### Dr. Mariam Hanna:

Hello, I'm Dr. Mariam Hanna, and this is The Allergist, a show that separates myth from medicine, deciphering allergies and understanding the immune system behind exam room doors. It's a teenager and his parent—one staring down at his phone, the other neatly arranging his stack of papers. At least it's not that colorful IgE testing stack that often appears as a staple ream of paper, as if its value was solely derived by those ridiculous bar graphs and the sheer number of foods that were tested. I digress. With introductions out of the way, it's time to get to his story. This child was born pre-paradigm shift. He reacted to a food, had atopic dermatitis, and was tested for many foods, which they diligently avoided throughout the years. This was perhaps a testament to the family's diligence or perhaps a flag to his lack of exposures. Or wait, was he even allergic to these things? We discussed goals for today's visit. "Retesting," the father chimes in. The patient, barely budging, eyes hidden by his baseball cap. "Okay, time for testing." Small golf balls appear on the child's arm. One or two look perhaps promising. The father is skeptical. "We've tracked this for years," he exclaims, and he points down to his paperwork." How do you tell people that we're experts in allergic disease? But not too long ago, we used to be not so great while we made recommendations with the best of intentions. Sorry, some of those may have worsened this tidal wave of food allergies we're still wading through today. Sorry, it's 2024. We haven't cured food allergies. That's the dream. We haven't even figured out precision diagnostics. We're working on that. Our aim is to work with our patients to give them the best guidance based on the best and latest evidence we have." And without further ado, I present to you today's allergist, Dr. David Stukus. Dr. David Stukus is a pediatric allergist and clinical immunologist. He's the director of the Food Allergy Treatment Center at Nationwide Children's Hospital in Columbus, Ohio. Dr. Stukus is the associate director of the fellowship program at Nationwide Children's. He is a past board member of the American College of Allergy, Asthma, and Immunology, and is a co-chair of the North American Pediatric Allergy and Asthma Congress. Dr. Stukus is the social media editor for the Quad AI, where he produces and hosts their podcast, Conversations from the World of Allergy. One of the inspirations behind the development of this very podcast, Dr. Stukus considers himself an honorary Canadian based upon attendance at CSACI meetings, and more importantly, enduring our attempts to make him try Canadian staples such as poutine, ketchup chips, and even a cup of Timmy's. Dr. Stukus, thank you so much for taking time out of your schedule to join us and welcome to the podcast.

#### Dr. David Stukus:

Thank you. It is my pleasure to be here. I'm so excited. Congratulations to you and the amazing podcast. I've been listening. I'm a fan. I could listen to you talk about patients and stories all day long, but no, this is going to be great. Thanks for having me.

#### Dr. Mariam Hanna:

Thank you, Dr. Dave. Okay, so I really want to know the truth of approaching how we discuss this food allergy pandemic with families. I always have a parent or grandparent in the back of the room. "We didn't deal with this as children. Our family doesn't have this." What's your spiel here?

#### Dr. David Stukus:

Yeah, I typically laugh and say, "That's the million-dollar question." I said, "Yes, you're absolutely right. We are seeing an increase in the number of people diagnosed with food allergy over the last 20 or 30 years." And then, I'm always very careful to point out, specifically, there's no single cause. This is not a story that has a very easy origin story here. There are multiple factors that we think may be contributing, and then I also tell parents, "There is nothing that you could have done that would've caused this nor prevented this." So, you want to absolve everybody of guilt. Everybody feels guilty about why my child has a food allergy when we didn't have it before. And then, depending upon the mood in the room, we sometimes go off on a tangent into the hygiene hypothesis or the way we feed babies. But yeah, I always hit those main points: there's no single reason why, but yes, we are seeing an increase.

# Dr. Mariam Hanna:

Absolving the appearance of guilt is so huge. I think that that's something that's always the hidden message in the room. Everybody carries a little bit of it. What's changed in the field of diagnostics? How have we progressed?

# Dr. David Stukus:

Not a whole lot, as you mentioned. So, we've had these IgE tests for years, and these IgE tests are really good at detecting IgE antibody. It's up to us to interpret that properly. A lot of folks out there are walking around with specific IgE antibodies to foods. In fact, about 40% of people can have detectable IgE to foods, but only five to 8% are actually allergic. So, that's on us as clinicians to understand the very significant limitations of these tests. So many of our colleagues hold such precision to these numbers and values, and they use words like positive and negative. These tests aren't positive or negative. They don't diagnose allergy; they detect IgE. We have to use the clinical story to help determine the pretest probability, look at the levels of IgE to help determine whether that supports a diagnosis of allergy, and then kind of go from there. Now, of course, we have newer component diagnostic tests that really tease out specific parts of the antigen that people's IgE may be reacting to. But even then, the companies that make these tests sort of tell us a false lie in some ways because they say any detectable component to certain segments of a peanut means that you're at risk to have

a severe life-threatening reaction, that has not been demonstrated at all the components. Try to tease out: are you at risk to have clinical reactivity, or are you just having nonclinical sensitization?

### Dr. Mariam Hanna:

The words positive and negative rank in patients' minds and in the physician's mind really hard. And so, I have found that this component testing has taken over for what we consider positive testing, and we've shifted somehow from panel testing with skin testing, although I still see that, to panel testing with blood work or component testing. I think we're evolving but in the wrong way. Why has the era of panel testing not yet ended? Why haven't we stopped?

#### Dr. David Stukus:

Because our patients have questions that they want answered, and we want to please people. They come to us because they're worried. They're worried about themselves or their children. They want answers as to what ails them. And oftentimes, us providing a long explanation about why chronic idiopathic urticaria is not caused by food allergy, they don't want to hear it. They just want to see the tests. And I get it. I completely get it. There's the art of what we do. So sometimes, even what I've adopted is the monogram. I talk to families. I offer an explanation. I say, "I'm glad you're here. I want to clarify the diagnosis, which is really important from a medical standpoint. There is no indication to test your child for food allergies." However, I meet enough parents to know that sometimes you need to see a negative result to give you the confidence to feed them. I'm happy to work with you and do limited testing if a negative test result will then give you the confidence to go home and feed your child. And then I tell them, "If we do detect an elevated result, I'm not going to diagnose them with food allergy. They've never had a reaction, but maybe we can feed them that food here in the office in a very safe way." So I think that's a very easy conversation you can have with folks. But you're right. It's much easier to say, "Thanks for coming in today. What do you want me to test you for?" and put the test on?

#### Dr. Mariam Hanna:

Yeah, yeah. I see that it's like the buffet cart has come through, and our tray has multiple foods, and you can almost see their eyes light up when you bring in this tray of different foods so that you can pull out the extract you want. It's like, "While you're here, can I have row three, number two? File two?" Oh,

### Dr. David Stukus:

Yeah, yeah. Sometimes I'll go through the explanation, and then I'll say, "So, do you feel comfortable if we don't do any testing?" And sometimes the parents will say, "Well, no, I still want you to test." And I say, "Okay, fine. What do you want me to test them for?" And every once in a while, they'll say, "You tell me; you're the expert." And I say, "I just spent the last 15 minutes telling you why we didn't have to do any allergy testing." Sorry,

#### Dr. Mariam Hanna:

I have recently tried this in my office over the last couple of patients, where I will say the explanation and then flip it on them and say, "Now, I want you to explain to me why it's a bad idea to test."

Dr. David Stukus:

I like that.

# Dr. Mariam Hanna:

I think it's something I learned in medical school, and I have just put it away, and recently we're trying this on some of our patients in the office. Okay. Are we at an era where having a component is helpful or harmful, and an IgE to whatever food possible? So our local labs have now developed immuno caps for almost any single food that you can think of. So, I can get an IgE to watermelon. Why does that even exist? Did I miss the paragraph about that in my medical school training or in my allergy training?

#### Dr. David Stukus:

So people really need to understand what these tests can and can't do, especially the more tests we do for fruits and vegetables. I mean, what we're really picking up more likely is just cross-sensitization with the aeroallergens that people have symptoms towards. From the rhinitis standpoint with the components, we need to understand what these mean. It's great to know if people's IgE are specific towards antigens that are known to cause clinical reactions, but just because you have an Ara h 2 that's 0.25, that doesn't mean that they're going to have a life-threatening reaction to peanut when they eat it. They're probably not even allergic in the first place. So I wish people would understand that we lack positive and negative predictive values for these component tests. They don't exist.

# Dr. Mariam Hanna:

We lack positive and negative values for these component tests. We lack this. Okay. Sorry, just trying to emphasize your point here. What do you say to physicians or peers that continue to use this practice? This is a fine line we walk sometimes.

#### Dr. David Stukus:

I've adopted the approach, so I've been in clinical practice for 16 years. I've been in my community for 13 years, and I send them very sternly worded letters back about why these tests are harmful. I talk about the patient that they sent me and the harm that's been brought into their life because they've avoided all these foods that they haven't had to do, and how we're going to have to do a series of food challenges to clarify it, and then I give them resources, whether it's the Choosing Wisely series or other references that explain to them why this is a harmful practice. Every once in a while, I'll have somebody say, "Thank you so much. I had no idea." I've stopped doing that more often than not. I have no idea what happens on the other end, but that's what I do.

# Dr. Mariam Hanna:

It's doing your part, which is important. Okay. I actually want to spend the bulk of our discussion talking about therapeutics. This is a part that gets people excited and goosebumps on their arms and standing ovations during American Academy meetings and this kind of stuff happening. So the most exciting thing about food allergies these days is that we can actually do something about it. My colleague used to say it was diagnose-and-adios for the longest time. So now we've stepped it up a little bit. What are you, Dr. Stukus, the most excited about in the next five years for food allergy treatments for our patients?

# Dr. David Stukus:

Oh boy. Truly individualized approaches. It's not going to be one size fits all. We're already there, frankly, but I think the approach we take with infants really should dramatically change in the next five years if we diagnose somebody with a new food allergy nine to 18 months of age, we could potentially alter their life in a positive manner relatively easily, whether we talk about oral immunotherapy or sublingual immunotherapy or anti-IgE biologics or things like that. But yeah, that's what I'm excited about most.

# Dr. Mariam Hanna:

Do you think we're going to flip and overtreat everybody because we're going to get too zealous with this?

# Dr. David Stukus:

I think we already are. I think everything in medicine, every time we get a shiny new toy to play with, we ruin it, right? It's like we overuse oral immunotherapy, we're going to overuse omalizumab. We overuse component testing, and what's the harm in it? Well, I have a really hard time when you have somebody who's not actually allergic in the first

place and then you put them on allegedly lifelong therapy to treat the allergen they never had. That doesn't sit well with me. So that's one potential harm, but we can talk about many, many more.

### Dr. Mariam Hanna:

Yeah. Okay. So what's ready for prime time today in 2024? What's ready for private practice?

### Dr. David Stukus:

Well, I think oral immunotherapy, we have over a decade's worth of experience, especially in the private practice setting. I mean, you and your colleagues in Canada have been leading the charge in many ways, and Richard Wasserman down here in the United States and his group, and we've learned so much from your cohorts of patients of what can work in the outpatient realm. We're starting to do oral immunotherapy more in the academic centers as well, especially here in the United States, but that is ready for prime time, and I would argue for just about any food, especially the most common food allergens, we have pretty well established protocols and ideas of how to mitigate risk and endpoints and things like that. And now we have Omalizumab, which was approved by the FDA in the United States as of this recording just within the last month. So that is something that we can also start discussing with patients right now.

# Dr. Mariam Hanna:

There is a wonderful podcast from the Quad AI with the lead author, Dr. Bob Wood, on this very topic, which was released at the Quad AI in cohesion with the article getting released and the presentation, it was actually perfectly timed. Again, that gave me goosebumps, but

#### Dr. David Stukus:

I appreciate you saying so. This was the day after the FDA approved it. I emailed Dr. Wood and he was very gracious. I said, "If we can record this before the meeting, this was five days before we were supposed to leave. We will embargo it until your presentation and then time it for release." So yes, I thought that was really cool as well, and thank you for noticing that.

# Dr. Mariam Hanna:

No, it was perfectly orchestrated in my feed of things happening. I'm like, "How is this possible?" The world of modern medicine is very aware of what might be happening. Alright. How should allergists go about getting comfortable with offering immunotherapy? We were not taught this in fellowship. A lot of our academic centers

are starting to incorporate immunotherapy, but it is not an official Royal College requirement, and many are not getting enough exposure. What should they do?

# Dr. David Stukus:

Honestly, I think you have to start by offering oral food challenges. If you're not doing oral food challenges in your practice, I think there's a strong argument that you should not be doing oral immunotherapy. So just getting used to feeding children of all ages because there's an art to this. At our center, we do about a thousand oral food challenges a year, and I've negotiated with hundreds of toddlers over my career, and they often break my spirit because they refuse to eat regardless of how you try it, but it's just, it's the logistics. That's what we need to teach people when you have to practice and practice. That's the hardest part with setting up an oral immunotherapy practice is just getting everything ready to go. It's all about math, right? We don't want to do the wrong dose, especially if you're just using retail food equivalents.

You have to figure out what the right amount of protein is, the different forms that you can offer it in, the dosing schedule, and then you have to have that communication with families because reactions are going to occur at some point. I think people often neglect, parents are desperate to treat their child, and I often say to them, "Well, we're giving your child what they're allergic to every single day, so they're eating what they're allergic to, and we hope we're not going to cause an allergic reaction, but we probably are at some point. It's my job to make sure that we try to reduce that risk as much as possible. It's your job to follow the protocol and communicate with me whenever symptoms do occur." So I think it's really taking the time to establish a good foundation in your practice setting, getting comfortable with feeding children of all ages. The behavioral aspect of it is paramount because that's what really causes people to drop out over time and then having that open line of communication.

# Dr. Mariam Hanna:

Our healthcare system in Canada is not meant to take care of as many oral food challenges as we should be doing. So oftentimes, my colleagues are telling me their wait times for an oral food challenge is a year and a half, so they may as well just get them started on immunotherapy. You talked about shiny new toys causing problems. I wonder if you can comment on this one for us. Should we be prioritizing quick immunotherapy over oral food challenges in these patients?

# Dr. David Stukus:

I think it depends on whether you want to prioritize accurate diagnosis or not. If we're not clarifying the diagnosis, then we're going to be treating a lot of people who don't need to be treated, which only compounds the problem. Right now, you're putting these

people in the system that they have to come back for frequent visits for their buildup, dosing, and things like that. And if you have somebody who's not allergic in the first place, then why would you even pursue this? So I think it's kind of backward. Do I have the easy answer for you? Absolutely not, but those are my thoughts on it at least.

#### Dr. Mariam Hanna:

Nope. Well, I appreciate that. Okay. What families, when you do your consultation, do you think, "This is a red flag; they shouldn't be doing immunotherapy"?

#### Dr. David Stukus:

Oh, we have to have, if there are two parents in the home, they both need to be on board. So if there's conflict there, and I've seen this, I don't think it's going to be successful. If the child is not ready to eat or willing to eat, and parents may want this desperately, but if that child is not even willing to try a small amount in the office setting, that's a red flag. This isn't going to go well. This is going to be an adherence issue. They're going to be butting heads every single day, arguing with them, yelling at them, and we don't want that. If the child has uncontrolled asthma, atopic dermatitis, severe seasonal allergies, or other health conditions that aren't under control, OIT can wait. We need to control that because OIT is going to impact all of that, and it's going to impact the response to therapy, put them at greater risk of having adverse reactions. It's just going to confuse things. Those are the biggest things. You have not heard me say IgE level or history of prior reaction; that has not been shown to predict who's not going to do well with OIT. In fact, you can argue that those with a history of more severe reactions are the ones we should be focusing on. What we're trying to do here is trying to protect them, but it's really all the other stuff that I worry about.

### Dr. Mariam Hanna:

That's a great answer. Okay, now we're going to make it harder. Which physicians should not do immunotherapy in their practice?

# Dr. David Stukus:

Those who don't do oral food challenges, I really, okay.

# Dr. Mariam Hanna:

I thought I was tricking you. I thought I was giving you a hard one.

# Dr. David Stukus:

No, you can't rush into it. It took me over a year to get our programs set up just because I had to get all of our, just the paperwork and the consent forms. How do we communicate with families, the decision-making? How do we communicate with our

nurses? Who's the point of contact and questions arise, when do you do the up dosing visit? Who runs those visits? What type of food are you going to use? How are you going to actually develop the protocol and all this other stuff? It took me a year just to get it established, and then I had to train everybody else how to do everything. So you can't rush into this, and I think we need to offer it. I think that's what our patients want, but think about, I think people don't remember what it's like when you set up allergen immunotherapy for inhaled allergens. If you're giving allergy shots, there's a big process involved in offering that in your practice. This is the same idea.

# Dr. Mariam Hanna:

Yeah. I recently did a fellowship training workshop about oral immunotherapy, and before I got started, I asked how many people are going to start OIT as soon as they get out, they all put up their hands, and this zeal is good, but scary, and it's almost like you need to redirect it, and these are good thoughts that you're putting out there. Okay. I'm going to give you another harder question. Allied Health non-allergists, they're starting to catch on to OIT is just done with foods that can be purchased from the store and the protocols are easy access. How do we ensure legitimization and, more importantly, safety to immunotherapy?

#### Dr. David Stukus:

Oh boy, that is a hard question. I don't know the answer to that. How do we ensure that these folks are giving proper diagnosis? Is there some testing that they get every year to make sure that they're up to speed with the latest and greatest in regards to diagnostics and evidence-based medicine? No. I think we can do our best to try to help. You're one of the leaders in this, and you lead these workshops of getting people trained on how to do this. So do we have to have some certification that they went through training at least before they start offering this? That's one possibility, I suppose. But you're right. I mean, a lot of what we do, it's the wild, wild west. There are parents out there doing this on their own because they read an article or went on Facebook and saw somebody doing it.

There's folks in primary care, I should say, that are offering this and have no idea what they're doing. I'm hearing of people offering sublingual peanut immunotherapy by having people put peanut butter under their tongue. Like, what are we doing? Yeah. Oh yeah. People are just making stuff up, and at some point, somebody's going to be harmed by this, and we don't want to get to that point, but I think people need to realize these kids, if they're truly allergic, we need to be as careful as we possibly can to help them. This is a long game. We're not using OIT for short-term gains here.

# Dr. Mariam Hanna:

This is a lifelong journey that we put these families on, so it's important to pick out the right ones. It's important to make sure that you're set up in practice to take care of all these ones moving forward. Okay. Lots of different thoughts today. Time to wrap up and ask today's allergist, Dr. David Stukus, for his top three key messages to impart to patients and physicians on today's topic, food allergy diagnostics and therapeutics. Dr. Dave, over to you.

#### Dr. David Stukus:

Alright. Number one, food allergy tests are not screening tests. I will pause for dramatic effect. Food allergy tests are not screening tests. They were not developed to be screening tests. If you look at the basics that we learned in medical school, but what makes a good screening test? IgE tests don't check any of those boxes. Stop using them as screening tests. That means don't use them as panels. End of arguments. That's it. That's number one. Number two, establishing a proper diagnosis is the most important thing that we can offer families and patients. We want to identify those that have a true food allergy so they know what to avoid so they don't put themselves at risk. And then we also want to help them with prognosis and follow them over time. We also, more importantly, want to identify those that aren't allergic so that they don't have to avoid a food unnecessarily.

I think that's really crucial. And then number three, we truly live in an age of individualized approach to management, and we really should be having long conversations with everybody about individual risk. We didn't even talk about thresholds and all that. People avoiding precautionary labeling and things like that help people navigate the world. We don't want people to be afraid to get on an airplane because somebody opens a bag of peanuts, six rows in front of them. We want them to understand what's realistic risk versus what's perceived risk, and then discuss realistic treatment options with every single family every time we see them. That's all.

# Dr. Mariam Hanna:

I have one question because you mentioned risk. When we talk about risk, do you think there's a difference in terms of risk tolerance among different allergists, and do you think that impacts what they pursue with their patients?

# Dr. David Stukus:

Yes. I think that paternalistic care is still offered across the board. Meaning, just because somebody happens to get an appointment with one allergist who's highly conservative versus somebody who isn't, that's not fair to that patient. It's not fair to them that the highly conservative allergist is telling them, "You can't do these certain things." It's not okay. And if you're not comfortable with that, you probably shouldn't be

treating food allergy, frankly. It absolutely has to be current evidence-based approaches to understanding risk and then a shared decision-making conversation with every family about this stuff. So, I feel very strongly about that. It makes me very sad when somebody goes to see somebody in my community, then they come see me and I tell them a completely different story, and they're living their lives in complete fear for no reason whatsoever.

Dr. Mariam Hanna:

Thank you, Dr. Stukus, for joining us on today's episode of The Allergist.

Dr. David Stukus:

It was my pleasure. Thank you for having me.

#### Dr. Mariam Hanna:

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