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Looking Back, Moving Forward: OIT's Origins & Emerging Insights

ANNOUNCER:This is ReachMD.

Welcome to *Cracking the Code on Peanut Allergies*, brought to you through an independent educational grant from Aimmune Therapeutics.

Here's your host, Mario Nacinovich.

MARIO NACINOVICH: Oral immunotherapy, or OIT, is therapy used worldwide for the treatment of food allergies. But where did OIT begin, and how are healthcare professionals across the world approaching OIT differently? This is *Cracking the Code on the Peanut Allergies*, and I'm Mario Nacinovich. Joining me to discuss the origins and global insights on oral immunotherapy is Dr. Jonathan Spergel, Chief of Allergy Section at Children's Hospital, Philadelphia. Dr. Spergel, it's nice to meet you.

DR. JONATHAN SPERGEL: It's nice to meet you, as well.

MARIO NACINOVICH: So, let's start with a refresher on this treatment approach. What is oral immunotherapy specifically, and how is it currently used to treat food allergies?

DR. JONATHAN SPERGEL: So, all immunotherapy is sort of an old idea that has been around for a long time, but it's really coming back into sort of more common use in the last couple of years. The idea is similar to what immunotherapy is, and immunotherapy itself has been around for 100+ years, and it is to make your body slowly get used to things. It is basically what allergy shots are; you give a little bit at a time and slowly increase, and your body gets used to it. Oral immunotherapy is doing, instead of by allergy shots, you are taking the food or the allergen; and taking it slowly by mouth, and slowly making your body get used to it. You are training your immune system that this is not a dangerous substance, and this is a substance that you should be saying, "Hey, this is not dangerous, and I can take it."

MARIO NACINOVICH: And as a treatment option, is oral immunotherapy on the rise within the allergy specialist community?

DR. JONATHAN SPERGEL: So, all immunotherapy is calling in the United States not standard of care, but it has been used on various research protocols from whether a single food in various NIH trials to the large ANU clinical trials. There are other variants on peanut therapy being done for oral immunotherapy. It is also being done by a large number of practices using variations on these protocols now, so it is definitely on the rise. It has not reached the point where every allergist is doing it at this point, but it is definitely becoming more common.

MARIO NACINOVICH: So, now I'd like to explore the origins of oral immunotherapy. So, from your own experience, when did healthcare professionals really begin to adopt this form of therapy into practice?

DR. JONATHAN SPERGEL: It's an interesting question. So, immunotherapy itself goes back hundreds of years. And it went away for a long time because it was believed that avoidance was a way to make people outgrow their allergies. About 15-20 years ago, there were some studies out of Italy using oral immunotherapy to treat some food allergies. And that was really based on the practice in Europe, they did a lot of oral immunotherapy to treat pollen allergies. And some of the pollen allergies cross-react with food allergies, and they were finding some benefit along those lines. So it really started back then, and it really sort of has come to the U.S. initially by some small practitioners, but really sort of the push forward was really done by the NIH. The Consortium of Food Allergy Research, or

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COFAR, did some clinical trials on oral immunotherapy, particularly for peanut and milk, looking to use that to move that forward. With those publications, people began to see that, hey, it worked, then some general allergist practices said, hey, and they created their own sort of protocol, and have adapted those protocols using sort of garden variety products off the grocery store and say, hey, we can really – it seems to work, let's move it forward.

MARIO NACINOVICH: So, with that background, let's dive into the origins of oral immunotherapy throughout Europe. Can you speak to the emergence of OIT there? And whether it was conceived or implemented differently from the American approaches?

DR. JONATHAN SPERGEL: It is a different approach in Europe. And parts of Europe have adapted it differently; there are different practices, and there are slightly different allergens. Milk, peanut, and egg are pretty common most places in the world, but not in all of Europe. Different parts of Europe eat things slightly differently than the U.S. So people have slightly different practices and things have taken off slightly differently. The implementation has been different in the United States – this has really gone down two paths in the United States; sort of the large NIH clinical trial and there are some other smaller trials and the big pharma trial, and there is also a private practice model in the United States. In Europe, a lot of the growth has been less pharma in practices, and there have been some research institute clinical trials in Europe, less than the U.S. More uncertain countries like Germany and England have more than Italy and Spain. So Italy and Spain have been driven more by the practitioners and they are beginning to develop guidelines, which I think we need to talk about a little later on, is where those things are in terms of what is now finally beginning to hit the next step.

MARIO NACINOVICH: So, with respect to where we are at the present, is it safe to call OIT one of the main treatment options for food allergies in both Europe and America?

DR. JONATHAN SPERGEL: The issue is, right now we have no other therapy besides avoidance, so OIT is probably the one that is the most advanced in terms of potential future therapies for oral immunotherapies for research.

There are a lot of things ongoing to figure out that next step. In terms of treatment in one place in Europe in Spain, they've developed sort of national guidelines on how to do it. No one else has done that yet. The rest of Europe and the United States are still calling up more research than true standard of care. It's beginning to approach standard of care in many places in some experienced practitioners, but We've got awhile to go still. We're approaching it, but there are a lot of things we still need to learn, how to do it safely. So we're not there yet, but we're approaching it.

MARIO NACINOVICH: So, for our listening audience, just so we can be absolutely crystal clear to them, how do the current guidelines or standard practices surrounding OIT relate or differ between Europe and America?

DR. JONATHAN SPERGEL: In the United States, the current standard of care is not to do OIT. That may change in the very near future. And the guidelines, as there is enough evidence being built up by the clinical trials, both from various foundations and the NIH, as well as some very large practice data that has been developed. It is beginning to develop sort of out of the research phase. In Europe, it's about the same with one exception where they publish guidelines on how to do it in one country. So in most places it is beginning to sort of hit that tipping point. None of the countries now say yes to do it, but that could change in the next several years. So I think we're just on the forefront of that.

MARIO NACINOVICH: Are there any shared or unique barriers for adoption of OIT here versus in Europe?

DR. JONATHAN SPERGEL: Sure, there are definitely shared and unique things in the United States and Europe. The shared things are more patient specific. This is more on educating patients on what the risks and benefits are of oral immunotherapy, and how to do it. It is a very time-consuming procedure. Typically oral immunotherapy is you do what we call up-dose, where you get increasing doses every two weeks. And when you get up-dosed, you have to be observed anywhere depending on the protocol, an hour or two hours after the dose to make sure you're safe. Most patients when they do oral immunotherapy, get mild reactions, and there is a percentage, and it is a pretty consistent percentage around 10% will get anaphylaxis. And that's going to be right now in any study we see because that's the way the human body is; you give them something they're allergic to, and you're slowly making them less allergic, but a lot of patients are going to have an allergic reaction. So that's a true stumbling block.The next big issue is sort of unique to countries and insurances, and that's how to pay for it. Insurance in the United States is different than insurance in Europe. Many parts of Europe have a single pay system; not all do, and the question is they will say "hey, this is a good way to pay it." Will they pay for the provider's time to do it so they can actually do it? Because it takes time. In the United States, will insurance companies pay for it? Will the Federal Government insurance plans pay for it? How will they pay for it? Will they compensate people enough for the time and effort? So these are major logistics and financial stumbling blocks. And the other big issue is that many patients are multi-food allergic. There are a few publications on multi-food OIT, and that really needs to be worked out because I think if someone is allergic to multiple foods, they don't want to spend six months to a year doing one food, then another six months to a year doing another food; they want to do it all at once. So those details need to be sort of worked on, as well.

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MARIO NACINOVICH: So that's actually a very good segue to our next part in our discussion where we want to understand a little bit about the ongoing research or practice improvement efforts that are underway to address some of these continuing challenges to adopting OIT.

DR. JONATHAN SPERGEL: So one of the biggest challenges is how to address patients who have more than one food allergy and how to standardize different foods. Because what's getting most looked at is peanut, They took good old peanut flour and standardized it. But what about milk and egg, and there are various protocols of whether you do milk in a liquid form or you do a base milk or do you do powdered milk. And the same thing exists for any other food. And then are there biologics that can reduce the rate of an adverse event? There are other clinical trials ongoing to look to cut down the side effects or the adverse event profile of OIT, trying to look at safety. So those are sort of the big things I think need to be worked on; is how to standardize dosing, how to reduce side effects. And the other big question is how long you need to do it for. Do you need to do it the rest of your life? Or can you just – okay, you've done it for one year and stop, and you're done? And probably the answer for that is one year is probably not enough. Almost every study has shown that when you stop after a year, about 75% of the people go back to where they were before. So when after three years, the number looks closer to 40-50%, so maybe we need to do it five years, ten years; we don't know what the right number is. Maybe they don't need to take a peanut every day at that point or a glass of milk every day; maybe it's three times a week. I think these are important questions that we don't have the answer for yet. We don't know where people need to go next.

MARIO NACINOVICH: Before we wrap up, Dr. Spergel, I'd love to get some insights on what you think that future does hold for OIT. Are there any unique directions you see this treatment approach heading?

DR. JONATHAN SPERGEL: I think in the next several years, it is going to be approached closer to mainstream. It's not there yet. I think these issues I was talking about of how to do multi-food OIT is going to be one of the biggest issues. And it's an important question as we go forward – what's the right time to figure that out? And I think that's where it is heading. And there are all these other therapies in food allergies, and we've primarily talked about all of immunotherapies, but there are other therapies under investigation. Would they be better, worse; used as a supplement; used as a maintenance compared to oral immunotherapy? There are a lot of things promised, but a lot of unanswered questions at the current time.

MARIO NACINOVICH: Well, unfortunately, between looking back and then forward on this topic, we've run out of time now. But I want to than my guest, Dr. Jonathan Spergel, for sharing his insights on oral immunotherapy, both in the U.S. and abroad. Dr. Spergel, it was absolutely great having you on the program here today.

DR. JONATHAN SPERGEL: Thank you so much for letting me share my insights.

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