends as you navigate survivorship. Whether you're currently dealing with a diagnosis of breast cancer or ovarian cancer at elevated genetic risk or supporting a loved one who is, tonight's webinar is designed to demystify recurrence risk testing so that you can walk into your next medical appointment feeling informed, prepared, and empowered.

And for those of you in our Embrace community facing metastatic breast cancer or advanced ovarian cancer, we invite you to stay on to tonight's Zoom following the Q&A for a more intimate breakout session with Dr. Drazin. Like I said, we received many, many questions in advance of the webinar, and we invite you to keep asking questions in the chat. You can write them in the chat box to all participants or privately to me by clicking on my name in the chat box. We'll do our best to get through as many as we can as time permits. Now let's get things started. First, it is my absolute pleasure to welcome Michelle to share her story. Michelle.

Michelle Weiss:

Unmute. Okay, so hi everybody. I'm Michelle Weiss. I'm in Los Angeles, and actually Dr. Drazin is my doctor. It's been 11 years, so that's quite a long time. So anyway, let me just tell you a little bit about myself. As you know, my name is Michelle Weiss. I'm BRCA negative. No one in my immediate family has been a victim of any type of cancer. Whatever. Not by marriage, but anyway, you understand. I was never a smoker. I never abused alcohol or other substances. I ate regular healthy meals, fruits, vegetables, lean meat, and fish. I regularly exercise. I was not obese. I breastfed my four children, and I always went for my annual gynecological exams, which included a breast exam. But despite all of those things, I'm a breast cancer survivor. My profile would indicate that I was at relatively low risk for having breast cancer.

And because of this, I neglected to get my mammograms for four years. So when I went back in year four, that's when it was discovered. I didn't think I was at risk. My gynecologist would give me the mammogram orders, and I stupidly ignored them. I finally went for a mammogram after skipping four years, and the mammogram discovered a cancerous lump in my breast. This was very shocking to me, and I could not believe it. It just was beyond a surprise. Every time I would hear about the risk, I just didn't think it was ever going to apply to me. After going through a lumpectomy and biopsy initially, my breast cancer was staged at 3A. This meant that I had to have chemotherapy in addition to radiation. And to make matters more fun, the surgery also discovered that I had LCIS, which is technically not cancerous, but is an indicator that I had a high risk of having breast cancer again and possibly on the other side. So just keep in mind that genetics is not the only indicator of breast cancer risk. The recommendation was a double mastectomy, which I also went through, and of course a reconstructive surgery.

Had I gone for my annual mammograms, the cancer could have been discovered sooner, and I could have been spare possibly the miserable experience of going through chemo. I also could have spared my family. And I have four kids. At the time they aged in range from 11 to 18. It was difficult for my kids to see their mother go through cancer treatment, and I had less time to devote to them because of the toll that the treatment took on me. Of course, it also put a burden on and took a toll on my husband who was wonderfully supportive during all of it. I cannot emphasize enough how important it is for annual mammograms. It frightens me to think how much worse the situation could have been if I had skipped another year.

Please, please, please. I cannot emphasize enough, learn from my mistakes. Don't assume you are not at risk for breast cancer. I encourage you to please go for your annual mammograms and encourage other women you know to do the same. And I know we're going to talk about survivorship today and all that, but I also still see Dr. Drazin every six months, and I encourage people who got through the experience to just keep taking care of yourself because early detection is just the most important thing. And I'm sure you guys are going to talk about the Natera test and all the other wonderful things that Dr. Drazin does for my healthcare.

Aimee Sax:

Thank you so much, Michelle, for sharing your story. Such important reminders of the importance of early detection. And you're so right. We talk about annual mammograms, and that is part of what we're talking about tonight, is all of the things that we need to do moving forward. And certainly these risk of recurrence tests are a big part of that. So thank you so much for sharing. So now it gives me so much pleasure to welcome our speaker this evening, Dr. Noam Drazin. Dr. Drazin is a practicing physician with the Cedars-Sinai Medical Group in Beverly Hills specializing in oncology and hematology. His clinical interests include the application of emerging therapies, precision medicine, and multidisciplinary approaches to the management of hematologic and solid malignancies. Dr. Drazin is dedicated to delivering evidence-based patient-centered care while translating the latest scientific advances into meaningful improvements in patient outcomes. He's passionate about education, collaboration, and advancing the field of oncology through clinical excellence, innovation, and compassionate care.

He's been a wonderful friend to Sharsheret serving on our community advisory board here in our Western region. And personally, I just have to share that I have the pleasure as a Sharsheret social worker of talking to many of his patients who really and truly all rave about his care in taking care of them. Just very, very sweet doctor, which is not what I hear about every doctor out there. So welcome, Dr. Drazin.

Dr. Noam Drazin:

Thanks so much, Aimee. And I really want to express my gratitude to Michelle, a friend, and a patient obviously who took time out of her day to share her story with us tonight. And I don't think her story is an uncommon one. And hopefully the goal tonight is to talk through some of the science of why we make choices and why women and the doctors and the team make choices about treatment options when it comes to breast cancer diagnosis. And then spend some time, probably the significant amount of time talking about the risk of recurrence and what we can do in the surveillance mode of following patients with breast cancer. So it's an absolute pleasure to be on the Southern California Advisory Board for Sharsheret. I have participated in multiple webinars, in-person live discussions. And typically, I spend most of my time doing my discussions with community members about the genetics of breast cancer. I'm not a geneticist, I'm a practicing medical oncologist and hematologist here in Los Angeles. So obviously this is really my wheelhouse of talking about the stuff we're going to be talking about tonight. So it's a real pleasure.

I put together just four slides to go through and help take me through this story and the content of what we wanted to address. And then obviously a lot of what we're going to be talking about today is probably going to be question-based, and I am hoping to be able to answer as many questions as you can. There are a lot of people out here, and as Aimee said, a lot of questions were submitted, and I'm sure as I saw, lots of questions coming in through the chat as people were talking already, so we'll do our best to answer those questions.

All right. So from an agenda standpoint, obviously I've done my introduction already in terms of who I am and what I do. We're going to look at the pre-surgical assessment of a breast cancer patient, and we'll talk about the adjuvant therapy determination. And when I talk about adjuvant therapy, for those of you who don't know that, that is either chemotherapy, immunotherapy, and/or hormone blocking therapy that is given post-surgery to prevent or to reduce the risk of relapse. So a lot of that determination is stuff we're going to be talking about tonight. And then the last section is going to be talking about surveillance or monitoring patients for relapse. And something that you may know about already, or MRD stands for minimal residual disease, and that is a very big buzz term when it comes to all cancers. But specifically in breast cancer, we

are using it a lot, and there are a lot of platforms that I will talk about that are looking at that technology. Michelle mentioned the company, Natera. There's a platform. Their actual product is called Signatera, but there are other ones that are out there, which we're going to talk about as well, but that's what we're going to be talking about today.

So let's talk about the pre-surgical assessment first. So I think if we think back to prior to molecular testing and all the technology we currently have, the most important way we used to determine the need for type of surgery, whether it be a lumpectomy or a mastectomy, or the potential need for preoperative chemotherapy, which is discussed as neoadjuvant therapy in the literature, depends on the size and the clinical lymph nodes. So how big the tumor is determines things like can a woman get away with a lumpectomy with breast-conserving therapy? Are there multiple tumors in the breast which make breast-conserving therapy less possible? Are there clinically positive lymph nodes which may impact the decision to proceed with a surgical approach upfront or do it on a later date? So that initial assessment is based upon a few things. We talked about size and talked about lymph node status, that is the clinical evaluation. And then post-biopsy ... And that is important because there needs to be some pathologic confirmation of the tumor. That is what we initially call a breast profile assessment. And I think most pathology departments still describe that as a breast profile.

And initially that breast profile is an estrogen receptor, a progesterone receptor staining, followed by a HER2 staining. And depending on the level of staining of HER2, then it's usually followed by a FISH, which is a fluorescent type of examination of the tissue to determine positivity. So that's the initial breast profile. Now, there are just offhand here, three clinical situations and pathologic diagnoses that almost always lead to a neoadjuvant or a pre-surgery treatment of a patient. And those are TNBC, which stands for triple negative breast cancer. So that means estrogen receptor, progesterone receptor, and HER2-negative. That would be defined as triple-negative breast cancer. Patients with clinical ... Not clincal. Sorry. That should have been spelled checked. But clinical stage three. So that would either be a combination of a larger tumor, primary tumor and positive lymph nodes or the number of positive lymph nodes or clinically palpable lymph nodes. So obviously in the pre-surgical assessment, we don't know the number of lymph nodes that are involved that are positive in the armpit in the axilla. But if you can palpably detect or feel lymph nodes in the armpit, that is what we would consider palpable positive or palpably positive lymph nodes. And that pushes you over into at least a pre-surgical stage three disease. And then HER2-positive disease.

So anyone with HER2-positive disease, I'd say barring the exception of maybe an 85-year-old or a 90-year-old going through this who has HER2-positive disease, I would say the majority of women that I see with HER2-positive disease undergo some form of preoperative chemotherapy or neoadjuvant chemotherapy. So two options here, the neoadjuvant approach for the standard triple negatives, the clinical stage threes or the HER2-positive disease, or proceeding directly to surgery at that point.

So now how do we determine what we do next? I don't think Michelle mentioned DCIS. She mentioned LCIS and someone I saw it pop up on the chat. But for those of you who don't know, DCIS is actually a precancerous lesion. It's ductal carcinoma in situ. It's considered stage zero breast cancer. Depending on the grade of DCIS, it could be a higher grade, grade two or grade three. And there's always a risk when you have higher grade DCIS that there might be invasive cancer that's found at the time of surgery. So DCIS ends up leading to a surgery. And if it remains DCIS, it remains a precancerous lesion, then if it is estrogen receptor or hormone receptor positive, tamoxifen or other type of hormone blockade is usually offered in that particular case. That is the extent, that is the total extent of adjuvant therapy for someone with

DCIS. The only time when we actually even consider chemotherapy and other directed therapies are when there's an invasive cancer component, which is either a lobular invasive cancer or a ductal invasive cancer.

Now, I will just mention ... I didn't put this on the slide. But LCIS, which is lobular carcinoma in situ, is something that is seen pathologically sometimes on biopsies. And it, as compared to DCIS, is not a precancerous lesion. So leaving it there doesn't become cancer as opposed to DCIS. If you leave DCIS in the breast and it eventually will become invasive cancer over time. LCIS is a marker, a marker for recurrence of cancer, and specifically a marker for recurrence of cancer in the opposite breast or in the contralateral breast. So if you have the LCIS on the right, there's a chance of developing a lobular cancer on the left. So what usually happens in patients who have underlying LCIS in addition to a cancer diagnosis is that they usually undergo bilateral mastectomy as a choice of surgery.

All right. So let's move on to invasive cancer. So invasive cancer is obviously ductal carcinoma. I think I lost my share. Hold on a second. Let me get that back. Sorry about that. Invasive ductal or invasive lobular cancer. So used to be that the tumor size and the nodal status, so positive lymph nodes and tumor size alone was helpful, and maybe age of the patient was helpful in determining whether or not a patient should need chemotherapy. And I will tell you in old school oncology, and I've been doing this about 23 years, back when I came out of training 20 years ago, we didn't have much else to go on. So it was a lot based on the tumor size and based on nodal positivity in anyone with a tumor greater than one centimeter, and probably anyone with a positive lymph node was getting chemotherapy regardless of age, regardless of anything. Now, the real challenge for an oncologist like myself is who not to give chemotherapy to, who to really decide and to really make the correct determination. Does this person actually need chemotherapy? Which as Michelle said, is not a fun time. It's necessary in most cases that we do it, but if we could avoid it, we would like to.

And a lot of that is actually based on what the technology has become. So we have two different ways of going at this, and I'd say the part that has grown the most has been the genomic analysis, genomic testing. And then there's also an AI or an AI-based technology, which is rather new, which we'll talk about that later on, I'm not going to have much to say about it because I don't personally use it now, is something called precise breast, which is a way for an AI-based model to look at the pathology and determine the risk of relapse.

What I would say most of us are utilizing and what is currently being recommended by all guidelines are the genomic analysis tests. And those are that third bullet there, Oncotype DX, MammaPrint, and Prosigna. So those are all pathologic tools. Specifically the Oncotype and the Prosigna are utilized in hormone receptor-positive cancers. So those are only utilized for hormone receptor-positive tumors. MammaPrint can be used in hormone receptor-negative tumors, so in triple-negative disease. And the data that this gives you, Oncotype, MammaPrint and Prosigna, are actually a recurrence score. So it gives you a score that says under a certain score, these patients do not need chemotherapy, over a certain score, we would recommend it. Now, what determines that recommendation? Pretty much that the benefit of doing chemotherapy is actually going to be significant. Significant enough that the toxicity of the treatment will ultimately be worth going through the treatment in order to reduce the risk of relapse. So I would say that in general, most cases that we do today are doing some sort of genomic analysis to identify a recurrence score. And I will tell you that most of my patients appreciate getting some sort of number, some sort of quantifiable data that tells them this is the risk of recurrence. And by doing this and that, whether it's chemotherapy plus a hormonal blocker, that risk reduces to a certain percentage. So we can give that information.

Now, as AI-based technology improve, I can almost guarantee that it's not going to be AI-based alone like the precise breast tests that currently exist, but probably some combination of a genomic analysis and a artificial intelligence-based model will be very helpful in helping us determine that. But this is the standard of care. I would say that doctors and clinicians out there and teams that are making determinations strictly based on tumor size and nodal status, regardless of age and regardless of any other thing else, is not following the standard of care. The standard of care is definitely utilizing these unbelievable tools that exist to help us modify treatment and help us tailor treatment that is necessary for patients. All right. So that's the adjuvant therapy determination, and I hope that was clear. And again, happy to answer any questions that come about.

And then we're going to just focus now on those last bit on surveillance and minimal residual disease, and I will speak to what I usually offer. I would say that the standard follow-up post-treatment ... Or again, there's two ways of looking at this. Patients who receive adjuvant chemotherapy or adjuvant hormonal therapy, whether that be tamoxifen or a aromatase inhibitor for anywhere between five and 10 years, then the follow-up is usually every three to six months until that therapy is completed, whether it's the chemotherapy or the hormonal blockade therapy. Once that is all complete, then usually we shift to an annual. And then some patients I see every six months to a year. So that's the standard. And I would say the guidelines that talk about surveillance and monitoring, it's usually in a three-month interval for the first two years of treatment, six months intervals for years three, four, and five, and then annually after that. Again, that's a general guideline. That's similar to what I see and what a lot of my colleagues see.

I would say something that is probably worth mentioning is my second bullet, that scans are not standard for surveillance. And again, that is also a big generalization. I would say that scans are typically utilized in the early part, probably prior to surgery in patients with higher stage disease. So it's a stage three and triple-negative breast cancer. So triple-negative breast cancer patients definitely require full body scannings and probably MRI of the brain in addition to HER2-positive patients usually also requiring full body scans and MRI imaging of the brain. However, post-treatment, scans are not standard. And when I say not standard, probably not going to be paid for by insurance either. So again, this is also something that we have, this is the real world. We can't just order tests because I do spend 30% of my day on the phone fighting for patients to get scans when the insurance company is not paying for them. And I would say the standard from an insurance company is to deny, deny, deny, and potentially offer it when a peer-to-peer or some appeal process is undertaken. And that's pretty standard. So if this is happening to you, this is a standard process. It's an unfortunate standard process, but it happens all the time.

So scans not standard for surveillance unless you have a patient with metastatic disease. And we're not talking about that right now. But patients who have metastatic disease obviously are getting scanned on a frequent basis. So let's talk about blood testing because that is pretty much the primary mode of testing in the surveillance mode for MRD. Now, let me start with markers because that is somewhat controversial. And it's something that a lot of patients request, and it's a lot of things that ... And I typically am a big utilizer of markers, but you have to understand what the limitations of tumor markers are. So let me just define that first. So tumor markers are protein detected in the blood. Three examples are CA15-3, CA27 ... It's not 27.23, it's actually 27.29. Sorry about that. Another typo by me. And CEA or carcinoembryonic antigen. So those three are your typical cancer markers. CEA is the most non-specific. We see CEA elevation in all different types of cancers such as colon and breast and in lung. But breast specific are the 15, three and the 27, 29.

Those markers detect the presence of tumor tissue that happens to secrete or excrete these particular proteins. Now, not every tumor does, not every breast cancer does, but some do, which is why prior to all these other available options for minimal residual disease testing, which we're going to be talking about, this was the only option. The only problem with these markers is it's a late detection. Once you have an elevation in 15-3 or 27.29 or potential CEA, it's almost a guarantee that you're going to find something on scan. So it is less helpful, but it's something that a lot of people test for. And unfortunately, it's a ... Well, I know about unfortunate. I would say the guidelines by the NCCN, which is National Comprehensive Cancer Network, and the guidelines from ASCO or the American Society of Clinical Oncology, they actually don't recommend obtaining routine markers for following patients with cancer, especially breast cancer. Now, having said that, we're still doing it and patients are requesting it, but just know the limitations of this particular test. And the reason it's not being recommended by the national guidelines is because of the limitations. And the limitations are the fact that once positive, it's already a little bit late. We already know that there is going to be some considerable disease that we're going to be able to detect. Okay, so that's markers.

And now to the Meat of what we're doing now, it's the very, very new technology, so much so that there is a lot of competition out there. And we have some of the sponsors of tonight's talk is Foundation Medicine, which FoundationOne has a MRD product called a minimal residual disease product. Guardant is one as well, as well as Signatera. The company name is Natera, but the product is called Signatera. They all have minimal residual disease platforms. And the science behind it is detecting microscopic circulating tumor DNA. So the markers, the CA15-3, the CA27.29, the CEA, there has to be significant disease for those markers to be elevated. When you are able to detect microscopic complimentary DNA from the tumor, which is what CTDNA is, you are able to detect microscopic disease before it actually is detected on scans. So that's the critical thing here. And it provides a negative test, provides a significant reassurance to patients in the surveillance setting that there isn't anything brewing. But a positive test is actually very prognostic for a high chance of eventual recurrence.

Now, a big question that gets asked all the time is what do you do with a positive test? And it's a discussion I have when I talk to my colleagues when it comes to doing MRD testing or minimal residual disease testing is what do we do with a positive test? And a lot of doctors out there are hesitant. And I don't know. I'm sure this might be a topic of the questions coming forward. But a lot of colleagues that I know are hesitant to offer MRD testing such as this because they're not sure what to do with a positive test. Now, my experience has been, I would say nine out of 10 women that I talk to about offering this in the surveillance setting want that information. They want that information because they want to be in charge of their lives and in charge of their bodies and they want more information rather than less information. But the truth of the matter is a positive test can mean a waiting time of anywhere between two and potentially nine months before we detect anything on CT scan. So that's the potential anxiety-provoking aspect of this. But I would say, as I said, nine out of 10 are more likely to want this information than not have this information.

And the benefit of knowing that it's positive and that eventually it's going to come back is that we can then start a more aggressive, vigorous scanning process. So as I said, scans are not standard for surveillance, but when you have a positive marker or a positive MRD test or a positive CTDNA test, then that then triggers the initiation of scans. So that's the change that's really happened in cancers, pretty much pan-cancer all around. But specifically for breast cancer. I personally am utilizing MRD testing as a standard. I also use it, and you may also be someone who's a recipient of this testing if you are a survivor or a current cancer patient. But you can also utilize this technology in the neoadjuvant setting, so prior to initiating treatment,

where you would expect the test to be positive. And then you watch the test become negative in the course of preoperative chemotherapy and surgery, and then go from a positive to a negative and stay negative.

So there is a benefit to that. I think there's a benefit to that as a patient to see the treatment actually working. And then the reassurance that comes along with the negative test is I think incredibly helpful and provides a bit of reassurance and optimism. So that concludes my actual ... Yes. The actual ... I'm going to stop the share. Formal remarks. And then I'm just going to turn it back over to Aimee so we could maybe start entertaining some questions and have a little bit of a discussion about anything that might've come up. So thank you so much for the opportunity.

Aimee Sax:

Absolutely. Well, first of all, thank you so much, Dr. Drazin. It's really amazing to see all of this laid out so clearly. I think you mentioned that it's new, so I'd love to hear how new is it? Because I've been a Sharsheret social worker for nine and a half years, and all of a sudden I'm talking about it constantly, and I can't even remember when it started, but it's only been the last couple of years, is that right?

Dr. Noam Drazin:

Yeah. I would say maybe three to four. It initially got approval only in colon cancer. That's where the majority of the data was, but now it's jumped to this pan-tumor model. And then it used to be only a Natera company and Signatera product, and now it's multiple products out there that do similar things. What I didn't talk about, Aimee, was different tests offer different ways of monitoring this and assessing it. The difference between the Signatera or the Natera approach and I believe the Foundation and the Guardant one is that the Signatera one takes the tissue and develops a standardized test against that particular tissue. So it's a tailored test for that patient and for that tumor, as opposed to the other ones, which uses a more of a generalized cancer detection model. And then I saw a chat that just came out. There is one called Haystack, which actually is a Labcorp product. So Labcorp bought Haystack, so it's there. I don't know if you're familiar with Labcorp, it's a big lab, but they pick that up. And that's also a non-pathology-informed test, which again is a different way of looking at it, but they're all very good. They're all very, very good at doing what needs to be done.

Aimee Sax:

Okay. Great. But yeah. I can't tell you how many conversations our social workers are having about this. So to have it all laid out so clearly is so helpful because it's just such a hot topic. And I think a lot of our callers are sounding very confused. I don't think their oncologists are always taking the time to really lay out how it works and what the options are. So we're going to move on to the formal Q&A as Dr. Drazin said. So please remember, we cannot address questions that reference uniquely personal situations. We might give some personal examples, but I just encourage everybody listening to listen for the nature of your question and not completely the specifics, but we're going to get through as many as possible. So I know MRD testing is what everybody really wants to talk about, but I want to scooch back to the beginning of your presentation and talk a little bit about the Oncotype and MammaPrint and Prosigna tests that happen as part of treatment planning.

We talk a lot about the percent of risk and people ask us a lot, how do they know? And what does that mean? I usually share what ... My grandmother was a pediatrician and she would talk

about percentages help you make decisions, but you are either 0% or 100%. It's either going to happen or it's not. So you need to take the statistics seriously, but also not get bogged down too deeply in them. So how do you help your patients understand that, either the Oncotype score or the percentage risks, and also how they change if you do radiation, if you do surgery, if you do hormonal therapy, if you do chemo versus not?

Dr. Noam Drazin:

Right. So maybe it's important to ... And I didn't talk about this to differentiate, and hopefully all the doctors out there taking care of patients with breast cancer are educating in addition to treating. And I think the most important thing is to know that surgery and radiation are local control. So it's preventing local relapse. So that's all that it affects. The chemotherapy or the hormonal blockade therapy affects a systemic relapse issue. So it's two different things. And I totally agree with you, Aimee, about the statistics is statistics, but it's not statistics for the individual. So statistics is a median, it's an average. There are people that do much better than the average and people do much worse than the average. And I think when it comes to statistics about survival, I think that's right down the line. The issue with recurrence risk is a little bit more scientifically based. So the data you're getting from the Oncotype and the MammaPrint and the Prosigna is actually a recurrence score, which takes thousands and thousands of data points and the genes that are involved that increase the risk of recurrence or decrease the risk of recurrence to get a number. And that number is really specific to your particular tumor.

So I think you can take that number as being true as opposed to when it says, "Oh, you have a 60% chance to survive or a 20% chance of survival." Those are totally different. That's when I steer people away from the internet and from ChatGPT and all that discussion when it comes to survival data, because again, yeah, you're zero or 100% when it comes to a person. But that particular data from those platforms, those you can rely on. And I will tell you ... And I don't know if we were going to get into this, Aimee, but everyone sees a percentage that's specific to them. So there are people, there are women that I've seen that says, "Oh my God, I have a 5% chance of relapse. I will do everything possible to bring that five to a zero." Most of those models will only recommend chemotherapy if the recurrence risk is over 30% because the chemotherapy or hormonal therapy is going to drop that usually down by 50 or 60%. So take a 30% chance of relapse down to 15 to 10 to 15. Now, I would say I would try to steer women away from doing an adjuvant chemotherapy for a 5% relapse because the toxicity of the chemotherapy is definitely not going to outweigh ... The toxicity definitely outweigh the benefit. But I hope that answered your question about the percentage.

Aimee Sax:

It helps a lot.

Dr. Noam Drazin:

Okay.

Aimee Sax:

Yeah. Absolutely. So how often is MRD testing usually recommended?

Dr. Noam Drazin:

Well, first it has to be recommended. So there are a lot of people that aren't doing it. So in general, it's very similar to the timeline that I utilize in managing patients. So I would tend to get MRD testing in the surveillance setting every three months for the first two years, and then every six months for years three, four, and five, and then annually after that. That's the standard. People on immunotherapy, which applies to patients with triple-negative breast cancer, the standard is getting MRD testing every two months throughout the treatment. So it depends. It depends. But typically, it's the standard kind of following. So whenever you see that patient in follow-up, you get that test.

Aimee Sax:

That's great. You mentioned all these different types of MRD tests, what factors help oncologists determine that this type of testing is needed, and how do you choose which one?

Dr. Noam Drazin:

Yeah. Well, I tend to be ... I'm going to help myself here a little bit. I tend to be one of those early adopters of technology. So I have every Apple product in the second it comes out and I tend to-

Aimee Sax:

You were one you were one of those waiting in line in the days. Yeah.

Dr. Noam Drazin:

When we had to, I was that guy. But I'm also an early adopter of emerging technology, especially when it's found to be useful and fits guidelines. So it is becoming standard across the board pan-tumor. I'd say it's probably the reason why a lot of people aren't doing it is because it isn't necessarily 100% recommended, but I typically find it useful and my patients find it useful, as I mentioned before, to obtaining as much information as possible in the course of their disease and their illness and their survivorship to provide them not only with good medical care, but also to provide them with the reassurance of, yeah, you're doing the right thing. So I've been using it just globally. And I'd say that may not be true of all my colleagues that I work with.

Aimee Sax:

We got a lot of questions about how do I convince my oncologist to let me do it or my oncologist won't let me do it. Is there a way I can do it myself somehow?

Dr. Noam Drazin:

Yeah. So you can't do it yourself. It needs to be a physician's order to get done. And I would say that is a prime reason to potentially get a second opinion, I think. I think it is. Especially if you're getting a lot of pushback. And I would be a strong advocate for yourself and say, "This is what I've learned, this is what I've read. This is I found to be helpful. I'd like this." Now, a lot of times you're going to get pushback because again, the doctors don't know what am I going to do with a positive test? I'm not going to know for how long that there is going to be something to treat. Because right now ... And I think that's important to mention. Right now we don't have any prospective trials right now that are out there that can tell us that we could act upon a positive test, an MRD test. You still need to prove that there is some disease somewhere on a scan, whether that's a CAT scan or a PET scan or something like that.

But I will tell you it's changing. There are a lot of prospective clinical trials that are now incorporating MRD testing in those trials so that we will have that answer soon. Will it be next year? Probably not. Will it be in three years? Possibly that we'll be able to initiate treatment based on MRD positivity instead of waiting. And that may trigger people, more clinicians having more comfort in offering that to patients, I think.

Aimee Sax:

Okay. That's really helpful because I have literally, I think, six questions here all about this disagreement about the efficacy and why doctors seem reluctant to adopt it. So I think that's a great one. But I do want to read this one question we got on that is if your oncologist doesn't use or order these tests, how much should you advocate for it or insist on it? Because they get cranky sometimes.

Dr. Noam Drazin:

Who gets cranky? The doctors get cranky?

Aimee Sax:

The oncologist. The oncologist gets cranky.

Dr. Noam Drazin:

Too bad. We're in the business of taking care of patients along ... I don't know. In Los Angeles, patient advocates come with patients too. Not only the patients are advocating upon themselves, but the advocates are advocating with them. So no, no, no. You just have to be an advocate for yourself and for your care.

Aimee Sax:

Yeah. And I love that explanation of if this is something that you want, then present the research. Is there somewhere that you can point to our callers where they can find the research? Where should they be looking?

Dr. Noam Drazin:

Yeah. You can go to any of the platform company names. If you can go to Natera, you can look up Signatera, you can look up the Guardant, you can look up FoundationOne. I would say the more common ones we see is the Guardant. We don't have a lot of use of FoundationOne in our institution, but any of those models.

Aimee Sax:

Mm-hmm. And if they are doing it, how many years after treatment can these tests be done? Of course, they're still new, so we don't know how long we're going to be using them.

Dr. Noam Drazin:

We don't know. Yeah. Well, at the five-year mark, I start doing them annually, so I'm still doing them. So I just don't know yet. I guess we don't know yet how long to continue. A big thing that comes up all the time is it paid for? And I think it's important to mention.

So it's becoming more globally accepted by a lot of insurance carriers out there, regardless of the tumor type, to get approved to use. However, if it's not approved, these companies, none of them are going to balance bill their patients. They are not going to make the patients pay for it and the cost. Now they will try their darnedest. They will try, and the patients will get a lot of paper and a lot of EOBs and a lot of denials and all that kind of stuff. But I promise you, you will not get a bill from Guardant and you will not get a bill from Natera because they want this data as much as you want them. And it's something that's being covered. I would be very, very shocked because it's not happened to a single patient of mine to be billed.

Aimee Sax:

That's fantastic to hear because yes, I can't tell you how often we're hearing from our callers. I wish cancer was my biggest stress, but it's often bills and insurance and all of that rigamarole. So that's great to hear. We got a lot of questions from people whose cancer diagnosis was years ago. They're already well into survivorship. So they weren't going to their oncologist when these tests were being ordered, and now maybe they see them annually and a lot of them actually heard about MRD testing from our email about this webinar, which is fantastic. If they're five years after a diagnosis or more or a few less, what do you think about them starting the MRD testing now? Should they be advocating to their oncologist to start it now?

Dr. Noam Drazin:

Yes. I guess I would say in more aggressive disease, further out, I probably would. So anything stage two or higher, even if five years out, I have started doing that when patients have asked for it. Again, the only test that you could use in situations like that, because by that point, tumor tissue is probably gone, is the non-pathology-informed test. So that would probably be either the Guardant or the-

Aimee Sax:

Guardant or the FoundationOne.

Dr. Noam Drazin:

Yeah. Exactly. And the Haystack. Those are non-pathology-informed. So those don't need a pathology test or a pathology tissue to initiate.

Aimee Sax:

That's really helpful.

Dr. Noam Drazin:

I did see a question that came through, and I think that's okay, Aimee, if I-

Aimee Sax:

Yes, please. They're coming in fast.

Dr. Noam Drazin:

They're coming in fast ...

Aimee Sax:

I don't have the list of the ones that came in before.

Dr. Noam Drazin:

No, no, right. So there's someone who asked, can it be used to detect other cancers?

Aimee Sax:

I had that question as well since so many of our callers have an ovarian cancer or other gynecological cancer.

Dr. Noam Drazin:

Correct. So the Guardant technology non-pathology-informed test has a way of determining the tumor fraction and giving a probability of the tumor, what the origin is from, and then give us that information. It probably will not be able to detect multiple cancers, and hopefully we're not in a situation where we're detecting multiple cancers in one particular person. Then the Natera test or the Signatera test is specifically to that. So the only blood that you're getting on subsequent tests are measuring the recurrence of that particular tumor, that one. So it's not finding newer cancers. If you ended up having breast-conserving therapy, you still have to do mammograms to look for other primary tumors, God forbid. So it's specific in that way.

Aimee Sax:

That's helpful. Thank you. We got a lot of questions. And like I said, we don't want to get too specific, but we've got lots of questions about does this work for lobular cancer versus ductal? You've talked a little bit about estrogen and progesterone receptive versus HER2 receptive, triple negative or triple positive, and even one question about HER2 with low metabolic activity. So can you speak a little bit to which types of cancer this is best for? Or if there are any types that it does not work for? Because a lot of questions about, does this not work for lobular cancer?

Dr. Noam Drazin:

No. I would say it works on all invasive cancer. So all invasive cancers, not on DCIS though. So not of the non-invasive precancerous lesions that we talked about for a second. So any invasive cancer. Which ones would I focus on if I had to? Probably those higher grade, the triple negatives, the HER2-positive, the stage threes, the ones with multiple lymph nodes, things like that.

Aimee Sax:

That's really helpful. Yeah. Lots of questions about triple negative. So you answered that. That's really helpful. And let's see. So I know you said at the beginning you're not a geneticist. And for anybody with genetic questions, we have two wonderful genetic counselors at Sharsheret that we're happy to put you in touch with to ask those questions. But someone asked, or we got a couple questions about where do genetics come into play with these tests? I know that some treatments are really geared towards people with a BRCA mutation versus not, or other

hereditary risk factors with other mutations. So is there any interaction between genetics and the use of these tests?

Dr. Noam Drazin:

Oh, yeah, very much. I think what's changed, and I didn't include this, is obviously BRCA-positive breast cancers are, there's now an adjuvant approach of using a PARP inhibitor, which is the specific drugs that are utilized for BRCA-positive malignancies to use it in the adjuvant setting. So we are using those PARP inhibitors in the adjuvant setting. That's also a big case that I would utilize for MRD testing as well. And a lot of the reason, and I would say the point of using minimal residual disease testing in those platforms is actually helpful in reducing the quantity of radiation because you are scanning these people less when they have really high-grade disease if you're going to do any scans. If you have negative Signatera tests or a negative Guardant or a negative haystack or a negative foundation one, then you could limit the potential scans if you were going to offer those.

Aimee Sax:

That's really helpful. We also got some questions both before, and I saw in the chat about the breast cancer index test. Genomic test that looks at risk of recurrence with

Dr. Noam Drazin:

Hormonal treatment. Yeah, so that's a specific test that we use routinely at the five-year mark of hormone. Again, this is only going to apply to hormone receptor positive tumors because obviously hormone blockade has with it lots of side effects, whether it be hot flashes or impairment of bone health as part of the side effects that come along with the benefits that it provides. So we want to be sure before we continue that treatment beyond five years, if that's what's recommended. And the Breast Cancer Index is a pathology type test that will define is your risk of recurrence higher from years zero through five or through five to 10? And you get a quite simple yes or no from this test. And in general, it should be utilized by every patient with hormone receptor positive disease, and it'll help determine if you need to continue that hormonal therapy beyond five years.

Aimee Sax:

That's so helpful. And I know this is very different than what we're talking about, but when we talk about all of these tests, we also got questions about this versus the Tyrer-Cuzick risk assessment, which we've heard so much about since Olivia Munn really came out hard talking about it. Of course, that's usually risk before a diagnosis. Is that right?

Dr. Noam Drazin:

Correct. Yes. Very much before. So it's all determinant of how aggressive we need to be with regard to imaging, whether it's MRIs, whether it's mammograms, whether it's ultrasound, but not so much once you've been diagnosed, then we shift to those other models and laboratory tests in order to define their particular risk. Once you have cancer, it's now 100% for that particular person.

Aimee Sax:

Yeah. Well, I'm mindful of everybody's time, but I'm also mindful of the amount of questions. So I'm going to ask one more question, even though it is technically it is 6:00 here in California. We got questions about this concept of a false positive. So would love to hear you talk about that.

Dr. Noam Drazin:

Yeah. False positive on the MRD or false positive on the marker or both?

Aimee Sax:

Well, I guess both.

Dr. Noam Drazin:

Yeah. So I thought I saw something on the marker as well. So I'll address both of those. So we do occasionally see false positives. They tend to be low value numbers. So all those tests, the MRD tests, give us quantifiable mean tumor molecules per deciliter, so an actual quantity. So if it's a very small number and we have very little, I guess, assessment that this might be coming back, then we sometimes get a follow-up MRD test within a month to see if that disappears. And occasionally it does disappear. And if it does disappear, then you move on. The issue of false positive tumor markers is a more complicated one because again, it is a very non-specific test. It's not based on pathology, it's not based on this new technology. It's old school. So you can have lots of things that can raise a CA15-3 and a CA27.29 and a CEA. So you might be fishing a lot more for potential disease with those tests rather than the MRD test.

Aimee Sax:

That's helpful. Thank you. Well, we are so grateful to Michelle for sharing your story, and of course to Dr. Drazin for sharing her expertise on recurrence risk testing and helping our community feel so much more informed and empowered. Thank you so much for your time tonight. It truly means the world to us.

About Sharsheret

Sharsheret, Hebrew for “chain”, is an international non-profit organization, that improves the lives of Jewish women and families living with, or at increased genetic risk for, breast or ovarian cancer through personalized support and saves lives through educational outreach.

With regional offices in the Midwest, Northeast, Southeast, West, and Israel, Sharsheret serves 275,000 women, families, health care professionals, community leaders, and students. Sharsheret creates a safe community for women facing breast cancer and ovarian cancer and their families at every stage of life and at every stage of cancer - from before diagnosis, during treatment and into the survivorship years. While our expertise is focused on young women and Jewish families, approximately 25% of those we serve are not Jewish. All Sharsheret programs serve all women and men.

As a premier organization for psychosocial support, Sharsheret works closely with the Centers for Disease Control and Prevention (CDC) and participates in psychosocial research studies and evaluations with major cancer centers, including Georgetown University Lombardi

Comprehensive Cancer Center. Sharsheret is accredited by the Better Business Bureau and has earned a 4-star rating from Charity Navigator for four consecutive years.

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

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