

Resuming Cancer Screenings & COVID-19

National Webinar Transcript

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Presented by:



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Jenna Fields:

Resuming Cancer Screening and COVID-19

Hey everybody. Welcome this evening to our webinar resuming breast cancer screenings and COVID-19 updates with Dr. Laura Esserman. We are so thrilled to have her this evening and really appreciate everybody on this call. I'm Jenna Fields, I'm the California regional director for Sharsheret. I'm going to speak for just a few minutes and then turn the floor over to Dr. Esserman. So I just want to share a little bit about Sharsheret if we are completely new to you. We are the national Jewish breast and ovarian cancer support organization. We provide free psychosocial support for people of all backgrounds across the country providing support and education, no matter where you are in your breast and ovarian cancer journey, as well as those who have increased genetic risk.

We know this is a really difficult time right now. We have a team of social workers who are available to talk with you about what you're dealing with. So please don't hesitate to reach out to us. We also provide community help education. We've been doing webinars every single week since the COVID-19 pandemic started. I want to plug two of our upcoming webinars. One is this Friday. We're doing a Shalom, Shabbat which is going to be during the daytime and an opportunity for anyone to join us to reflect on the week, the month, the year that has been and to feel empowered and have an opportunity to reflect at the end of the week. And then we are also doing a program I am so excited about which is on August 16th, Ruth Bader Ginsburg's personal trainer is going to be our guest speaker and he's going to be talking about the RBG workout. How she stays strong and so can you in partnership with 2Unstoppable. So we'll be sending out information about that training. Right now you can actually register for both of those webinars. The link is in the chat box.

A quick medical disclaimer. Sharsheret is a national not for profit cancer organization and does not provide any medical advice or perform any medical procedures. The information provided tonight is not a substitute for medical advice or treatment for specific medical conditions. We always want you to seek the advice of your physician or qualified health provider. I want to thank our sponsors, the Sigmund and Edith Blumenthal Memorial Foundation. I see there's a survey that popped up on the screen so we're also going to ask you to take a quick survey as I'm finishing here which is our Zoom etiquette. So everyone on this call has been muted. Please keep yourself on mute throughout the remainder of the program. If you have questions we have a great active chat box. Please type in your questions and when we get to the end of Dr. Esserman's presentation we'll go back to those questions and get to as many as we can. If you would like to remain anonymous now is the time to turn off your video at the bottom left hand corner of your screen by clicking stop video. You can also rename yourself by clicking on the three dots on the top right side of the screen so your name is anonymous.

This program is going to be recorded, so if you miss anything we will be sending out the recording within the next week. But your video will not be on the recording. Only the video of the people speaking. And now it's my pleasure to introduce Dr. Esserman. She is an MD/MBA and an internationally recognized breast surgeon, breast oncology specialist and a visionary in personalized medicine who is revolutionizing breast cancer screening and treatment throughout our nation today. As a professor of surgery and radiology at the University of California San Francisco and the director of UCF Carol Franc Buck Breast Cancer Center, Dr. Esserman's breast cancer work expands a spectrum from basic science to public policy issues and the impact of both on the delivery of clinical care. She has been involved with many studies, but I want to highlight her creation of the University of California wide Athena Breast Health Network, a learning system designed to integrate clinical care and research as it follows 150 women from screening through treatment and outcomes and as part of the network, she's spearheading the development of the Wisdom Study to learn how to improve breast cancer screening by testing and comparing the safety and efficacy of a personalized screening strategy.

She's published more than 300 articles in peer review journals and is regularly consulted by the prestigious scientific business and consumer media. I could read so much more from her bio, but I won't

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because I want to turn it over to our esteemed presenter Dr. Esserman thank you so much for sharing your time this evening.

Dr. Laura Esserman:

You're welcome and thanks so much for inviting me to talk. I'm happy to talk to you guys tonight. I think it's a really challenging time for everybody. I think everyone is sick of sheltering in place or social distancing and wearing masks and it's feeling like when is this all going to end? Are we ever going to get back to normal or what is the new normal? So I think that for the time being I think we have to really think about how we deliver care in the time of COVID.

So first just in case any of you wanted a little more detail about what COVID really is. So the virus is SARS-CoV-2 the disease it causes is COVID-19. 19 actually stands for the year that it was discovered, that was in November 2019. So that's why it's called COVID-19. So coronavirus is an RNA virus and viruses work, they by themselves are innocuous things. They're basically a piece of RNA surrounded by a protein envelope. By themselves they do nothing but what they do is they find a way into normal cells and harness the machinery of those cells to basically replicate themselves. They basically turn your cells into a little virus factory. This virus originated in bats. Went to pangolins and then jumped to humans. So it's got pieces of bat, pangolin and now human and the disease itself actually ranges in severity from mild to lethal and we're going to focus on this thing because this comes up over and over again. Almost every disease we know of has this range where some people get very ill or just like a cancer it can be incredibly aggressive or it can be really innocuous. That's true for this virus too.

Now, how does the virus, how does this particular virus get in? It gets in through something called ACE inhibitors and these ACE you may have heard about it through the ACE receptor. ACE inhibitors are very common blood pressure medications. These are things that are regulated. The ACE inhibitors are in many cells. One of the reasons why we think that kids are not as infectious as adults is because they have fewer ACE receptors. Another interesting thing is this little thing TMPRSS2, this is actually regulated by male hormones and testosterone and this is actually a target in prostate cancer for hormonal suppression, androgen suppression is through TMPRSS2 and this combines to when the virus binds to the ACE inhibitor it's then able to sneak in that way. So that's the virus, that's what it looks like and what's a pangolin? Well a pangolin is just a scaly, just in case you wanted to know what a pangolin looked like. It's a scaly anteater like animal and this is probably the reason why this happened is that pangolins are sold in these Chinese markets and that's actually how the virus got from the bats to the pangolins to people in this very crowded market.

So this will not be the last pandemic and you'll see when we get back to it we really have to have put things in place so that we know how to respond so every time something like this happens the economy doesn't stop. Your world doesn't stop and we have to be able to think about it. So it's interesting when you look at the incidents of death of coronavirus worldwide, when I first made this slide there were eight million cases and 435 deaths. A month later there were 14,000 cases and almost 600,000 deaths and just yesterday we are up again another four and a half million, up to 18 million with almost 700,000 deaths. So this virus worldwide is just going at this incredibly steady pace and unfortunately we in the United States are leading the charge.

So, what have we learned and what happened when the virus first came into play? So when the virus, when it first became clear that this was going to be a pandemic what did we do? All these hospitals shut down and why did that happen? It happened because we just weren't prepared. We didn't have mechanisms in place to screen everybody. We didn't have enough personal protective equipment. We didn't know what the pace was going to be. We didn't know if our facilities were going to be overwhelmed and some of them were. Like in New York I think Colombia or Columbia Presbyterian

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Hospital at one point had 1500 people in their hospital system with 500 people in their ICUs and people in not just in operating rooms, but in cafeterias that were set up. So when that happens simple things happen. I mean oxygen tanks run out because they're not in a standard way of doing things. This is what all hospitals are trying to avoid is being overwhelmed so they can't take care of people.

We needed time also to figure out how to organize surgical procedures. When you put someone under anesthesia and you're incubating someone, all their air sterilization of particles can infect everybody in the room. So, again we had to have testing in place, make sure the people didn't have the virus so we wouldn't put them at risk when they were put to sleep nor the anesthesiologist nor the teams in the room.

We needed time to figure out exactly how this was being spread? Was this being spread through coughing? Is it being spread through surfaces? And by and large, this virus is spread in a respiratory fashion. And the most important thing you can do is wear a mask. And if everybody were to wear a mask, if 95% of people in this country wore a mask it would be the equivalent of a shutdown and we would be able to get this in control and especially with the prevalence today we must do everything we can to fight against the politicization of mask wearing. It's nothing to do with democrat, republican, smart, stupid, red, blue, black whatever. It's all about being smart and wearing a mask. I think it's important that we don't ever want to be in a position where hospitals are overwhelmed with COVID cases and where that's true that's not a great place to get your care.

So, how did people adjust? Well people adjusted with things that we actually have known now for many years and in fact, one of the ways in which we're advancing care for women with very aggressive breast cancer is to start with systemic treatment like chemotherapy or biologic treatments first because it turns out the order or treatment doesn't change your survival, but it can really improve your options. If you know whether someone's responding, you know that they're getting the right medicine. And if you have a great response, your surgical options may be very much better. You could do quite a bit less. So this becomes super important and guidance from the oncology society is recommended at the beginning when we had shut down our ORs to think about starting with systemic therapy.

Now, and also to remind people that treatment is not an emergency. Treatment isn't an emergency because you know about it. It's not usually because it showed up that morning. It's usually been there for months or longer and that there's plenty of time to sort out what your options are. Getting special tests to really understand. Getting the treatment right is much more important than doing it fast. We know that. It just is something that people don't understand very well. How many major medical centers and the leaders in care already follow these practices and in fact the focus of practice changing trials like I-SPY and others is really all about trying to figure out how to get that treatment right so we can accelerate the pace of learning and increase the chance that people will survive even a bad cancer.

Now one of the big challenges for people is care support at the medical center and for many months no one was allowed in with people and we went back to a time when people were given information alone and told about things by themselves and that really was a struggle and people getting care often were isolated and couldn't be around someone. Someone getting chemotherapy was told not to go out, be completely isolated and couldn't be really around someone who was going in and out of the home. This is just when you need it most and just when you need your friends around you, having that void is a big problem. So we can't just say, "Oh, well that's COVID and we have to do that." We have to make adjustments to make it better for people.

So I think a lot of active cancer patients and survivors faced this heightened challenge because they felt much more vulnerable. Now it turns out that when you're getting chemotherapy you are at higher risk and if you happen to get COVID your outcomes are worse. So you shouldn't be the one going to the store. You shouldn't be going out doing a bunch of other things. But you can get care support through

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Zoom, through calls. It doesn't mean that it's not important that you shouldn't be doing it. But I think this made people at all stages, even when they're well into their survivorship period, it intensified their fear of recurrence. People then were afraid to go to the store, they weren't getting safe access to basic nutrition and healthy things. I think that plus all the demands on households taking care of kids and all the things that have made it so challenging in this pandemic has made it really very challenging. And we know that social isolation increases anxiety and depression and we've seen this. Our psychosocial services at our institution and almost all institutions have been overwhelmed by calls and appointment requests.

So, how do we try and adapt? The silver lining is that every crisis brings opportunity and finding better ways to provide support may actually change the way we do support, even after COVID. Having the support of loved ones is just simply an essential part of care. No patient should ever have to face any treatment decision alone. Video visits are now, were vanishingly rare prior to COVID. Now all of a sudden they're paid for by every insurer, by Medicare, by Medicaid. 80% of all visits are being done that way and I don't think we're ever going back to the old way of doing things. If you have to come in, you come in. If you don't have to come in, you can do a video visit. This is good for patients and it's good for physicians. The good thing is that family can join, friends can join. They can be part of that video visit so you don't have to be alone. Caregivers and note takers can join in person appointments by Zoom. There's no reason not to do that and if you want someone to join insist on it. Don't feel like you have to then start and forget to bring someone in. Insist that the people you want to be present should be present.

We have a program where we use students as interns, we have a post baccalaureate internship program. People spend one or two years in our program and they have been doing it for decades calling patients ahead of time. Finding out what their concerns and questions are providing the support to the patients, I mean to the physicians and then showing up at the sessions and recording the consultation and they are the note takers. And in fact you can do that in COVID just as well and now more people are taking up those services and spreading something that we think is really, really important and they can be the ones to help get families to participate in the Zoom calls.

Another really important thing that's happened is that we transitioned our survivorship and wellness programs into a telehealth based program and this was actually great because it expanded the reach of the program and it tripled the number of people that could participate. If you think about people who work, they have small children, they live far, access is actually a really huge problem. So this may actually really increase the reach of our psychosocial group support programs and again magically now insurance companies are covering that. So these are the silver linings and are really important.

Okay, so what about screening and what about care? I mean if I have cancer should I get care? Do I need to get screened? Should I go in? So initially screening was put on hold. So really from March until about middle of June, middle of March, middle of June everyone shut down. I think until we knew what was going on people just weren't going in. So then the real question is, is it safe to get care? Really what should I do? So I'm going to take you through a series to try, a series of examples to show you what the relative trade offs are. So you want to compare, what's my chance at getting COVID versus finding an early cancer with screening where it might really benefit me to have that cancer taken care of early. So if you take 100,000 women and you say what is their chance of getting COVID if they go into get a mammogram. That's about one to three versus 100 to 200 people who might have a cancer that would be found. And if you're older where the cancer rates are higher, now we're talking about something that's 500 times more benefit. The chance of finding cancer of course depends on your age.

Dr. Laura Esserman:

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Well what about your chance of dying if you skip cancer treatment compared to your chance of dying of COVID? So if you take a million women and you go in for 10 treatments that are important your chance of dying of COVID would be about three versus somewhere in the 100 to 500,000 fold. So we're talking about 100,000 fold difference. And again, the risks and benefits depend on your age, your overall health, everything else. Even when you're older, where you're at much bigger risk of dying of COVID if you got it, you're still looking at something that's 1,000 to 100,000 times more important to get treatment for in terms of saving your life. So if you have cancer don't skip treatment. If you have cancer, find out what your treatment alternatives are because you might be surprised that some of them are much easier. Maybe you only need hormone therapy or maybe you could do hormone therapy for six months before you have surgery. There's lots of options and there's lots of ways to mix and match treatments. That's one of the things that we've learned.

Now is this true for everyone? Well what does this depend on? It depends on the prevalence of SAR Co-V2 in the population. Now this is estimated for the prevalence in the bay area which is one percent. I was just in Miami where the prevalence is 20% so it's quite a bit different there and the situation is different. It depends on your access to transportation to a medical facility. In that first case example I gave you was if you drove and you didn't have to take public transportation and it also depends on whether the healthcare facilities in your area are taking safety precautions. Are they screening everybody? Do they have ... Are they making everyone wear masks? Is everyone gelling up and is everyone being careful and are you minimizing the risk of exposure in waiting rooms, et cetera.

So if you add the challenge of access and public transportation and we'll just take the example of screening, it's still the chance is about 10 to 50 times higher that you would find cancer where the benefit would way outweigh the risk of getting COVID. Well what if the prevalence is 10%, or even 20%? Again, if it's just that 10 to 20 you're still, it's still reasonably easy to go in, as long as you can get there safely. But if the prevalence was 10% and you had to go into a public transportation, now it's maybe 10 fold higher or 20 fold higher starting to be not quite as big a benefit.

And if you have contact with many, the prevalence is 10% and no one is wearing a mask, okay your chance of getting COVID is higher. So it does depend, right? But if you're in an area where the prevalence isn't high you can drive to a facility, there is no reason for you not to be able to get away and do things safely. If you have to take public transportation, no one is wearing a mask and especially if you're not going to wear a mask, don't go out because the risk of this virus is that people are ... it's spread by people who are not ill. That's the problem. So if anybody wants the math here it all is. I won't go into it and bore you. But I wanted to let you know really that we did go through the math and it's all been checked with the epidemiologist.

So what's the bottom line if you have safe access to care. If you wear a mask. If you go to a facility that follows the public health precautions and everyone wears a mask it's safe to proceed with care and you are worse off by not getting your cancer treated, no question about it.

So, then people would say, "Well how do I know I should even go in and get screened? Does it really matter there's all of this confusion about screening." Does everyone need the same screening treatment and what's the right frequency to screen? This general confusion really is highlighted by the crisis with COVID and makes it even more important to know when should I screen? Maybe my friend Sandy is screening every six months. Do I need to screen every six months or what about my physician told me to come in every two years and my radiologist told me to come in every year. So how do I know what to do? Well this is actually a big problem and it didn't start with COVID. The experts don't agree and there are at least seven different guidelines and some say start at 40. Some say start at 45. Some people say start at 50. What's a person to do? How do we figure all this out?

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So let's take a step back. So why do we screen in the first place? We screen because breast cancer can be deadly. There are more than 40,000 women a year who die from breast cancer in the U.S. alone. By the way they're dying despite screening every year. So we've made some progress. Some of it's from treatment. Some of it's from screening. But clearly what we're doing still isn't good enough. So how do we apply what we've learned about breast cancer treatments to screening? We don't treat everybody the same when they have breast cancer. So maybe one size doesn't fit all for screening either. So it turns out there have been a lot of advances in science and technology. We know a lot about, a lot more about prevention. We've learned a lot more about risk assessment. About 24 years ago the BRCA1 gene was sequenced. 23 years ago the BRCA2 gene was sequenced. There are now nine or 10 genes that are associated that you can inherit and have a much higher risk of getting breast cancer. Now these are pretty rare, only one to two percent of the population maybe has these.

But then there's a bunch of genes that you can inherit that the small variations and small differences actually make a difference in how risky it is for you to get breast cancer. It turns out the laws fortunately that most of these have stayed intact, protect you if you have genetic information that tells you at risk, you can't lose your insurance. That's what HIPAA actually really is. It's a health portability act, actually protects you and then there's the GINA law that also says that you can't be discriminated against on the basis of genetic information. And the Supreme Court actually said you can't own the genome, so Myriad no longer has the patent on genetic testing, which then opened the door to next gen sequencing and much cheaper, faster better ways of doing these tests and gosh, now we can do the genetic sequencing for the price of the mammogram. So that turns out to be a huge and actually cheaper than a mammogram. So maybe you should get screened based on your risk. Family history, genetics, breast density, age, your race, other types of breast disease, lifestyle and exposure.

So what we designed was a study called Wisdom, women informed to screen depending on measures of risk. We said, "Well we think that it's high time that we look at trying to personalize screening." Some people need more. Some people need less and even within the guidelines we could test to start down the path of trying to do more for some, less for others and as we learn we can further improve. If you had a super low risk of getting breast cancer you might just get the harms of screening and what are those? Getting called back, any of you who have been called back for a mammogram it's a terrifying experience and who wants that if you don't need it, right?

But if you are at high risk it's probably important for you to screen even more frequently and more important than screening is prevention. If you actually have high risk the first thing to do is reduce your risk and screening doesn't do that. It reduces the risk that you'll die of the cancer, but it doesn't reduce your risk of ever getting that cancer. So we wanted to put a comprehensive program in place and test it against the annual screening starting at 40. Any woman between 40 and 70 can do this anywhere around the country. You could go to Wisdomstudy.org and sign up even while you're listening to me. It's that easy. But we're asking people to commit and be part of the study to help us learn all changes, all advances in science come from people participating in science and believing that they can make a difference and if you've had cancer, I'm sure you must know 10 people who haven't had cancer who can participate. We want to randomly assign people to personalize screening versus annual screening because that's one of the ways we learn. But it turns out that we want everybody to participate so that if you have a strong preference and you want the personalized arm or you want the annual screening because you're not going to do anything other than annual screening, then choose that arm and there's lots we can learn and you can participate.

And we want to ask, right? Is it just as safe to do it this way? Does it reduce false alarms to do a personalized approach? Do most women actually prefer to have a personalized approach? By knowing your risk, are you more motivated to take up preventive interventions? And at the end of the day do we do better? Is it better value for you and better value for the country? We know that risks vary based on

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race and ethnicity. African-American women used to be less likely to get cancer, now they're catching up. But their mortality rate is higher because they are more at risk for certain kinds of cancer like triple negative cancers but not everybody. So it's really important to us that people of all backgrounds participate in this study because we want our policies to reflect everyone in the country. And the great news is you can do this while you're sheltering in place. This is something you can do online. So it is actually time to improve the way in which we screen and it's something that everyone can help us with and if you do join us we hope you'll stay with us. You just have to make sure that you stay in contact and you say, "Well this is really important to me. This is a way I can contribute and learn for myself, my sisters, my mother, my kids and all my friends."

We have almost 30,000 women on board. We do want to get another 50,000 women if we can. So spread the word. So it's very remote. You can do it remotely and even if you're in the personalized arm, the genetic testing kits come right to your door. You do have to go in and get a mammogram at some point. So, again what's the silver lining. Some things actually are better. We have a streamline process for telemedicine and care support. And it's clear that we need to determine who needs what. So really what that says is that research is essential and just like we said around the program for screening, part of the reason why I'm pushing a personalized medicine approach is there are people who have really indolent cancers. They're very low risk. So why, especially in a pandemic? If you were 70 and had an ultra low risk cancer, you don't need it, you barely even need hormone therapy. You don't need to go in for radiation. There's a lot of things you don't need to go. So if you have less risk, you want to do less. You want to de escalate.

If you have a higher risk you want to do more. If you have a great response to therapy, you don't have to keep getting more and more therapy. If you don't have a good response then you have to do more. So this is the way in which personalized medicine is going to be changing not just breast cancer actually, but all of cancer. This is actually part of a big trial that we run called the I-SPY trial. This is actually a trial, we did not shut this trial down during the pandemic. A lot of people shut down all research, but I actually believe I'm the national leader of this trial and I felt like the options that we offered as part of this trial actually gave people better outcomes than the standard treatments that we have. And over the course of the study we've had two people who have gotten COVID, one during treatment, one in survivorship and everyone who's done fine.

I think the focus of this trial really is to say who are the people who are most at risk to die early? Those are people with stage two and three breast cancer whose tumors are two or three centimeters at least or node positive. These are the people who are likely to get recurrence early. And what we really tried to do is move the treatment to an earlier stage. So all these new medicines that are being developed, we want to give them not in a med aesthetic setting, but up front so that we can prevent people from getting that aesthetic disease. Again it's that notion of changing the order of therapy. I'm a surgeon. Someone comes in with a cancer that's likely to be risky because it can spread somewhere in the body, surgery doesn't fix that. Systemic treatment fixes that. So you want to use your craft wisely.

So it also gives us this chance to learn early in the course of care and by creating one trial where we constantly put in more and more agents and we keep testing. We've tested now we're on our 24th agent that's come in. We have 20 sites across the country that are learning together. Helping change the way in which we approve medicines and move things forward. This is the whole number of cases that have come through. And what we're trying to do, this is someone who had a big cancer. You can see this big cancer right here. This happened to be someone who was on one of the immuno oncology agents and not everybody, not everyone, not every type of cancer responds to this. But we figured out which tumors responded and it went away. Why is that important? It's important because and this is the difference in our hormone negative cancers were the ones that responded the best.

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Why did that matter? Because people who respond well have a 92% chance of survival whereas people who don't respond well are down around 65%. So we want to find out sooner, we want to drive these changes. This is the kind of thing that we're trying to do. So we did not change, we did not stop this trial because we've got the new agents which we think aren't going to matter. But we did make a lot of changes to the trial. Patients who are doing well as I say instead of making them come in for an in person visit, we can do video visits in the weeks when the treatments weren't being given. We reduced some of the interventions. We allowed labs to be drawn locally. There's lots of ways in which we can make it easier for people to participate in research because truly that's ... Clinical trials are today's trial therapies. Tomorrow, sorry. They're tomorrow's therapies that you can get access to today. That's the purpose and a lot of people think, "Oh, why would I be part of a trial?" Well, that is the vanguard. You want to be part of, I think better care, and you often get a study coordinator who also gives you special attention which is good.

So now why do I bring this up? Because with COVID there's an even greater urgency. At one point in the pandemic, more people were dying of COVID than heart disease or cancer altogether. And what is the real problem with COVID-19? The problem is not that everyone is getting sick and dying. In fact, 90% of people who get COVID don't get that sick. Half the people who get it, it's a mild disease. But the problem is for about 10% of people they get very sick and one or two percent will die and we don't really understand why that is. So like cancer, everyone doesn't have a lethal disease and they don't have a lethal case. So this is important for everyone to think about how we think about disease and how we think about treatments and how we think about personalizing treatments. So solving this problem is crucial, not just for this virus, but for other future viruses.

So we have to prioritize finding these high impact treatments for people who are critically ill and getting into the ICU. So, saving the person who's got a mild case just like someone who's got a very mild case of breast cancer and over treating them doesn't help them, right? Over treating someone with a mild case of COVID isn't going to save the person in the ICU. Just as important as finding a vaccine is finding the treatments for the people who are really sick. The economy is not going to recover until we solve this problem and this is our problem. We have truly well over 100,000 deaths that we should never have had. But here we are with five million cases and 154,000 deaths. Still high, coming down a little bit. We have to solve this problem.

So, what was the fastest way forward for those who are critically ill? We actually took the I-SPY network and all the principles we put in place for that I-SPY trial which is the first and longest running platform adaptive trial where you're testing multiple agents with one control. So it's a much more efficient approach and we've taken that same platform and turned it into a learning engine for COVID. We partnered with our colleagues in the ICU and we're looking again for those same exciting new agents that might make a difference. There's a lot of repurpose drugs that we can use. Finding agents with a big impact with speed time to recovery and drop mortality and finding fast what does have an impact and what doesn't. And harnessing that same infrastructure and building a learning engine and that's how we built the I-SPY COVID trial.

So we have four drugs at a time and we just opened up and that's really exciting. So what are we looking at? We're looking at things that change the immune system because some people get sick because their immune system overreacts. So it's just the opposite of what we need in cancer. So we'd have to drop that down. Some of it's about repairing the cells that are attacked. You know that it is drugs that are affecting how you clot. Drugs that are affecting how you form the problems I'm looking at drugs for Cystic fibrosis that stop that allow people to breathe better. Then combining that with antivirals. So the exciting thing is this trial just opened. We opened our first patient last Thursday. We're very excited and the rest is; there are eight more sites opening up this week. So we're very excited about that.

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And so I'm very optimistic because I'm optimistic by nature. I believe that research is the key to changing the world and I think that there is ... one of the things that's amazing is the unprecedented, I would just say that the COVID RND lines I have been working in drug development for over a decade and I have never seen the kind of collaboration people have. People are finding everything they think could possibly work. People are working together, thinking about how to manufacture things. People should take hope. I am sure that within that pile of ... I mean I can barely keep up with the things that are promising to be able to test. What we have to do is have efficient platforms to test them and if everybody were on a trial like this we would find it by the end, something at the end of the year. So be hopeful.

So I would say before opening up for questions, I would say the COVID for now is pretty well established in the population. So for many months to come we're going to have to live with it. So you're going to have to make some adjustments. Everyone has to wear a mask. So, that's okay. That's not going to kill anyone to wear a mask. Get everyone you know, every kid, every adult, everyone should just be wearing a mask. It's safe to get care if the prevalence in your area is fairly low. You wear a mask and your healthcare facility is following public health precautions and if you have cancer even if the problems in your area are not that low, it's still by far safer for you to get treatment. But you can be creative and work with your physicians about better options for care and rearranging the order of therapy because that's safe.

So we have to find ways to integrate social support, that really matters. Maybe we can do better than we've done in the past. And I'd say the critical research questions need to be asked. The key to better options for screening, care, survivorship and COVID are all going to come from research. So with that I'll take questions.

Jenna Fields:

Thank you so much Dr. Esserman there was a lot in your presentation to digest and I really appreciate the fresh perspective you brought to a lot of these issues. I'm going to take questions in the chat as well as questions that have come in advance. I'm going to start with questions about COVID. So, questions about risk for COVID-19 and someone's immunity. Someone said that she's out of chemotherapy for five years, but was told that her immune system is still impaired and she's at higher risk for COVID because of it. Is that something that you are advising patients or what are your thoughts on that?

Dr. Laura Esserman:

I think that depends. I mean most people who are out of chemotherapy are not at persistent risk. There are some people who's white count is affected and just have never recovered. That's actually fairly unusual. But that may be true. You should make sure that that really is true and that your immune system isn't working. Once your counts have recovered you really aren't at increased risk. And again, if everyone takes precautions it's actually fairly safe. Remember if everyone wore a mask, if we just got that message out, everyone would be so much safer.

Jenna Fields:

And would you recommend going to an outside imaging facility versus one attached to a hospital? Does that affect risk at all?

Dr. Laura Esserman:

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I think, again it depends. Some of the hospitals I think are really well organized with the way in which they are using personal protection. I mean everyone is using personal protective equipment and screening everyone at the door. If the facility that you go to is expert, again it's important to go to a facility where there's a lot of expertise in reading mammograms. If not, your chance of getting a false positive or missing a cancer is much higher. So really important to go to a place where there's a lot of expertise and people are used to doing that. And I think it's important to go to a place where you're sure that they are taking precautions and they have the resources to keep everything clean and safe for you.

Jenna Fields:

Great, great. A question about MRIs versus mammograms. When is an MRI recommended versus a mammogram?

Dr. Laura Esserman:

Okay, MRIs are way overused. I use MRIs in the part of I-SPY and I worked with a person who actually developed all the sequences for MRI, so I know lots about them and I think they're great. However, they're often misused and used too often. If you have a new cancer and it's found on exam and it's not seen on mammogram and MRI is important to see what's there. If you have very dense breast tissue an MRI could be useful. For screening only people at much higher risk should be given MRIs because their false positive rate is extremely high, 30 to 40%. And the only way you can find things sometimes is with an MRI biopsy and people over call things on MRIs all the time. So it's good to use if you need it. If you're in one of those like less than five percent of people are really recommended in Wisdom to use MRIs. But it's the people truly at a high risk.

Dr. Laura Esserman:

If you're a mutation carrier or you really have super high risk, yes it's important you should get screened every year with an MRI every year, with a mammogram and alternating in between. And by the way, if you have a very dense breast and if you're at high risk it's not ultrasound you should use, it's an MRI. But if you're not at high risk and especially if you've got relatively [inaudible 00:45:26] breast issue you don't want to get an MRI it's not helpful.

Jenna Fields:

And what are your thoughts on thermography as a way to-

Dr. Laura Esserman:

Great idea, doesn't work.

Jenna Fields:

Okay.

Dr. Laura Esserman:

Don't waste your money and it's not covered for a reason and I'm sure you could take ... Think about the money you would spend on a thermogram and go find something really fun and good to buy with that and go do that.

Jenna Fields:

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Question about BRCA testing. I have BRC-2 mutation as does my daughter and sister. My granddaughter is 11. At what age do you recommend testing?

Dr. Laura Esserman:

So we don't usually recommend people get tested until they're like at least over 18 and you have to think about it. The hallmark of a BRCA cancer is that you get it at an early age. But you can look in families and see sometimes families get it at 40s and some are getting it very young. So, if it's really if the history is young then you have to think about it early on. A lot of people when they get to be 21 or so should they get tested or not? I think that it's probably better to get tested because remember there's a 50-50 chance that you'll be negative and I was arguing with that with one of my patients and she said, "Well no point in my getting tested." I said you know she was having all these false positive exams. I said, "Get tested before we do another biopsy." She turned out to be negative. So I think most people think they've got it, until they get tested. So you might as well get the test and figure it out if it's in your family. And we'll see, maybe Wisdom will show us that sometime around the age of 30 everyone should know what their mutation status is.

Jenna Fields:

So that's one of the questions we got. Does the Wisdom study include genetic testing?

Dr. Laura Esserman:

It does, yes.

Jenna Fields:

For what size panel?

Dr. Laura Esserman:

We actually are focusing on the nine genes that are associated with breast cancer risk. We actually partnered with a company called Color. They actually test, they have a 30 gene panel. But many of those genes are about colon cancer and so they're really only nine or ten genes that really are associated with any significant risk for breast cancer right now.

Jenna Fields:

And I saw this asked and answered in the chat box, but I'll just confirm with you. Can men participate in the Wisdom study?

Dr. Laura Esserman:

Not men. Men can participate in I-SPY if they get breast cancer. But, the reason is that the risk of getting breast cancer for men is so rare that it doesn't warrant screening.

Jenna Fields:

So what is for men, who are high risk? What is the recommendation for men for screening?

Dr. Laura Esserman:

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So if you are a brca carrier for example. I think it's really probably getting a mammogram once a year and probably for men getting an exam is probably one of the most important things. So at least doing that probably on a six month basis.

Jenna Fields:

And I'm going to take two more questions and then we have run out of time. Regarding I-SPY COVID, is it open to those people with breast cancer?

Speaker 3:

Can I ask a question

Jenna Fields:

Oh, you know what we'll take all of our questions through the chat box and any question I don't get to tonight, we'll ask Dr. Esserman to follow up with us after the program.

Dr. Laura Esserman:

And I'm willing since we've got about eight minutes left. I'm willing to stay a couple extra minutes if we ... I'll give you short answers. Let's try and get through as many as we can.

Jenna Fields:

Thank you Dr. Esserman. Okay, the I-SPY COVID study is open to those with breast cancer or breast cancer survivors?

Dr. Laura Esserman:

The COVID trial is really for people who are critically ill in the ICU.

Jenna Fields:

Okay.

Dr. Laura Esserman:

So it doesn't matter if you have breast cancer or not. If you had breast cancer and you are critically ill and you were at a site that's participating it would be open to you, yes.

Jenna Fields:

Okay. And then one of the things that we actually hear a lot at Sharsheret was asked in the chat box is around communicating clinical trials to patients, so that we can increase education advocacy so it's not so scary.

Dr. Laura Esserman:

Right.

Jenna Fields:

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What have you found most helpful to be able to communicate that?

Dr. Laura Esserman:

Every single treatment that we have come from a clinical trial. If you had a HER2 positive breast cancer everyone would want to get Herceptin. If it weren't for all the people who participated in that study, there would be no Herceptin. Every new trial has to be introduced in a way that it has to be tested because a lot of the things we think will work, actually turn out not to work. And many of the things do and that's how we make advances and we're trying to do it in as efficient a way as possible. But participating in studies usually means you get the standard of care plus something else. It's not that people are not given appropriate treatment. Usually high quality are in trials. Just like in the Wisdom study, none of the treatment recommendations are outside of the guidelines. It's just the guidelines are very varied, right? So we're trying to sort that out and with that I mean it might be that what we find is that from this trial we can go even farther and do further refinements. But for now it's all within one guideline or another.

Jenna Fields:

And going back to screenings, for people who are long term survivors, someone who had a bilateral mastectomy and chemotherapy, what is your typical recommendation for screening for long term survivors?

Dr. Laura Esserman:

So, I think it depends. If you had a bilateral mastectomy and you had a triple negative breast cancer your risk period is usually five years. So you probably don't need any screening after about five years. If you're hormone receptor positive the problem with those your risk up front isn't as high, but the risk persists and it can persist for 20 years. So just being aware of your body and thinking about it. Again you don't necessarily have to screen more than every year and if you had a very low risk cancer and again people got treated a lot 10 years ago or 20 years ago that wouldn't get that same treatment today. So reassessing where you are and how much risk you have and you have to put in perspective with what your other health conditions are. But you don't want to over screen there either.

Jenna Fields:

Right, right. And we got a follow up question about breast MRIs. What percent do you deem as high enough risk to need a breast MRI once a year? This person has a 25% risk, tested negative for gene mutations, but has a strong family history of breast cancer.

Dr. Laura Esserman:

So I think all that depends a little bit on your breast density. That's one of the reasons why we're doing the Wisdom study. We don't do MRIs except for the people's who's five year risk is five or six percent. We think that you really need to be in that risk of 30% lifetime risk or higher. And I think it really depends. If your risk came because in your family there's a known mutation and you don't have it, you don't have that risk. That's really important to know. If in your family there's a lot of breast cancer and no one's got a mutation then you can't explain your risk by mutation and you then have to presume that you've got that higher risk too. It's another reason why we're trying to do the Wisdom study. So we're actually really trying to figure out better ways to assess risk, communicate it to patients and find the appropriate pathway forward to give people the best care.

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Dr. Laura Esserman:

And if you have high risk by the way, the most important thing for you to do is go sit down with someone that knows a lot about breast cancer prevention. And find out especially if everyone had hormone receptor positive breast cancer in your family and you're young, take Tamoxifen. Take five milligrams. Take 20 milligrams whatever it is. Why not drop your risk in half, right? If you're older there's three medicines that are approved to take for breast cancer prevention. Do something. If you're overweight, try and lose weight. Get exercise. Think about the things that you can do to really reduce your risk if you're at high risk. That's really just as important as screening, more important.

Jenna Fields:

I think that's a wonderful way to end. I know we had more questions in the chat box. Dr. Esserman you offered to stay a few extra minutes so we can go through them.

Dr. Laura Esserman:

But before we do that I want to tell everybody don't forget to tell everyone you know about the Wisdom study. Wisdomstudy.org. Tell everyone you know. Again if you all want ... Everyone should demand to have better, right and the only way we get better is to try some new things. So, I would really ask everybody to tell everyone they know about it. Okay, yes.

Jenna Fields:

Thank you. And we put the link in the chat box.

Speaker 3:

Excuse me for a moment. I am only on the telephone and if I don't get the chance because the chat box takes first, is there any way to text the wonderful lady here to answer one or two questions outside of this meeting because I am just on the telephone. I didn't know.

Dr. Laura Esserman:

Send an email to Sharsheret and she'll send it to us and we'll get you an answer.

Jenna Fields:

Yeah.

Speaker 3:

What is it Sharsheret, what? How is the email to Sharsheret?

Jenna Fields:

If you registered for this program we'll follow up with you after with our email so you can ask your question. We'll make sure to get it to Dr. Esserman.

Speaker 3:

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Well what do you mean email? Oh, because you have my email so I have to email you? I'm a little bit confused. Can you just clarify?

Dr. Laura Esserman:

Would you like us to give you a call back?

Speaker 3:

Wonderful, wonderful.

Dr. Laura Esserman:

Wonderful, we can do that. We see your number on the screen. We'll call. They'll call you and they'll get the question and I'll answer it for you, yes okay. Next question.

Jenna Fields:

Okay, so I'm going to go back to our chat box. So I want to thank everyone for participating. We're going to get through a few more questions. But feel free to sign off at any time and take our survey as you head out the door. So, are there any new developments Dr. Esserman for treating lymphedema, ketoprofen anything on the horizon for ER PR positives after the AI?

Dr. Laura Esserman:

There are new things on the horizon for everything and how are we going to find out if they work? We're going to do that through clinical trials. So, I would say for lymphedema there is a number. So if you have had more than lymph nodes out, there are special exercises in weight training programs that you can get that reduce your chance of getting lymphedema by 75%. Probably the most important thing we can do to prevent lymphedema is to not take a lot of lymph nodes out from under the arm. The best centers aren't doing that very much anymore. It's very rare that we really clear out the axilla even if the nodes are positive because it turns out that that's not ... it doesn't really help. All it does is increase your risk of lymphedema. So getting to the right place for treatment matters. So having less surgery matters and really asks about that. But also there are people working on lymph nodes transfers and there's a number of things that people are working on. There needs to be a lot more research because a lot of people are just doing stuff that doesn't necessarily help. But there are now super micro surgeries to reconnect some of the lymphatics that can help.

In terms of estrogen receptor positive there's a new class of agents called selective estrogen receptor degrader, SERDS. We actually are starting a whole trial called our endocrine optimization program. It's part of I-SPY to take people who have hormone receptor positive breast cancers who's molecular subtypes are lower risk but they have this long arc, they are clinically high risk. We want to start finding better, more tolerable treatments for women because they have to take them for a long time and try to find the right combinations. So there are lots of exciting new agents that are out there. So we're very excited and hopeful that this is going to make a huge difference as well.

Jenna Fields:

That's great. Okay this person wanted to know about new treatments for invasive stage two. Initially misdiagnosed as ECIS, now on seven years of I'm going to say this wrong, aromatase inhibitors. I'm pronouncing wrong.

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Dr. Laura Esserman:

Aromatase inhibitors by the way.

Jenna Fields:

Thank you, sorry. Anything new coming along for that?

Dr. Laura Esserman:

Yes. So just the things that I just talked about if you're hormone positive. I think there's a new class of agents that are coming on the market. I bet within five years they'll have replaced the aromatase inhibitors. There's another class of drugs that's EDK inhibitors that are being tested. Probably everybody doesn't need it. Just people who are at high risk and again the trick is trying to figure out who needs what and can you do it early enough so that people don't have to take a lot of treatment that they don't need that sometimes is hard on them.

Jenna Fields:

Got it. And this is another question about visiting doctors during COVID. If someone has already had a breast exam, a mammogram and done a bone density test, is there really another reason to meet with an oncologist in person or can it be done virtually?

Dr. Laura Esserman:

It can be done virtually. That's actually one of the great things about, that's a silver lining about COVID. If you don't need to come in for something and you're doing all right, just check in and you can do it online. No one has to get in your car. You don't have to waste your time looking for parking or taking public transportation. So it's really great. You can have anybody you want on the phone with you too, that's also nice.

Jenna Fields:

Great. I think you've answered all of our questions. Oh, here's one more. Surgery doesn't happen first, when is the oncotype test done?

Dr. Laura Esserman:

So there are several tests that can be done on the tissue. It can be MammaPrint, it can be oncotype, there's like three or four different molecular tests. These are all about trying to understand what your risk is and what we think the response is likely to be. That could be done on the core biopsy. And sometimes it's really there's no reason it can't be done on the core biopsy. In fact, that's probably a better sample to have it done on. There are reasons why you might want to start with even a short exposure to hormone therapy if you want to see how the tumor behaves under the pressure of the endocrine agents. And you can look to see how fast the cells grow later and that can actually provide a lot of important information about the biology of the tumor. The reason we get the chemotherapy up front, we do this in I-SPY is what we do standardly and we happen to use the 70 gene test for MammaPrint because it gives us information about the molecular subtype. Whether they're [inaudible 01:00:35] or luminol or HER2 type, and we're finding that the new therapeutics that are being

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developed we can predict which ones are going to work best and then not only do we predict, but we can actually find out if that's true.

Dr. Laura Esserman:

Does the tumor go away, just like I showed you in that case example. Not everyone's tumors go away. So then, if it's not working then what you want to do is find something else while you still can make a difference. So that's what's important. So you can do it on a biopsy now. There's no reason to do surgery first. Sometimes we will do surgery first if we can't quite figure out how big it is or how risky it is, sometimes doing the surgery first makes sense. Or if we think it's really super low risk and really all you need is it removed, there's actually an ultra low risk threshold out there. It's also off the 70 gene test. If it's that, maybe you really don't need much of anything else. Just have it removed and you don't need radiation and for women who are 60, 65 and older if you have hormone positive tumor, the addition of radiation doesn't really add that much. It can reduce your local recurrence by maybe five percent.

But it's not going to make a difference on whether you live or die. So it's really important to know. Some people say, "Well I just don't want radiation." Well you don't actually have to have it. But you have to be able to take chemotherapy and so you can actually do that first to see if you tolerate it and if you do then those are good options for you. So there's lots of ways in which you can be creative about how you order your treatments to learn, to help make better choices, to help reduce the toxicity of therapy and to maximize the chance that you're getting the right thing. So that's the way we personalize treatment based on science and based on the data we've learned from clinical trials, right?

Jenna Fields:

Right.

Dr. Laura Esserman:

So every person who participates in a trial not only is often helping themselves, but they're also helping everyone who comes after them to make it. And for screening it's one of the reasons why we say participate in a screening trial. You spend 30 years of your life screening. Why not spend five years, work with us, help us find the answer. Be part of that whole movement of saying, "Hey I'm tired. Why am I doing the same thing I did 30 years ago? I want better. I want the iPhone 20 for screening." But we can't get there without everybody helping us. So that's the best way to explain why research matters because you want something better for yourselves and you want something better for your mothers, your daughters, your sisters and your friends.

Jenna Fields:

Yeah. Yeah. And if someone is high risk, what type of doctor should be consulted? It's a really important question.

Dr. Laura Esserman:

It is an important question. So, the universities almost always have a high risk or breast cancer high risk clinic. It can be that some OBGYNs are really interested in this. A lot of breast surgeons do this. Sometimes it's a medical oncologist. Sometimes it's a nurse practitioner. What you want is someone who really is really steeped in this. Part of the Wisdom trial we actually have a whole educational program and we have tools to help people understand their risk. And do counseling as part of that

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because it's not, as I said, it's not just about screening. It's about prevention and integrating the two with risk assessment. And so then we also help make sure that people can not only get counseling, but then get to a facility where they can get an intervention if that's the appropriate thing for them.

Jenna Fields:

Fantastic. Dr. Esserman thank you. So much for this. This is really incredible. I'm sure everybody learned as much as I did. I'm so excited that we had you and we really appreciate your education and we'll be sending out this webinar recording next week. So anyone who wants to look back at the charts, information that she provided, you'll be able to do that as well as to share this with friends and convince all of them to join the Wisdom study and clinical trials. We appreciate you.

Dr. Laura Esserman:

Okay, very good. Thanks for having me. It was really a pleasure.

Jenna Fields:

Thank you so much Dr. Esserman, take care.

About Sharsheret

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Sharsheret, Hebrew for “chain”, is a national non-profit organization, 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 four offices (California, Florida, Illinois, and New Jersey), Sharsheret serves 150,000 women, families, health care professionals, community leaders, and students, in all 50 states. 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, more than 15% of those we serve are not Jewish. All Sharsheret programs serve all women and men.

As a premier organization for psychosocial support, Sharsheret’s Executive Director chairs the Federal Advisory Committee on Breast Cancer in Young Women, 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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