LYNNE WAGNER: Thank you so much for the conference planners, for the opportunity to speak with you today. I'm a professor in the department of social sciences and health policy, and I'll be talking about managing fear of cancer recurrence based on my background as a clinical psychologist and also as a patient-reported outcomes researcher. So I'll briefly talk about fear of recurrence and how we define fear of recurrence.

It actually is a constellation of cognitive and emotional components, and understanding that can help think about how to collaborate with our patients in teaching them strategies to better manage their concerns about recurrence. I'll talk about the prevalence of fear of recurrence, features that are associated with elevated fear of recurrence, and then I'll talk about some of my own research on a study called FoRtitude, which is an eHealth intervention designed to teach breast cancer survivors strategies to manage their anxiety about recurrence. And then I'll conclude with some suggestions for clinical management.

So I know this slide is busy. I hope that you're able to see it, and I'll just highlight some of the key points here. Hopefully, I can figure out how to use the laser point-- here we go-- to do so. This is an adapted conceptual model of fear of cancer recurrence, initially published by Lee Jones. And what I like about this model is that it illustrates how fear of recurrence includes cognitive components-- worry, preoccupation, intrusive thoughts about recurrence, and avoidance of thoughts related to cancer-- and an emotional component, fear and anxiety about cancer, that is often triggered by antecedents which may include physical symptoms.

I'm sure many of you have heard your patients tell you they were starting to get sick and not feeling well and immediately worried that perhaps it was a sign that their cancer was returning. Increased fatigue is often a trigger for patients to cue them to worry about a cancer recurrence, and external cues, contact with health care professionals, going in annually for a scan, for surveillance, and media contact. The month of October is so hard for many of our cancer survivors. They can't go anywhere without seeing pink and reminders of breast cancer, which is great to the extent that it mobilizes advocacy and greater awareness. But it can be very challenging as reminders of cancer for our survivors, which can then trigger an increase in fear of recurrence.

And a lot of the work that I do relates to bolstering psychosocial resources that can help patients to better manage their fear of recurrence, specifically teaching coping strategies and

building self-efficacy. And as many of you are very aware, there are behavioral consequences of increased fear of cancer recurrence-- excessive health care utilization, excessive bodily self-checking. It's very difficult, of course, for our survivors to define that optimal surveillance schedule. We want them to contact us if they've noticed something new. We want them to come in for recommended surveillance, but certainly there is a fine line between following recommended surveillance and excessively utilizing health services for concerns that may be better addressed through teaching some coping strategies.

On the opposite end of the spectrum is avoidance of health care. Some of our highly anxious patients don't come in as recommended for follow up. And more general, more global psychological effects-- increased overall anxiety, distress, and decreased quality of life.

A fear of cancer recurrence has been most extensively documented among breast cancer survivors, largely because most of the psychosocial research that we do involves breast cancer survivors. It's the largest population and the most accessible for our research studies. Long-term survivors, the American Cancer Society surveyed a few thousand long-term cancer survivors. And the overwhelming majority of survivors reported that help managing uncertainty about the future was their most common unmet need.

So while it has been most widely documented in breast cancer, certainly, we can think about concerns about recurrence as universal and present among all types of cancer survivors. It has been estimated that 48%-- one study found that 48% of breast cancer survivors experienced intrusive thoughts, so thoughts that were unwelcomed, that disrupted functioning. 48% reported fear of recurrence related intrusive thoughts, and estimates of what we consider to be clinically elevated fear of recurrence tend to be all over the place, as you can imagine.

It depends on how we define clinically elevated fear of recurrence. An Estimates range from 24% to 56% of breast cancer survivors have reported moderate to severe levels of fear of recurrence. It may be very surprising to you to see that the research that has been done to date has found that disease-related variables are not associated with fear of recurrence severity. In breast cancer, this includes stage at diagnosis, histology, the number of years of living cancer free. I so often hear from oncology colleagues that it's puzzling why patients with DCIS can be so highly anxious.

That's because fear about cancer recurrence is more driven by psychological factors than disease-related factors, specifically proneness to worry and self-efficacy. Proneness to worry,

self-efficacy, one's confidence in one's ability to manage a situation are often much more related to the extent to which a survivor struggles with fear of recurrence. Proneness to worry, I, as a psychologist in my own clinical practice, got into the habit of asking my patients, before you developed cancer, did you worry about things?

And the patients just say, oh, yes. I've always been a worrier. I called them the what-ifers. You know, what if this happens? What if that happens? Having that psychological style really predisposes our patients to experiencing long-term fears about cancer recurrence. And self-efficacy, one's belief in one's ability to manage a situation, can really have a protective effect.

So why should we be concerned about fear of recurrence? I think that it's easy to think that, you know, well, you've had cancer. Of course, it's going to run through your mind that you might have cancer again and that this could be distressing. My position on this is it's similar to experiencing fatigue if you have anemia.

If you have anemia, it makes sense that you're going to have fatigue, but we still want to treat the anemia. So I think that there are things that we can do to help our patients in reducing their disruptions to quality of life associated with fear of recurrence. Certainly, there are psychological consequences-- increased overall anxiety and depression, quality of life impairments, as I've already mentioned from that model. Behavioral consequences, these are the patients who will call you or message you through the patient communication portal asking the same questions again and again, or perhaps becoming very savvy about asking you the same question about their risk of occurrence, but in slightly different, slightly variant ways.

These are also the patients that you probably have to repeat the same message a number of times. And because of the way that our brain works and the way that we process information, it's very, very difficult to process, to even attend to information, let alone encode it and recall it, when we're highly anxious. So this drives a lot of the repeat phone calls and messages and correspondence that you receive from your patients.

And health care avoidance also certainly is a concern. When our patients are so highly anxious about a recurrence that they're not able to come in for recommended surveillance, that's a concern. And clinician quality of life, I hope that you leave today after I talk with a little bit more of an understanding of how this plight here of occurrence plays out in your patients and perhaps some things that you can do to work with your patients.

And so as I mentioned, I recently completed an eHealth intervention called FoRtitude. Fear of

Recurrence often is referred to using the acronym FoR. And so playing on that, I called-- I'm sorry. I keep reversing. There we go.

So in building on that acronym, I called this site FoRtitude, representing strength and resiliency in the face of life's challenges, and uncertainty. And this was the graphic that we had on the intervention site, and I'll show you some screenshots in just a minute. Research was funded by the National Cancer Institute.

In my own clinical practice, I saw a lot of breast cancer survivors who were overall adjusting to life pretty well post treatment but occasionally experienced great disruption due to fears of recurrence and ebbs and flows in fear of recurrence. So I looked at the literature to see how do other psychologists like myself treat this concern. And I was astounded that I found zero publications, literally zero publications on treatment protocols.

So I looked at the literature on treating other anxiety disorders, not in health populations, but general anxiety disorders, given that to me fear of recurrence clinically represented generalized anxiety and difficulty controlling worry about bad things that might happen and had also some post-traumatic anxiety type features. So I adapted those treatment protocols to managing fears about recurrence and found that it tended to work pretty well with my patients. I also found then that I was giving the same spiel over and over again.

And I thought, you know, I don't need to take time out of these survivors' very busy schedules. I can put this online. They can read it and work with the material on their own, at their own pace, when it's convenient for them, and we'll see if it works. And so that's the research question that I asked with this study.

And again, as I mentioned, there are a few targeted interventions for fear of recurrence. And also in eHealth, a web-based strategy helps to overcome many of the barriers to psychosocial care-- dealing with insurance, dealing with time away from work. The last thing that a survivor wants is to have more medical appointments, so they're trying to get their life back on track.

So I based this study, I based the intervention, on this theoretical model, specifically to bolster coping strategies and self-efficacy. Top three coping strategies, diaphragmatic breathing and relaxation, cognitive restructuring, and scheduled worry practice, and I'll briefly talk about each of these in the rationale, and then examined fear of recurrence severity and secondary outcomes as part of the trial. In working with the Center for Behavioral Intervention

Technologies at Northwestern University, we translated these clinical interventions into an online format, texts, didactic lessons that were presented as texts, and some interactive tools.

We also included some videos. The length of the intervention was four weeks. And we encouraged our survivors to log onto the website a minimum of four times a week, but recommended daily if possible, just to review the educational content and to use the tools that we put on the site.

We also randomized participants to either a coping strategy or inert content because we also wanted to see is the content helpful. Or is it just something about using the website that has some education that perhaps might be helpful to our participants? And we also included an SOS text messaging feature, and I'll discuss that more when I show some screenshots of the site.

So the rationale for relaxation training-- anxiety triggers a physiological response, the fight-or-flight response. Diaphragmatic breathing reverses this response through triggering parasympathetic dominance, parasympathetic activity. And teaching someone who is anxious this technique can have great power. In those times when their anxiety increases, to know that they can do some breathing to calm themselves down can be a very helpful technique, and to help them reverse the physiological response associated with a perceived threat, such as concerns about having cancer again.

The rationale for cognitive restructuring-- my training is in cognitive behavior therapy. And based on this school of thought, when we see clinically significant disorders, oftentimes those are accompanied by underlying cognitions that drive the emotional response. So basing on that theory, there are some underlying cognitions that drive cognitive aspects of fear of recurrence.

And you've probably heard many of these from your patients. If I expect to hear bad news, then I won't be disappointed again. I was so caught off guard when I was diagnosed with breast cancer, at least if I expect it, I won't be let down. Or now I'm just waiting for the other shoe to drop.

Start listening for these types of things in your clinical practice. This is your survivor's way, and every person has their own personal way of thinking about it. But this is them expressing their underlying belief that if I worry about it, then I'll have some control over the outcome.

That, of course, is completely untrue, and worry, of course, diminishes quality of life. So the key here is to try to highlight this cognition and then teach our survivors to replace it with something that's more adaptive such as if my cancer returns, I'll keep focusing on the things I can do to be as healthy as possible and then try to set those worries aside. And this isn't easy.

Now I'm going through this in a very quick manner. So it's much more in depth than just telling your patients, you know, put on rose-colored glasses and expect the best. That's actually not a great strategy. Early on in my clinical training days, I tried it. That doesn't work well. But I understand these can be difficult concepts to teach, but it is possible.

And then the third coping strategy is worry practice. This is totally and completely counter-intuitive. I recognize that. When you're able to sell this rationale to your patients and get them to see the potential value, it seems to work very well.

Worry practice involves scheduling a time, either every day or a few times a week, 5, 10 minutes where the survivor focuses on their worry about recurrence or their worries about the feared event. And again, this is based on an empirically-validated treatment protocol for generalized anxiety and for post-traumatic stress as well. Worry practice encourages the person to break through their avoidance.

A lot of times they get caught in this loop of thinking, what if it comes back? Oh, I can't handle it. What if it comes back? I can't handle it. By scheduling time to focus on this worry, it pushes them to mobilize their coping resources. And if they're learning some adaptive coping strategies, then they can engage in those strategies to then reduce their anxiety, as opposed to thinking about it and then avoiding it, which just compounds the anxiety.

Also, the way that I explain this to patients is we know that you're worrying. You've found that you've been worrying for months or for years. Why don't you call the shots then?

You know it's going to happen, so you call the shots on when and where. And also in teaching this strategy, patients can remind themselves. When they have these intrusive thoughts at other times, they can say, no.

I'm watching a movie right now. I'm going to focus on these worries about recurrence tomorrow at 3:00 PM. I've got it on my calendar. And it can also help them to redirect their attention to other things when they experience these intrusive thoughts.

So this is a screenshot of the intervention home page. We release new content every few

days. And so we had a bar at the top they could click for today's coping tips, and that would take them to the new material.

Again, the site was tailored for each participant based on their randomisation assignment. And then there were sections on how to use the site. And then the tools that we were teaching them were on the home page, as well as a video introducing them to the site and this SOS text messaging feature which I mentioned.

And we purchased images through iStock photos, of course, with the intent to create a site that's very calming and aesthetically pleasing. And the screen shot shows how we laid out the didactic content. So we would release didactic content, for example, on relaxation, what it is and why it works, and then a tool a few days later which includes audio recordings of relaxation exercises, and then a second didactic lesson on how to apply this coping technique and suggestions on how to use it day to day.

And the intervention was over a period of four weeks of participants receiving coping strategies or inert content for three weeks. This is a screenshot of the lessons. We tried to keep the screens very simple and brief.

So didactic content was presented over several pages, starting with each lesson to set up expectations and a description of what the lesson would teach them. Also as part of this study, we put the content and the website in front of 15 breast cancer survivors and conducted qualitative interviews to get their feedback on the site, which then led to us refining the site based on input. This is a screenshot showing the relaxation tools.

So we had different types of relaxation-- progressive muscle relaxation, visualization based exercises. And participants told us the variety is helpful. One person told us, I don't know what [INAUDIBLE] is, which is helpful. So we created some hover text to describe each of the techniques.

And this is also part of the relaxation tool. So participants could rate their anxiety level before they started, listen to an exercise, and then re-rate their anxiety after the exercise. And they had the ability to save their records so that if they tried different relaxation exercises, we had about 15 on the site. Now they could keep track of their pre and post ratings, so then go back and remember which ones they liked the most.

And our participants really liked relaxation. They said it's something you can do wherever you

are at. It's a quick, simple fix, but they liked the more brief exercises.

This is an example of the thought record tool, where they put in text the situation. Describe what happened. What was your initial emotion? This is from a dropdown menu.

Rate the intensity of your emotion. What were your thoughts? And then we taught participants about different thought distortions, for example, catastrophizing. If my breast cancer recurred, it would be the worst possible thing that could happen.

And then we encourage participants to generate alternative thoughts again and provided illustrations, such as it would be certainly upsetting if my breast cancer returned. However, I would work with my medical team to come up with a new plan of treatment. And our participants really liked this.

"The concept of mind over body is huge. Self-talk and having a positive attitude is invaluable." "It was clear and straightforward. The definitions go way too fast, which created more anxiety." So we fixed that. And then this participant, "I just applied this to a recent trip to the doctor that frustrated me and created anxiety, so I totally applied it to a real-life situation."

And this is the Worry Practice Tool. And we received mixed feedback on this. And I think most importantly, we received feedback that being guided through worry practice would be helpful.

Some participants said, I liked it. Others said, I feel like this is a weird concept and would make me worry about things on a more regular basis. Another participant said, you know, this reminds me of when I was going through chemotherapy, and I had all these intricate, very detailed instructions. So we decreased the complexity of the instructions.

I recorded a video, describing why this tool works. And then we had a video-based guided worry practice where I talked participants through the worry, including some techniques at the end to help them release their worries once the exercise was over. We also included an SOS text messaging feature.

In my clinical practice, I so often heard from patients that they would be doing pretty well. But then they'd run into someone who would ask them, how are you doing? Are you done with your cancer treatment? Or going around during the month of October, seeing reminders or commercials, and that would really trigger their anxiety.

So I created this feature where they could send a text message to the site, saying SOS to the

website. We gave them the phone number, and they would receive back a text message that was tailored to whatever intervention piece they were receiving that week. So if they were being taught relaxation, they would receive a text message that said, remember to breathe.

If they were in the worry practice week, they would get a text message, saying, put some time on your schedule and revisit this worry at that time. We also allowed participants to schedule text messages. If they knew that they had an upcoming scan or an upcoming medical appointment, they could go into a calendar feature and put it on the schedule so that they then around the time of that appointment would get a reminder.

The participants gave us primarily positive feedback. "The reminders are helpful." "I want to be the person to initiate the message. I don't want to get unsolicited text messages." So that's why we created this on-demand feature.

We also heard, "I can't pre-think when my anxiety would occur. I'm not likely to use the scheduled feature." And then another participant said, "the text reminded us of quick actions, and they should have three or four key words."

So here is our summary of our participants. 405 participants were approached. We recruited from Northwestern University and from three NCI Community Oncology Research Program sites-- Metro, Minnesota, in Minneapolis and throughout Minnesota, the Aurora NCORP site, which is in Milwaukee, and Wisconsin and Northern Illinois, and the Colorado Cancer Research Program in Denver, Colorado. We approach 405 participants and had just under a 60% participation rate and about a 25% refusal rate.

So for a behavioral study, those rates are pretty good. We're very pleased with that participation rate. And of participants who consented and completed the screener, 85% were eligible. And one of the biggest challenges to conducting eHealth studies is keeping people engaged in the site and engaged in the study.

We found that 92% of women who enrolled in the study followed through with logging onto the website. And 81% completed the four-week assessment, and 85% completed the eight-week assessment. And we initially powered our study to have 112 patients at 8 weeks in order to look at our study endpoints, and we had well, well over that, as you can see, and enrolling 196 participants.

The survivors were on average 55 years of age, predominantly white. And to be eligible, they

had to have stage 0 to 3 breast cancer, no current evidence of disease, be 1 to 10 years post-treatment, and have a moderate to severe fear of recurrence at the time that we screen them for this study, along with familiarity with the internet and a mobile telephone with text messaging capabilities. 70% of participants were currently on hormonal treatment, and 70% of participants had prior chemotherapy and prior radiation therapy. Almost all participants had prior surgery, and 21% received targeted therapy Herceptin.

So this is an early snapshot at our outcomes. We're just taking a look at our data. So we found that from a baseline to week four, the severity of fear of recurrence significantly reduced. And that finding is even more profound at eight weeks and is statistically significant. Although we did not find an increase in patients' self-reported skills to cope with fear of recurrence, we found that many of the subscales on our fear of cancer recurrence measure decreased their total score on the fear of cancer recurrence inventory as well as additional subscales looking at distress, interference in function, triggers, and reassurance strategies to manage fear of recurrence.

And looking at our secondary outcomes, we also found a reduction in the impact of events scale. This is a measure of post-traumatic type anxiety, which assesses intrusive thoughts, avoidance, hypervigilance, and response to triggers. We found a reduction in overall anxiety and depression. We also measured patient-reported cognitive problems, sleep disturbances, fatigue, and global health. And we observed statistically significant improvements on all of these outcome measures, from enrollment to four and eight week follow up.

However, when we looked at our-- this was a randomized trial, using a factorial design. We randomized participants to four factors, either telecoaching, yes or no, and then three cognitive strategies-- again, relaxation, worry practice, and cognitive restructuring. The weeks that they did not receive one of these intervention components, they received inert content, and we did not find any statistically significant differences in participants who were randomized to telecoaching, yes or no, or who were randomized to each of these three coping techniques or inert content.

And I think that I have some insights there. It was very, very difficult to write content that was inert that seemed to be related to fear of recurrence so that the website had face validity so that participants would keep using it and interacting with it. So we wrote the inert content based on managing co-morbidities, on diet, and diet-specific suggestions for cancer survivors.

Anecdotally, our study participants told us they loved the information on diet. And I set up to the next talk. They loved information on diet and nutrition because it gave them things they can do.

So I think the inner content may not have been as inert as we thought. So in our next research study, we need to be more careful in our control group design. And we are currently in the process of extracting and analyzing website use metrics to also see if we observe a dose-response relationship, if we see greater reductions among those who use the website more, but those analyses are currently underway.

So just to conclude with some suggestions for the clinical management of fear of recurrence, as much as possible, normalize your survivors' thoughts and fears about recurrence. You may even encourage them to view their concerns about recurrence as adaptive, to the extent that it motivates them to engage in healthy behaviors and engage in recommended surveillance. Dispute the myth that thinking about cancer can increase their risk of recurrence.

I know people love that book, "The Secret," but it can be very challenging. When cancer survivors say, well, if I think about recurrence then it might increase the risk that I'll have it, that says that for those who recur, they actually did something wrong in the way that they thought about their cancer. And we know that that is not true whatsoever.

So you can tell your patients, there is no empirical evidence whatsoever showing a link between thinking about having a cancer recurrence and it actually recurring. But the more salient issue is that worrying about recurrence is diminishing your quality of life, so let's talk about how to deal with that. Of course, tailor your discussion of risk of recurrence to patients' preferences.

Some patients want numbers. Some don't. You know this more than I. And bolster patients' self-efficacy. You, of course, can talk about their risk, if they're asking for that information.

Try to avoid telling them, oh, it's never going to come back. No one has a crystal ball. No one can foretell the future. Rather send the message, if your cancer does return, we'll work together.

You can manage it. You've been through it once already. You'll get through it again, and we'll work on it together. And there are things that we can do.

And provide your cancer survivors with concrete suggestions on things they can do. Consider

these discussions about their fears about recurrence as a teachable moment. Talk to them about their tobacco use, about their physical activity, about their diet.

Exercise patience. I know it's challenging when patients are calling and asking repeatedly for medical instructions or repeatedly finding new and creative ways to get your reassurance. But it does go a long way. Anticipate peaks in anxiety in their follow-up appointments.

When patients are coming in for scans, try to get their results back as quickly as possible. Also anticipate that your patients are going to use all information available to them to try to interpret the results of their tests before they hear back from you. I have heard some stories that would really surprise you of patients coming in and saying, well, my oncologist always calls me back in the morning. And he or she didn't call me back until the afternoon, and I was thinking that means something. That means it's a more serious result.

They're going to do anything to try to read the tea leaves, so know that that applies also to your interactions with them. Patients also will try to read your tone to anticipate what results you may have. Just be thoughtful about that and your mode of communication also in returning results.

And help your patients to conceptualize their anxiety as an understandable and a normal response to an abnormal life event. There is actually something adaptive about being anxious about having cancer again. Cancer is a real threat, and anxiety is a natural, emotional response to a threat.

Also referral to cancer support organizations may be indicated. There are some wonderful programs for patients through CancerCare, CancerCare.org. They have some wonderful podcasts on managing anxiety and managing stress for cancer survivors. They also maintain a great referral line, as does the American Cancer Society.

And Imerman Angels is an organization that pairs patients newly diagnosed with cancer with cancer survivors. So that peer support can be very helpful as well. Here at Wake Forest, if you have concerns about patients who perhaps should be evaluated clinically, refer through Andrea Edwards.

I also quite often refer patients to this website, healthjourneys.com. There is a charge. It's, I think, around $10 or $15 to either download relaxation audio recordings or purchase CDs.

I most commonly refer to this website because they do research on their audio recordings, on their relaxation exercises, and they have many that are very good. Headspace is an app that teaches mindfulness. And I know I didn't talk at all about mindfulness. I talked about cognitive behavioral strategies, but mindfulness may also be a strategy that your patients can learn.

And recommended reading, this book was written by a colleague of mine from Northwestern, Mark Reinecke. And it's called "Little Ways to Keep Calm and Carry On-- 20 Lessons to Manage your Anxiety and Self-Soothe." And this is a fantastic book.

My patients have said they've been able to find it at Walmart for $5. You could order it on Amazon for, like, $7 or $8. And it's packed with evidence-based, concrete strategies, not specific to cancer, but for managing anxiety, but that I think can easily be extrapolated.